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Cardiac Safety of Neuromuscular Incapacitating Defensive Devices

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McDANIEL, W.C., ET AL.: Cardiac Safety of Neuromuscular Incapacitating Defensive Devices. *Neuromuscular incapacitation (NMI) devices discharge a pulsed dose of electrical energy to cause muscle contraction and pain. Field data suggest electrical NMI devices present an extremely low risk of injury. One risk of delivering electricity to a human is the induction of ventricular fibrillation (VF). We hypothesized that inducing VF would require a significantly greater NMI discharge than a discharge output by fielded devices. The cardiac safety of NMI discharges was studied in nine pigs weighing 60 ± 28 kg. The minimum fibrillating level was defined as the lowest discharge that induced VF at least once, the maximum safe level was defined as the highest discharge which could be applied five times without VF induction, and the VF threshold was defined as their average. A safety index was defined as the ratio of the VF threshold to the standard discharge level output by fielded NMI devices. A VF induction protocol was applied to each pig to estimate the VF threshold and safety index. The safety index for stored charge ranged from 15X to 42X as weight increased from 30 to 117 kg ($P < 0.001$). Discharge levels above standard discharge and weight were independently significant for predicting VF inducibility. The safety index for an NMI discharge was significantly and positively associated with weight. Discharge levels for standard electrical NMI devices have an extremely low probability of inducing VF. (PACE 2005; 28:S284–S287)*

neuromuscular incapacitation, ventricular fibrillation, electrical safety

Introduction

Neuromuscular incapacitation (NMI) devices discharge electrical energy at high peak voltage, low average current, in 10–100 μ s pulses delivered in 10–19 per-second trains.¹ Parameters for the electrical discharge of NMI devices have been empirically determined to maximize neuromuscular stimulation, cause pain and muscle contractions, and temporarily incapacitate a human subject.²

TASER® (Taser International, Scottsdale, AZ) is an electrical NMI defensive device which has been widely tested.^{3–7} There has been no report directly related to its risk of inducing ventricular fibrillation (VF), although preliminary findings suggest that the likelihood of inducing VF by an NMI discharge is extremely low.^{2,8,9} We hypothesized that the induction of VF would require significantly greater discharge levels than delivered by electrical NMI devices fielded by law enforcement agencies.

Methods

Study Design

The cardiac safety of the electrical discharge by NMI devices was studied in a prospective controlled trial design with the standard NMI discharge as control, compared with discharges that induced VF in a large pig. The animals were anesthetized with isoflurane, their arterial blood pressure, oxygen saturation, respiration, and heart rate were continuously monitored until sacrifice.

Experimental Device and Electrodes

A custom device was built to deliver an NMI electrical discharge that matched the waveform characteristics of the commercially available TASER®, model X26 device. The experimental device allows the output capacitance to vary as a multiple of the nominal capacitance (and charge) for a standard NMI device (0.008 μ F, Fig. 1). All experimental NMI discharges were delivered with a fixed voltage of 6000 V. The waveform, as a short-electrical pulse, was delivered at a repetition rate of 19 pulses per second for 5 seconds. The standard NMI stored charge for the experiment control was (0.008 μ F \times 6,000 V) = 48 μ C. The standard NMI discharge represented the same amount of charge (coulombs) delivered by fielded NMI devices. The pulses were discharged across the thorax of the animal, using metallic barbs that matched darts deployed in fielded NMI devices. One pulse delivery

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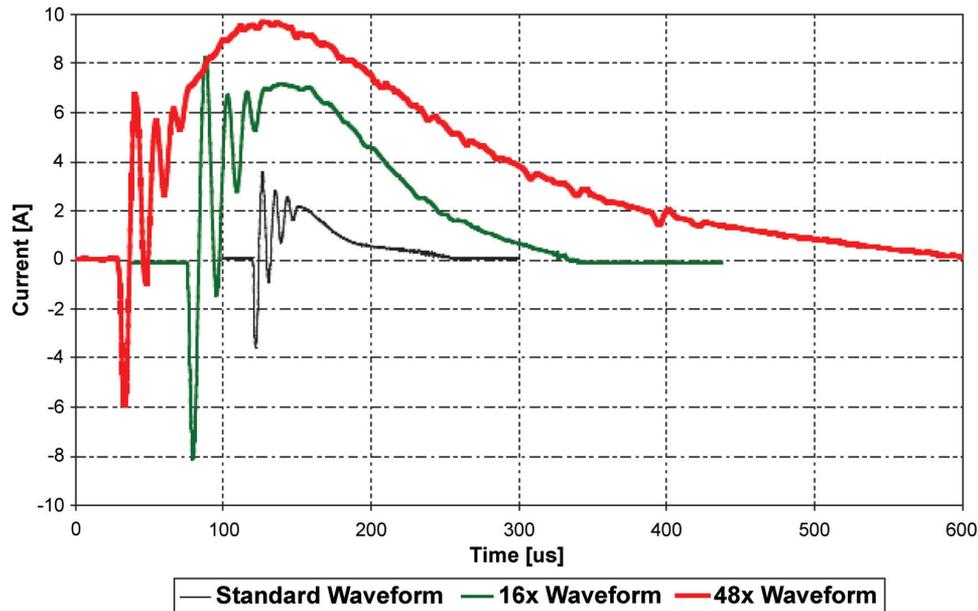


