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Prehospital Double Sequential Defibrillation: A Matched Case-Control Study

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Disclaimer: The views expressed in this article are those of the author(s) and do not necessarily reflect the official policy or position of the Department of the Army, the Department of the Navy, Department of Defense, or the United States Government.

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ABSTRACT

Study Objectives: The goal of our study is to determine if prehospital double sequential defibrillation (DSD) is associated with improved survival to hospital admission in the setting of refractory ventricular fibrillation/pulseless ventricular tachycardia (VF/pVT).

Methods: This project is a matched case-control study derived from prospectively collected Quality Assurance/Quality Improvement (QA/QI) data obtained from the San Antonio Fire Department out-of-hospital cardiac arrest database between JAN 2013 and DEC 2015. The cases were defined as out-of-hospital cardiac arrest (OHCA) patients with refractory VF/pVT that survived to hospital admission. The control group was defined as OHCA patients with refractory VF/pVT that did not survive to hospital admission. The primary variable in our study was prehospital DSD. The primary outcome of our study was survival to hospital admission.

Results: Of 3469 consecutive OHCA patients during the study period, 205 OHCA patients met the inclusion criterion of refractory VF/pVT. Using a predefined algorithm, two blinded researchers identified sixty-four unique cases and matched them with sixty-four unique controls. Survival to
hospital admission occurred in 48.0% of DSD patients and 50.5% of the conventional therapy patients (p>0.99) (OR 0.91, 95% CI [0.40, 2.1]).

**Conclusion:** Our matched case-control study on the prehospital use of double sequential defibrillation for refractory ventricular fibrillation/pulseless ventricular tachycardia found no evidence of associated improvement in survival to hospital admission. Our current protocol of considering prehospital double sequential defibrillation after the third conventional defibrillation in out-of-hospital cardiac arrest is ineffective.

**INTRODUCTION**

**Background**

The optimal management strategy of prehospital refractory ventricular fibrillation/pulseless ventricular tachycardia (VF/pVT) is controversial. The Minnesota Resuscitation Consortium (MRC) has implemented a management strategy of mechanical cardiopulmonary resuscitation (CPR) facilitated transport, extracorporeal membrane oxygenation (ECMO), and primary coronary intervention (PCI). Alternatively, some emergency medical services (EMS) systems are using prehospital beta-blockers based on limited emergency department (ED) data. Another proposed management strategy is the prehospital use of double sequential defibrillation (DSD). However, in the setting of out-of-hospital cardiac arrest (OHCA), prehospital DSD is an unproven therapy.

In DSD, the “double” refers to the use of two separate defibrillators on the same patient. The operator attempts to deliver simultaneous defibrillations from both devices. Human limitations result in “sequential” administration of the defibrillations. Other authors have also referred to the technique as “dual defibrillation,” “double simultaneous defibrillation” and “dual sequential defibrillation” in the literature. DSD was first developed and tested in canine models of refractory VF. Limited
observational data suggest that DSD is efficacious in the setting of refractory VF/pVT during routine electrophysiology testing. DSD continues to be used sporadically by electrophysiologists to treat refractory VF.

Numerous hypotheses exist about the mechanism of action. Limited observational data suggest that delivering sequential shocks may lower the defibrillation threshold compared to a traditional single shock. Alternatively, others hypothesize that defibrillation is a weight based treatment and larger individuals may require more joules. The last leading theory for the mechanism of action is that DSD changes the vector of the therapy and may result in more myocardium depolarization.

Importance

There is one case report, three small case series and two retrospective cohort analyses evaluating the use of DSD in the prehospital setting. However, to date, there have been no matched case-control studies to evaluate the efficacy of prehospital DSD for refractory VF/pVT.

Goals of this Study

The goal of our study is to determine if the San Antonio Fire Department’s (SAFD) current usage of prehospital DSD is associated with improving survival to hospital admission in the setting of refractory VF/pVT.

MATERIALS AND METHODS

Study Design and Setting

This project is a matched case-control study derived from prospectively collected Quality Assurance/Quality Improvement (QA/QI) data. The dataset was obtained from the San Antonio Fire Department (SAFD) OHCA QA/QI database between JAN 2013 and DEC 2015. The study was designed to adhere to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement. The University of Texas Health Science Center at San Antonio (UTHSCSA)
Institutional Review Board approved our study as part of an ongoing cardiac arrest performance improvement initiative.

