

A MULTIDIRECTIONAL BALLOON TIPPED CATHETER SYSTEM FOR CONDUCTING HIS BUNDLE SENSING AND PACING

1 CROSS REFERENCE TO RELATED APPLICATIONS

2 This application claims the priority of U.S. Provisional Application Serial No. 62/977,973,
3 filed on February 18, 2020, which is hereby incorporated herein by reference in its entirety.

4 BACKGROUND

5 Natural Atrioventricular (AV) conducted ventricular contractions utilize the cardiac
6 conduction system. This conduction system is a group of specialized cardiac muscle cells in the
7 walls of the heart that send signals to the heart muscle causing it to contract. The main components
8 of the cardiac conduction system are the sinoatrial (SA) node, AV node, bundle of His, bundle
9 branches, and Purkinje fibers. The SA node (anatomical pacemaker) starts the sequence by causing
10 the atrial muscles to contract. From there, the signal travels to the AV node, through the bundle of
11 His, down the bundle branches (left and right bundles), and through the Purkinje fibers, causing
12 the ventricles to contract. Patients who have AV nodal disease exhibit conduction issues between
13 the atrial and ventricular chambers. Most often, this conduction issue occurs above bundle of His
14 and presents as dyssynchrony of the atrial and ventricular chambers. If the conduction block occurs
15 below the bundle of His and in only one of the left and right bundle branches (LBB and RBB),
16 with intrinsic AV conduction occurring through the remaining intact bundles, but not both, the
17 patient will exhibit a left or right Bundle Branch Block (LBBB or RBBB). Bundle branch blocks
18 are identified by a delayed intrinsic ventricular electrical time. A complete bundle branch block
19 (LBBB or RBBB) is identified as having an electrical activation time greater than 120 ms. Bundle
20 branch blocks are not totally benign, particularly LBBB, and can lead to negative outcomes.

21 Currently, the standard pacing therapy for patients with AV conduction disease and
22 requiring ventricular pacing, is to place a transvenous lead through the tricuspid valve and into the
23 right ventricle (RV). This RV lead paces the ventricular myocardium which causes a cell by cell
24 slow wave depolarization across the ventricles. This “cell by cell” depolarization of the ventricles
25 utilizing a lead in the right ventricles causes the ventricles to contract in an unnatural way. With
26 conventional RV pacing, the activation sequence of the ventricles is not the same as natural AV
27 conducted contractions, with the right ventricle to depolarizing first and the left ventricle
28 depolarizing slightly after. When patients are right ventricularly (RV) paced at a high percentage,
29 there is an alarming progression of cardiac heart failure and pacing-induced cardiomyopathy.

1 Pacing-induced cardiomyopathy (PICM) is most commonly thought of as a drop in left ventricular
2 ejection fraction (LVEF) in the setting of chronic, high burden right ventricular (RV) pacing. It
3 has been reported that about 20% of patients develop PICM after 3 to 4 years of RV pacing. These
4 negative effects are thought to be a direct result of the unnatural contraction dynamics and resultant
5 ventricular dyssynchrony resulting from RV pacing.

6 His Bundle Pacing (HBP) has emerged as an alternative to traditional RV pacing. By
7 directly pacing the His bundle, HBP engages electrical activation of both ventricles by means of
8 the cardiac Purkinje fiber network through the natural cardiac conduction system. This type of
9 cardiac pacing may avoid ventricular dyssynchrony and preserve cardiac ejection fraction. Recent
10 studies have also demonstrated the potential of HBP in correcting an underlying left bundle branch
11 block and reversing cardiomyopathy caused by traditional RV pacing. HBP holds promise as an
12 attractive mode to achieve physiological pacing. Widespread adaptation of this technique is
13 dependent on enhancements in technology.

14 The His bundle lies in most people within the membranous portion of the interventricular
15 septum, with a proportion of the proximal bundle lying on the right atrial portion of the septum,
16 superior to the tricuspid valve annulus. The His bundle is surrounded by fibrous connective tissue
17 rather than myocardium, and then enters the muscular septum and divides to form the right and
18 left bundles. It has been demonstrated that transvenous HBP could reduce QRS duration and
19 normalize electrocardiographic appearances in patients with bundle branch block. There is
20 currently widespread consensus regarding the benefits of HBP and enthusiasm that this therapy
21 may prove patient outcomes.

