United States Patent [19]

Charms

[11] **3,738,370**

[45] **June 12, 1973**

[54] **METHOD OF DEFIBRILLATION WITH ELECTRODES LOCATED IN THE ATRIUM**

[76] Inventor: **Bernard L. Charms,** 2921 S. Park Boulevard, Shaker Heights, Ohio

[22] Filed: **Jan. 18, 1971**

[21] Appl. No.: **107,312**

[52] **U.S. Cl.** ..... **128/419 D**

[51] **Int. Cl.** **A61n 1/36**

[58] **Field of Search** ..... 128/419 D, 419 P, 128/419 R, 421, 422

[56] **References Cited**

UNITED STATES PATENTS

3,664,347	5/1972	Harmjanz et al.	128/419 P
3,605,754	9/1971	Jaros et al.	128/419 D
3,680,544	8/1972	Shinnick et al.	128/419 P
3,144,019	8/1964	Haber	128/419 P
3,614,955	10/1971	Mirowski et al.	128/419 D

OTHER PUBLICATIONS

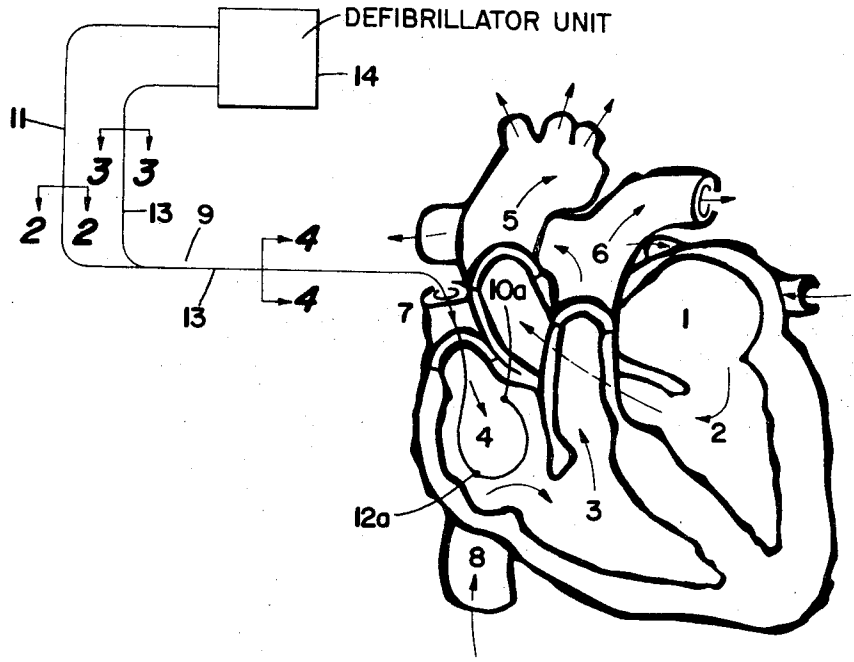
Hopps et al., "Surgery", Vol. 36, No. 4, Oct. 1954, pp. 833–849 (only pp. 834 & 841 relied on)

Primary Examiner—William E. Kamm
Attorney—Isler & Ornstein

[57] **ABSTRACT**

A bi-polar coaxial cable or catheter is passed transvenously into the right atrium or auricle of the heart, and the electrodes or poles of the cable are so positioned within the atrium and exposed to the interior of the atrium that when the cable is connected to a defibrillator unit, direct current shocks of very low energy or intensity may be transmitted by said unit through the cable to effect defibrillation, without causing pain or appreciable discomfort to the patient undergoing defibrillation.

