PACING APPARATUS AND METHOD UTILIZING IMPROVED CATHETER

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ABSTRACT
Improved apparatus and method for temporary pacing, comprising a catheter having a first electrode positioned for placement in the patient's heart and a second electrode positioned to be within the patient's body but sufficiently proximal that it is outside the patient's heart, the second electrode having a surface area about an order of magnitude greater than the first, the electrodes being connected through respective leads within the catheter to a pacemaker (registered trademark, U.S. Patent Office), with the first electrode connected as the cathode.

23 Claims, 4 Drawing Figures
PACING APPARATUS AND METHOD UTILIZING IMPROVED CATHETER

BACKGROUND OF THE INVENTION

1. Field of the Invention
This invention lies in the area of heart pacing apparatus and, more particularly, in the area of catheters used with external and implanted Pacemaker for temporary and permanent pacing in a clinical environment. The apparatus and method of this invention are particularly adapted for "demand" pacing.

2. Description of the Prior Art
Temporary pacing of a patient in the post-operative period following cardiac surgery is an established and effective means of treating arrhythmias or increasing cardiac output. Additionally, temporary pacing is particularly important and widely used with respect to complete heart block, especially in patients undergoing acute myocardial infarction. Such temporary pacing has been a well-recognized clinical procedure in this country for many years, and the technique of inserting the catheter into the patient and pacing from an external source is a common technique of cardiology. A number of instrument manufacturers produce clinically acceptable catheters, and there are several models of Pacemakers well known to cardiologists and suitable for carrying out this technique.

There have been two basic types of catheters available and in use for such external, or temporary pacing. A first type is what is referred to as a unipolar catheter, having one lead extending substantially the length of the catheter and being electrically connected to an electrode which is positioned inside the patient's heart for transmitting the desired electrical signal thereto. This cardiac electrode is connected through the catheter lead to a first terminal of a Pacemaker device which, in temporary pacing, is external to the patient, and which is designed to produce a desired periodic pacing signal. The second terminal of the external Pacemaker is connected to an electrode which is generally clamped to the patient's skin around or near the point of entry of the catheter, which may be approximately at the large vein opposite the patient's right elbow. Another suitable site, such as in the femoral vein, may also be used for catheter insertion. Such electrode must be maintained in firm electrical contact with the patient, usually requiring some sort of electrically conductive paste be applied to the patient's skin, as well as the use of additional means (such as suturing an electrode beneath the skin at the site of incision) for maintaining the electrode in firm position. The time required to attach the second electrode to the patient's skin is considered, by most physicians, to be at best a considerable annoyance, and external electrodes attached to the skin are unreliable and require constant attention. When both the external electrode and the electrode which is placed in the patient's heart are connected to the Pacemaker, the periodic output signals from the Pacemaker terminals produce biopotentials in the patient's heart of a character so as to induce stimulation of the heart, i.e., so as to pace the heart.

The second type of standard catheter in common use, and clearly the preferred type, is what is referred to as a bipolar catheter. having both electrodes positioned near the distal end of the catheter, such that when the catheter is fully inserted into the patient's heart, both electrodes are inside the heart and in proper position to transmit the desired signal from the Pacemaker directly to the patient's heart. The advantage of the bipolar catheter over the unipolar form is the obvious one of eliminating the requirement of making an external attachment of one electrode to the patient's skin. Using the bipolar catheter, the two leads of the catheter are simply connected directly to the external Pacemaker, or to whatever device is in clinical use.