22 The current procedural method of achieving HBP involves employing a lead with a fixed
23 screw helix for fixation and one of two catheters to achieve lead position. The fixed helix pacing
24 lead is advanced past the distal end of the catheters while manual catheters manipulation and
25 unipolar mapping utilizing the exposed helix is preformed to locate the His bundle potential signal.
26 Care must be taken when mapping inside the heart with the exposed fixed helix. This helix is fully
27 exposed and can cause local intracardiac surface edema while surface mapping which can mask
28 the His bundle potential. The process of mapping with the exposed helix can often create an acute
29 bundle branch block which may or may not resolve with time. Another pitfall to avoid is the
30 potential for tissue to become stuck in the exposed lead helix which prevents adequate mapping
31 and fixation of the lead helix. The target region for HBP is relatively robust and the current

1 catheters are rather flimsy, which avoids the potential for catheter perforation, although the risk of
2 perforation is possible if the catheter is advanced unintentionally into the incorrect position.

3 The adoption of HBP has been hindered by the procedural difficulty of achieving good lead
4 position without causing cardiac damage or perforation. The procedural success rates are much
5 lower when compared to traditional RV pacing procedures due to the difficulty in mapping the His
6 potential with the exposed helix and maintaining position while the pacing helix is fixated. The
7 tools currently employed are currently simplistic and lacking the ability to adjust to varying
8 anatomical differences or accurately maintain position within the beating heart during the implant
9 procedure.

10 SUMMARY

11 Embodiments of the disclosed invention provide a solution through a multidirectional
12 balloon tipped catheter with sensing capability and will lead to increased procedural success and
13 more widespread adoption of His Bundle Pacing (HBP) that has not been used prior and solves
14 this problem.

15 These advantages and others are achieved, for example, by a multidirectional balloon
16 tipped catheter system for conducting His bundle sensing and pacing. The catheter system includes
17 a multidirectional catheter body having a proximal end and a distal end. The catheter body includes
18 a plurality of curls and flexion points for multidirectional deflections. The catheter body further
19 includes a plurality of lumens which include a pacing lead lumen including an exit port at the distal
20 end and at least one balloon lumen including a balloon port near the distal end. The catheter system
21 further includes an anchor balloon mounted to near the distal end of the catheter body, one or more
22 mapping electrodes mounted to the distal end portion of the catheter body, and a pacing lead placed
23 in the pacing lead lumen. The anchor balloon is in fluid communication with the balloon port and
24 overhangs the distal end of the catheter body by a predetermined distance when the anchor balloon
25 is inflated. The one or more mapping electrodes are configured to sense His bundle potential. The
26 pacing lead is configured to protrude beyond the distal end of the catheter body when the pacing
27 lead is in use.

28 The anchor balloon may be inflated with a fluid including air, saline, or contrast, and may
29 be configured to be inflated in various sizes. The anchor balloon may be configured to expose the
30 one or more mapping electrodes when the anchor balloon is deflated. The anchor balloon may

1 overhang the distal end of the catheter body by two to three millimeters when the anchor balloon
2 is inflated. The anchor balloon is a hydrophilic balloon.

3 The one or more mapping electrodes may include a first mapping electrode disposed at the
4 distal end of the catheter body and a second mapping electrode disposed on the catheter body and
5 spaced apart from the first mapping electrode. The first and second mapping electrodes may form
6 a bipolar sensor. A diameter of the pacing lead lumen may be equal to or greater than 0.91 mm. A
7 distance of a distal end of the anchor balloon from the distal end of the catheter body may be in a
8 range of 10 mm to 20 mm when the anchor balloon is deflated. The pacing lead may include a
9 screw helix. The catheter body may be configured to be insertable into a subclavian vein or other
10 vascular access to approach His bundle. The plurality of lumens may further include one or more
11 wiring lumens that house electrical wires connected to the one or more mapping electrodes.

