

Clinical Paper

Achieving safe hands-on defibrillation using electrical safety gloves – A clinical evaluation[☆]Charles D. Deakin ^{a,*}, Jakob E. Thomsen ^{a,b}, Bo Løfgren ^{b,c,d}, Graham W. Petley ^e^a NIHR Southampton Respiratory Biomedical Research Unit, University Hospital Southampton, Southampton, UK^b Research Center for Emergency Medicine, Aarhus University Hospital, Aarhus, Denmark^c Department of Internal Medicine, Regional Hospital of Randers, Randers, Denmark^d Institute of Clinical Medicine, Aarhus University, Aarhus, Denmark^e Faculty of Health Sciences, University of Southampton, Southampton, UK

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ABSTRACT

Introduction: Safe hands-on defibrillation (HOD) will allow uninterrupted chest compression during defibrillation and may improve resuscitation success. We tested the ability of electrical insulating gloves to protect the rescuer during HOD using a 'worst case' electrical scenario.

Materials and method: Leakage current flowing from the patient to the 'rescuer' during antero-lateral defibrillation of patients undergoing elective cardioversion was measured. The 'rescuer' maintained firm (20 kgf) contact with the patient during defibrillation, wearing Class 1 electrical insulating gloves while simulating an inadvertent contact with the patient, through an additional wired contact between 'rescuer' and patient.

Results: Data from 61 shocks from 43 different patients were recorded. The median leakage current from all defibrillations was 20.0 µA, (range: 2.0–38.5). In total, 18 of the shocks were delivered at 360 J and had a median leakage current of 27.0 µA (range: 14.3–38.5).

Conclusion: When using Class 1 electrical insulating gloves for hands-on defibrillation, rescuer leakage current is significantly below the 1 mA safe threshold, allowing safe hands-on defibrillation if the rescuer makes only one other point of contact with the patient.

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1. Introduction

The quality of external chest compression during resuscitation is crucial to successful defibrillation, admission to hospital alive and survival to hospital discharge.¹ Four factors indicate the quality of external chest compression: adequate compression rate, adequate depth of compression, complete chest recoil and a high compression fraction (percentage of time during which chest compressions are being delivered). The chest compression fraction is a key determinant of subsequent survival in patients with a shockable rhythm and current resuscitation guidelines therefore emphasise the need to minimise interruptions to chest compressions during CPR. Interruptions to chest compressions are surprisingly common and when they do occur, are often of considerable duration. Studies have demonstrated typical compression fractions (no-flow time) of

24–63%.^{2–5} Common reasons for interruption to CPR during out-of-hospital resuscitation include the need to secure the airway and subsequently ventilate the patient, assessing the rhythm or performing a pulse check, and performing defibrillation. Interruptions relating to defibrillation occur as the rescuer stands clear for the rhythm check and then subsequent shock delivery.¹ The associated pre-shock pause closely relates to the success of the ensuing defibrillation, with pauses longer than 10 s adversely impacting on defibrillation success.⁴

Interruptions to CPR in order to defibrillate are aimed at ensuring the safety of rescuers and avoiding an inadvertent shock from the electrical discharge of the defibrillator; typically as much as 3000 V and 20 A for biphasic defibrillators and 5000 V and 40 A for older monophasic defibrillators. Although accidental electrical contact during defibrillation generally results in no more than the sensation of a shock, some case reports have documented myalgia, neurapraxia and burns.² Clearly any risk to the rescuer, however small is unacceptable and international safety standards preclude contact with the patient during defibrillator discharge.³ The ability to safely perform 'hands-on' defibrillation (HOD – the rescuer continues performing chest compressions during the defibrillation)

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would make a significant contribution to minimising no-flow time and potentially contribute to improvements in survival, and as such, has been recognised as a research priority by the international resuscitation community.⁷

