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CRITERIA OF EFFICIENCY AND SAFETY OF THE DEFIBRILLATING IMPULSE

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SUMMARY

The effectiveness and safety of the defibrillating effect of a bipolar impulse produced by a Soviet DK1-01 defibrillator and the Monopolar impulse Ed-Mark have been tested in 14 experiments on the anaesthetized dogs. A quantitative criterion to compare the safety of different defibrillators and an electro-therapeutic index of the defibrillating action are being suggested. It is defined as the ratio of the thresholds of energy in joules causing lesions to that causing defibrillation. In the above experiments the mean value of this therapeutic index was 1.59 ± 1.41 for the Ed-Mark impulse and 4.32 ± 2.78 for the defibrillator DK1-01 impulse. The difference of the mean values was statistically significant ($P = 0.02$).

INTRODUCTION

The high efficiency of electroshock treatment of certain disorders of cardiac rhythm is today universally recognized. However, it is known that the discharge of current can produce various morphological and functional disorders of the heart, to which belong the so-called post-conversion arrhythmias (Lown, 1964; Ganelina, Bricker and Volpert, 1970; Syrkin, Nyedostup and Mayevskaja, 1970). The latter often represent a serious danger, especially in cases when they supervene in patients with pronounced pathology of the cardio-vascular system. In particular, irreversible post-conversion asystolos have been described, which occurred as a result of efforts to eliminate paroxysmal tachycardia in patients with myocardial infarction (Ganelina et al., 1970). This explains the persistent efforts of the research workers to look for the possibility of decreasing the active dose while retaining its efficiency. However, in recent years some authors have maintained that the energy for defibrillation of 400 J is insufficient to defibrillate patients weighing over 80 kg. (Tacker and Geddes, 1974). Many firms have already started to manufacture defibrillators delivering a load of 500 J up to even 1000 J (Editorial, 1977). It is to be noted that DI-03 and DKI-01 defibrillators made in the USSR deliver not more than 200 J, but nevertheless are used successfully in the treatment of various types of arrythmias in 80—100% of patients, irrespective of the weight of the patient.

Contradictory recent findings on the levels of energy required for defibrillating the patients stimulated us to compare in experiments on animals the efficacy and the safety of the defibrillating action of a bipolar impulse (impulse 'B') and the monopolar impulse Ed-Mark (impulse 'M'), typical of defibrillators now manufactured by the majority of the firms in the West and in the U.S.A.

The data on average and threshold levels of energy are insufficient for objective comparison of results of cardiac defibrillation in patients by impulses of different form. In the present paper we give the experimental basis for an electro-therapeutic index of the defibrillating action, which permits one to make a quantitative assessment of the safety of different forms of impulses.

MATERIALS AND METHODS

Experiments were carried out on 14 anaesthetized mongrel dogs of both sexes, weighing from 7 to 32 kg. In the course of each experiment two main indices were determined — the defibrillation threshold (DT) and the lesion threshold (LT) — separately for each of the impulses compared. Their ratio, i.e. LT/DT, which we shall call the 'electro therapeutic index' served as a quantitative expression of the safety, as it pointed to the permissibility of use of such doses which, while stopping the ventricular fibrillation, did not produce lesions of the myocardium and of its conductive system.

In experiments for testing the defibrillating threshold, ventricular fibrillation was provoked with alternating current (127 V, 50 Hz) which was applied for 2 s through needle electrodes, introduced subcutaneously in the left anterior and the right hind limbs. After 5—10 s, the arrhythmia was removed by several discharges of the defibrillator, the doses being progressively but insignificantly increased. Several tests were usually made on one animal to verify the first dose which was below the threshold for defibrillation. As lesion threshold (LT) we regarded the minimum action on a normally functioning heart outside the vulnerable phase of the cardiac cycle, i.e. in the area of the peak of the T wave of the electrocardiogram, after which one or several ventricular extrasystoles appeared. LT and DT were determined several times throughout the experiments, after which the data obtained were treated statistically.

During the preparation of the experiment, electrodes of the defibrillator (metal discs 100 mm in diameter), covered with gauze well soaked with saline, were fixed on the chest wall which had been shaved and degreased on both sides of the sternum in the area of the cardiac beat. Their position during the experiment did not change. The EGG was monitored continuously, the monitor being able to record cardiac electrical activity not later than 100 ms after the defibrillator discharge.

