Forensic Science International 204 (2011) 50–57

Contents lists available at ScienceDirect

Forensic Science International

journal homepage: www.elsevier.com/locate/forsciint

Human cardiovascular effects of a new generation conducted electrical weapon

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ARTICLE INFO

Article history:
Received 2 March 2010
Received in revised form 26 April 2010
Accepted 3 May 2010

Keywords:
TASER
Electronic control device
Conducted electrical weapon
Cardiac

ABSTRACT

Objectives: The conducted electrical weapon (CEW) is used by law enforcement to control potentially violent people. Much of the research in CEW safety has focused on the TASER X26, which uses a single deployment cartridge. New Generation CEW (NGCEW) technology has been developed that uses a different circuit and multiple cartridges that can be simultaneously deployed. The objective of this study is to examine the cardiovascular effects of the NGCEW in different deployment possibilities.
Methods: This was a prospective study of human subjects during NGCEW training courses. Subjects received a NGCEW probe deployment to the frontal torso in 1 of 3 configurations: 2, 3,or 4 embedded probes and then underwent a 10-s exposure. Before and after vital signs, electrocardiograms (ECGs), and serum troponin I values were obtained. Real-time echocardiography was utilized before, during and after the exposure to evaluate heart rate and rhythm.
Results: Initially, a 1st version NGCEW (NGCEWv1) that was in the final stages of manufacturer verification was used at the training courses. It had not been publicly released. During a NGCEWv1 exposure with 2 probes, there was an apparent brief episode of cardiac capture. Testing was halted and the manufacturer was notified. The device was redesigned and the study continued when a redesigned, 2nd version (NGCEWv2) was used. The NGCEW1 was studied in 8 subjects. The NGCEWv2 was studied in 45 subjects with no evidence of cardiac capture. There were no important post-exposure vital sign, troponin I or ECG changes found in any volunteers.
Conclusions: An apparent brief myocardial capture event occurred with the NGCEWv1. This device was not released and was redesigned. The NGCEWv2 appears to exhibit a reasonable degree of cardiac safety with frontal torso exposures and multiple probe combination configurations.

1. Introduction

Conducted electrical weapons (CEWs) are popular tools of force used by law enforcement authorities (LEAs) to control or repel potentially violent persons in higher risk situations. The CEW induces neuromuscular incapacitation through the use of conducted electrical current. Because a CEW is typically only used during a high-risk situation to control an agitated or violent subject, emergency medical personnel are often asked to evaluate subjects after a CEW exposure.

The most prevalent CEW in use today is the TASER X26 Device (TASER International, Inc., Scottsdale, AZ, http://taser.com/products/law/Pages/TASERX26.aspx) and represents previous generation technology. There have been a number of human studies conducted involving this CEW that have demonstrated a high degree of safety both from clinical basic science and surveillance perspectives [1–10]. A limitation of the X26 is that it only holds a single cartridge in the firing position at any time. This results in the ability to only deploy it once before having to reload another cartridge into the deployment position. This can be a problem if the LEA misses the suspect during deployment or needs to engage more than one suspect at the same time.

New Generation handheld CEW (NGCEW) technology has been developed (TASER X3 CEW, TASER International, Inc., Scottsdale, AZ, http://taser.com/products/law/Pages/TASERX3.aspx). The X3 has the capability of being loaded with and deploying 3 sets of conductive

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doi:10.1016/j.forsciint.2010.05.003

probes. The X3 also utilizes different electrical circuitry than the well-studied X26. There has not yet been published literature examining the physiologic effects of the X3. The goal of this study was to evaluate the cardiovascular effects of the NGCEW X3 device when applied to humans in its various deployment possibilities.

2. Methods

This was a prospective, observational study design using human volunteers. The institutional review board at Hennepin County Medical Center (Minneapolis, MN) approved the study. The study was conducted at NGCEW training courses over a 4-month time period. The subjects were a convenience sample of law enforcement and correctional officers participating in a TASER International, Inc. training course and who were going to receive an exposure to the NGCEW with 2, 3, or 4 probes as part of the course.

Participants of the training course were eligible for enrollment. Volunteers were taken on a first come, first served basis. As part of their training course, they understood that they could receive up to a 10-s NGCEW application. They did not have to participate in the study as a requirement for successful course completion but declining to participate in the study did not necessarily absolve them from receiving the NGCEW application. Exclusion criteria were known pregnancy and inability to be at full-duty status with their employer. Subjects were given a TASER X26 CEW for their participation upon completion of the study protocol.

Subjects provided informed consent and completed a medical screening questionnaire that was reviewed by a study physician. Subjects had an antecubital 18 or 20 gauge intravenous catheter placed by a physician or paramedic prior to the exposure. Baseline blood pressure, heart rate, and pulse oximetry measurements were taken using a Nonin 2120 monitor (Nonin Medical, Inc., Plymouth, MN). Body fat determination was made using the HBF-306 commercial skin resistance analyzer (Omron Healthcare, Inc., Bannockburn, IL), and baseline serum was drawn for troponin I analysis. Troponin I specimens were analyzed at an offsite laboratory (Laboratory Corporation of America, Burlington, NC). A "positive" troponin I was defined as any result above the Laboratory Corporation of America normal reference range (0.00–0.04 ng/mL).

