A randomized control hands-on defibrillation study - barrier use evaluation

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Abstract

Introduction: Chest compressions and defibrillation are the only therapies proven to increase survival in cardiac arrest. Historically, rescuers must remove hands to shock, thereby interrupting chest compressions. This hands-off time results in a zero blood flow state. Pauses have been associated with poorer neurological recovery.

Methods: This was a blinded randomized control cadaver study evaluating the detection of defibrillation during manual chest compressions. An active defibrillator was connected to the cadaver in the sternum-apex configuration. The sham defibrillator was not connected to the cadaver. Subjects performed chest compressions using 6 barrier types: barehand, single and double layer nitrile gloves, firefighter gloves, neoprene pad, and a manual chest compression/decompression device. Randomized defibrillations (10 per barrier type) were delivered at 30 joules (J) for bare hand and 360J for all other barriers. After each shock, the subject indicated degree of sensation on a VAS scale.

Results: Ten subjects participated. All subjects detected 30j shocks during barehand compressions, with only 1 undetected real shock. All barriers combined totaled 500 shocks delivered. Five (1%) active shocks were detected, 1(0.2%) single layer of Nitrile, 3(0.6%) with double layer nitrile, and 1(0.2%) with the neoprene barrier. One sham shock was reported with the single layer nitrile glove. No shocks were detected with fire gloves or compression decompression device. All shocks detected barely perceptible ($0.25(\pm 0.05)$ cm on 10 cm VAS scale).

Conclusions: Nitrile gloves and neoprene pad prevent (99%) responder's detection of defibrillation of a cadaver. Fire gloves and compression decompression device prevented detection.

1. Introduction:

CLEAR, Clear, Clear - has been the pre-shock dogma taught by resuscitation educators for decades[1]. Defibrillation is the standard of care for the management of ventricular fibrillation and ventricular tachycardia[2] (VF/VT), and involves the discharge of direct current through the chest[3]. Unfortunately, being “clear” requires all rescuers to remove their hands from the chest, resulting in the immediate cessation of blood flow, i.e. pre-shock pause. In 2011, the Resuscitation Outcomes Consortium (ROC) reported that pre-shock and peri-shock pauses were independently associated with a decrease in survival to hospital discharge[4, 5]. As such, minimizing interruptions on chest compressions has now become the primary goal of cardiac resuscitation.[5].

This places defibrillation, and continuous chest compression standards in direct conflict. The risk of electrocution for any rescuer touching the patient during the electrical discharge of defibrillation is the underlying source of the conflict - rescuer safety[6].

The purported electrical shock hazard of defibrillation was due to the large, rigid, metallic electrodes which allowed for substantial variability with respect to electrode contact and the performance of the conductive gel[7]. Current state-of-the-art electrode technology is vastly improved with self-adhesive pre-gelled and conforming electrode pads resulting in enhanced electrode-skin coupling.[8] In addition, monitor technology has incorporated real-time impedance monitoring reducing required peak voltage.

This paper reports on the concept of delivering a defibrillatory shock without removing the rescuer's hands in an experimental cadaver model, and the assessment of various potential rescuer safety barriers.

Hypothesis: Defibrillation is undetectable with an insulating barrier between the rescuers hands and the cadaver.

2. Methods:

2.1 Ethic Review

This protocol was reviewed by The University of Texas Health Science Center at San Antonio's Institutional Review Board for ethical consideration in human subjects research (Protocol Number: HSC20140411H). All subjects provided full informed consent prior to participation. A Licensed emergency physician and on duty EMS crew were on site at all times.

2.2 Study Design and Setting

This was a blinded prospective double-randomized (order of shocks and types of barriers) control study comparing a rescuer's ability to detect defibrillation in a fresh unembalmed cadaver while performing chest compressions using several hand barrier types. The study was conducted at the Centre for Emergency Health Sciences in Bulverde Texas. All participants were certified or licensed prehospital providers.

2.3 Study Protocol

A fresh unembalmed cadaver was placed on a nonconductive wooden table, with a nonconductive plastic slideboard between the cadaver and table. Two identical monitor defibrillators (LIFEPAK 15 Physio Control, Redmond WA) were placed behind a cloth partition. One of the defibrillators had self-adhesive defibrillator pads attached to the chest of the cadaver in the Anterior-Apex configuration (active). The second defibrillator was attached to a module designed to safely and silently accept a defibrillator discharge (sham). Both monitors provided identical auditory signals during the charge and discharge process.

