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Cardiovascular effects of SPARK conducted electrical weapon in healthy subjects

Carlos Scherr [a,b,*], Antonio Carlos de Carvalho [a,c], Luciano Juaçaba Belem [b], Luiz Henrique Loyola [b], Renata Leborato Guerra [a], Fernanda Blanco [a], Claudio Mangia [a]

[a] Fundação Procoração, Brazil
[b] Instituto Nacional de Cardiologia, Brazil
[c] Universidade Federal do Rio de Janeiro, Brazil

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ABSTRACT

Background: The increasing use of conducted electronic weapons (CEW) cause concern regarding its secure application, specially regarding the implications in the cardiovascular system.
Methods: The objective was to determine Spark CEW safety through cardiovascular parameters analysis of healthy volunteers subjected to its use.
Results: Volunteers over 18 years without cardiovascular disease or recent use of illegal drugs were submitted, before and after being affected with Spark CEW, to clinical evaluation; blood collection for serum laboratory tests; transthoracic electrocardiography at rest, transthoracic echodopplercardiogram and 24 hour Holter.
Results: All 71 patients reported being incapable of any voluntary reaction during the shock of the application time. No arrhythmia or myocardial necrosis was related to the use of non-lethal weapon SPARK. Reported adverse events were self-limited, and mostly mild.
Conclusions: SPARK brand CEW is effective in incapacitating individuals by the shock of the application time, without causing.

1. Introduction

The use of non-lethal weapons by law enforcement agencies has become increasingly common around the world. In many countries, police use conducted electronic weapons (CEW) as a non-lethal alternative to firearms as CEW cause suspect's paralysis and immobilization, therefore avoiding the use of firearms that would put at risk the suspect's life.

In the US, more than 225,000 policemen currently use this type of weapon and 120,000 citizens use it for personal defense [1].

It is estimated that TASER brand weapons were tested by more than 600,000 volunteers and in more than 425,000 police confrontational situations [1]. Consumer Product Safety Commission approved TASER based on theoretical calculations [2] but current preclinical and clinical research data are available and they demonstrate a good safety profile of the weapon's usage [1,3]. However, 167 TASER related deaths was been reported so far [4]. Most of these deaths were associated with use of illicit drugs, such as phencyclidine, methamphetamine and cocaine [5–7]. Death's reports the subjects suffered cardiopulmonary arrest (CPA) for 5 to 40 min after being subjected to electrical discharge of the CEW [8].

The incapacitating electric gun SPARK is an electronic device used to control individuals through neuromuscular incapacitation. Electrical stimuli are delivery through copper wires connected to darts that penetrate target muscles causing strong contractions and temporary paralysis. SPARK`s circuit delivers electric pulses using a damped sinusoidal waveform with a medium current of 2.2 milliamps (mA) and peak voltage of 7000 volts (V) at frequency of 18 Hertz (Hz). When pulling SPARK's trigger, previously loaded with its cartridge, two darts are projected into the target, by action of a nitrogen capsule, and an electric shock is applied for 5 s, incapacitating the target during the time period. The person promptly recovers when the electric shock is ceased. In contrast to TASER, which shock remains as long as the trigger remains pulled, SPARK ceases the shock after 5 s, even if the trigger remains activated.

Based on SPARK safety profile determined by non-clinical studies in pigs, performed by Federal Rural University of Rio de Janeiro [9], and clinical trials performed abroad [1,10–15], the National Cardiology of Institute (INC) performed a prospective study to evaluate cardiovascular risk in healthy volunteers subjected to SPARK electrical discharge.

* Corresponding author at: Fundação Procoração.
E-mail address: scherr@all.com.br (C. Scherr).

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2. Objective

Overall objective was to determine SPARK CEW safety through cardiovascular parameters analysis of healthy volunteers subjected to its use.

Specific objectives were, in volunteers subjected to SPARK CEW (i) to compare the results of physical, laboratory tests, electrocardiogram (ECG), echocardiogram and 24 hour Holter monitoring before and after volunteers been subjected to SPARK CEW use; (ii) to quantify SPARK CEW related adverse events and to correlate them with pretest cardiovascular parameters.

3. Methods

This was an intervention study, single-center, with healthy volunteers. Informed consent form (ICF) was obtained from each patient and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's human research committee.

Sample of subjects were selected by convenience, once this study was not designed to test a preconceived hypothesis, but to generate hypotheses from data on cardiovascular parameters in volunteers subjected to the SPARK use. The recruitment of volunteers, where among policemen that have been trained in the use of SPARK. Inclusion criteria were: (i) age equal or greater than 18 years old; (ii) no pre-existing heart disease; and (iii) body weight higher or equal to 60 kg. Volunteers were excluded if they had (i) deemed relevant sign detected by examiner in cardiovascular clinical evaluation performed prior to testing, such as hypertension or tachycardia; (ii) cardiac arrhythmia identified by ECG; (Iii) use of illicit drugs within six months prior to the study.

After signing the ICF, the volunteers underwent a clinical evaluation and resting ECG in 12 leads to determine eligibility for the study.

Eligible patients were submitted to the following tests before and after being subjected to the use of incapacitating electric gun Spark: (i) clinical evaluation; (ii) blood serum laboratory tests collect; (iii) ECG; (iv) transthoracic echodopplercardiogram (ECO TT); (v) 24 hour Holter monitoring. All these procedures were performed and interpreted by two skilled examiners with experience in cardiology and in performance and interpretation of these tests.

Clinical evaluation, which included cardiovascular physical examination, was conducted through structured and specialized questionnaire. The evaluations were performed before and immediately after the shock has been delivered.

