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Cardiovascular effects of SPARK conducted electrical weapon in healthy subjects

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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.

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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.

Table 2
Pre-test cardiovascular evaluation.

Parameters		Result
Blood pressure (mmHg)	Systolic	118 ± 13
	Diastolic	73 ± 09
Heart rate (bpm)		70 ± 11
Electrocardiogram	No findings	54 (76,1%)
	Unspecific repolarization	15 (21,1%)
	Left ventricle hypertrophy	02 (02,8%)
	Tachycardia	01 (01,4%)
	Bradycardia	01 (01,4%)
	Left bundle-branch block	01 (01,4%)
Echocardiogram TT	No findings	63 (88,7%)
	Mitral insufficiency	04 (05,6%)
	Left ventricle hypertrophy	03 (04,2%)
	Aortic ectasy	01 (01,4%)
	Impaired myocardial relaxation	01 (01,4%)
	Mitral valve prolapse	01 (01,4%)
Holter	Number of valid analysis	60 (84,5%)
	SVE presence	28 (46,6%)
	VE presence	18 (30,0%)
	Supraventricular tachycardia presence	03 (05,0%)

Data showed as average ± standard-deviation or absolute number (percentage).
TT: transthoracic; SVE: supraventricular extrasystole; VE: ventricular extrasystole.

prolapse. The second most common change was slight or mild left ventricular hypertrophy, found in 3 participants (4.2%), related to "athlete's heart" (Table 2).

In Holter, 60 analyzes were valid (84.5%). Maximum, minimum and average heart rate were, respectively, 144 ± 16, 47 ± 08; and 75 ± 11 bpm. Supraventricular extrasystole (SVE), ventricular extrasystole (VE) and supraventricular tachycardia occurred in 28 (46.6%) 18 (30.0%) and 3 (5%) subjects, respectively.

4.3. Incapacitation

All subjects reported being incapable of any voluntary reaction during the time the shock was discharged.

4.4. Adverse events

The principal adverse event was pain at the site of shooting, which occurred in 30 subjects (42.3%) (Table 3). The pain was mild in most cases (16 patients, 53.3% of cases of pain), with an average duration of 5 seconds and all of them showed complete resolution. One participant felt moderate pain for 10 seconds, and another felt slight pain for 30 seconds.

Site erythema occurred in 14 subjects (19.7%), all of them were mild, without need of medical intervention. Only 2 subjects reported the feeling for more than 5 seconds (10 and 30 seconds). All of them had complete resolution (Table 3).

Systemic symptoms were also reported. Muscle weakness occurred in 8 participants (11.3%), most of them were mild (not noticeable on physical examination). An individual showed noticeable weakness on physical examination and other disabling muscle weakness (an individual has no data of severity or duration). All of them had complete resolution up to 5 seconds. Palpitation occurred in 2 subjects (2.8%), all of them were mild (without need of intervention), up to 5 to 10 seconds in duration. Breathlessness and dizziness also occurred in 2 cases of mild severity and up to 5 seconds long. Bleeding occurred in 2 patients (2.8%), mild severity, which resolved after 30 seconds long.

All reported adverse events were resolved without medical intervention or hospitalization.

No pre-test parameters could predict the occurrence of adverse events, including age. There were no differences between group divided by age using 40 years as cut-off, regarding any of the symptoms.

Muscle weakness was related to pain, palpitation, dyspnea, and dizziness. Among the patients with muscle weakness, 06 (85.7%) also had pain, while only one (14.3%) did not report this symptom (p: 0.037). All patients with palpitation, dyspnea or dizziness also had muscle weakness (p: 0.011 for all 3 parameters).

Table 3
Adverse events related to the shock of the incapacitating electric gun SPARK.

Parameters		Results
Local pain	Absent	40 (56,3%)
	Present	30 (42,3%)
Severity	Mild	16 (22,5%)
	Moderate	12 (16,9%)
	Severe	2 (02,8%)
Duration (seconds)	≤5	28 (93,3%)
	5–10	01 (03,3%)
	>10	01 (03,3%)
Site erythema	Absent	57 (80,3%)
	Present	14 (19,7%)
Severity	Mild	14 (100,0%)
	Moderate	00 (00,0%)
	Severe	00 (00,0%)
Duration (seconds)	≤5	12 (85,7%)
	5–10	01 (07,1%)
	>10	01 (07,1%)
Muscle weakness	Absent	63 (88,7%)
	Present	08 (11,3%)
Severity	Mild	05 (62,5%)
	Moderate	01 (12,5%)
	Severe	01 (12,5%)
Duration (seconds)	≤5	07 (100,0%)
	5–10	00 (00,0%)
	>10	00 (00,0%)
Palpitation	Absent	69 (97,2%)
	Present	02 (02,8%)
Severity	Mild	02 (100,0%)
	Moderate	00 (00,0%)
	Severe	00 (00,0%)
Duration (seconds)	≤5	01 (50,0%)
	5–10	01 (50,0%)
	>10	00 (00,0%)
Dyspnea	Absent	69 (97,2%)
	Present	02 (02,8%)
Severity	Mild	02 (100,0%)
	Moderate	00 (00,0%)
	Severe	00 (00,0%)
Duration (seconds)	≤5	02 (100,0%)
	5–10	00 (00,0%)
	>10	00 (00,0%)
Dizziness	Absent	69 (97,2%)
	Present	02 (02,8%)
Severity	Mild	02 (100,0%)
	Moderate	00 (00,0%)
	Severe	00 (00,0%)
Duration (seconds)	≤5	02 (100,0%)
	5–10	00 (00,0%)
	>10	00 (00,0%)
Bleeding	Absent	69 (97,2%)
	Present	02 (02,8%)
Severity	Mild	02 (100,0%)
	Moderate	00 (00,0%)
	Severe	00 (00,0%)
Duration (seconds)	≤5	00 (00,0%)
	5–10	00 (00,0%)
	>10	02 (100,0%)