The volunteers were fitted with face, neck, and groin protection. Male subjects wore shorts but no shirt. Female subjects wore shorts and a T-shirt or sports bra depending on subject preference. The subjects then underwent the exposure that was part of their training course. A certified TASER Master Instructor deployed the NGCEW from 10 feet away with a "dummy device" which only fired the probes but did not immediately discharge any electrical charge. The cartridge and probes were standard field-deployable devices. Subjects were sequentially assigned to one of three groups. The groups represented 3 possible deployment scenarios with a single suspect that could occur with the NGCEW capable of deploying 3 cartridges in rapid-fire sequence:

Group 1: subjects were shot in the anterior torso with 1 cartridge (2 probes embedded, at least 1 in the anterior torso).
Group 2: subjects were shot in the anterior torso (top probe) but the instructor intentionally missed the target with the bottom probe. The subjects were then shot again in the anterior torso (both probes embedded in anterior torso). This resulted in 3 probes in the subject.
Group 3: subjects were shot in the anterior torso 2 times. This resulted in four probes in the anterior aspect of the subject.

The subjects were laid supine for testing and a factory-standard NGCEW was attached to the previously deployed cartridge(s). Subjects had a surface electrocardiogram (ECG) obtained with a Welch Allyn Cardioperfect™ computer based system (Welch Allyn, Inc., Skaneateles Falls, NY) just prior to CEW exposure. A Sonosite M-Turbo ultrasound machine with a 1–5 MHz phased-array transducer (Sonosite, Inc., Bothell, WA) was used before, during and after exposure by a non-blinded emergency physician with special training in cardiac ultrasound to determine cardiac rate and rhythm of the volunteer. Parasternal long-axis views including the anterior leaflet of the mitral valve were obtained. The two-dimensional view of the heart was assessed in real time by the ultrasonographer prior to switching to M-mode for measurement of the heart rate and determination of the rhythm. Heart rate was determined by measuring the time between contractions. Heart rhythm was determined by imaging the anterior leaflet of the mitral valve. The presence of both ultrasonic E and A waves in correct sequence was used as evidence for sinus rhythm.

Subjects had a 10-s continuous exposure from the NGCEW. The skin to heart distance from where the superior probe embedded was measured with ultrasound. If the distance between the skin and heart was too great to obtain a measurement, the distance from the superior probe to the point on the skin that yielded the closest skin to heart distance in the parasternal view was obtained. A blinded cardiologist interpreted the surface ECGs post hoc for evidence of significant abnormality. Vital signs were repeated immediately (within 30 s to 1 min) after the exposure, and again at 10 min after the exposure. Venipuncture occurred at 24 h post-exposure to obtain another blood sample to measure for troponin I.

Data were entered into an Excel spreadsheet (Microsoft Corp., Redmond, WA) and exported into STATA 10.0 (Stata Corp., College Station, TX) for analysis. Descriptive statistics were applied where appropriate.

3. Results

A total of 53 subjects participated in this study. The health histories of all the volunteers that participated in this study included asthma ($n = 2$), diabetes ($n = 1$), peptic ulcer disease/gastritis ($n = 2$), hypertension ($n = 3$), seizure disorder ($n = 2$), bradycardia ($n = 1$), and gender reassignment ($n = 1$). Twenty-six had some history of previous surgery, predominantly orthopedic. Seventeen reported no medical history. Medications reported included: Androderm, Atenolol, Celexa, Depakote, Albuterol, Lasix, Clonidine, Metoprolol, Zyrtec, and Norvasc.

During exposure of one of the subjects, an observation of apparent electrical cardiac capture occurred (measured heart rate of 240 beats/min). The echocardiographic images of this subject are presented in Fig. 1. The onset correlated very closely with the start of the exposure and immediately terminated upon cessation of the exposure. The skin to heart distance of the superior probe in this subject was 2.57 cm and the probe positions are shown in Fig. 2. This event occurred while using a 1st version of the X3 NGCEW (NGCEWv1), an experimental pre-production device in final stages of verification testing. The subject had no complaints consistent with cardiac ischemia or arrhythmia before, during or after this exposure. The study was halted and the X3 device manufacturer was immediately notified of this finding. A total of 8 subjects received an exposure from the NGCEWv1 (median age 32 years, range 22–52, 90% male, median BMI 30.11 kg/m^2, range 20.1–44.0, median body fat 21.6%, range 4.4–35.8). The median distance between the probes in these 8 subjects was 44 cm (range 37–47). In subjects where the superior probe location was too far from the heart to obtain a probe tip to heart surface distance, a measurement from the probe location to the point on the chest closest to the heart surface (determined ultrasonically) was made. This median distance was 15 cm, range 12–31. Vital sign results of these subjects are presented in Table 1. All of these subjects were exposed with 2 probes only. Prior to the exposure, 6 of the subjects had a normal sinus rhythm with no abnormalities on ECG, 2 had sinus tachycardia with no other abnormalities. There were no changes in the ECGs noted after the exposure. All 8 subjects had echocardiography performed. The median heart rate prior to exposure was 84.5 beats per minute (bpm), with a range of 55–146. The median heart rate during exposure was 126 bpm, with a range of 98–240. The echocardiography demonstrated sinus rhythm in 5 of the subjects and the rhythms of the remaining subjects were unable to be determined. In the subject with a rate of 240 during the exposure, the rhythm was assumed to be electrical capture by the device. The median heart rate for these volunteers after the exposure was 88.5, with a range of 79–115. One other subject in this group experienced a power failure during the exposure resulting in an exposure time that was less than the full 10 s. Only 1 subject in this group demonstrated the apparent cardiac capture phenomenon. The oversight IRB was notified of this event.

After manufacturer evaluation of this event and re-design of the NGCEWv1, a 2nd version of the X3 NGCEW (NGCEWv2) was released for final verification use in the training courses. This 2nd version used a modified waveform with a lower output charge specification. This 2nd version was released for production. Our study of the voluntary exposures during the training courses resumed. Subjects were informed of the possibility of cardiac capture based on the previous event during their consent process. A total of 45 subjects received an exposure from the NGCEWv2 and their characteristics are presented in Table 2. Twenty-four subjects