7 Claims, 4 Drawing Figures



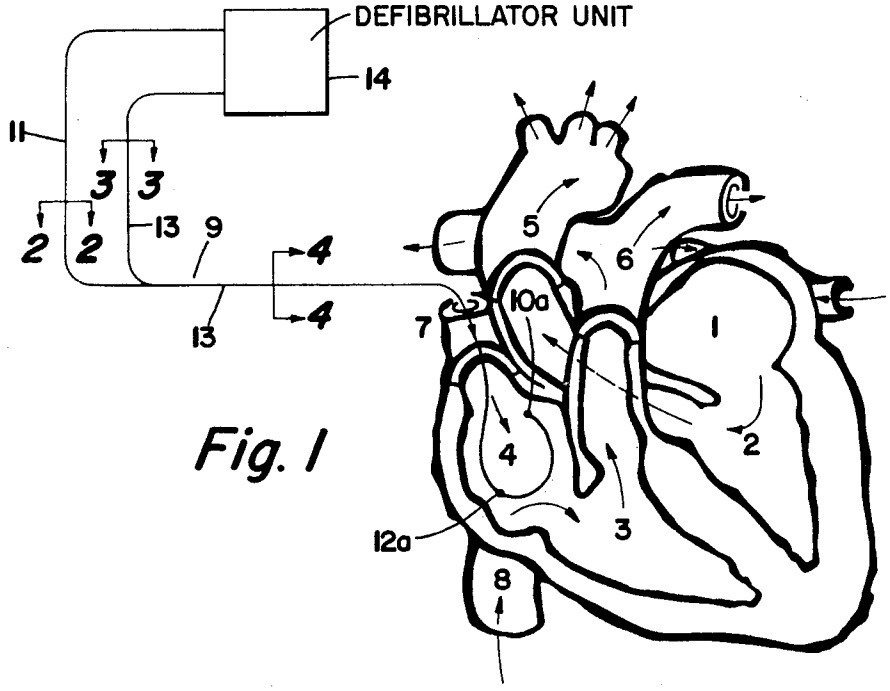


Fig. 1

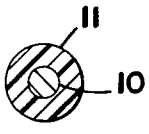


Fig. 2

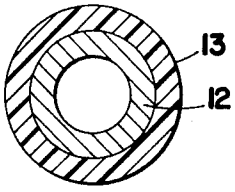


Fig. 3

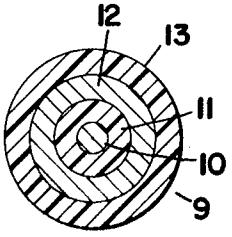


Fig. 4

INVENTOR.
BERNARD L. CHARMS
BY
Isler & Ornstein
ATTORNEYS

METHOD OF DEFIBRILLATION WITH ELECTRODES LOCATED IN THE ATRIUM

The human heart beats about 70 times a minute, and while all of the fine mechanisms and forces that trigger the heartbeat are not known with precision, a small knot of tissue known as the pacemaker or sinus node is a vital spark plug. It is located in the upper part of the heart near where great veins enter the right auricle. It consists of specialized nerve and muscle cells which ignite a wave of muscle contraction in the heart. This wave spreads over auricular muscles and, although there is no direct connection, appears to travel from auricles to ventricles and muscles of the heart valves over a bridge, the auricular-ventricular or A-V node.

The electrical nature of impulses that spark the heartbeat is shown by the success of artificial pacers in triggering normal rhythms in some forms of heart disease. These artificial pacers are battery-powered devices, worn over the shoulder like a camera or implanted under the skin, which are connected to electrodes in heart tissue, and which feed tiny jolts of electric current to a faulty heart, to spark its beat and keep it running rhythmically.

An implantable cardiac Pacemaker is described in Greatbatch U.S. Pat. No. 3,057,356, this pacer permitting innocuous, painless, long term cardiac stimulation at low power levels by utilizing a small, completely implanted transistorized, battery operated Pacemaker, connected via flexible electrode wires directly to the myocardium or heart muscle. A subsequent Chardack U.S. Pat. No. 3,198,195, was an improvement, in that it taught variable Pacemaker controls, adjustable from outside the body by a percutaneous needle, to change Pacemaker rate and/or output level.

In a more recent Greatbatch U.S. Pat. No. 3,478,746, a cardiac implantable demand Pacemaker is described, consisting of a portable, self-contained device including circuitry which senses each natural heartbeat and resets the Pacemaker pulse generator timing in response to it. This device stimulates only skipped beats and does not compete with natural beats, the first generated impulse after a natural beat occurring after a preset time interval longer than the natural interval unless another natural beat has intervened. When a natural beat intervenes, the Pacemaker timer is coordinated with it.

Other irregularities of the heart beat, or arrhythmias, include atrial fibrillation, found most often with rheumatic valvular disease (chiefly mitral stenosis), thyroid overactivity, or coronary disease with congestive failure, as well as a far more serious and often fatal disturbance of rhythm, known as ventricular fibrillation, in which condition the ventricle is not pumping, and which is rapidly fatal unless the heart can be "defibrillated" by means of electrical machines which shock the heart out of its dangerous standstill. Ventricular fibrillation occurs most commonly in acute coronary attacks, and during cardiac surgery, although it may unexpectedly occur during other forms of surgery.

Such "defibrillators" are described, by way of example, in U.S. Pat. Nos. 3,211,154; 3,258,013; 3,389,704; 3,442,269; 3,454,012; 3,518,997 and 3,527,229.

The methods described in these patents and others, for the most part, employ electrical shocks applied to the external surface of the heart with the chest open, or through the chest wall.