There are two basic reasons which lead to the conclusion that the new and novel catheter design of this invention is not only advantageous but should be required for safe clinical use. The first of these concerns the phenomenon of induced ventricular arrhythmias associated with the use of artificial Pacemaker. The possibility of Pacemaker induced ventricular arrhythmias has been recognized for some time, but the extent of the clinical risk of such arrhythmias has not been known. In fact, research has shown that an electronic Pacemaker stimulus can cause a dangerous arrhythmia by failing during the vulnerable period of a preceding ventricular beat. This possibility exists most commonly when an asynchronous artificial Pacemaker is in competition with normal sinus rhythm or ectopic beats from any source. The problem is particularly important in patients requiring pacing during acute myocardial infarction, as these patients are most susceptible to life-threatening ventricular arrhythmias. I have found evidence that ventricular arrhythmias are evoked by anodal stimulation, which evidence suggests that in the majority of instances an anode on or within the heart, of size and configuration to permit anodal stimulation, is necessary to produce ventricular tachycardia or ventricular fibrillation in humans with permanent or temporary pacing systems. All the available evidence points to the anode as the most common site or origin of Pacemaker induced ventricular fibrillation. Although commercially available Pacemakers have outputs which are probably too small to produce arrhythmias in normal human hearts, such units must be designed to produce stimuli exceeding the excitation thresholds of 90 percent or more of all patients encountered. With time the excitation threshold for an implanted electrode system can rise to 10 times the initial implantation threshold, and therefore Pacemakers are designed to deliver 10-30 times as great a stimulus as is required for effective pacing at the time of electrode implantation. Thus, under adverse conditions, such as acute myocardial infarction, etc., Pacemaker induced ventricular arrhythmias are possible, especially if the anode is positioned on or inside the ventricle.

As a result of the above conclusions, it is clear that only unipolar cathodal pacing should be used. As most pacing in a clinical situation is through temporary catheter electrodes, either a remote indifferent electrode (anode), or catheter with a distal pacing cathode and a large proximal anode, i.e., an anode at least ten times the surface area of the cathode, and positioned outside of the right ventricle, should be used. Since, as was discussed hereinabove, there is an overwhelming preference for a bipolar type of cathode which eliminates the requirement of attaching an electrode externally to the patient's skin, there is a need for a catheter construction having a first (cardiac) electrode which is adapted to be positioned within the heart, and a second electrode positioned such that it will be within the patient's body, but outside of and proximal to the heart and preferably of greater surface size than the cardiac ele-
trode. Furthermore, the cardiac electrode should be used as the cathode, and the proximal electrode as the anode.

The second discovery which has led to my novel catheter apparatus design, and method for use of same, relates to the use of demand, or non-competitive Pacemakers. In the demand Pacemaker, the pacing signal is generated only upon demand, i.e., when the natural pacing signal of the patient is not sensed. For ventricular pacing, such demand Pacemakers are commonly used to avoid competition with sinus or ectopic beats. Competition between artificial and natural Pacemakers can result in an unacceptable increase in heart rate and may precipitate serious ventricular arrhythmias. I have recently encountered samples of failure of proper demand function in the post-operative period resulting in either of these complications, and at each case the failure was due to a low voltage signal coming from the bipolar electrodes of the catheter in use, and normal demand function was restored by conversion to a unipolar system.

Although epicardial voltages in a bipolar system are usually well in excess of those required for demand function, in any heart bipolar electrodes can be positioned so as to detect a signal too small for demand sensing. A bipolar system adequate to detect sinus beats may not detect beats from a different origin such as ectopic ventricular beats. However, in every case that I have observed, regardless of the amplitude of the bipolar electrogram, a unipolar electrogram could be obtained which was greater in magnitude and sufficient for proper demand function. Conversion of a bipolar electrode system to a unipolar system, with only one electrode in the heart, results in a simple and effective means of increasing the signal detected by the Pacemaker.

SUMMARY OF THE INVENTION

It is the primary object of this invention to provide catheter apparatus and a method for artificial pacing of a patient's heart, which has the advantages of a bipolar electrode system in terms of ease of clinical use but which avoids the disadvantages of a bipolar electrode, and particularly which provides that the anode be outside of the patient's heart, and which provides efficient pickup for demand pacing.

In accordance with the above object, there is provided catheter apparatus for pacing of a patient's heart comprising a catheter having a first electrode, utilized as a cathode, positioned on the catheter such that it is within the patient's heart when the catheter is fully positioned, and having a second electrode, utilized as an anode, and positioned proximal to the first electrode, having a surface area much larger than that of the cardiac electrode, and positioned so that it is external to the patient's heart during the pacing operation. Pacing is achieved by periodically delivering the pacing signal between a cathode positioned within the heart and an anode positioned outside of the heart.

It is another object of this invention to provide an improved apparatus and method for temporary pacing of a patient by which pacing signals are generated outside of the heart, transmitted within the patient through a catheter of improved design, and connected between a first electrode positioned within the patient's heart and a second electrode positioned within the patient and outside of the patient's heart.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagrammatic sketch showing the placement of a catheter within a human body, and which indicates the critical areas of electrode placement according to this invention.