The SAFD is the sole 911 provider for a population of approximately 1.4 million people spread over a 460-square-mile area. The UTHSCSA Department of Emergency Health Sciences’ Office of the Medical Director (OMD) provides medical direction for the SAFD. EMS physicians and fellows provide all online medical direction. The SAFD deploys a four-person fire company and two dual-paramedic-staffed mobile intensive care ambulances to all OHCA calls. The SAFD staffs approximately seventy-five percent of its fire companies with at least one paramedic.

During the entire study period, the SAFD EMS VF/pVT protocol directed the lead paramedic to consider DSD after administering three 200J conventional defibrillations (Zoll-X Series Biphasic Defibrillator). The OMD delegated the decision to administer DSD to the lead paramedic. In our system, we utilized anterolateral pad placement combined with anterior-posterior pad placement for double sequential defibrillation (Figure 1).

**Selection of Participants**

Our matched case-control study was derived from consecutive SAFD OHCA patients between JAN 2013 and DEC 2015. Our inclusion criterion was refractory VF/pVT; defined as the administration of at least three conventional 200J defibrillations without conversion to a non-shockable rhythm. We excluded any patients with incomplete relevant data. The cases were defined as patients that survived to hospital admission. The matched controls were defined as OHCA patients that did not survive to hospital admission.
Exposure

The exposure was prehospital double sequential defibrillation.

Methods of Measurement

The UTHSCSA OMD utilizes an internal OHCA database as part of an ongoing QA/QI program. Our database captures a wide variety of variables including: patient demographic information, resuscitative efforts, and patient outcomes. The OMD reviews all SAFD OHCA electronic patient care reports (ePCRs). Relevant data elements are pulled from the ePCR and entered into the database. As soon as practicable after the event (typically within 24 hours), an OMD staff member will conduct a structured interview of the resuscitation team leader. SAFD EMS equipment can be interrogated to collect relevant data if required. The OMD collects patient outcome data for any patient transported to the hospital for further care. Hospital records, obituary reviews, and the Social Security Death Index are used to determine hospital survival.

One author (JM) extracted the patients with refractory VF/pVT from our OHCA database. He was blinded to patient outcomes, but not to the study hypothesis at the time of extraction. The two authors (AH and AD) responsible for performing the case-control matching were blinded to the study hypothesis and patient outcomes. The case-control matching team matched the cases following an internally derived algorithm that attempted to control for known confounders. First, the algorithm directed the two researchers to match the cases with controls within the same year of arrest to attempt to control for any changes in paramedic education and inpatient treatment modalities. After AH and AD segregated the patients by year of arrest, the matching occurred. The algorithm directed the two researchers to match the cases by the following categories: EMS witnessed arrest, witnessed arrest, bystander CPR, age +/- 5 years, race, and time of arrest. EMS witnessed arrest was given the highest priority for matching and time of arrest was given the lowest priority. The two authors matched each
unique case with the best available unique control. After the unique cases were matched with unique controls, one author (JM) performed the data analysis.

**Outcomes**

The primary outcome of our study was survival to hospital admission. Secondary outcomes were prehospital return of spontaneous circulation (ROSC), survival to hospital discharge, and neurologically intact survival to hospital discharge (defined as Cerebral Perfusion Category (CPC) 1&2).

**Statistical Analysis**

Our team used Fisher’s exact test to examine the association between DSD and our identified outcomes. Statistical significance was defined as \( p<0.05 \). We utilized an odds ratio (OR) to estimate the magnitude of the effect that double sequential defibrillation had on our identified outcomes. We used the Wilson/Brown method to determine the 95% confidence intervals (CIs) of proportions. Microsoft Excel (Microsoft Corp., Redmond, WA) was used to manage the data. We analyzed the data with Graph Pad Prism 7 (GraphPad Software, Inc., La Jolla, CA).

