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Clinical paper

Hands-on defibrillation with a safety barrier: An analysis of potential risk to rescuers

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Abstract

Background: Interruptions in compressions reducethe efficacy of cardiopulmonary resuscitation (CPR) and are inevitable during hands-off periods for shocks. Clinical exam gloves were found to facilitate safe contact with patients during shock delivery but the safety of this practice has been questioned. Polyethylene is of interest because of its safety record in the medical arena and its electrical insulation properties.

Methods: This study measured the current leak through 2 mil (0.002 inch) polyethylene drapes during shock delivery. The current leak was assessed by measurement of voltage changes in a circuit recommended by the International Electrotechnical Commission (IEC) for current leak safety testing. Current flowed off the drape, through the circuit and to electric ground in a manner consistent with standardized testing. Perceptibility was assessed in a subset with the investigator's bare hands pressed into the drape during shock delivery.

Results: Thirty-three patients undergoing elective cardioversion at Emory University Hospital underwent analysis (age 23–90, 36% female). Biphasic energies were 200–360 J. The root mean square (RMS) current leak averaged 0.072 ± 0.022 mA and peak current leak averaged 0.67 ± 0.21 which is well below IEC recommendations of 3.5 mA RMS and 5.0 mA peak. Finally, no instances of dielectric breakdown occurred and no shocks were perceptible.

Conclusions: Polyethylene is a common medical material which may facilitate safe hands-on defibrillation. Our data illustrates that a thin, semitransparent layer of polyethylene is a safe and feasible adjunct to cardiac arrest kits to allow continued compressions and simplification of the CPR process.

Keywords: Defibrillation, Rescuer safety, Chest compressions

Introduction

Sudden cardiac arrest is a major public health concern, with approximately 420,000 cases occurring annually in the United States.[1] "Shockable" arrhythmias, including ventricular tachycardia and ventricular fibrillation (VT/VF), account for significant portion of sudden cardiac arrests. In CPR of VT/VF, studies have demonstrated a substantial relationship between the success rate of defibrillation and the amount of time delay between stopping compressions and shock delivery.[2,3] The requirement that rescuers stand clear during shock delivery is one factor contributing to hands off time, especially in the crucial period leading up to shock delivery.[4]

Researchers have hypothesized that continuing compressions through shock delivery would be ideal. Previous research has shown that clinical exam gloves could facilitate continuation of compressions through shock delivery while providing adequate safety for rescuers in contact with patients during shock delivery by measuring leakage current through rescuers in contact with humans receiving defibrillation.[5] Subsequent studies found that not all glove types are effective.[6,7]

An alternative to allow the safe continuation of compressions is the utilization of a physical electrical insulation barrier draped over a patient's chest. There has been interest in use of this type of barrier as

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part of defibrillator pads to allow better protection between rescuers and victims while still allowing access to the victim. Polyethylene material is of particular interest due to their common use in medicine and its high electric resistance properties. Polyethylene is commonly used in high voltage insulation systems.[8,9]

This study assessed the effectiveness of 2 mil (0.002 inch) polyethylene drapes in protecting potential rescuers by analyzing the leakage current or "touch current" off the drape and through a model of human electrical impedance.

Methods

The study protocol was approved by the Institutional Review Board at Emory University. Written informed consent was obtained from all patients. The patient population recruited for the study included those undergoing elective cardioversion for atrial fibrillation or flutter. The external defibrillator used was a Lifepac 15 (Medtronic Corp., MN), which delivers a truncated biphasic waveform. The defibrillator power source was a grounded standard mains outlet. The shocking electrodes were self-adhesive pads placed in the anteroposterior position for all patients.