12 These advantages and others are achieved, for example, by a method for conducting His
13 bundle sensing and pacing with a multidirectional balloon tipped catheter system including a
14 multidirectional catheter body. The method includes inserting the catheter system into a subclavian
15 vein or vascular access, guiding the catheter system towards His bundle, sensing His bundle
16 potential with one or more mapping electrodes disposed near the distal end of the catheter body,
17 positioning a distal end of the catheter body at a location of the His bundle that is determined to
18 be appropriate for pacing, anchoring the distal end of the catheter body at the appropriate location
19 with inflated anchor balloon, and implanting a pacing lead into the appropriate location of the His
20 bundle. The catheter system includes the anchor balloon mounted to the distal end portion of the
21 catheter body, and the anchor balloon is inflated with a fluid supplied through at least one balloon
22 lumen formed in the catheter body. The pacing lead is disposed in a pacing lead lumen formed in
23 the catheter body and advances beyond the distal end of the catheter body while being implanted
24 into the appropriate location of the His bundle.

25 **BRIEF DESCRIPTION OF THE DRAWINGS**

26 The preferred embodiments described herein and illustrated by the drawings hereinafter be
27 to illustrate and not to limit the invention, where like designations denote like elements.

28 FIGS. 1A-1C show an embodiment of multidirectional balloon tipped catheter system of
29 the disclosed invention for sensing His bundle and positioning pacing lead.

30 FIGS. 2A-2C show side views of the distal end portion of the multidirectional balloon
31 tipped catheter system.

1 FIG. 2D shows a cross-sectional view of the section A-A' of the distal end portion of the
2 multidirectional balloon tipped catheter system shown in FIG. 1C.

3 FIG. 3 shows an exemplary embodiment of a deflection mechanism that may be employed
4 to control deflections of the distal end portion of the multidirectional balloon tipped catheter
5 system.

6 FIG. 4, shows a workflow diagram for a method for conducting His bundle sensing and
7 pacing with the multidirectional balloon tipped catheter system.

8 DETAILED DESCRIPTION

9 The following detailed description is merely exemplary in nature and is not intended to
10 limit the described embodiments or the application and uses of the described embodiments. As
11 used herein, the word “exemplary” or “illustrative” means “serving as an example, instance, or
12 illustration.” Any implementation described herein as “exemplary or “illustrative” is not
13 necessarily to be construed as preferred or advantageous over other implementations. All of the
14 implementations described below are exemplary implementations provided to enable persons
15 skilled in the art to make or use the embodiments of the disclosure and are not intended to limit
16 the scope of the disclosure, which is defined by the claims. Furthermore, there is no intention to
17 be bound by any expressed or implied theory presented in the preceding technical field,
18 background, brief summary or the following detailed description. It is also to be understood that
19 the specific devices and processes illustrated in the attached drawings, and described in the
20 following specification, are simply exemplary embodiments of the inventive concepts defined in
21 the appended claims. Hence, specific dimensions and other physical characteristics relating to the
22 embodiments disclosed herein are not to be considered as limiting, unless the claims expressly
23 state otherwise.

24 With reference to FIGS. 1A-1C shown are an embodiment of multidirectional balloon
25 tipped catheter system **100** of the disclosed invention for sensing His bundle and positioning
26 pacing lead. With reference to FIGS. 2A-2C shown are side views of the distal end portion of the
27 multidirectional balloon tipped catheter system **100**. With reference to FIG. 2D, shown is a cross-
28 sectional view of the section A-A' of the distal end portion of the multidirectional balloon tipped
29 catheter system **100**.

30 The multidirectional balloon tipped catheter system **100** includes a multidirectional or
31 deflectable flexible catheter body **110** that includes a proximal end **101** and a distal end **102**. The

1 catheter body **110** is French sizes, and includes curls and flexion points to be multidirectional or
2 deflectable. For example, the catheter body **110** may include a plurality of flexion points **103**, **104**
3 to facilitate the multidirectional deflections or bending. The catheter body **110** has a length
4 sufficient to reach a selected location in a patient's cardiac structures. The catheter body **110** is
5 configured to be insertable into a subclavian vein or other vascular access to approach His bundle.
6 The catheter body **110** includes a plurality of lumens. The plurality of lumens include at least a
7 wire lumen **111** for cord **112** connected to a pacing lead **113**. The wire lumen **111** includes a wire
8 access port (not shown) accessible to an operator at said catheter proximal **101** end and a wire exit
9 port **111a** at said flexible catheter distal end **102**, and a balloon lumen **114** for inflating and
10 deflating at least one anchor balloon **115**. The balloon lumen **114** includes a balloon control port
11 (not shown) for connecting to balloon control device accessible to an operator at the catheter
12 proximal end **101** and a balloon port **114a** near the multidirectional catheter distal end **102**. The
13 plurality of lumens may further include other lumens such as lumens **125**, **126** for wires **123**, **124**
14 connected to mapping electrodes **121**, **122**.