This study is retrospective in nature. Therefore, we used all years with finalized data in our registry to arrive at our initial cohort. We assumed that an OR equal to 3.47 correlates to a moderate effect size. Additionally we predicted that the percentage of the exposure (DSD) among the controls would be 20%. Our team opted for a 1:1 matched study design based on the size of our available sample. Given these factors our power analysis suggested that a minimum of 49 matched pairs (49 patients that survived to hospital admission, and 49 patients that did not survive to hospital admission) would be needed to obtain statistical significance (80% power for a significance of 0.05).

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RESULTS

Characteristics of Study Subjects

Of 3469 consecutive OHCA patients during the study period, 205 OHCA patients met the inclusion criteria of refractory VF/pVT. Ten cases had incomplete outcome data and were excluded from analysis. Sixty-four unique cases of survival to hospital admission were identified and matched with sixty-four unique controls (Figure 2). The demographics of the DSD and conventional therapy groups are reported in Table 1. A breakdown of the therapies administered to the DSD and conventional therapy groups are reported in Table 2.

Main Results

In our matched case-control study, survival to hospital admission occurred in 48.0% of DSD patients and 50.5% of the conventional therapy patients (p>0.99) (OR 0.91, 95% CI [0.40,2.1]). Prehospital ROSC occurred in 20.0% of the DSD patients and 40.8% of the conventional therapy patients (p=0.07) (OR 0.36, 95% CI [0.14,1.06]). Survival to hospital discharge occurred in 16.0% of the DSD patients vs 23.3% of the conventional therapy patients (p=0.59) (OR 0.63, 95% CI [0.22,1.9]). Neurologically intact survival to hospital discharge occurred in 12.0% of the DSD patients vs 19.4% of the conventional therapy patients (p=0.56) (OR 0.57, 95% CI [0.17,2.1]). (Table 2).

DISCUSSION

We found no association between the use of prehospital DSD for refractory VF/pVT and survival to hospital admission. Additionally, none of our secondary outcomes demonstrated a difference between the DSD cohort and the conventional therapy cohort. This analysis of the effectiveness of our prehospital DSD protocol had sufficient power to detect a moderate effect on the patient-centered outcome of survival to hospital admission. Currently, we believe this study is the largest to date that compares prehospital DSD with conventional therapy in refractory VF/pVT management. Additionally, using a matched case-control design allowed us to mitigate some confounding variables from our cohort.

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Previously, we reported our experience with DSD in recurrent and refractory shockable rhythms OHCA.\textsuperscript{16} Amongst the authors, there was disagreement over whether or not recurrent and refractory shockable rhythms should be analyzed together. Our previous study did not attempt to control for differences between the two populations. This matched case-control study was designed to alleviate these concerns. The three case series on the prehospital use of DSD found neurologically intact survival rates of 0\%, 16.6\%, and 28.6\% respectively.\textsuperscript{17,19,20} The London based retrospective cohort analysis found a 7.0\% survival to hospital discharge.\textsuperscript{21} Our finding of 12\% neurologically intact survival to hospital discharge is in line with these publications.

Our study suggests that there is no benefit to our current protocol of considering prehospital DSD after the third conventional defibrillation for refractory VF/pVT. One hypothesis for our findings is that we deployed the DSD therapy too late in the patient’s clinical course to make a significant difference in their outcome. The fact that we typically deploy DSD after the 4th shock in our system supports this hypothesis. By deploying DSD as a salvage therapy in our system, we selected for the most refractory electrical storm cases. The IQR of the total EMS defibrillations of the DSD cohort (6-8.75) and the standard therapy cohort (4-5) supports the assertion that patients in the DSD cohort were more “refractory” than the standard therapy cohort. If one extends this theory to its ultimate conclusion, the fact that there was no difference in the DSD cohort vs. conventional therapy cohort may be indicative of DSD having some clinical effect. Alternatively, it is equally plausible that DSD is no more effective than conventional defibrillation. The primary endpoint of survival to hospital admission is merely a step to the ultimate objective of neurologically intact survival to hospital discharge. In order to make a significant impact on the real objective, the effect size on the intermediate step of survival to hospital admission needs to be significant. The 95\% CI of our OR (0.40 to 2.1) is not consistent with the required effect size that would make DSD an essential link in the chain of survival for electrical storm patients.
As a result of these data, we critically examined our policy. In our system, two defibrillators will be present at all of our OHCA resuscitations. Therefore, implementing DSD requires no change in how we allocate our resources. We modified our treatment strategy to include more aggressive DSD implementation in combination with a plan to screen these electrical storm patients for a combination of mechanical CPR facilitated transport, ECMO, and PCI.