4.5. Post-test evaluation

Physical examination revealed no difference between before and after SPARK's use.

There was a statistically significant difference when comparing the systolic blood pressure pretest to the measure after the application of SPARK weapon (118 ± 13 vs 125 ± 17 mmHg, $p < 0.001$), but there was no difference in relation to diastolic blood pressure (73 ± 9 vs 73 ± 11 mmHg, p: 0.821). Fifteen participants (21.1%) had increase systolic blood pressure greater than 20 mmHg; only two (2.8%) had a decrease above this limit.

Table 4
Comparison of lab exams pre and post-test.

Parameters	Reference value	Pre-test	Post test	Valor p
Hematocrit (%)	40 a 54 (men) 38 a 47 (women)	43 ± 4	42 ± 5	0,013
Anemia		13 (18,3%)	16 (23,2%)	
Pleocytosis		11 (15,5%)	06 (08,7%)	
Leucocytes (mcL)	5.000 a 10.000	7731 ± 2210	9040 ± 3266	0,003
Leucopenia		01 (01,4%)	03 (04,3%)	
Leukocytosis		08 (11,3%)	16 (23,2%)	
Platelets (mil/mcL)	150 a 450	249 ± 55	259 ± 58	0,001
Trombocytopenia		01 (01,4%)	01 (01,4%)	
Trombocytosis		00 (00,0%)	01 (01,4%)	
glucose (mg/dL)	70 a 99	91 ± 10	97 ± 18	0,020
Hypoglycemia		02 (02,8%)	03 (04,3%)	
Hyperglycemia		12 (16,9%)	27 (39,1%)	
Sodium (mEq/L)	135 a 145	138 ± 3	138 ± 2	0,462
Hyponatremia		07 (09,9%)	05 (07,2%)	
Hypernatremia		00 (00,0%)	00 (00,0%)	
Potassium (mEq/L)	3,5 a 5,1	4,4 ± 0,3	4,2 ± 0,2	0,009
Hypokalemia		00 (00,0%)	00 (00,0%)	
Hyperkalemia		01 (01,4%)	00 (00,0%)	
CPK (U/L)	< 171 (men) < 145 (women)	158 [11 to 2321]	117 [48 to 4080]	<0,001
Increase CPK		34 (47,9%)	17 (24,6%)	
CKmb (U/L)	< 24	15 [8 to 46]	14 [8 to 58]	0,022
Increase CMmb		06 (08,5%)	03 (04,3%)	
Troponine (ng/mL)	0,03 a 0,05	0,00 [0,00 to 0,75]	0,00 [0,00 to 1,43]	0,560
Increase Troponine		1 (01,4%)	1 (01,4%)	

Data presented as average ± standard deviation (if variable is parametric) or median [minimum to maximum] (if variable is non-parametric); or number of participants (%).
Paired T-students and Wilcoxon tests were used to determine the difference between pre and post test values of parametric and non-parametric variables, respectively.

The average heart rate also increased significantly compared to pre-test values (70 ± 11 vs 75 ± 13 bpm, p: 0.002). Five subjects (7.0%) had increased above 20 bpm, whereas 4 (5.6%) had more than 20 bpm decrease.

There was no difference between ECG results pre and post-test, even among subjects with more than 40 years-old.

The individuals with aorta ecstasy and relaxation deficit remained with the same diagnosis, as well as the individual with mitral valve prolapse and mild mitral regurgitation, in the ECO TT exam. Three individuals with normal pre-test examination showed abnormal tests: diastolic dysfunction grade 1 and aorta ecstasy; diastolic dysfunction grade 1; and minimal mitral and tricuspid insufficiency. Three individuals with minimal or mild mitral regurgitation and three with left ventricular hypertrophy, showed normal post-test exam.

The examination Holter had 59 individuals with valid exams. Of these, 2 (3.4%) showed ESV and 4 (6.8%) had EV in the pre-test exam, and one (1.7%) had supraventricular tachycardia. All these participants had the same findings in the pre-test exam, even among subjects with more than 40 years-old.