The discharge on load was determined for each action in the accumulator condenser (standard kilovoltmeter), as was the amplitude of current through the electrodes and the voltage on the electrodes. The error of measurement did not exceed ±1.5%. The resistance between the electrodes was calculated from the currents and voltages. Energy delivered by the defibrillators on load was determined by consideration of the resistance between the electrodes, the discharge voltage of the accumulating condenser, and the parameters of the discharge in the condenser and the induction coil and the inductance, the error of measurement did not exceed ±1%.

The Soviet defibrillator DK1-01 was used for impulse 'B' generation. Impulse 'M' was obtained from a portable defibrillator produced by a Western firm.

Figures 1 and 2 show oscillograms of impulses generated with the loads of 25, 50 and 100 Ω by defibrillators used in experiment. An essential difference in the impulses compared was the presence in the 'B' impulse of a second half-wave with a sign opposite to the first one. Figures 3 and 4 show the simplified schema of discharge contours of these defibrillators and the parameters of elements measured; the error of measurement did not exceed ±1%.

Both defibrillators formed the impulse during the condenser discharge to the load through the induction coil. The difference consisted in the presence of diodes switched in parallel to the accumulating condenser in the difibrillator, forming the 'M' impulse and of the chain diode-resistor, switched in parallel to the load in the contour of the defibrillator DK1-01. The

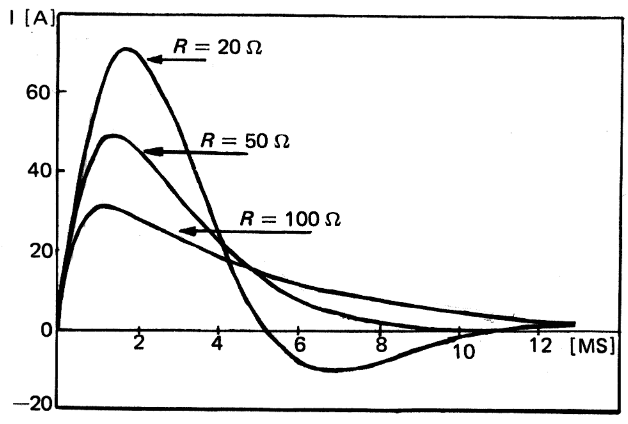


Fig. 1. Oscillograms of 'M' waveform during defibrillator discharge with active loading 25, 50 and 100 Ω with stored energy 400 J. The current calibration was 10 A per vertical division. The oscilloscope sweep speed was 2 ms/horizontal division.

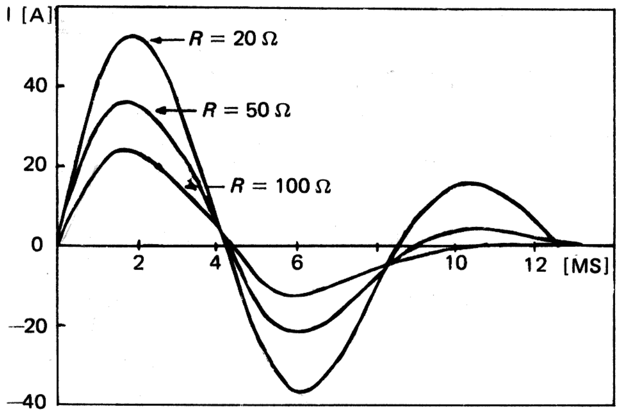


Fig. 2. Oscillograms of 'B' waveform current during the discharge of the DKI-01 defibrillator used in the tests with active resistances 25, 50 and 100 Ω and accumulated energy 400 J. The current calibration was 10 A/vertical division, and the oscilloscope sweep speed was 2 ms/horizontal division.

capacities of accumulating condensers, induction and inductance of coils differed similarly.

Diode V in the circuit of the defibrillator forming the 'M' impulse prevented the transition of the discharge from aperiodic into the oscillation under load resistance below 47.1 Ω. The maximum voltage of the discharge of the accumulating condenser in this defibrillator was 4.2 kV which corresponded to the accumulating energy of 400 J from which was delivered to the 50 Ω load of 320 J.