Future studies are needed from other large volume EMS systems. Researchers should attempt to compare DSD outcomes with conventional therapy outcomes in those systems. Due to the low incidence of the disease process and lack of clear benefit of the therapy, a prospective multisystem cohort analysis is the best option for determining if DSD is a beneficial prehospital therapy.

LIMITATIONS

Our study has limitations. First, matched case-control studies are inherently vulnerable to selection bias. We attempted to mitigate this by blinding the individuals responsible for matching cases and controls. Additionally, our predefined matching algorithm was designed to minimize the subjective nature of matching cases with controls. Second, our protocol leaves the decision to administer double sequential defibrillation to the lead paramedic. This protocol structure increases the possibility of an unknown confounding variable causing bias. In our system, the data suggests that DSD was employed as a salvage therapy for refractory ventricular fibrillation patients. Third, a matched case-control study is only generalizable to a similar target population. This dataset was derived from a large, highly resourced advanced life support (ALS) EMS system. Additionally, the source of our refractory VF/pVT cohort is QA/QI data. Therefore, it is not generalizable. Fourth, we were not able to control for quality of CPR. Although we do use a standard CPR feedback device during our resuscitations, that data point is not imported into the ePCR. The UTHSCSA OMD lacks the workforce to manually download CPR quality data for all of our OHCA patients. Previous datasets that yielded negative
results after analysis have subsequently yielded positive results on reanalysis after controlling for CPR quality.²⁸ Finally, data fidelity was not complete in the existing OHCA database for some of the relevant data elements. As a result of the omitted data, 4.8% of the relevant patient population was not eligible for inclusion. These missing data points are a source of information bias.

CONCLUSION

Our matched case-control study on the prehospital use of double sequential defibrillation for refractory ventricular fibrillation/pulseless ventricular tachycardia found no evidence of associated improvement in survival to hospital admission. Our current protocol of considering prehospital double sequential defibrillation after the third conventional defibrillation in out-of-hospital cardiac arrest is ineffective.
References:


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**Figure legends**

**Figure 1.** Graphic depiction of pad placement for double sequential defibrillation. The primary set of pads (blue) is placed in the anterolateral position. The second set of pads (red) is placed in the anterior/posterior orientation.

**Figure 2.** There were 205 cases from the cardiac arrest database that met inclusion criteria for refractory ventricular fibrillation (VF) or pulseless ventricular tachycardia (pVT). Ten cases were excluded as they were missing outcome data. Of the 195 remaining cases of refractory VF/pVT, 64 survived to hospital admission. The matched controls did not survive to hospital admission.

**Table 1.** Demographic information about the two groups, double sequential defibrillation and those receiving conventional therapy.

**Table 2.** Treatment information about the two groups, double sequential defibrillation and those receiving conventional therapy.

*Includes Fire Department AED defibrillations, EMS defibrillations, and EMS Double Sequential Defibrillations.

