(57) Abrégé/Abstract:
Intravenous cardiac leads (10) having at least one electrode (12) intended to be implanted within the coronary veins (4, 5), are disclosed. Also disclosed are structures and techniques for advancing such leads through the atrium (3) and coronary sinus (4) into the coronary veins (5) overlaying the left ventricle (7).
(54) Title: CARDIAC LEAD ARRANGEMENT

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Intravenous cardiac leads (10) having at least one electrode (12) intended to be implanted within the coronary veins (4, 5), are disclosed. Also disclosed are structures and techniques for advancing such leads through the atrium (3) and coronary sinus (4) into the coronary veins (5) overlaying the left ventricle (7).
CARDIAC LEAD ARRANGEMENT
BACKGROUND OF THE INVENTION

I. Field of the Invention

This invention relates to cardiac leads used in combination with a cardiac rhythm management device, e.g., heart pacemakers or defibrillators, to monitor and control the rhythm of the heart. This invention is more particularly directed toward lead configurations adapted to be implanted in the coronary veins on the left side of the heart and to methods for implanting such leads.

II. Discussion of the Prior Art

As explained in U.S. Patent 4,928,688 to Morton M. Mower dated May 29, 1990, under normal circumstances impulses from the SA node affect contraction of the atria and then propagate to the AV node. The AV node then emits a second nerve impulse which affects contraction of the ventricles. In healthy individuals this is done in a coordinated manner to circulate blood through the body. However, many patients suffer from conditions which inhibit the transfer of nerve impulses from the SA node to the AV node and from there to the ventricles. In such cases, the chambers of the heart do not contract in a coordinated fashion and hemodynamic efficiency of the heart is decreased. This has profound adverse implications for the health and well-being of the patient. In minor cases, the quality of life is considerably reduced. More severe cases can result in death.

The Mower 4,928,688 patent describes a method for improving the hemodynamic efficiency of a sick heart. The method proposed in that patent is to place electrodes in both the right and left ventricles, monitor the cardiac signals originating in the right and left ventricles, analyze these signals and the absence thereof in a control circuit, and provide stimulating pulses to one or both ventricles within a time interval designed to improve the heart's hemodynamic efficiency.
Others have discussed the advantages of implanting leads in both the right and left ventricles to permit a sick heart to be more effectively defibrillated. See, for example, U.S. Patent 4,922,407 to Williams; U.S. Patent 5,099,838 to Bardy; and U.S. Patents 5,348,021, 5,433,729, and 5,350,404 all to Adams et al. Each of the patents describe inserting a lead through the right atrium and coronary sinus into one of the coronary veins. None of these patents, however, discuss the difficulties encountered in doing so.

Important health advantages are achieved by positioning an electrode in a branch of the great vein of the heart. A lead so positioned can be used to stimulate the left ventricle. While it would be possible to position the electrode within the left ventricle, this can increase the potential for clot formation. If such a clot were released to the brain, the situation could be life threatening. However, traditional leads are not well suited for implantation in the coronary vein. Traditional leads tend to be too big, tend to have some type of fixation device (such as tines or a screw) that must be altered to advance the lead into the sinus, or tend to require a stylet for positioning which is not flexible enough to negotiate the coronary vessels.

An arrangement intended to address such difficulties associated with the implantation of leads is disclosed in U.S. Patent 5,304,218 granted to Clifton A. Alferness on April 19, 1994. The arrangement disclosed in this patent includes a lead having an electrode. The electrode has a follower means for slidably engaging a guide wire. The electrode is implanted by feeding the guide wire along the desired path, engaging the follower means to the guide wire, advancing the lead along the guide wire until the electrode resides at the implant site, and retracting the guide wire from the follower means after the electrode is implanted at the implant site.
A review of the specification and drawings of U.S. Patent 5,304,218 and an understanding of the anatomy and physiology of the heart demonstrates several problems with this approach. First, the path through which the lead must be fed is very restricted. The increased size of the distal end of the lead, given the presence of the follower, may make it more difficult to advance such a lead along the desired path so as to be positioned on myocardial tissue of the left ventricle. Second, the direction of blood flow through the veins tends to force electrodes implanted there out of the vein. This problem is likely to be exacerbated by the increase in the profile area of the distal end given the presence of the follower. Third, the profile of the distal end of a lead implanted in a coronary vein may need to be made as small as possible to limit occlusion and permit blood to flow as freely as possible through the blood vessel when the lead is in place and to limit damage to the vessels and/or myocardium.