The discharge circuit of the defibrillator DK1-01 differed from the above in the parameters of its elements and in the presence of the chain diode-resistor switched in parallel to the load. The diode was switched according

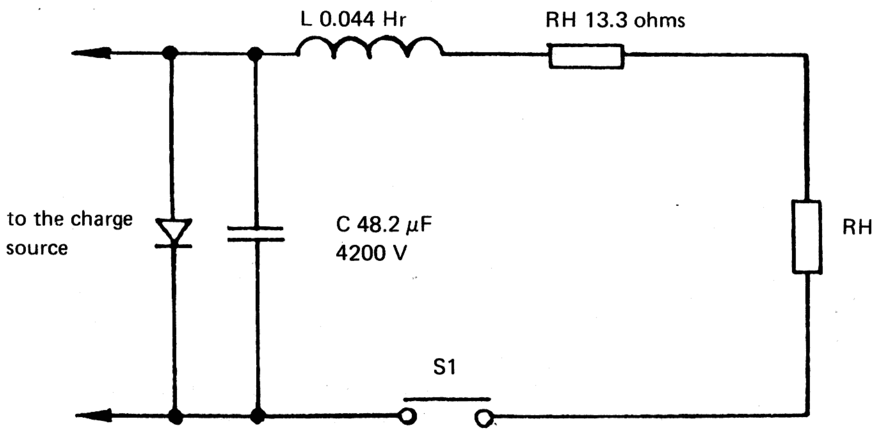


Fig. 3. Simplified diagram of discharge circuit for the 'M' waveform.

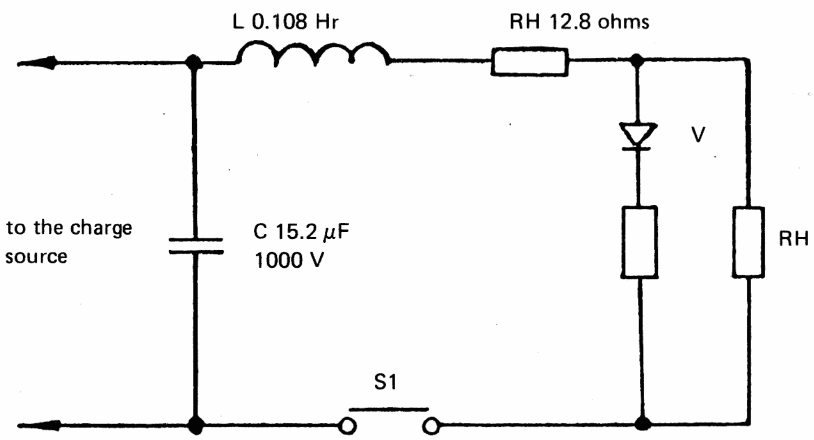


Fig. 4. Simplified diagram of the DKI-01 defibrillator circuit for the 'B' waveform.

to the polarity, directly to the voltage in the condenser, which ensured shunting of the load by the resistor in the alternate half-periods of the discharge. During the even half-periods the diode was closed and the discharge current only passed through the overload, without being fed into the shunt. In such a scheme it was possible to control the correlation of current amplitudes in the first and the second half-periods of discharge within wide limits by changing the conductivity of the shunt. In the DK1-01 defibrillator circuit, the parameters and shunt conductivity were chosen so that the current amplitude of the second half-wave was 0.6 of the amplitude of the first. This shunting of the load decreased its influence on the parameters of the impulse formed. Thus within the load resistance of 25—100 Ω the ratio of the current amplitudes of the second and the first half-wave changed less than ±20% from the value of 50 Ω load. The dependence of duration of the first half-wave on the load resistance also decreased essentially under the influence of the diode-resistor-shunt. The maximum charge voltage of the condenser in the defibrillator DK1-01 was 7000 V, which corresponded (for the sample tested) to accumulated energy of 372.4 J, of which 187 J went to the 50 Ω load.

The load characteristics of the defibrillators are presented, i.e. the dependency of the maximum delivered to load energy on the load resistance, in order to compare the value of delivered energy (Fig. 5); the different type of load characteristics of the defibrillators compared should be noted. The load characteristic of the defibrillator DK1-01 was maximum with the load of 35 Ω and two falling curves. The energy delivered to the load by the defibrillator forming the 'M' impulse increased with the growth of its resistance, tending towards value of energy accumulated.