Although the majority of current supplied by the defibrillator flows through the heart, a small amount follows alternate pathways. This non-functional current is defined as a leakage current, some of which may flow through the rescuer. Previous studies have provided useful data on electrical pathways, but have not been able to conclusively recommend a technique with which to achieve safe hands-on defibrillation. Further studies have suggested that clinical examination gloves may provide adequate electrical insulation,⁴ but clinical reports of electrical shocks to rescuers suggest that this recommendation is flawed.^{5,6} Not only are clinical examination gloves not certified for this purpose, but several studies have demonstrated that clinical examination gloves lack the necessary dielectric strength and provide insufficient electrical resistance in these situations.^{10–12} Although several authors have advocated the use of HOD using no more than clinical examination gloves,^{4,7–9} other groups have appropriately cautioned against this practice based on theoretical,^{3,10,11} laboratory^{12,13} and clinical^{5,6} data.

This study aims to establish the feasibility of safe HOD when using electrical safety gloves (IEC 60903)¹⁴ to insulate the rescuer from the patient, studying patients undergoing electrical cardioversion as a clinical model replicating the electrical pathways encountered when performing defibrillation during resuscitation. When undertaking hands-on defibrillation, the rescuer will have both hands in contact with the patient and may, inadvertently, have an additional part of their body in contact with the patient; their hips or waist when a patient is on a bed or trolley, and knees when the patient is on the floor. We therefore aim to replicate this worst-case scenario. That is, direct physical contact with the patient's chest via the rescuer's hands, insulated by safety gloves, with an additional wired contact between patient and rescuer at a single additional point, to simulate an unintended contact. The additional contact was placed, unlike other studies, at a point giving the highest voltage difference and therefore resulting in maximal leakage current through the rescuer.¹⁵ Unlike previous studies, we will also use an anterior-lateral defibrillation electrode position, more typical of that used during cardiac arrests. This study is therefore a feasibility study aiming to assess the safety of using electrical safety gloves in order to provide a safe method of hands-on defibrillation.

2. Methods

2.1. Study design

To measure the electrical leakage current flowing through a rescuer protected by insulating gloves during hands-on defibrillation, we conducted a study on patients attending University Hospital Southampton for elective day case cardioversion of atrial fibrillation. The principles of the study were similar to those previously described by Lloyd,⁹ but with several differences. Rescuers, trained in basic or advanced life support, wore insulating safety gloves while simulating chest compressions by maintaining firm contact with the patient's skin while a defibrillator discharged. Further, to simulate a likely worst-case scenario, a second point of contact was made between rescuer and patient, the latter connection being a direct electrical connection with no electrical insulation, with the patient electrode placed at a point of maximal defibrillator output.

2.2. Study population

This study involved two subjects; the patient and a researcher acting as a rescuer. Following Research Ethics Committee approval

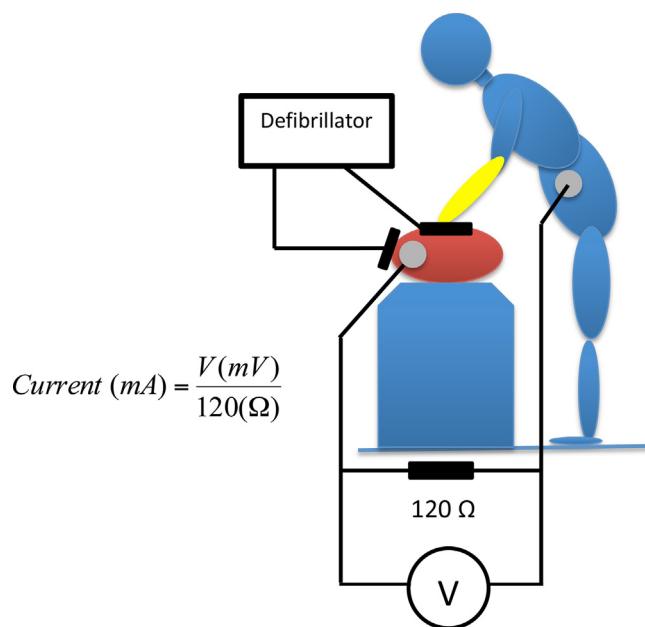


Fig. 1. Schematic showing the electrical circuit during defibrillation using the anterior-lateral configuration. ECG electrodes (●) were placed on the patient (adjacent to the lateral pad) and rescuer (waist) to simulate inadvertent contact.