Participants were assigned a packet containing a randomized order of: bare hands, single layer 8 mil nitrile medical exam gloves (HighFive, Microflex Corp, Reno NV), double layer nitrile gloves, 15 cm X 20 cm neoprene pad insulator, National Fire Protection Association compliant structural firefighter gloves or a manual compression/decompression CPR device (ResQPUMP®, Advanced Circulatory® Roseville, MN). In all gloves groups, both hands used the same type and number of glove. The subject's electrocardiogram was monitored throughout the study, and a volt meter (in the μ A setting) measured the electrical potential between the subject's forearms.

The subject was instructed to perform chest compressions as per AHA guidelines using the assigned barriers. For each barrier, 10 defibrillations were administered, with half of the defibrillations being randomized to the cadaver, and half to the sham device. Subjects were blinded to the order of shocks. For defibrillations in which bare hands were in contact with the cadaver's chest, both monitors delivered 30 joules. For all other barrier methods, 360 joules were delivered.

After each shock, the investigators asked the subject if he/she was able to feel the shock (yes/no). If the shock was felt, a 10 cm visual analog scale (VAS) was administered to determine the level of shock experienced, with zero being "the shock was not perceptible" and 10 cm being "systemically painful."

2.4 Statistical Analysis

Excel (Redmond, WA) was used to develop descriptive statistics, and GraphPad QuickCalcs was used for inferential analysis. Results are presented as means, standard deviation and 95% confidence intervals. Power analysis was calculated using two-tailed Fisher's exact test.

3.0 Results

3.1 Participation

Ten subjects participated in this study. There were a total of 100 defibrillations (30 joules) delivered while the subject used bare hands, and 500 defibrillations (360 joules) delivered while the subject used some type of insulating barrier. One-half of the defibrillations were actively transmitted to the cadaver. Two cadavers were utilized.

3.2 Defibrillation perception

3.2.1 Bare Hands

With bare hands on the chest, 49 of 50 (98%) 30 joule defibrillations were detected by the subject. Mean detection level was 3.2 of 10 (± 2.2 , 95%CI, 2.6-3.8) $p < 0.001$. Only one (2%) active shock was not detected, and no sham shocks were detected. The volts meter reported a mean 0.48 (± 0.4 , 95% CI 0.34-0.61) μA between the forearms of the subject.

3.2.2 Nitrile Gloves

During defibrillation with single layer nitrile gloves only two shocks (2%) were detected. One shock was detected during active defibrillation, and one detected sham shock. Both shocks were reported as barely perceptible, < 0.1 cm on a 10 cm VAS $p < 0.001$.

With double gloves, 3 active defibrillations were detected and no sham defibrillations were detected. Mean detection level was 0.23 cm of 10 cm (± 0.6 95%CI 0.09-.037) $p < 0.001$. The mean volt meter reading was 0.2 (± 0.07 95%CI 0.11-0.29) μA .

3.2.3 Other Barriers

One shock was felt using bare hands over the neoprene pad. This single detected defibrillation was an active shock with a detection rating on 0.3 cm of 10 cm (barely perceptible), and no change from baseline on the volt meter.

No defibrillations were detected with either the structural firefighting gloves or the manual compression/decompression device. There were no changes in volt meter reading with either device.

4.0 Discussion

This study demonstrated that defibrillation was essentially undetectable with any level of insulating barrier between the rescuers hands and the cadaver. The data demonstrate the feasibility of continuous manual chest compressions throughout the resuscitation cycle as long as the rescuers wear even standard nitrile exam gloves. This is critical because of the hemodynamic consequences of stopping compressions. The ROC study group demonstrated the clinical impact of the preshock pause alone was predictive of hospital discharge. Discussion continues on the impact of both pre and post shock pauses in compressions, still no clear evidence on outcome consequence.

There are a few case reports in the literature of rescuers “getting shocked” while in contact with a patient during defibrillation. Karidis et al report a caregiver performing chest compressions when an internal implanted defibrillator was discharged. In this case the caregiver was barehanded, and the report described the caregiver was “thrown back”[9]. After interrogation of the defibrillator, the patient was shocked at 22 joules. This was a very brief report and provided no details on the outcome of the caregiver. Another report of a rescuer detecting an implanted defibrillator discharge reported having some minor ulnar nerve effect that lasted an hour, and nonclinically detectible symptoms for a few months. This case reports the rescuers hand was in contact with the chest, but there was no mention of glove usage or energy exposure[10]. This report also indicated that other rescuers touching the patient’s head while performing airway maintenance, were aware of the discharge, but that was secondary to the sudden patient movement, and not electrical current.