A schematic of the patient, polyethylene drape and current measurement apparatus schematic is shown in Fig. 1. In assessment for current flow off the drape, a conductive grounding pad with adhesive conductive gel was applied to the drape over the approximate location contact in cardiopulmonary resuscitation (CPR). The wire from the grounding pad was connected to the IEC 60990 weighted touch current circuit terminal A in Fig. 2. This circuit represents a well-established model for human electrical impedance which is utilized in electrical safety testing. Rs and Cs represent human skin resistance and capacitance respectively. Rb represents internal human body resistance.[10] R1 and C1 adjust for the dependence of human body impedance upon frequency.[11] Terminal B was connected to the same or adjacent electric ground as the Lifepak 15. The current leak was assessed by measurement of changes in the voltage U2 across the 500 Ω resistor as described in IEC 60990 in conjunction with Ohm's law. The voltage changes were captured with a laptop Picoscope 2202 and a Tektronix P2220 Voltage probe. To simulate pressure in a CPR situation, approximately 20 lbs of downward force was applied to a towel over the drape and grounding pad during shock delivery. The current leak was assessed at least 4 times through each drape to assess whether shocks caused polyethylene to breakdown and loose strength as an electrical insulator.

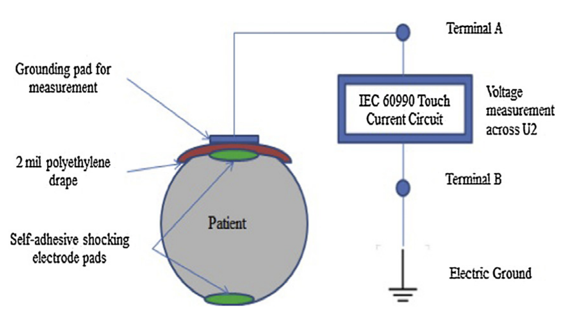

Fig. 1 – Patient — measurement apparatus setup. The 3′ × 3′ polyethylene drape was placed over the patient's anterior chest. A grounding pad was attached to the drape in the approximate location of chest compressions. The wire from the grounding pad was attached to terminal A in the IEC 60990 circuit and terminal B was connected to electric ground.

Shock energy and transthoracic impedance values were also recorded with each shock. After data collection, linear regression was preformed to analyze the effect of shock number, shock joules and transthoracic impedance upon current leakage. Additionally, to assess the proper functioning of the measurement apparatus, the grounding terminal was attached to other far electric ground outlets and metallic objects in separate test cases. The perceptibility of the shocks was assessed subjectively by a single investigator with bare hands pressed over the 2 mil (0.002 inch) polyethylene drape. The investigator pressed their hands over the anterior chest in the location of the ideal compressions with approximately 20 lbs of downward force.

Results

Current leak data was gathered from 23 patients receiving a total of 27 shocks. In 4 of the 27 shocks, there was no trigger of the oscilloscope yielding 23 shocks for analysis. 18 of the 23 shocks were 200 J and 5 were 360 J. Of the 23 shocks, the mean AC RMS current leak was 0.07 ± 0.02 mA (range 0.038–0.116 mA) and the mean peak current leak was 0.67 ± 0.21 mA (range 0.266–1.078 mA). This was well below maximum IEC AC RMS and Peak current leaks based upon recommendations for measurements using the same circuit and general setup. The shock capture durations were approximately 15 −20 ms and aligned with the known duration of the Lifepak shock sequence as seen in Fig. 3.[12] The morphology of the waveform did not differ in the separate test cases of the functioning of the measurement apparatus. The net average current leaks, current leaks based upon drape shock number are shown below in Tables 1 and 2. The average transthoracic impedance was 76 ± 20 Ω (range 53–133 Ω). The current flow corresponded to the onset and offset of each part of the biphasic shock (Fig. 3).

Linear regression analysis of peak current and AC RMS current based upon the shock number, patient impedance and shock energy was performed. There were no impedance values for 3 patients who were not included in the regression analysis. There was a non-significant trend towards lower peak leak currents with additional shocks of the same drape ($\beta = -0.053$ mA/shock, $p = 0.17$). There was also a non-significant trend towards higher peak leak currents with increased shock energy ($\beta = 0.0015$ mA/J, $p = 0.07$). The patients' impedance had little impact upon the leakage current ($\beta = 0.0011$ mA/Ω, $p = 0.66$). Regression of AC RMS current based upon the same variables showed the same results. There trend towards lower AC RMS currents with additional shocks of the same drape ($\beta = -0.005$ mA/shock, $p = 0.24$). There was a trend towards higher AC RMS currents with increased shock energy ($\beta = 0.00015$ mA/J, $p = 0.08$). The patients' impedance had little impact upon the AC RMS current ($\beta = 0.00014$ mA/Ω, $p = 0.58$).