In U.S. Pat. No. 3,442,269, for example, reference is made to the fact that in closed chest utilization of the defibrillator, one of the electrodes is placed on the right border of the sternum just below the sternal notch, while the other electrode is placed on the midclavicular line near the fifth interspace, with the heart approximately midway therebetween, while for internal use, following thoracetomy, the electrodes may be applied directly across the heart itself.

Due to the high electrical resistance of the skin and other tissues between the heart muscle and the electrodes, and the distance of the electrodes from the heart, large or high electrical voltages are necessary to overcome this resistance. Shocks incident to the use of such high voltages, produce pain, and anesthesia is required to eliminate or lessen this pain, so that the shocks cannot be repeated at frequent intervals. Moreover, burns of the skin are frequently produced, and recurrence of the abnormal rhythm within a matter of weeks, is common.

For example, conversion of atrial fibrillation to normal rhythm by direct current countershock through the chest wall requires from 100 to 400 watt seconds of electrical energy, usually delivered very rapidly, i.e., for periods of 3–4 milliseconds.

In artificial pacers, to which reference has hereinbefore been made, it has been proposed, as in Chardack U.S. Pat. No. 3,348,548, to provide an implantable bipolar electrode which is inserted through a vein, one of the jugular veins, for example, and brought to lie in contact with the inner lining of the heart. However, in such a pacer, in common with all pacers, small electrical impulses are delivered to the electrode, that is to say, impulses of the order of 1 to 5 milliamps at 6 volts, and at a frequency of 50 to 100 per minute. Such impulses are effective to stimulate the ventricle to beat, but are far too small to be used with any useful effect for defibrillation.

I have discovered that by proper placement of a bipolar coaxial cable, of novel or unique construction, in the right atrium, and inserted transvenously, as through the jugular vein, I can quickly convert a rapid irregular rhythm to a normal rhythm, by the administration of direct current shocks, of the same duration as those delivered through the chest wall, but of very low energy or intensity, i.e., 1 to 10 watt seconds.

I have further found that the closer the two electrodes are to each other, the greater the electrical energy that is required to accomplish the defibrillation, and that the distance between the two electrodes should ideally be that equivalent to one-half the circumference of the right atrium.

I have further noted that a the delivery time or period of 3–4 milliseconds, sufficient insulation for the bipolar coaxial cable to prevent shocking the body generally must be provided, because the voltage and amperage levels required may reach 1,000 volts and 70 amperes. However, as previously shown by others, successful defibrillation by countershock, up to 100 milliseconds in duration can be accomplished. With the longer duration, lower voltages and amperages can be used, avoiding the problem of overall shocks, and reducing the requirements for insulation. This also makes possible the permanent implantation of a self-contained power unit attached to the cable positioned in the right atrium. Such a unit could be set to determine the presence of a too rapid or irregular heart rate and deliver a shock

synchronized with the next intrinsic heart beat. The energy required for such a unit can be derived from an inductively rechargable battery source connected to a series of condenser plates for storage of the charge, as described, for automatic internal defibrillation. The small energies required should permit miniaturization of the unit sufficient for practical permanent implantation in the body. Moreover, the cable could be interchangeably connected to a conventional pacer, so as to become usable for ordinary pacer purposes, thereby providing a complete control for all cardiac rhythm disturbances, whether too fast or too slow.

The invention may be explained with reference to the accompanying drawings, wherein

FIG. 1 is a cut-away view, somewhat diagrammatic in nature, showing the blood circulation of a normal heart, and showing, also, the manner in which the coaxial cable of the present invention is introduced into the right atrium or auricle of the heart, as well as the optimum or desired placement of the electrodes;

FIG. 2 is a cross-sectional view, on an enlarged scale, taken on the line 2—2 of FIG. 1;

FIG. 3 is a cross-sectional view, on an enlarged scale, taken on the line 3—3 of FIG. 1; and

FIG. 4 is a cross-sectional view, on an enlarged scale, taken on the line 4—4 of FIG. 1.

Referring more particularly to the drawings, reference numeral 1 designates the left atrium or auricle of the heart, 2, the left ventricle, 3, the right ventricle, 4, the right atrium or auricle, 5, the aorta, 6, the pulmonary artery, 7, the superior vena cava, and 8, the inferior vena cava.

For purposes of effecting defibrillation, a coaxial cable or "catheter," generally indicated by reference numeral 9, is used.

The coaxial cable consists of a lead wire 10, insulation 11 surrounding this lead wire, a tubular lead wire 12 surrounding the insulation 11, and a covering insulation 13 surrounding the lead wire 12.