15 The multidirectional balloon tipped catheter system **100** includes compliant or non-
16 compliant anchor balloon **115** that is mounted on the multidirectional catheter body **110** near the
17 distal end **102** of the catheter body **110**. FIGS. **1A** and **2A** show deflated anchor balloon **115**, and
18 FIGS. **1B** and **2B** show inflated anchor balloon **115** at the distal end **102** portion of catheter body
19 **110**. The anchor balloon **115** is connected to the balloon port **114a** of the catheter lumen **114**, and
20 is in fluid communication through the balloon lumen **114**. Fluid, which is injected or removed at
21 the balloon control port at the proximal end **101**, inflates or deflates the anchor balloon **115** through
22 the balloon lumen **114**.

23 The anchor balloon **115** may be inflated with air, saline, contrast and other solutions, and
24 may be inflated to various sizes. The anchor balloon **115** is placed at a selected distance from the
25 distal end **102** of the catheter body **110**. For example, when the anchor balloon **115** is deflated, the
26 distance **L1** of a distal end of the anchor balloon **115** from a distal end **102** of the catheter body
27 **110** may be in the range 10 mm (0.4 inches) to 20 mm (0.8 inches). When the anchor balloon **115**
28 is inflated, the anchor balloon **115** may overhang the distal end **102** of the catheter body **110** by a
29 distance **L2** which may be two to three millimeters.

30 The multidirectional balloon tipped catheter system **100** includes at least one mapping
31 electrode **121** near the distal end **102** of the catheter body **110**. The mapping electrode **121** allows

1 atraumatic mapping of the His bundle potential. The mapping electrode **121** works as a unipolar
2 sensor for detecting and mapping the His bundle potential. In another embodiment, the catheter
3 system **100** may include second mapping electrode **122** that is placed a few millimeters behind the
4 first mapping electrode **121** (toward proximal end **101**). In this configuration, mapping electrodes
5 **121**, **122** together work as a bipolar sensor for atraumatic mapping of the His bundle potential,
6 making bipolar sensing possible. The anchor balloon **115** is configured such that the mapping
7 electrode **121** is exposed at the distal end **102** of the catheter body **110** when the anchor balloon
8 **115** is deflated so that mapping the His bundle potential may be performed by using the electrode
9 **121** and/or electrodes **121**, **122** to find an appropriate location of the heart tissue **140** for His bundle
10 pacing.

11 The catheter body **110** may include wiring lumens **125**, **126** that house electrical wires **123**,
12 **124** connected to the mapping electrodes **121**, **122**. The wires **123**, **124** at the proximal end **101** of
13 the catheter body **110** may be coupled to an external device that may send signals to or receive
14 signals from the mapping electrodes **121**, **122**.

15 The multidirectional balloon tipped catheter system **100** includes pacing lead **113** that is
16 connected to cord **112** disposed in the lumen **111**. The catheter body **110** includes pacing lead
17 lumen **111** that includes a cord access port (not shown) accessible to an operating device at the
18 proximal end **101** and exit port **111a** at the distal end **102** of the catheter body **110**. The pacing
19 lead lumen **111** may be positioned at a center of the cross-section of the catheter **110** as shown in
20 FIG. **2D**. The diameter of the pacing lead lumen **111** may be equal to or greater than 0.91 mm
21 (0.035 inches). The pacing lead **113** may be placed inside the pacing lead lumen **111** while
22 mapping His bundle potential and positioning the catheter system **100** against heart tissue **140**. The
23 pacing lead **113** may advance out of the pacing lead lumen **111** beyond the distal end **102** of the
24 catheter body **110** to be placed or implanted on the heart tissue **140**. The pacing lead **113** may have
25 a form of screw helix. FIGS. **1C** and **2C** show the pacing lead **113** advancing out of the distal end
26 **102** of the catheter body **110**.