(REC No: 13/SC/0064) informed written consent to participate in the study was obtained from both patient and rescuer. A convenience sample of sequential patients attending for elective day case cardioversion for atrial fibrillation between May 2013 and February 2014 were invited to participate in the study. Patient exclusion criteria were age <18 years, inability to give informed consent, and a rhythm other than atrial fibrillation displayed on the defibrillator monitor prior to commencing the procedure.

2.3. Study protocol

Cardioversion was carried out following the usual local procedure and according to the current resuscitation guidelines.^{16,17} Patients were taken to the anaesthetic room where intravenous access was established and monitoring including ECG, non-invasive blood pressure and pulse oximetry commenced. Following pre-oxygenation, general anaesthesia was induced using a sleep dose of propofol (2–3 mg·kg⁻¹).

Cardioversion was performed using a Lifepak 15 monitor/defibrillator (PhysioControl, Inc., Redmond, WA). Following manufacturer's guidelines, self-adhesive electrodes (Quik-Combo defibrillation electrodes) were applied to the patient's chest in an antero-lateral position, shaving chest hair if necessary. Following normal protocol for cardioversion, defibrillation energy was increased sequentially until cardioversion was successfully achieved using a standard sequence of synchronised shocks: 150J, 200J and 360J. Having reached 360J, a further 360J shock was delivered if necessary resulting in a maximum of four shocks.

2.4. Measurement intervention

In addition to the regular defibrillator pads, a third (ECG) electrode was attached immediately adjacent to the lateral defibrillation pad on the patient. This was connected to another ECG electrode placed on the rescuer's waist in order to simulate inadvertent, direct physical contact with the patient (Fig. 1). Replicating the method of Lloyd,⁹ a resistor (120 Ω) was introduced along this interconnecting cable to enable current to be measured. Resistance

Table 1
Demographic details of patients included in the study.

	Median	Range
Age (years)	63	40–85
Height (cm)	177	152–198
Weight (kg)	92	54–154

was chosen to be small compared with other impedances in the circuit and hence have negligible impact on the current flowing.

Prior to shock delivery the rescuer put on a pair of Class 1, electrical insulating gloves complying with IEC903 and therefore rated to 7500 V and the demands for mechanical strength required by this standard.^{18,19} Gloves that meet this standard are similar to those worn by linemen working with high voltage lines. Following guidelines,²⁰ and after obtaining written informed consent, the rescuer then placed their hands on the midpoint of patient's sternum in order to simulate the contact during chest compressions (in common with Lloyd⁹) to ensure a firm pressure was consistently applied to the patient's chest. This was achieved by the rescuer standing on a force-measuring platform, applying increasing pressure until 20 kg force was reached. The 20 kgf was chosen to ensure a firm pressure and adequate electrical contact without risking rib fractures in elective patients. This force was then maintained throughout the procedure.

2.5. Data collection and analysis

Voltage across the 120 Ω resistor was measured during shock delivery using a BIOPAC MP150 acquisition system (BIOPAC System Inc., Goleta, California) sampling at 100 kHz with an anti-aliasing filter attached to the input channel. From this, the current flowing through the known resistance (and therefore also flowing through the rescuer) was calculated using Ohm's Law.

The primary outcome measure was the root mean square (RMS) current over the duration of shock delivery. Following the method of Lloyd,⁹ transient artefact present during the first 50 μs of the onset, phase change and termination of the pulse was excluded.⁹ For each energy level, the median and range of currents were determined and compared with the safe threshold of 1 mA.³

Data are presented using simple descriptive statistics for non-parametric distribution. Leakage current at different energy levels was compared using one-way analysis of variance (ANOVA), with statistical significance being taken as $P \leq 0.05$.