Table 4 shows the comparison between the preoperative laboratory tests and post-test. There was a decrease of hematocrit values (43 ± 4 vs 42 ± 5%, p: 0.013). More subjects presented with anemia after the SPARK weapon (13 (18.3%) vs 16 (23.2%)). There was also an increase in the total number of leukocytes, platelets and glucose. Of the 27 individuals who had hyperglycemia in the post-test examination, 3 showed results above 126 mg/dL. No patient had these values in the pre-test period.

Comparing the laboratory parameters related to cardiac injury, there was a decrease of CPK and CK-MB. There was no change in troponin.

5. Discussion

The increasing use of non-lethal weapons cause concern regarding its secure application, with legal and civil implications. Among the possible complications of its use, the implications in the cardiovascular system are the most reckless for morbidity, justifying this study.

Mild potency electroshock, as the result of direct contact with domestic electricity of 110–220 V, can cause cardiovascular effects such as myocardial infarction, transient accelerated hypertension, left ventricular dysfunction, cardiac rupture and arritmia [17]. Follow-up studies demonstrated that arrhythmias prevalence after electrical damage ranges from 10 to 36%, such as premature ventricular contraction, ventricular tachycardia, ventricular fibrillation, bundle branch block and atrioventricular block [17]. Cardioversion, used for cardiac arrhythmias treatment, can also develop complications, even if the technical implementation is perfect, such as sinoatrial block, transient atrioventricular block or ventricular arrhythmias [18].

Despite the known effects of electroshock on the cardiovascular system, it was believed that there was little likelihood of a CEW to cause CPA in healthy individuals. Once immediate onset of ventricular fibrillation in a healthy heart requires a too early stimulated ectopic beat, and the threshold for a premature beat is greater than for a less premature beat, ventricular fibrillation events occur only if (i) electroshock time was large enough to overcome the time of depolarization of the heart cells, (ii) the myocardial necrosis occurred, or (iii) eletropermeabilization (cell permeability increase by generating electric field) [19]. Both eletropermeabilization and myocardial necrosis was believed to be unlikely due the low voltage generated with CEW. Sun M et al determined that the probability of a gun electroshock cause ventricular fibrillation was 6×10^{-6}, based on data with pigs [20]. However, this value was defined in studies with limited shock duration. Several police videos documented loss of consciousness and subsequent ventricular fibrillation in individuals who were submitted to these weapons [21]. The researcher Zipes DP gathered evidence that led him to opine that the X26 gun causes CPA in humans [21]. One study revealed without any doubts the occurrence of heart rate increase in the order of 240 bpm in one individual submitted in an experimental model of CEW for 10 s [22].

This study was designed to document the occurrence of arrhythmia, both acute and chronic thought resting ECG and 24 hour Holter, respectively. No arrhythmia related to SPARK occurred, even among subjects with more than 40 years-old. No myocardial necrosis occurred, as evidenced by cardiac enzyme levels and ECO TT test.

The subjects showed changes with the use of weapon that may be related to acute stress caused by the scare of being shot at, or perhaps by the electric discharge. The resulting adrenergic response may be

the cause of increase in systolic blood pressure and heart rate, as evidenced in the post-test evaluation. The evidenced laboratory abnormalities, such as increased white blood cells, platelets, glucose and reduction of potassium, may also be related to acute stress.

Reported adverse events were self-limited, and mostly mild. Pain and local erythema were probably associated with the penetration of darts in the skin. Systemic factors were related to each other, and can also be explained by heightened adrenergic discharge, which can cause breathlessness, palpitation and dizziness.

All individuals reported being incapable of any voluntary reaction during the time the shock was applied. Therefore, not only the weapon was efficient, but also one can conclude that all received electroshock and consequently validates the safety data generated in this study.

Together, these results demonstrate the efficiency and safety of the disabling electric gun SPARK, even among subjects with more than 40 years-old. The fact of the non-lethal weapon SPARK stop the application of shock after 5 seconds, even if the trigger remains pulled by the policeman, is an important safety factor that may have contributed to this result.

This study has some limitations. These results cannot be extended to participants with existing cardiovascular disease or in use of illicit drugs, once they were excluded from the study and are related to greater propensity to develop cardiovascular complications [21]. The distance dart insertion site relative the heart is another factor related to the occurrence of arrhythmia [21]. Although one of the darts was inserted in the thoracic region, darts inserted in the left side is nearer to the heart.

6. Conclusion

Physical, laboratory tests, 12-lead resting ECG, ECO TT and Holter tests showed no change when compared to pre-test results. There was no post-shock cardiac arrhythmias, or evidence of myocardial necrosis.

The increase in hematological parameters, blood pressure and heart rate after the shock with SPARK, although they have reached statistical significance, may reflect acute stress and did not represent danger for the health of subjects who participate in the study.

In conclusion, SPARK CEW is effective in incapacitating individuals by the time the shock is being discharged, without causing cardiovascular effects in healthy volunteers submitted to its use.

Conflict of interest

The authors report no relationships that could be construed as a conflict of interest.

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