Finally, as a means of some form of physiologic confirmation of the low leakage currents measured in our dataset, perception was assessed separately in 8 patients receiving a total of 10 shocks including one instance where the investigators right ankle was connected to electric ground. 8 of the 10 shocks were 200 J and 2 were 360 J. None of the 10 shocks were subjectively perceptible by the nonblinded investigator.

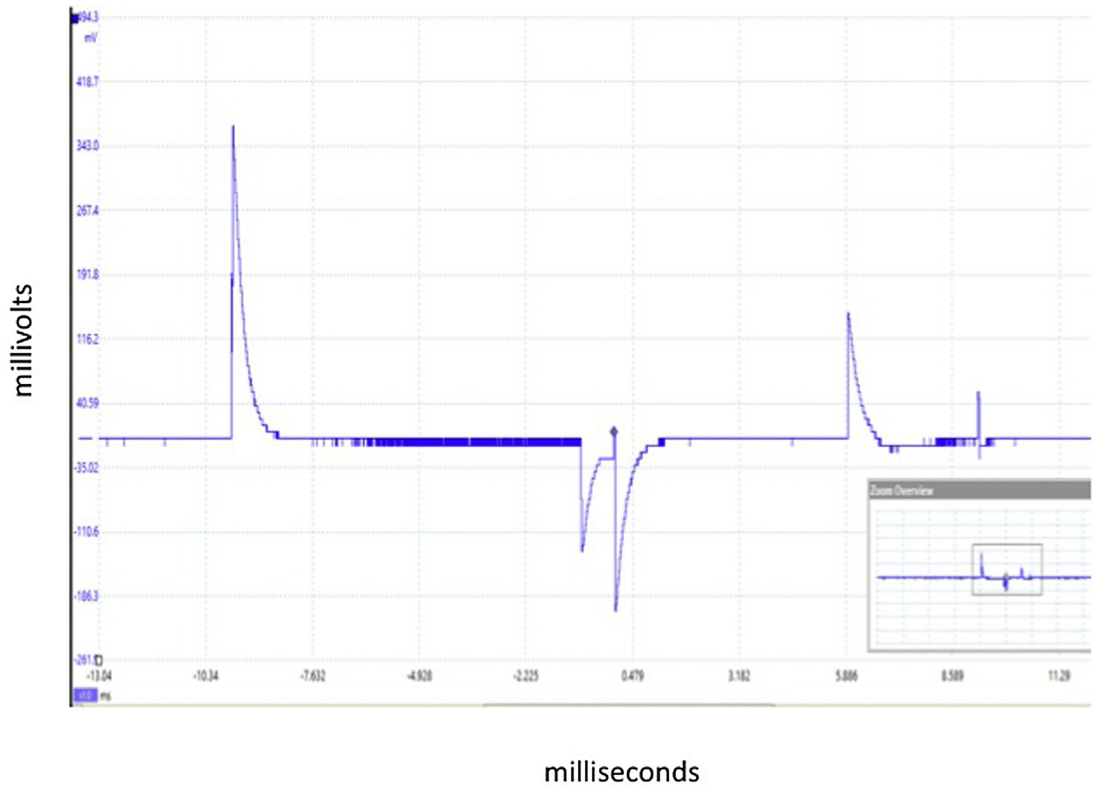

Fig. 2 – IEC 60990 weighted touch current circuit. Voltage changes were measured across U2 in this figure. Currents were then calculated across utilizing Ohm's law.

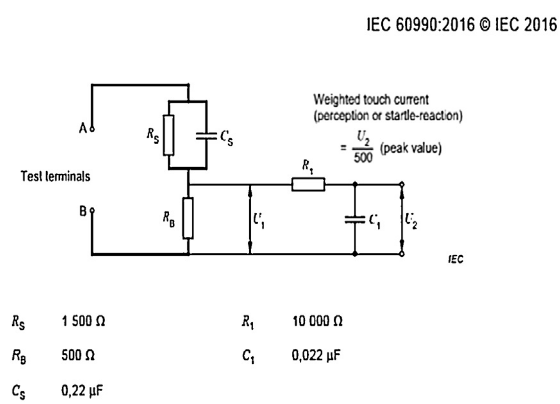

Fig. 3 – Voltage across U2 during shock capture. The AC RMS and peak currents were derived from these waveforms with Pico scope software functions.