3. Results

Sixty one subjects consented to participate in the study, receiving a total of 82 shocks. Of these, two subjects (three shocks) were excluded due to the patients receiving low energy defibrillation (<150 J) as a result of having atrial flutter, two shocks were delivered in an AP orientation and equipment was not triggered to acquire data for a further 10 shocks. This resulted in measurements of leakage current being made on a total of 67 shocks, involving 49 different subjects (42 male, 7 female).

Demographic details of subjects included in the study are summarised in Table 1.

Rescuers were unable to perceive current flowing for any shocks, irrespective of energy. The median RMS leakage current over the duration of defibrillator discharge was 21 μA (range: 2–106). Closer inspection of data revealed six data sets that contained noise of unknown origin that was not associated with defibrillator discharge. Exclusion and reanalysis of remaining data gave a median current over all energies of 20 μA (range: 2–38). Data are summarised in Table 2 and Fig. 2.

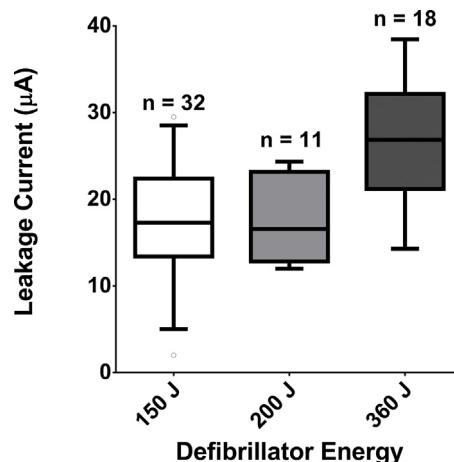


Fig. 2. Box and whisker plot showing the leakage current flowing between patient and rescuer for different defibrillation energies. The boundaries of the box indicate the upper to lower quartiles, and the line within the box denotes the median. Whiskers above and below the box indicate the 95th and 5th centiles respectively. Outliers are shown as circles. The safe threshold for rescuers is 1.0 mA.

Although the leakage current for 360 J is low, it was significantly higher than either the 150 J or 200 J shocks ($p < 0.001$). No significant difference was found between leakage currents associated with 150 J and 200 J shocks. The median duration of shock was 15.7 ms (interquartile range: 13.9–18.0). Variability is likely to be due to the instrumentation compensating for variable transthoracic impedance. All shocks, irrespective of energy, were well below the safe threshold of 1 mA; the highest recorded being 38 μA (0.038 mA).

4. Discussion

Hands-on defibrillation performed while wearing Class 1 electrical safety gloves is safe for the rescuer, even in the scenario of a single, inadvertent point of direct contact with the patient. We have shown that in this case leakage current through the rescuer is no more than one twenty fifth of the international safety threshold of 1 mA, even when using maximal defibrillator output at 360 J. We have sampled a range of patients across varying body mass to be confident that leakage current through the rescuer is unlikely to exceed this safe threshold, even in the most extreme of situations.

In drawing these conclusions, we ensured that the study simulated a worst-case scenario for exposing the rescuer to leakage current. We have previously discussed electrical issues in relation to these current pathways in detail.³ We replicated the most common clinical scenario during resuscitation by using the antero-lateral defibrillator pad position. In this configuration, both defibrillation pads are exposed, thereby maximising the voltage to which a rescuer may potentially be subjected. Conversely, in the antero-posterior pad position employed in other studies⁹ the posterior pad may not be accessible when the patient is lying supine thereby limiting the maximum voltage to which the rescuer can be exposed and therefore the resulting current.

The study design also considered the reasonably foreseeable scenario of the rescuer making inadvertent direct electrical contact with the patient. Not only was direct electrical connection made between patient and rescuer, but the patient electrode was placed immediately adjacent to the lateral electrode. With the insulated hands being placed immediately adjacent to the sternal electrode, this maximised the voltage to which the rescuer was exposed, and so maximised rescuer current.

In order for a significant amount of current to flow through the rescuer, there must be two uninsulated points of contact, one point

Table 2

Leakage current flowing between patient and rescuer by energy selected.