SUMMARY OF THE INVENTION

The present invention provides an improved lead for implantation of an electrode into a coronary vein on the left side of the heart. The lead includes an elongated, flexible body member made of an electrically insulative material. The body member includes a proximal end and a distal end. A lumen extends through the body member from the proximal end toward the distal end. The lumen may extend all the way to the distal end so that the distal end includes an opening. The lead also includes a conductive member extending through the body member from the proximal end toward the distal end. Electrically coupled to the conductive member near its distal end is an electrode. Additional lumens, electrodes and conductive members may be included within and on the lead body.

Leads made in conformance with the present invention can be inserted in a number of different ways. For example, a guide catheter can be inserted and then the lead passed through the guide catheter until it is properly
positioned. The lead can be coated with a lubrious coating to reduce friction in the guide catheter. The guide catheter can then be retracted. Similarly, a guide wire can be advanced to the implant site alone or through a guide catheter. Using the open distal lumen, the lead can be slid over the guide wire until the electrode is properly positioned. The guide wire or guide catheters can then be retracted. Also, the lead can be temporarily fixed to a guide catheter. The fixator may be designed to be dissolved by body fluids. The lead is then inserted along with the guide catheter. After the electrode is in place and the fixator dissolves, the guide catheter can be retracted.

In accordance with one aspect of the present invention, there is provided for use with a cardiac rhythm management device including a pacemaker for applying pacing pulses to the heart, an intravenous lead having:

an elongated, flexible body member made of an electrically insulative material and having a proximal end and a distal end, said body member being of a size to permit the distal end to be advanced through the right atrium and coronary sinus into the coronary veins;

a lumen extending through the body member from the proximal end toward the distal end of the body member, said lumen having a first opening through the proximal end and a second opening through the distal end of the body member;

a conductive member extending through the body member from the proximal end toward the distal end of the body member; and
an electrode electrically coupled to said conductive member and configured to apply pacing pulses to the left ventricle.

Alternative embodiments of the present invention offer other advantages and features. For example, the wall of the lumen can be coated with a lubricious coating or a polymer with a low coefficient of friction to reduce friction between a guide wire and the wall of the lumen. The lumen can also be used to deploy a separate electrode past the distal end of the lead’s body member. Additional lumens can be provided and the cross-section of the body member can be modified to provide a channel for a guide wire. These features are shown in the drawings and discussed in further detail below.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a plan view of an intravenous cardiac lead having an electrode positioned in a coronary vein.

Figure 2 is a cross-section of a distal end portion of the intravenous cardiac lead shown in Figure 1.

Figure 3 is a longitudinal cross-section view of a distal end portion of an intravenous coronary lead of the present invention with a tapered end and deployable electrode.

Figure 4 is a longitudinal cross-section of a distal end portion of an intravenous coronary lead inserted within and temporarily fixed to a guide catheter.
DETAILED DESCRIPTION OF THE INVENTION

Figure 1 shows a human heart 1 with the intravenous coronary lead 10 of the present invention passing through the superior vena cava 2, the right atrium 3, and the coronary sinus 4 into the great vein of the heart 5 so that a surface electrode 12 on the lead 10 is implanted in a branch of the coronary vein. When positioned as shown, the electrode 12 can be used to sense the electrical activity of the heart or to apply a stimulating pulse to the left ventricle 7 and without the need of being in the left ventricular chamber.

Figure 2 shows in greater detail the structure of the intravenous coronary lead shown in Figure 1. As shown in Figure 2, the lead 10 includes an elongated body member 14 having a proximal end 16 and a distal end 18. The body member 14 is preferably made of a flexible, electrically insulative material. The outer surface of the body member 14 is preferably treated to prevent fibrotic attachment and to reduce inflammation response to the lead. Such a treatment could include a carbon coating, a steroid embedded in the material, a steroid eluting collar, or the like.

The body member 14 encapsulates a flexible electrically conductive member 20 extending from the proximal end 16 toward the distal end 18 of the lead's body member 14. Conductive member 20 is shown as a flexible wire coil in Figure 2. Alternatively, the conductor member 20 could be in the form of a conductive wire, a thin ribbon, a plurality of fine wires formed as a cable, or a flexible tube without deviating from the invention.