Table 1 – Cumulative meanpeak and AC RMS current.

	Measured mean	IEC maximum
RMS current	0.072 ± 0.022 mA	3.5 mA
Peak current	0.67 ± 0.21 mA	5 mA

Table 2 – Mean peak and AC RMS current based upon the number of shocks each the drapes were exposed to.

Shock #	Waveforms acquired	Mean peak current	Mean AC RMS current
1	6	0.75 ± 0.21 mA	0.08 ± 0.02 mA
2	4	0.84 ± 0.16 mA	0.09 ± 0.02 mA
3	6	0.58 ± 0.16 mA	0.06 ± 0.01 mA
4	6	0.56 ± 0.17 mA	0.06 ± 0.02 mA
5	1	0.67 mA	0.07 mA

Discussion

This study was meant to assess touch current leak through 2 mil polyethylene drapes to medical personnel during defibrillator shocks. Through this analysis, 2 mil (0.002 inch) polyethylene was shown to reduce current flow to potential rescuers to low and safe levels. These findings are important because they add to previous evidence that continuing compressions through shock delivery is an achievable and safe potential improvement in CPR protocol. Preventing hands off time has been repeatedly demonstrated to improve patient outcomes, and data suggests that continuing compressions closer to shock delivery may additionally improve the efficacy of the shock in converting arrhythmias back to sinus rhythm.[3]

The exact interpretation of the current leak in this scenario has some nuance. Most standards for current leak utilize root mean square currents (RMS) which is effectively an evaluation of the area under the curve. Because the current flow across the drape was limited to short spikes, with effectively no current flowing through the majority of the ≈15–20 ms shock, the RMS touch leakage currents were far below the maximum IEC touch current of 3.5 mA and well below even the other more stringent standards for handheld devices of 0.750 mA RMS.[10]

The peak currents measured in our analysis were significantly higher with a mean of 0.67 ± 0.21 mA and a max of 1.08 mA, but still well within the maximum acceptable peak touch current of 5 mA based upon IEC standards.[11] These peaks were also extremely brief, with timings under 1 ms. Shorter durations of current exposures, due to less total energy, are well-known to be safer.[11,13] Past research on current leak and the fact that none of the ten shocks were perceptible including one with an electrode attachment to ground provides some physiologic reassurance that our results are reasonable.

There was no increase in the current flow with subsequent shocks of the same drape, indicating that there was no electrical breakdown of the polyethylene over multiple shocks of the same drape. There was a slight trend towards decreased current flow with subsequent shocks which likely represents the some loss in conductance of the adhesive grounding pad between shocks as the pad dried. In cardiac arrest scenarios, where numerous shocks may be given in the same episode, our data suggest that this insulator's dielectric can withstand repeated defibrillations.

Our study has several limitations. This IEC circuit and method of current leak is intended for stable continuous current leak where measurement can take place in a time frame longer than 1 s in duration.[14] A physicist and electrical engineer with whom we consulted agreed that our use of the circuit and interpretation of the waveform captures were reasonable.

Additionally, our method did not fully account for wet contact between all surfaces which is known be associated with higher leakage currents.[15] Furthermore, we only focused on the current pathway described for use in IEC 60990.

The perception tests, due to the nature of the potential risk to volunteers, was only performed on non-blinded investigators. Now that the general parameters of the apparatus and the magnitudes of the current leak are established, future studies could reasonably include volunteers with blinding and simulated shocks. Finally, we did not account for the physical stress of compressions upon polyethylene drapes in our analysis.

Summary

Uninterrupted chest compressions during shock delivery are an achievable advancement in CPR protocol. Thin, 2 mil (0.002 inch) polyethylene is enough to reduce current leaks to low and safe levels.

Disclosures

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