The wires 10 and 12 may be made of any metal which has excellent electrical transmitting properties, and which is completely compatible with body fluids while the insulation 11 and 13 may be any electrically-insulative inert material which has good insulating properties, such, for example, as Teflon, and which is also completely compatible with body fluids.

The cable 9 is passed transvenously through the body, and caused to enter the right atrium or auricle in the manner depicted in FIG. 1, that is to say, the leading portion of the cable is coiled within the atrium, so as to lie closely adjacent the inner wall or endocardium of the atrium. Before this is done, however, portions of the insulation are removed to expose the wire 10 at the point 10*a*, and the wire 12 at the point 12*a*, these points thus becoming the electrodes or poles of the cable. These poles are, of course, completely insulated from each other.

It is to be noted that the poles or electrodes 10*a* and 12*a* are located at diametrically-opposite sides of the atrium, that is to say, at points which are at a maximum distance from each other diametrically of the atrium cavity or chamber. With the poles or electrodes thus positioned, the electrical countershock, i.e., defibrillation shock, passed between the poles or electrodes, traverses the entire atrium, and exerts a maximum defibrillatory action, covering the entire chamber wall. If the poles or electrodes are located closer to each other, shocks of greater intensity would have to be administered to effect the desired results.

The distance between the poles 10*a* and 12*a* will vary in accordance with the size of the atrium.

The inner and outer leads of the cable are then connected to a defibrillator machine or unit, indicated generally by reference numeral 14 in FIG. 1. This unit is a source of direct current shocks of very low energy or intensity, i.e., from 1 to 10 watt seconds, and is so designed as to administer countershocks having a time duration of 3 to 50 milliseconds.

This time duration of the countershocks will depend on the thickness and qualities of the insulation provided in the cable, and, in some cases, countershocks up to 100 milliseconds in duration can be used to successfully accomplish defibrillation while avoiding the problem of overall shock, to which reference has previously been made.

The defibrillator unit 14 may be a portable DC defibrillator unit, such as described in Druz U.S. Pat. No. 3,258,013, to which reference has been made. Synchronization may be effected by an automatic selector of the type described in the Tischler U.S. Pat. No. 3,135,264, which is designed for ratios too slow for the purposes of the present invention, but which can be adapted for ratios which are too fast. A unit such as described in the McLaughlin U.S. Pat. No. 3,527,228 could also be adapted for use in the present invention, and a synchronizer such as described in the Berkovits U.S. Pat. No. 3,345,990 could be adapted to show R-R intervals. In this connection, the curves shown in FIGS. 2*a*, 2*b*, 2*c*, 2*d* and 3 of the above Druz patent are of interest.

By reducing the requirements for insulation, it becomes possible to utilize a permanently-implantable self-contained power unit, which could be set to determine the presence of a too-rapid or irregular heart beat and deliver a shock synchronized with the next intrinsic heart beat. The energy required for such a unit can be derived from an inductively rechargable battery source connected to a series of condenser plates for storage of the charge.

Although the invention has been described with particular reference to the use of a bi-polar coaxial cable, it is to be understood that any cable containing two wires in parallel spaced arrangement with each other, but fully insulated from each other, may be used, or, for that matter, insulated wires which are entirely separated from each other may be used, the important desideratum being the placement of the wire or wires in the atrium, and the spacing of the poles, electrodes or terminals of the wires in the atrium chamber or cavity.

It is to be understood that various changes in the method and apparatus which has been described may be made without departing from the spirit of the invention and the scope of the appended claims.

Having thus described my invention, I claim:

1. In a method of defibrillating a malfunctioning heart, the steps of introducing a pair of electrical conductors transvenously into the right atrium of the heart, positioning said conductors within the atrium in widely spaced relation to each other, to thereby provide spaced poles located entirely within the atrium generating electrical impulses of an intensity of from 1 to 10 watt seconds sufficient to cause defibrillation of the heart, and delivering said impulses to said poles for a period of from 3 to 100 milliseconds.

2. The method, as defined in claim 1, wherein said poles are disposed adjacent the wall of the atrium.

3. The method, as defined in claim 1, wherein said poles are disposed at diametrically-opposite sides of the atrium.

4. The method, as defined in claim 1, wherein said impulses are direct current impulses.

5. The method, as defined in claim 1, wherein said electrical impulses or shocks are generated externally of the body of the person who is being defibrillated.

6. The method, as defined in claim 1, wherein said electrical impulses or shocks are generated within the body of the person who is being defibrillated.

7. The method, as recited in claim 1, wherein said placement of the poles is effected by coiling the leading portions of said conductors about the atrium in closely spaced relation to the inner wall of the atrium.

* * * * *