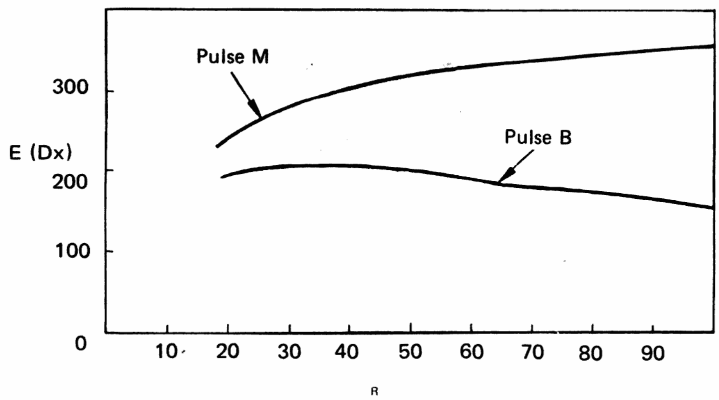


Fig. 5. Loading characteristics (Dx) of the defibrillators shaping 'M' and 'B' waveforms.

RESULTS

The peak values of the threshold defibrillating and damaging currents as well as the corresponding values of energy delivered by the defibrillators to loads are given in Tables I—IV. For 'B' impulses (apparatus DK1-01) the energies and currents of the first half-wave are the sums of amplitudes of currents of both half-waves of the impulse and the energy liberated on load per discharge are given separately. Correlation of the peak values of the defibrillating currents for the impulses compared were calculated from the results of experiments (Tables I—II). The mean value of the ratio: threshold defibrillating current of impulse 'M' to the threshold defibrillating current of the first half-wave of impulse 'B' was 1.42 ± 0.16 (with the reliability of $P = 0.99$).

The mean value of the relation of the threshold defibrillating energies of impulses 'M' and 'B' with the reliability 0.99 was observed in the interval 1.77 ± 0.45. This result shows that in the experiments energy of the 'B' impulse was on the average 1.77 times more effective in defibrillation than the energy of the impulse 'M'.

The peak value of the current of the first half-wave of the impulse 'B' in defibrillation was always less than the current of impulse 'M'. This difference was more considerable in the experiment No. 7, where the amplitude of the first half-wave of impulse 'B' was 50% of the impulse 'M', while in the experiment No. 9 it was less than 87%. At the same time the mean value of the ratio of the threshold amplitude of the impulse 'M' to the threshold sum of amplitudes of both half-waves of impulse 'B' differed slightly from one (0.95 ± 0.12). This confirmed the opinion earlier stated (Gurvich, 1975) that synchronization of stimulation in the heart, i.e. defibrillation, was due to the summation of the action of half-waves of different polarity. If, however, for the elimination of fibrillation the decisive significance has the sum of the peak values of currents of the first and second half-waves

TABLE I

THRESHOLDS OF CURRENTS (A) FOR DEFIBRILLATION WITH DIFFERENT WAVEFORMS

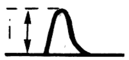
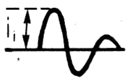
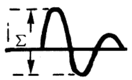
Pulse waveforms	Number of test													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	Currents threshold													
	9.7	6.4	14.4	6.3	13.7	12.3– 19.0– 29.0– 36.2–	10.5	10.9	8.7	16.4	16.1	19.0	7.0	6.9
	6.1	4.7	9.5	5.45	10.5	10.4	6.0	7.2	7.6	13.8	10.4	12.8	4.6	5.4
	9.2	6.7	14.5	8.45	16.2	17.1	8.9	10.9	11.4	21.5	15.5	19.7	6.3	7.6

TABLE II

THRESHOLD DEFIBRILLATION ENERGIES (J) WITH DIFFERENT WAVEFORMS

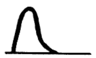
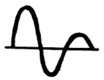
Pulse waveforms	Number of test													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	Threshold defibrillation energy													
	12.1	10.1	36.1	11.0	37.6	45.4– 79.3– 17 7– 27 3–	15.0	12.0	18.0	55.1	49.7	74.1	28.8	15.5
	6.2	6.7	21.1	9.4	17.7	61+	12.0	8.7	15.5	36.8	24.8	29.6	10.6	7.4