27 The anchor balloon **115** may be used in an atraumatic fashion over cardiac structures. The
28 anchor balloon **115** may glide over the cardiac structures, while sensing is performed by using the
29 mapping electrodes **121**, **122** to obtain the best site for lead implantation. Once an appropriate
30 location of the heart tissue **140** is determined for His bundle pacing, the catheter system **100** is
31 used as a conduit for implantation of the pacing lead **113**. The anchor balloon **115** may be inflated

1 to anchor the distal end **102** of the catheter body **110** at the appropriate location of the heart tissue
2 **140**. When the distal end **102** of the catheter body **110** with the inflated anchor balloon **115** is
3 positioned and stabilized at the location, the pacing lead **113** may be advanced to be implanted in
4 the heart tissue **140**. Once the pacing lead **113** is in place, the catheter body **110** may be removed
5 using multiple methods which may include slitting and splitting the catheter body, or may be
6 removed by methods that are general practices for lead implantation.

7 With reference now to FIG. **3**, shown is an exemplary embodiment of a mechanical
8 deflection device **130** that can be employed at the proximal end **101** portion of the catheter body
9 **110** to control deflections of the distal end portion of the catheter system **100**. Mechanical
10 deflection mechanism may enable distal end of catheter body **110** to be deflected or angulated to
11 various angles with respect to a longitudinal axis (from the proximal end **101** to the distal end **102**)
12 of the catheter system **100**. Mechanical deflection device **130** may include a pull wire anchor **131**
13 affixed to the catheter body **110** and pull wire actuator **132** connected to pull wire anchor **131** with
14 pull wire (not shown). Rotation of pull wire actuator **132**, as shown, may exert force on pull wire
15 anchor **131** that deflects or angulates distal end of the catheter body **110**. Pull wire actuator **132**
16 may be rotated by handle connected thereto (not shown). The deflection device **130** together with
17 the flexion points and curls formed in the catheter body **110** enables the catheter body **110** to easily
18 navigate over heart structures. . U.S. Patent Application Serial No. 17/061,761 filed on October 2,
19 2020 by the same inventor discloses an improved handle that can be used for the catheter system
20 **100** of the disclosed invention to provide deflections.

21 With reference to FIG. **4**, shown is a workflow diagram for a method **200** for conducting
22 His bundle sensing and pacing with a multidirectional balloon tipped catheter system **100** including
23 a multidirectional catheter body **110**. The catheter system **100** is inserted into a subclavian vein or
24 vascular access, block **210**. The catheter system **100** is guided towards His bundle, block **211**. The
25 catheter system **100** senses His bundle potential with one or more mapping electrodes **121**, **122**
26 disposed at a distal end portion of the catheter body, block **212**. The distal end of the catheter body
27 **110** is positioned at a location of the His bundle **140** that is determined to be appropriate for pacing,
28 block **213**. The distal end of the catheter body **110** is anchored at the appropriate location with
29 inflated anchor balloon **115**, block **214**. A pacing lead **113** is implanted into the appropriate
30 location of the His bundle, block **215**. After the pacing lead **113** is implanted, the catheter body
31 **110** with deflated anchor balloon **115** may be removed while leaving the pacing lead **130** in place.

1 The anchor balloon **115** is atraumatic and allows for use of a more robust catheter designs.
2 The increased rigidity of the catheter body facilitates increased positional precision and an
3 improved procedural success rate. In an embodiment, the anchor balloon **115** may be a hydrophilic
4 balloon with a surface having hydrophilic nature. The catheter system **100** of the disclosed
5 invention provides advantages over the conventional devices. Unlike the conventional devices, the
6 pacing lead **113** of the catheter system **100** of the disclosed invention is not exposed while the
7 catheter system **100** maps the His bundle potential to find an appropriate location of heart tissues
8 for His bundle pacing, preventing any issues that can be caused by exposed screw helix in the
9 conventional devices. The catheter system **100** of the disclosed invention utilizes atraumatic
10 anchor balloon that allows maneuvering of the catheter system **100** over cardiac structures without
11 causing any injuries or damages to heart tissues and also allows to use more rigid multidirectional
12 catheter body, which increases the ability to adjust to varying anatomical differences and to
13 accurately maintain position within the beating heart during the implant procedure.

14 Since many modifications, variations, and changes in detail can be made to the described
15 preferred embodiments of the invention, it is intended that all matters in the foregoing description
16 and shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense.
17 Consequently, the scope of the invention should be determined by the appended claims and their
18 legal equivalents.