Figure 2 also shows the lead 10 as including a central lumen 22 extending from the proximal end 16 to the distal end 18 of the body member 14. In fact, in this embodiment, there is an opening 24 through the distal end 18 to the lumen 22. A coating of a material such as polytetrafluoroethylene (Teflon\textsuperscript{*}) preferably forms the wall 26 of the lumen 22 to increase its lubricity. The coating

\textsuperscript{*}Trademark
material, of course, could be some other polymer having a low coefficient of friction.

The electrode 12 shown in Figure 2 is preferably created by removing an annular portion of the insulative body member 14 to expose a portion of the underlying conductive member 20. When the conductive member 20 is a coil as shown in Figure 2, the turns of the coil can be melt-banded such as by application of laser energy, to form the surface electrode 12. Those skilled in the art will recognize that a ring electrode electrically coupled to the conductive member 20 will also suffice. Likewise, the position of the electrode 12 along the body member 14 can be changed. Certain advantages may be achieved, for example, if the electrode 12 is at the tip of the lead.

The lumen 22 can be put to many uses. For example, a surgeon can advance a guide wire through the coronary sinus and coronary veins to the proper position for the electrode 12. The free proximal end of the guide wire can then be inserted through the opening 24 in the distal end 18 and the lead 10 slid over the guide wire to position the electrode 12. The guide wire can then be retracted through the lumen 22. The lumen 22 can also be used to insert a small separate structure with an electrode or sensor deployable beyond the tip of the lead. This allows separation of the electrodes and can be used for bipolar pacing or for a combination of pacing and defibrillation. Likewise, the lumen could be used to inject a contrast fluid to facilitate fluoroscopic viewing. The lumen can also be used to deploy a fixation mechanism, deploy an extraction mechanism, or deploy a plug to close the opening 24 and seal the lumen.

Figure 3 shows how the lead 10 can be modified to provide a tip 40 of a reduced diameter. The body member 14 of lead 10 has a distal end 18 with an opening 24 in communication with the lumen 22. Figure 3 shows how the lumen 22 can be used to deploy a separate structure such as second, miniaturized lead 42. The deployable lead 42 has
a lead body 44, an electrode 46 and a conductive member (not shown) coupled to electrode 46 and running from the electrode 46 to the proximal end of the lead body 44. The lead body 44 may be designed to coil after it exits the lumen to fix the electrode 46 in the correct position. Figure 3 also shows a ring electrode 47 surrounding a portion of the tip 40. The ring electrode 47, when present, is electrically coupled to conductive member 20. Additional electrodes and conductors can be added for sensing, pacing or defibrillating as desired. As indicated above, the ring electrode can also be formed by exposing and laser bonding the coils of the conductive member 20. The electrode 46 may be multipolar. It can be used for defibrillating and the electrode 47 is used for pacing. Alternatively, electrode 46 may be used for pacing and the electrode 47 used for pacing. Electrodes 47 and 46 could also be used for sensing electrical activity of the heart. Electrodes 47 and 46 can also be used together for bipolar pacing. Without limitation, the main portion of body member 14 could have an outside diameter in the range of 0.020 inches to 0.100 inches. If, for example, the main portion of the body member has an outside diameter of 0.058 inches, the diameter of the tip 40 could have an outside diameter of approximately 0.046 inches and the deployable lead 42 could have an outside diameter of 0.014 inches. When used, the main lead body can be positioned first over a guide wire. Once the lead is in place the guide wire is removed and replaced with the deployable structure which can be advanced beyond the tip of the larger lead body.

Figure 4 is provided to assist in explaining an alternative method for implanting an electrode 12 in a coronary vein. As shown in Figure 4, the lead 10 is loaded and temporarily fixed to the inside of a guide catheter 70 designed to be placed in the coronary sinus. The fixation means 72 may consist of a material such as mannitol which will dissolve after short exposure to blood. Once the guide catheter 70 is properly positioned and the fixation
means 72 is dissolved, the guide catheter 70 can be retracted leaving the lead in place with an electrode at a desired position. The lead can then be advanced further if necessary using a stylet and/or guide wire as previously described.

While not shown in any of the views, each lead will have one or more connectors of a type known in the art at its proximal end for mating with the pacer and/or defibrillator pulse generator whereby depolarization signals originating in the heart can be sensed and stimulating pulses applied in accordance with the device's control algorithms.