There is a single case of death reported, but this was a case where the decedent had placed the electrodes directly in his chest and delivered discharged the defibrillator. The result if this deliberate

misuse of the defibrillator was unsuccessful resuscitation from ventricular arrest [11]. While this was an unfortunate event, it is not directly related hands on defibrillation nor does it significantly impact the results of this current study.

As a therapy, the goal of defibrillation is the delivery of energy to the patient's chest via self-adhesive conductive electrodes. The level of energy required for successful defibrillation is generally accepted to be 100 joules to 360 joules for an adult patient[12]. However there are several reports of the use of double sequential defibrillation with energy selected to 360 joules each on two defibrillators and both defibrillators discharged by simultaneously pressing the shock buttons [13]. The intent is to deliver the full dose of energy to safely terminate the ventricular arrhythmia. The actual dosage of energy that would be delivered to the rescuer should be much lower, especially with electrical barriers between the patient being defibrillated and the rescuer. Lloyd et al demonstrated safety of hands on defibrillation with gloved hands[14].

Deakin et al studied the protection afforded by standard nitrile medical exam gloves[15]. Here the gloves degraded during physical activity of chest compressions. Notwithstanding, this looked only at the electrical conductivity of unused gloves compared to those after use. This would assume that the rescuer would be in contact with the patient with hands in the direct path of the patient, and that there was another patient-rescuer contact that would allow completion of the electrical circuit. This is a valid concern especially in the uncontrolled environment of a prehospital resuscitation. This concern led to the concept of double gloves and other barriers commonly utilized by prehospital personnel. Deaken also tested the use of electrical safety gloves, while these would maximize the safety during hands on defibrillation, these are not common in prehospital medicine and were not tested in real CPR situations. [16].

In the interest of subject safety, for this study, any time a subject placed hands on the chest we reduced the energy level to 30 joules. This energy setting is well below the therapy threshold for cardioversion in children, and was therefore considered safe for this experiment in adults. Even at the lower energy setting, defibrillation was easily detected, with only a single shock going undetected. This experiment was not designed to test for safety of this practice, but it appears bare handed hands-on defibrillation is likely not a good idea, especially considering the higher energy settings typically used for adult defibrillation.

For the study described here, all of the defibrillations were performed with the self-adhesive defibrillation pads placed in Sternum – Apex configuration. Our subjects then placed their hands between the pads on the center of the chest, presumably in the primary vector of electron flow. To date there have been no data showing this configuration has any clinical benefit over other pad placement configurations. Another common configuration is the anterior-posterior placement. Here the anterior pad is placed on the lower half of the chest just to the left of the sternum. This places the pad nearest the ventricular myocardium. This placement would potentially have the rescuers hand on or very near the pad. Anterior-posterior configuration was not tested in this study.

An unknown factor associated with this experiment is potential change in electrical conduction as time elapses after death. To minimize this confounder we utilized a fresh unembalmed cadaver, and measured transthoracic impedance. The transthoracic impedance did not significantly change throughout the day, and was not remarkable different from those seen in active resuscitations (data not shown).

Another necessary limitation of this study involved the great care that was taken to keep subjects safe and to minimize the risk. We maintained a very clean and dry “rescue area” throughout the study, whereas environmental conditions in a real life rescue setting would be quite different with suboptimal

hygiene and moisture control. Clearly, mimicking that setting exactly would negatively affect the safety profile.

5.0 Conclusions

Structural firefighter gloves and compression decompression device prevent detection of a 360 joule defibrillation of a cadaver during active chest compressions. Nitrile gloves or a neoprene pad essentially prevent (99%) responder's detection of a 360J defibrillation on a cadaver. Defibrillation with bare hands on the chest was easily detectable even at a reduced energy level.

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Figure 1.

Monitor “A” was the active monitor with defibrillation pads applied to the cadaver’s bare chest in the sternum apex configuration. Monitor “B” was the sham, and was connected to the Test Load, which safely and silently accepts a defibrillation. A visual barrier was used for the purposes of blinding, and both defibrillators provided identical auditory stimulus during the “charge” and “discharge” events.

Table 1.

Barrier method	Real Shocks		Sham Shocks	
	Detected	not Detected	Detected	not Detected
No Barrier	49	1	0	50
Single Layer nitrile Gloves	1	49	1	49
Double layer nitrile gloves	3	47	0	50
Neoprene Pad	1	49	0	50
Firefighter gloves	0	50	0	50
Comp/Decomp Device	0	50	0	50