Figure 1. Experimental NMI waveforms compared to waveforms discharged by standard NMI devices (standard waveform, black). Experimental waveforms are shown for 16 times standard discharge (μA , green) and for 48 times standard discharge (μA , red). The waveforms represented a single pulse of a two-stage capacitor discharge; standard NMI devices apply 19 pulses per second for 5 seconds. The two-stage incapacitation discharge was designed to first penetrate high impedance barriers (AC-like portion of waveform) and then to incapacitate neurological and muscular activity (pedestal portion of waveform).

probe was placed at the sternal notch and another on the anterolateral thorax at the point of maximum impulse.

Threshold Procedure

NMI discharges were applied in an up-down method to determine a threshold for VF induction, beginning with a standard NMI discharge. Increasing stored charges were applied to the animal until VF was induced. The stored charge was increased in steps by increasing the size of the experimental NMI device capacitor. Each stepped stored charge had a capacitor value equal to a multiple of the standard capacitance unit ($0.008 \mu\text{F}$), using an increasing number of charge multiples (2 and multiples of 4 from 4 to 48). Following the first VF induction, a decreasing series of capacitance-stepped discharges were then applied until VF was no longer induced by five discharges of equal stored charge. The animals were defibrillated with an automatic external defibrillator. A recovery period of at least 90 seconds was allowed after discharges that did not induce VF. If a discharge did induce VF, a recovery period of at least 5 min was allowed following defibrillation.

Study Endpoints and Safety Index

The primary study endpoint was the determination of a safety index for each animal based on its

weight. Discharge data were collected during the experiment for each NMI discharge applied during the VF threshold procedure. Minimum fibrillating discharge level determined by the VF threshold procedure was defined as the lowest discharge that induced VF at least once; maximum safe level was defined as the highest discharge which could be applied five times without induction of VF; VF threshold was defined as their average. The safety index was defined as the ratio of the VF threshold to the standard NMI discharge ($48 \mu\text{C}$).

Statistical Analysis

All continuous variables are expressed as mean \pm standard deviation. Two sample *t*-tests for samples with equal variance were used to compare mean values. For all comparisons, a $P \leq 0.05$ was considered statistically significant.

Institutional Review

The study protocol received approval from the Institutional Animal Care and Use Committee of Sinclair Research Farms. All animals received humane care.

Results

Nine experiments were completed. The average weight of the swine was 60 ± 28 kg, ranging from 30 to 117 kg. All animals remained

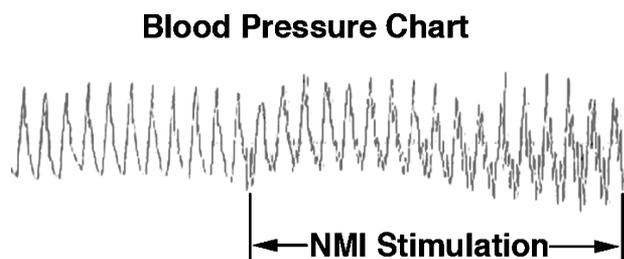


Figure 2. Example of blood pressure before and during an NMI discharge.

hemodynamically stable throughout the experimental procedures, despite an average of 26 ± 12 NMI discharges per animal (Fig. 2).

The safety index for stored charge ranged from 15X to 42X as weight increased from 30 to 117 kg ($P < 0.001$, Table I, Fig. 3). The VF induction threshold level ($1339 \pm 463 \mu\text{C}$ stored charge) was significantly higher than the standard level for applied charge ($48 \mu\text{C}$ stored charge, $P < 0.0001$). The charge multiple at the VF induction threshold was 28 ± 10 compared to the standard charge multiple of 1 ($P < 0.0001$, Table I). The maximum safe charge multiple was 26 ± 9 with an average stored charge of $1,227 \pm 423 \mu\text{C}$, and the minimum VF inducing charge multiple was 30 ± 11 with an average stored charge of $1,451 \pm 509 \mu\text{C}$.