Defibrillation energy (Joules)	Number of shocks	Median leakage current (μ A)	Range (μ A)
150	32	17	2–29
200	11	17	12–24
360	18	27	14–38

for entry of the current, the other for exit. This study was designed to assess current under the reasonably foreseeable scenario of a single unintended point of contact between patient and rescuer and has shown it to be safe. However, measurements were performed in a controlled environment according to rigorous protocol. A second unintended point of contact would lead to rescuer current not only exceeding safety guidelines, but also potentially causing significant harm. If the existing record for rescuer safety is to continue then any future routine clinical protocol should be designed to ensure no direct contact between rescuer and patient when a rescuer is using insulating gloves. Treating any single point of contact, other than the deliberate placement of the rescuers hands, as unacceptable, significantly reduces the likelihood and therefore risk of the potentially fatal scenario of two points of contact.

This study measured current flowing with direct contact between the patient and rescuer waist. Contact with a more distal point on the rescuer (e.g. knees) is likely to result in a lower leakage current flowing through the rescuer's heart due to the increased impedance associated not only with an increased distance of travel, but also legs of a reduced cross sectional area compared to the abdomen. We can therefore be confident more distal points of contact are also safe.

This is the first study to assess the feasibility of hands-on defibrillation using electrical safety gloves, demonstrating a leakage current approximately one tenth of that documented by Lloyd who used clinical examination gloves and an antero-posterior defibrillation pad position, together with an electrode position that may not always have resulted in exposure of the rescuer to the maximal defibrillator voltage.⁹ Lloyd rightly concluded that the principles explored in his study may pave the way for this technique to be adopted in the future, but did not recommend equivocally that hands-on defibrillation was a safe technique. With the addition of Class 1 electrical safety gloves, we have demonstrated that hands-on defibrillation may be performed safely, even when the rescuer is in contact with the patient at their waist or below. Studies that have used sensory perception of current as an indicator of safety were performed on pigs,⁴ and although they provide interesting data, the differences in 'patient' size, electrical conductivity, and electrical pathways caution translation of results to clinical practice. The sensory perception of current occurs at approximately 1 mA so by definition, the perception of an electrical shock during defibrillation suggests that the leakage current is above safe limits. The shocks reportedly perceived by 7% of rescuers during out-of-hospital defibrillation confirm that clinical examination gloves alone do not provide a safe electrical barrier, even if there were no "serious adverse events".⁵ Even though there have been no documented serious injuries or deaths occurring from accidental (or more recently deliberate) hands-on defibrillation, international safety standards (and common sense) preclude use of a technique where the perception of a shock is commonplace.

The benefit to the patient of reducing no-flow time by carrying out HOD could potentially be offset by any detrimental impact on the quality of chest compressions associated with use of potentially cumbersome electrical insulation gloves. Initial findings suggest electrical insulation gloves were not significantly different to regular clinical examination gloves, although more work is needed.²¹

The limitations of our conclusions are mostly related to the specific scenario that we have tested. Although we are confident

that the electrical pathways we have measured represent a worst-case scenario, the conclusions are only valid when the rescuer is in contact through their gloved hands and has, at most, a single additional point (waist or below). We discuss the potentially disastrous consequence of two direct points of contact between rescuer and patient, however care should also be taken to avoid current flowing between patient and rescuer via parallel conductors present in the environment. Introduction of this technique into clinical practice would therefore require a thorough understanding of safety issues in both in-hospital settings and particularly in out-of-hospital settings where the presence of multiple conductors in previously unassessed environments is extremely likely.

In conclusion, hands-on defibrillation is safe when the following criteria are met:

1. Class 1 electrical safety gloves are worn.
2. The rescuer makes only one, unintended other point of contact with the patient; at the level of the rescuer's waist or lower.
3. All other rescuers stand clear as is currently recommended.
4. The only conductor the rescuer is in contact with is the patient.

Practical implementation of HOD will require careful consideration and appropriate protocols if it is to be applied safely. However, this technique should allow less interruption to chest compression during defibrillation and thereby contribute to an improved chest compression fraction, thought to be associated with better outcome from cardiac arrest^{22–26} and consistent with current guidelines recommendations.²⁰

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