FIG. 2 is a sketch showing the catheter apparatus of this invention in combination with an artificial Pacemaker.

FIG. 2a is a detail sketch showing the connection of the anode of the catheter of this invention to one of the catheter electrical leads.

FIG. 2b is a detail sketch showing the connection of the cathode of the catheter of this invention to the other of the catheter leads.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to FIG. 1, there is shown a diagrammatic sketch of a catheter 20 inserted into a human. Most commonly, the catheter is inserted at about position 21, into the right basilic vein. The tip of the catheter is manipulated through the superior vena cava, the right atrium, and into the right ventricle. The catheter may also be introduced through the external (or internal) jugular veins, subclavian veins, or femoral veins. At the end portion of a bipolar catheter external to the body a pair of electrical leads (or one lead for a unipolar) are connected to the Pacemaker for pacing. There are a number of commercially available Pacemakers which may be used in the practice of this invention. Such Pacemakers, and their manner of use, are well known to cardiologists.

In a commonly used prior art bipolar catheter, the two electrodes are both caused to reside in the right ventricle, as shown at 24, 25. When a prior art unipolar catheter is utilized, there is only one heart electrode, such as 24, and a second electrode is placed upon the patient's skin near the point of entry at 21. The same catheter apparatus is utilized for demand pacing.

Referring now to FIG. 2, there is shown a diagrammatic sketch of the catheter 30 utilized in the practice of this invention, connected to a Pacemaker 32. Pacemaker 32 may be either a conventional Pacemaker type device or a demand type Pacemaker device. The catheter is an elongated and flexible instrument, constructed preferably of a plastic material such as nylon or Teflon, and of generally tubular form with substantially constant outer diameter from end to end. The catheter of this invention has two electrical leads 34, 35, constructed of electrically conductive material, and embedded in the non-conductive plastic material. The larger of the two electrodes, 38, suitably a cylindrical ring, of conductive material, is positioned so that when the catheter is in place within the patient, it is outside of the patient's heart. It is connected to a first of the catheter leads, 34, as shown in FIG. 2a, which in turn is connected to the positive terminal of Pacemaker 32, such that it is the anodal electrode. At the far distal end of the catheter, near the tip thereof, is an electrode 40, which also is suitably a ring of conductive material around the outside of the catheter, and in electrical contact with the other of the two conducting leads, 35, as shown in FIG. 2b. Lead 35 in turn is connected to the negative terminal of Pacemaker 32, such that electrode 40 is the cathodal electrode. This electrode is of relatively small surface area, and typically has a width of
about 1-3 millimeters. For a catheter with outside circumference of approximately 6-10 millimeters, the total surface area would be approximately 6-24 square millimeters.

In accordance with the discussion hereinabove, and in order to achieve the purpose of avoiding anodal stimulation of the heart, it has been found that the second electrode, which is used as the anode, should be placed preferably at least 4 centimeters proximal to the heart (to the right atrium). This point is indicated in FIG. 1 by the dashed line indicated at 50. In addition, to accommodate the occurrences where the catheter may be introduced through the subclavian vein, the anode should not extend beyond the region indicated approximately by the dashed line 52. For a typical human, the distance from the distal electrode (cathode) to dashed line 50 is about 23 centimeters, and the distance from dashed line 50 to dashed line 52 is about an additional 6 centimeters. Accordingly, the proximal electrode (anode) is suitably placed within this 6 centimeter distance (but need not be that long). For a catheter having an outside diameter of 2-3 millimeters, the surface of the anode should be about 100-300 square millimeters.

It is highly desirable that the proximal anode be much larger in surface area than the cathode, in order to distribute the anodal-induced, or positive-induced electric field intensity, so as not to stimulate surrounding structures. By making the anode at least about 10 times as large as the cathode in surface area, this is achieved.