The maximum safe levels and minimum VFI levels of stored charge for experimental data were regressed linearly for significant trends. The relationship between stored charge as a function of weight (kg) was compared to experimental stored charge for minimum VF induction discharge. The maximum safe discharge was modeled by $12.5 * [\text{weight (kg)}] + 473$ ($n = 9$, $r^2 =$

0.69) and the minimum VF induction discharge was modeled by $16.5 * [\text{weight (kg)}] + 460$ ($n = 9$, $r^2 = 0.82$). The analysis revealed a linear, increasing relationship of maximum safe and minimum VFI discharge multiples (and therefore safety index) as a function of weight (kg). The relationship further confirmed a significantly greater discharge required to induce VF compared to standard discharge levels for a fielded NMI device.

Logistic regression showed that the mean charge multiple for a 50% likelihood of VF induction was 24 ± 13 , with an odds ratio of 0.85 after adjustment for weight (95% Wald confidence limits: 0.83, 0.88, $P < 0.0001$). Therefore, an increasing charge multiple was shown to be independently related to an increase in VF induction.

Discussion

This study confirmed the cardiac safety of an experimental NMI device emulating the performance of commercially used devices. An NMI discharge that could induce VF required 15–42 times the charge of the standard NMI discharge. Furthermore, this study demonstrated a safety index strongly correlated with increasing weight. In addition, the observation of the hemodynamic stability of the animals suggests that these devices may be safely applied multiple times if needed. Discharge levels output by fielded NMI devices have an extremely low probability of inducing VF.

This study used adult domestic pigs chosen to simulate a range of adult human body weights between 30 and 120 kg, likely to be encountered in police work. Our results suggest a safety index

Table I.

Experimental Outcomes for 19 Pulse per Second Discharges

Pig	Weight (kg)	Max Safe Multiple	Safe Stored Charge (μC)	Min VFI Multiple	VFI Stored Charge (μC)	Threshold Charge (μC)	Safety Index
1	83	28	1344	32	1536	1440	30
2	54	28	1344	32	1536	1440	30
4	48	28	1344	32	1536	1440	30
5	81	40	1920	44	2112	2016	42
6	49	20	960	24	1152	1056	22
7	42	20	960	24	1152	1056	22
8	37	16	768	20	960	864	18
9	117	36	1728	48	2304	2016	42
10	30	14	672	16	768	720	15
	60 ± 28	26 ± 9	1227 ± 423	30 ± 11	1451 ± 509	1339 ± 463	28 ± 10

μC = microcoulombs; VFI = ventricular fibrillation induction.

SAFETY OF NEUROMUSCULAR INCAPACITATING DEVICE

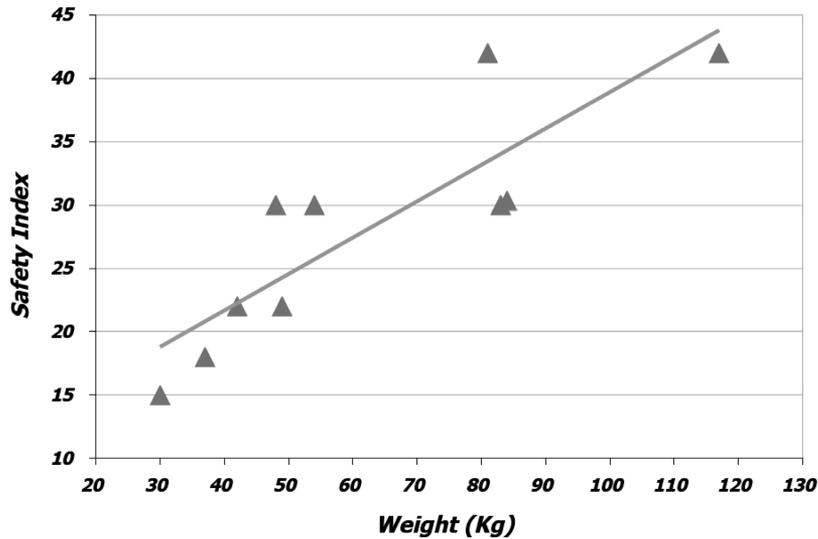


Figure 3. NMI safety index (\blacktriangle , triangle) in relationship to weight (kg). The safety index is the ratio of VF induction threshold discharge to fielded NMI discharge.

≥ 20 for human adults >45 kg. The standard NMI devices may therefore have a safety index significantly >20 for field applications to adult humans.

The minimum discharge that would cause fibrillation was approximately 15 times the charge of the standard pulse when used on the smallest pig.

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