TABLE III

THRESHOLD DAMAGING CURRENTS (A) WITH DIFFERENT WAVEFORMS

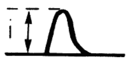
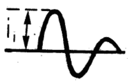
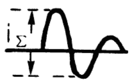
Pulse waveforms	Number of test													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	Threshold damaging current													
	14.4	8.05	27.2	—	8.7	—	9.7	—	18.3	—	13.7	—	5.1	7.3
	22.2	12.7	30	19.6	13.05	—	14.5	—	17.1	—	17.9	—	5.6	8.1
	34.9	18.4	46.7	27.6	20.2	—	22.7	—	26.3	—	27.4	—	7.7	11.7

TABLE IV

THRESHOLD DAMAGING ENERGIES (J) WITH DIFFERENT WAVEFORMS

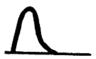
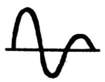
Pulse waveforms	Number of test													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	Threshold damaging energy													
	29.7	16.9	100.2		11.6		13.7		66.7		32.2		15.6	18.4
	56.1	42.7	144.8	57.9	26.0		35.0		63.2		59.1		13.5	1.8

TABLE V

THERAPEUTIC INDEX (K_i) WITH DIFFERENT WAVEFORMS

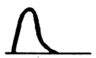
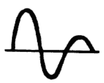
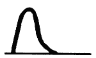
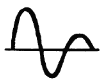
Pulse waveforms	Number of test													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	Electro therapeutic index													
	1.5	1.3	1.9	—	0.63	—	0.92	—	2.1	—	0.85	—	0.73	1.06
	3.6	2.7	3.2	3.6	1.24	—	2.4	—	2.25	—	1.72	—	1.22	1.5

TABLE VI

THERAPEUTIC INDEX (K_E) WITH DIFFERENT WAVEFORMS

Pulse waveforms	Number of test													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	Electro therapeutic index													
	2.47	1.7	2.8	—	0.31	—	0.9	—	3.7	—	0.65	—	0.54	1.2
	9.1	6.4	6.9	6.2	1.5	—	29.0	—	4.1	—	2.4	—	1.3	2.4

of the impulse, the damaging effect was related to the magnitude of the current of one direction (Gurvich, 1975).

The threshold damaging currents differed essentially for impulses 'B' and 'M'. The peak value of current of the first half-wave of the threshold damaging impulse 'M' was generally less than the analogous current of the impulse 'B'. The mean value of the ratio of peak damaging currents of the 'M' impulse to the first half-wave of impulse 'B' was 0.72. Results obtained show that when impulse 'M' currents and the sum of currents of two half-waves of impulse 'B' are equal, the monopolar impulse 'M' exerted greater damaging effect on the heart. This justifies the assumption that the second half-wave exerts a protective action sui generis, which is apparently due to the compensation of discharge passing through the heart (Tables V and VI).

DISCUSSION

The conception 'cardiac lesion' used in discussing the experimental material requires explanation. Different authors have described the morphological lesions of the myocardial structure, resulting from an impulse of high current, changes in enzymatic activity and also different disorders of the rhythm and conductivity; the so-called post-conversion arrythmias (Poukov, Abinder and Frolov, 1966; Syrkin et al., 1970; Chazov and Bogoliubov, 1972). These methods of assessment of myocardial lesions have a qualitative, descriptive character. This renders difficult or impossible the comparison of the damaging action of impulses with similar parameters. And yet, practice demands the elaboration of a standard and easily reproducible method, enabling quantitative assessment of the damaging action of the impulses used in treatment. Such a method was described previously (Negovsky, Gurvich, Tabak and Bogushevich, 1973), but no detailed description of it has been given.

Summing up the results of the earlier works and of the present investigation, it is possible to formulate the main features of the reaction of the intact heart to the excitatory action of a single electric impulse:

(a) electrical impulses acting on the normally functioning heart always caused different disorders of the rhythm and conduction, their character depending on the form of the pulse and its power. With the exception of the cases occurring during the vulnerable phase of the cardiac cycle (the *T* wave peak), impulses of subthreshold or threshold defibrillating power usually caused only sinus tachycardia, lasting several tens of seconds.