Blood collection was the first procedure performed after clinical evaluation. Blood tests were performed in the INC laboratory, and included the following analysis and their methods and reference values: (i) complete blood count (automation), glucose (hexokinase, 70–99 mg/d), potassium (ion selective, 3.5–5.1 mEq/L), sodium (ion selective, 135–145 mEq/L), troponin I or T (chemiluminescence, 0.03–0.05 ng/ml), total creatinokinase (CK) (UV kinetic, <171 U/L (men), <145 U/L (women)), and creatinokinase MB (CK-MB) (enzyme, <24 U/L).

Resting ECG examination was performed before and immediately after blood collection after the shock has been delivered.

ECO TT examination was held at device Philipps IE 33, with annual maintenance by outsourced firm. This examination was performed before and immediately after ECG procedure, immediately after the shock has been delivered.

The 24 hour Holter was held at Mortara H3+ device (Mortara), with annual maintenance by outsourced firm. The device was installed in volunteers on average 21 h and 33 min before use to 2 h and 7 min after the use of the electric gun. Therefore, subjects were monitored during the shock's delivery.

The test consisted of a single application of the shock produced by SPARK in the voluntary in lying position (to avoid injury with the fall). The darts are inserted manually into the skin of individuals to a depth of 11 mm. One dart was inserted into the chest muscle (right side) and another one in the abdomen, in the transverse direction. The distance between the darts were 50 cm. The characteristics of the electric discharge are approximately as follows considering a resistance of 60Ω (i) peak voltage of 7000 V; (Ii) average current of 2.2 mA; (Iii) pulse duration of 35 ms.

The case report's form was specifically developed for this study, and a trained professional filled it. Adverse events were classified according to their severity according to the *Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 (National Institutes of Health – NIH, USA)* [16].

Numerical variables were evaluated for distribution to determine whether the data were parametric. Data were presented as medium ± standard deviation (if parametric variable) or median [minimum to maximum] if variable with non-parametric distribution. Categorical variables were expressed as number of patients (%). Paired T-students and Wilcoxon, adjusted by Bonferroni, were used to determine the difference between pre and post-test for parametric and non-parametric variables, respectively. The following tests were used to evaluate whether there was a correlation between the independent variables: for categorical parameters, chi-square or Fisher's exact test (when less than 5 counts); for numerical parameters with normal distribution, T-Students test; for numerical parameters with non-normal distribution, Mann Whitney test. Analyses were performed using SPSS (Statistical Product and Service Solutions) 13.0 students Windows version. Significance (p) less than 0.05 were considered statistically significant.

4. Results

4.1. Volunteer population

77 volunteers were selected to participate in the study. Six subjects were excluded: two gave up, two presented hypertension, one due to congenital heart disease (atrial septal defect - CIA) and one case of illicit drug use in the past 6 months. Among the 71 selected, the Holter monitoring was not technically satisfactory in 11 subjects and blood samples after 7 test subjects were invalidated.

Sociodemographic characteristics, medical history, social habits and anthropometric measurements are shown in Table 1. Most are men (76.1%), blacks (46.5%), non-smokers (67.6%), with mild alcohol consumption (60.6%), who never used illicit drugs (90.1%) and without co-morbidities (94.4%) or medications use (87.3%), with mean age of 32 years and body mass index (BMI) of 28 kg/m^2. Sixteen subjects (22.5%) had more than 40 years-old. Nine volunteers were using drugs: mesalazine, timolol, sibutramine, Lipomax/omeprazole/scopolamine, omeprazole, levonorgestrel/ethinyl estradiol and thermogenic supplement.

4.2. Pre-test evaluation

Physical examination was abnormal in only one volunteer, a sharp lesion in occipital region, considered irrelevant to the study. The mean systolic and diastolic blood pressures were 118 ± 13 and 73 ± 9 mmHg, respectively (Table 2).

Approximately 28% of the volunteers had some electrocardiographic alteration. The most common abnormality was unspecific repolarization (15 individuals (21.1%)) (Table 2)

Approximately 11% of the volunteers had some alteration in ECO TT test. The most common abnormality was slight or mild mitral insufficiency, found in 4 subjects (5.6%), one of which related to mitral valve

Table 1
Sociodemographic characteristics, medical history, social habits, anthropometric measurements and physical exam.

Parameters		Results
Age (years)		32,0 ± 8,2
Gender	Male	54 (76,1%)
	Female	17 (23,9%)
Race	White	12 (16,9%)
	Black	33 (46,5%)
	Non-black non-white	26 (36,6%)
Physical activity	None	27 (38,0%)
	1–2 ×/week	19 (26,8%)
	3–5 ×/week	17 (23,9%)
	Daily	08 (11,3%)
Tobacco use	Never	48 (67,6%)
	Current	12 (16,9%)
	Ex-user	11 (15,5%)
Alcohol use	None	27 (38,0%)
	1–2 ×/week	43 (60,6%)
	3–5 ×/week	00 (00,0%)
	Daily	01 (01,4%)
Illicit drug use	Never	64 (90,1%)
	Ex-user	07 (09,9%)
	Marijuana	05 (07,0%)
	Cocaine	04 (05,6%)
Co-morbidities	None	68 (94,4%)
	Diabetes	01 (01,4%)
	Dyslipidemia	01 (01,4%)
	Metabolic syndrome	01 (01,4%)
Medicine use	No	62 (87,3%)
	Yes	09 (12,7%)
Weight (kg)		84,5 ± 16,9
Height (cm)		173,5 ± 7,9
BMI (kg/m^2)		28,0 ± 4,8

Data presented as average ± standard-deviation or absolute number (percentage).
BMI: body mass index.