In practice, the distal electrode of the catheter is made the cathode by connecting it to the negative terminal of the Pacemaker 32, and the proximal electrode is made the anode by connecting it, through lead 35, to the positive terminal of Pacemaker 32. It is seen that, in clinical use, the apparatus of this invention provides that the anode is positioned safely outside of the patient's heart, and preferably at least 4 centimeters away from the patient's heart, while the cathode is positioned within the patient's right ventricle. By thus placing the anode outside of the heart, and in addition providing the anode with a surface area much larger than that of the cathode (so as to reduce electric field concentration around the anode) the possibility of anodal stimulation of the heart is effectively eliminated, and cathodal pacing is ensured. At the same time, however, the apparatus of this invention provides the advantages of the bipolar catheter, in that both electrodes are permanently affixed to the catheter, and there is no need for external placement of an electrode upon the patient's skin. At the same time, the positioning of the electrodes in accordance with this invention provides an effective unipolar type of pickup from the heart, so that when the catheter apparatus of this invention is used with a demand Pacemaker, the danger of detection of less than threshold signals is substantially reduced.

It is to be understood that in order to ensure against anodal stimulation, it is desirable both to remove the anode from the vicinity of the heart and to make the surface area of the anode large. Although the design as shown in FIG. 2 is considered to be the best and safest design, it is to be understood that improvement over prior art forms of catheters may be achieved with various compromise designs. For example, if the anode were to extend into the heart, but had a large and extended surface area such as would be obtained if the anode were continuous almost to the point of entry, the distribution of the large anode surface would mitigate against anode stimulation. Similarly, simply positioning the anode outside of the heart, but making it of the same order of magnitude and surface size as the cathode, would achieve some improvement over the prior art. While the design criterion of positioning the anode at least 4 centimeters external to the heart is a critical limitation necessary to ensure a factor of safety against anodal stimulation, placement of the anode within less than 4 centimeters of the heart would still be an improvement over the prior art in accordance with the principles of this invention. Similarly, the design criterion of making the anode at least 10 times as great as the cathode is also a critical limitation necessary to ensure against anodal stimulation, but use of an anode of lesser size would still be within the broad scope of this invention.

1. Catheter apparatus adapted to be positioned in a patient for use in cardiac pacing of the patient, with a predetermined end extending into the patient's heart, comprising:
   a. an elongated flexible catheter tube having two conducting leads extending through respective lengths thereof;
   b. a distal electrode of predetermined surface size positioned near said predetermined end of said catheter tube, and connected electrically to a first of said leads; and
   c. proximal electrode positioned on said catheter at a distance at least about 23 cm from said distal electrode, and connected electrically to the second of said leads.

2. The apparatus as described in claim 1, wherein said proximal electrode has a surface area at least 10 times as great as said distal electrode.

3. The apparatus as described in claim 2, wherein said proximal electrode is positioned a distance within a range of 23-29 cm proximal from said distal electrode.

4. The apparatus as described in claim 1, wherein said proximal electrode extends less than 6 centimeters along said catheter tube.

5. The apparatus as described in claim 1, wherein said proximal electrode is of greater surface area than said distal electrode.

6. Pacing apparatus adapted for generating electrical pacing signals outside of a patient, communicating said signals inside of the patient, said delivering said signals between a position within the heart of the patient and a position external to said heart, comprising:
   a. a catheter adapted for insertion into a patient, having a distal electrode positioned near a first end thereof, a proximal electrode on said catheter and positioned a distance at least 23 cm from said distal electrode, a first lead connecting said distal electrode with the opposite end of said catheter, and a second lead connecting the proximal electrode with said opposite catheter end;
   b. signal generating means, for generating electrical pacing signals, said signal generating means having first and second terminals across which said electrical signals appear;
   c. connecting means for connecting, at said opposite end of said catheter, said first lead to the first terminal of said signal generating means and said sec-
ond lead to the second terminal of said signal generating means.

7. The apparatus as described in claim 6, wherein said proximal electrode is positioned at a distance within a range of about 23-29 cm from said distal electrode.

8. The apparatus as described in claim 6, wherein said signal generating means is further characterized in that said signals are negative at said first terminal with respect to said second terminal, such that said distal electrode is the cathode and said proximal electrode is the anode, whereby cathodal pacing of the heart is achieved when said catheter is positioned such that said distal electrode is within the patient's heart and said proximal electrode is within the patient and outside of the patient's heart.

9. The apparatus as described in claim 6, wherein said signal generating means is a demand type pacing generator.

10. A method of artificially pacing a human patient comprising periodically generating outside of said patient electrical pacing signals, positioning a first electrode at a first position within said patient's heart and a second electrode at a second position within said patient's vascular system but outside of said patient's heart, transmitting said signals into said patient and connecting them to said electrodes with said signals being negative at said first position with respect to said second position.