(b) When the dose was increased above the threshold for defibrillation, ectopic activity in the shape of single or group extrasystoles occurred, and intraventricular conductivity decreased. The minimum power of the discharge current provoking 1—2 extrasystoles was considered by us as the lesion threshold.

(c) Further increase of dosage above the damage threshold caused rhythm disorders of varying severity. There were attacks of supraventricular and ventricular tachycardia, the latter sometimes passing into ventricular fibrillation. In this case ventricular fibrillation could be stopped by a subsequent weaker shock. Defibrillation with a current of excessive power could provoke complete atrioventricular block, and occasionally an idioventricular rhythm. Disturbances of the rhythm and conductivity as sequelae of the discharge current on the heart were easily reversible, and were possibly of a functional nature. This is confirmed by the fact that even severe arrhythmias such as complete atrioventricular block or ventricular tachysytole ceased spontaneously within 1–1.5 min, after which sinus tachycardia was restored. Ventricular fibrillation was an exception, demanding repeated electric defibrillation for its elimination. If the intervals between separate tests were sufficiently extended (5—10 min), the 'threshold lesion' could be reproduced repeatedly during one experiment. It is important to note, that every impulse tested provoked a specific pathological reaction in the shape of a different disorder of rhythm. Parallel testing of the apparatuses generating different impulses showed that each of them had a corresponding definite value of the defibrillation threshold and lesion threshold.

Analysis of the experimental material drew our attention to another finding, that the thresholds were directly dependent on the weight and status of the animals. Hence, a new index has been suggested, to facilitate the comparison of different experiments, the electro therapeutic index K, being a ratio of lesion and defibrillation thresholds. As earlier experiments showed, K was a sufficiently stable value, greatly influenced by the parameters of the impulse tested, while other factors like the height of animals, the depth of anaesthesia etc., were minimised.

Table V gives calculated values K for impulses 'B' and 'M' (for impulse 'B' the sum of the peak current of both half-waves was taken). The mean value K_i for the impulse 'M' as determined by the current was 1.22 ± 0.62 while for the impulse 'B' it was within 2.34 ± 1. The difference of the mean values was statistically significant ($P = 0.99$). Even more demonstrative was the result of combination of K for the above impulses, calculated as a ratio of the damaging and defibrillating energies, K_E. The mean value K_E for the impulse 'M' was 1.59 ± 1.41, and for the impulse 'B' was 4.32 ± 2.73. The difference of mean values K was statistically reliable to $P = 0.98$ (Tables V and VI).

The advantages of the bipolar impulse was most evident when comparing the electro-therapeutic indices. Thus, for the impulse 'M' in four out of nine experiments K was below 1. This means in practice that in many cases the cardiac defibrillation by the impulse 'M' was possible only with doses which damaged the heart. In experiment No. 5, in which the electro therapeutic index of the impulse 'M' was 0.31, cardiac defibrillation was achieved by a dose exceeding the lesion threshold three times. It must be mentioned here that the electro-therapeutic index of impulse 'B' in all experiments exceeded 1, i.e. the cardiac defibrillation was always achieved with doses below the lesion threshold.

If the lesion was minimal or manifested only by 1—2 extrasystoles, it could hardly be regarded as threatening the life of the animal. Another situation occurred in cases in which the defibrillation threshold exceeded the lesion threshold several times ($K = 0.31$), as regular severe rhythm and conductivity disturbances developed, which can lead to very serious sequelae. Hence the conclusion, that the optimum impulse had a therapeutic index above 1. When assessing the experimental data, it should be pointed out that they reflect the different types of cardiac reactions of a healthy dog to an electric impulse and cannot be directly transferred to clinical conditions of patients. Our personal experience with cardioversion in patients with different arrhythmias as a result of severe pathological changes in the myocardium, particularly after coronary thrombosis, leads us to think that in such cases the lesion threshold can be considerably lowered. One must also take into consideration that certain arrhythmias are prone to frequent relapses and hence it becomes necessary to resort to multiple applications of electrical defibrillation in the same patient, which further increase the danger of damaging the heart by the discharge current. Hence the employment of the electro-therapeutic index under standard experimental conditions is absolutely necessary to specify the feasibility of using a particular defibrillator in clinical practice.

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