The foregoing discussion is intended to illustrate various preferred arrangements for meeting the objections of the present invention. Modifications and variation can be made by those skilled in the art without departing from the invention. Accordingly, the invention is limited only by the scope of the following claims which are intended to cover all alternate embodiments and modifications as may fall within the true scope of this invention.

What is claimed:
What is claimed is:

1. For use with a cardiac rhythm management device including a pacemaker for applying pacing pulses to the heart, an intravenous lead having:

   an elongated, flexible body member made of an electrically insulative material and having a proximal end and a distal end, said body member being of a size to permit the distal end to be advanced through the right atrium and coronary sinus into the coronary veins;

   a lumen extending through the body member from the proximal end toward the distal end of the body member, said lumen having a first opening through the proximal end and a second opening through the distal end of the body member;

   a conductive member extending through the body member from the proximal end toward the distal end of the body member; and

   an electrode electrically coupled to said conductive member and configured to apply pacing pulses to the left ventricle.

2. The lead as claimed in claim 1, wherein the conductive member comprises a helical coil surrounding the lumen.

3. The lead as claimed in claim 2, wherein said lumen has an inner surface comprising a polymer material with a low coefficient of friction.

4. The lead as claimed in claim 3, wherein said polymer material is a sleeve contained within the helical coil.

5. The lead as claimed in claim 1, further comprising a separate structure deployable through the lumen past the second opening.

6. The lead as claimed in claim 5, wherein said separate structure includes an electrode.

7. The lead as claimed in claim 5, wherein said separate structure includes a guidewire.
8. The lead as claimed in claim 1, further comprising a plug sealing the lumen.

9. The lead as claimed in claim 8, wherein said plug is deployable using said lumen.

10. The lead as claimed in claim 1, wherein said conductive member comprises a tube of a conductive polymer.

11. The lead as claimed in claim 1, wherein said electrode comprises an opening in the body member exposing a portion of the conductive member.

12. The lead as claimed in claim 1, wherein said electrode is a ring electrode.

13. The lead as claimed in claim 1, wherein said intravenous lead further comprises a second electrode coupled to the body member.

14. The lead as claimed in claim 13, wherein said electrodes are adapted to be used for bipolar pacing.

15. The lead as claimed in claim 13, wherein said second electrode is adapted to be used for defibrillation.

16. The lead as claimed in claim 13, further including a separate structure deployable through the lumen past the second opening, the separate structure including the second electrode.
17. The lead as claimed in claim 1, wherein the distal end of the elongated, flexible body member has a tapered shape and a rounded tip.

18. The lead as claimed in claim 1, wherein the lumen includes a reduced diameter portion at a distal end portion of the lumen.

19. The lead as claimed in claim 1, wherein said body member includes a coating of an anti-inflammatory agent.

20. The lead as claimed in claim 19, wherein said coating of an anti-inflammatory agent comprises a carbon coating.

21. The lead as claimed in claim 1, further including a steroid eluting collar coupled to said body member.

22. The lead as claimed in claim 1, further including a polymer having a low coefficient of friction which defines said lumen.

23. The lead as claimed in claim 1, wherein said electrode is disposed at a distal end portion of said lead.

24. The lead as claimed in claim 1, wherein said lead has an outer diameter ranging between 0.02 and 0.1 inches.

25. For use with a cardiac rhythm management device including a pacemaker applying pacing pulses to the heart, a system for implanting an intravenous lead for pacing the left ventricle into a coronary vein, comprising the intravenous lead of any one of claims 1 through 24 and a guidewire for facilitating advancement of the intravenous lead into the coronary veins.

26. The system as claimed in claim 25, further comprising a guide catheter surrounding the intravenous lead, said guide catheter adapted to be retractable about the intravenous lead.
27. The system as claimed in claim 26, further comprising dissolvable means for securing the lead to said guide catheter.

28. A cardiac rhythm management system including a pacemaker for applying pacing pulses to the heart, the system comprising an implantable pulse generator for connection to at least one intravenous lead for use with the cardiac rhythm management system, wherein the improvement comprises a system having the intravenous lead of any one of claims 1 through 24 for pacing the left ventricle and a guidewire for facilitating advancement of the intravenous lead into the coronary veins, said guidewire extending through the first and second openings in said lumen and past the distal end of the body member during implantation of the intravenous lead and being removable from the intravenous lead after placement of the intravenous lead in a selected coronary vein.

29. The cardiac rhythm management system of claim 28, further including a defibrillator adapted to deliver a defibrillation pulse.
FIG. 1