11. The method as described in claim 10 wherein said first electrode has a first surface of a predetermined area, and said second electrode has a surface area greater than said first surface, and comprising distributing the electric field generated at said second electrode along said second electrode.

12. The method as described in claim 10, comprising periodically generating pacing signals with a demand pacer, and also sensing biopotentials at said first and second positions and developing therefrom biopotential signals, coupling said biopotential signals to said demand pacer, and generating with said demand pacer said electrical pacing signals as a function of said sensed biopotential signals.

13. The method as described in claim 7 wherein said first position is in the right ventricle of the patient's heart.

14. The method as described in claim 10 wherein said positioning step comprises positioning a bipolar catheter having said first and second electrodes thereon in said patient such that said first electrode is within said patient's heart and said second electrode is at least 4 cm outside of said patient's heart, said method further including coupling said electrical pacing signals to said electrodes, whereby said patient is cathodally paced.

15. The method as described in claim 10, wherein said positioning step comprises positioning a catheter having first and second electrodes thereon in said patient such that said first electrode is positioned within the patient's right ventricle.

16. A method of artificially pacing a human patient through a catheter, said catheter having first and second electrodes, with said first electrode being near one end of said catheter, comprising:
   a. positioning within said patient a portion of said catheter, said positioning step including positioning said first electrode within said patient's heart and said second electrode within said patient and outside of said patient's heart;
   b. maintaining the opposite end of said catheter outside of said patient;
   c. periodically generating outside of said patient bipolar pacing signals;
   d. connecting said pacing signals to said catheter and transmitting said signals through said catheter to said electrodes so that said signals appear across said electrodes, whereby said patient is paced.

17. The method as described in claim 16, wherein said pacing signals are connected so that said pacing signals have a negative polarity at said first electrode with respect to said second electrode, whereby said patient is cathodally paced.

18. The method as described in claim 17, wherein said positioning step comprises positioning said second electrode at least 4 cm outside of the patient's heart.

19. The method as described in claim 17, wherein said positioning step comprises positioning said second electrode within about 10 cm from the patient's heart.

20. A method of artificially pacing a human patient comprising positioning a bipolar catheter having first and second electrodes in said patient such that said first electrode is positioned within said patient's heart and said second electrode is positioned at least 4 cm outside of said patient's heart, periodically generating outside of said patient electrical pacing signals, connecting said electrical pacing signals between said first electrode and said second electrode with said signals being negative at said electrode outside of said patient's heart, whereby said patient is cathodally paced.

21. The method as described in claim 20, comprising positioning said first electrode in the right ventricle of said patient's heart.

22. Catheter apparatus adapted to be positioned in a patient for use in cardiac pacing of the patient, with a predetermined end extending into the patient's heart, comprising:
   a. an elongated flexible catheter tube having two conducting leads extending through respective lengths thereof;
   b. a distal electrode of predetermined surface size positioned near said predetermined end of said catheter tube, and connected electrically to a first of said leads; and
   c. a proximal electrode positioned on said catheter, said proximal electrode being at its distal end a distance of at least about 23 cm from said distal electrode, and connected electrically to the second of said leads.

23. The apparatus as described in claim 22, further comprising:
   a. signal generating means, for generating electrical pacing signals, said signal generating means having first and second terminals across which said electrical signals appear;
   b. connecting means for connecting, at the end of said catheter opposite said predetermined end, said first lead to said first terminal and said second lead to said second terminal; and
   c. said signal generating means producing signals which are negative at said second terminal with respect to said first terminal, so as to provide apparatus for cathodal pacing.
UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,893,461 Dated July 8, 1975

Inventor(s) Thomas A. Preston

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 6, line 5l, after "patient," change "said" to --and--.

Signed and Sealed this
twenty-eight Day of October 1975

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks
UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,893,461 Dated July 8, 1975
Inventor(s) Thomas A. Preston

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 6, line 51, after "patient," change "said" to --and--. Column 7, line 45, change "7" to --10--.

Signed and Sealed this ninth Day of December 1975

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

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Commissioner of Patents and Trademarks