** Data only available for 2014 and 2015.

**Table 3.** Comparison of outcomes for the two groups, double sequential defibrillation and those receiving conventional therapy.
<table>
<thead>
<tr>
<th>Mean Age</th>
<th>58.3</th>
<th>10.6 (SD)</th>
<th>58.4</th>
<th>13.3 (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Male</td>
<td>88%</td>
<td>70.0% - 95.8%</td>
<td>77.7%</td>
<td>68.7% - 84.6%</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>16%</td>
<td>6.4% - 34.7%</td>
<td>16.5%</td>
<td>10.6% - 24.9%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>60%</td>
<td>40.7% - 76.6%</td>
<td>38.8%</td>
<td>30.0% - 48.5%</td>
</tr>
<tr>
<td>White</td>
<td>20%</td>
<td>8.9% - 39.1%</td>
<td>40.8%</td>
<td>31.8% - 50.4%</td>
</tr>
<tr>
<td>Other</td>
<td>4%</td>
<td>0.2% - 19.5%</td>
<td>3.9%</td>
<td>1.5% - 9.6%</td>
</tr>
<tr>
<td>% Bystander CPR</td>
<td>32%</td>
<td>17.2% - 51.6%</td>
<td>50.5%</td>
<td>41.0% - 59.9%</td>
</tr>
<tr>
<td>% Public AED usage</td>
<td>8%</td>
<td>1.4% - 25.0%</td>
<td>3.9%</td>
<td>1.5% - 9.6%</td>
</tr>
<tr>
<td>% Bystander Witnessed Arrest</td>
<td>52%</td>
<td>33.5% - 70.0%</td>
<td>61.2%</td>
<td>51.5% - 70.0%</td>
</tr>
<tr>
<td>% EMS Witnessed Arrest</td>
<td>8%</td>
<td>1.4% - 25.0%</td>
<td>1.9%</td>
<td>0.3% - 6.8%</td>
</tr>
</tbody>
</table>

Table 1. Demographic information about the two groups, double sequential defibrillation and those receiving conventional therapy.
<table>
<thead>
<tr>
<th>Information</th>
<th>Double Sequential Defibrillation</th>
<th>Conventional Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALS Response</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dispatch to EMS arrival, median (IQR) - min</td>
<td>8 (6-12)</td>
<td>8 (6-10)</td>
</tr>
<tr>
<td>CPR augmentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical CPR, percentage (95% CI)</td>
<td>40.0% (23.4-59.3)</td>
<td>21.0% (14.6-30.3)</td>
</tr>
<tr>
<td>Drugs Administered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amiodarone, median (IQR) - mg</td>
<td>450 (450-450)</td>
<td>450 (450-450)</td>
</tr>
<tr>
<td>Epinephrine, median (IQR) - mg</td>
<td>6 (4.5-6.5)</td>
<td>5 (4-6)</td>
</tr>
<tr>
<td>Defibrillations administered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BLS AED usage, percentage (95% CI)</td>
<td>28.0% (14.3-47.6)</td>
<td>40.8% (31.8-50.4)</td>
</tr>
<tr>
<td>Total EMS defibrillations, median (IQR)*</td>
<td>7 (6-8.75)</td>
<td>5 (4-5)</td>
</tr>
<tr>
<td>Defibrillations prior to DSD attempt, median (IQR)**</td>
<td>4.5 (4-6.75)</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Treatment information about the two groups, double sequential defibrillation and those receiving conventional therapy.

*Includes Fire Department AED defibrillations, EMS defibrillations, and EMS double sequential defibrillations.
<table>
<thead>
<tr>
<th>Primary Outcome</th>
<th>Double Sequential Defibrillation</th>
<th>Conventional Therapy</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival to Hospital Admission</td>
<td>48% (12/25)</td>
<td>50.5% (52/103)</td>
<td>1.00</td>
</tr>
<tr>
<td>Secondary Outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prehospital ROSC</td>
<td>20% (5/25)</td>
<td>40.8% (42/103)</td>
<td>.07</td>
</tr>
<tr>
<td>Survival to Hospital Discharge</td>
<td>16% (4/25)</td>
<td>23.3% (24/103)</td>
<td>.59</td>
</tr>
<tr>
<td>CPC 1 or 2 Survival to Hospital Discharge</td>
<td>12% (3/25)</td>
<td>19.4% (20/103)</td>
<td>.56</td>
</tr>
</tbody>
</table>

Table 3. Comparison of outcomes for the two groups, double sequential defibrillation and those receiving conventional therapy.
Figure 1: Graphical depiction of pad placement for double sequential defibrillation. The primary set of pads (blue) is placed in the anterolateral position. The second set of pads (red) is placed in the anterio/posterior orientation.
Figure 2. There were 205 cases from the cardiac arrest database that met inclusion criteria for refractory ventricular fibrillation (VF) or pulseless ventricular tachycardia (pVT). Ten cases were excluded as they were missing outcome data. Of the 195 remaining cases of refractory VF/pVT, 64 survived to hospital admission. The matched controls did not survive to hospital admission.