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ZHANG(10) **Pub. No.: US 2016/0270684 A1**(43) **Pub. Date: Sep. 22, 2016**(54) **CATHETER FOR USE IN RECORDING HIS
ELECTROGRAM ALTERNANS AND
APPLICATION TO VARIOUS CONDITIONS****Publication Classification**(51) **Int. Cl.***A61B 5/042* (2006.01)*A61B 5/00* (2006.01)*A61M 25/00* (2006.01)(52) **U.S. Cl.**CPC *A61B 5/0422* (2013.01); *A61M 25/00*
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(US)(21) Appl. No.: **14/848,901**(22) Filed: **Sep. 9, 2015****Related U.S. Application Data**(60) Provisional application No. 62/056,902, filed on Sep.
29, 2014.

(57)

ABSTRACT

The invention relates to a catheter useful in recording His electrogram alternans. The catheter includes a catheter probe containing at least one row of receiving poles positioned at an edge of the catheter probe, equidistantly spaced from each other.

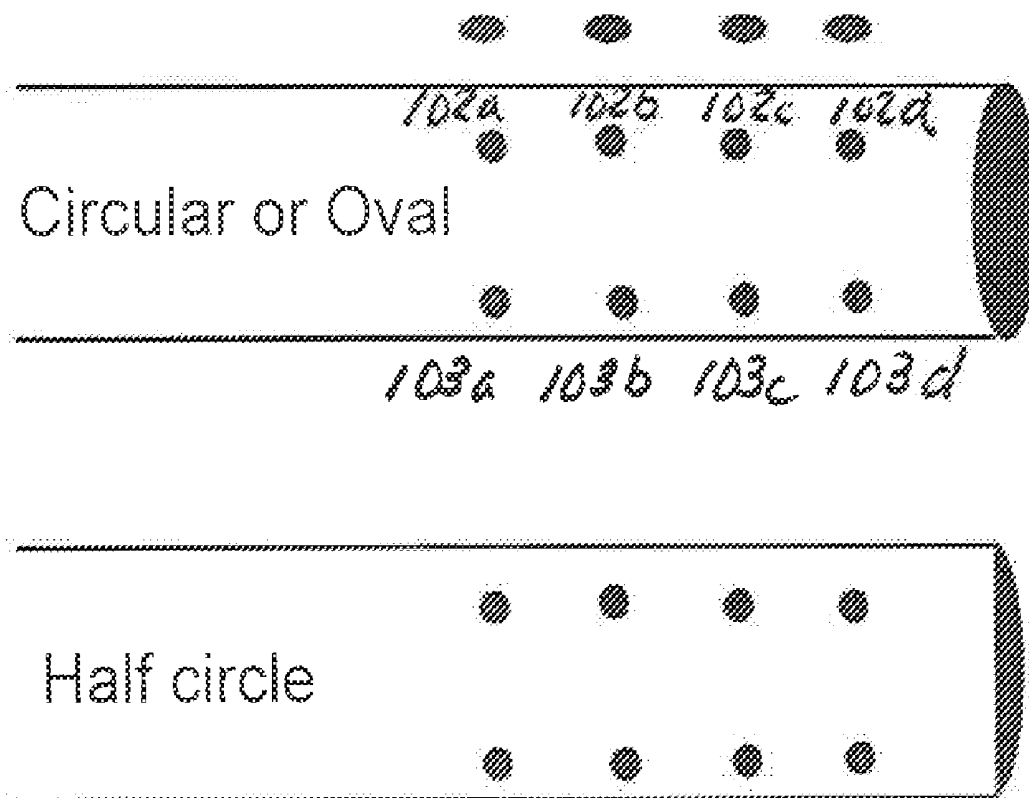


Fig 1 PRIOR ART

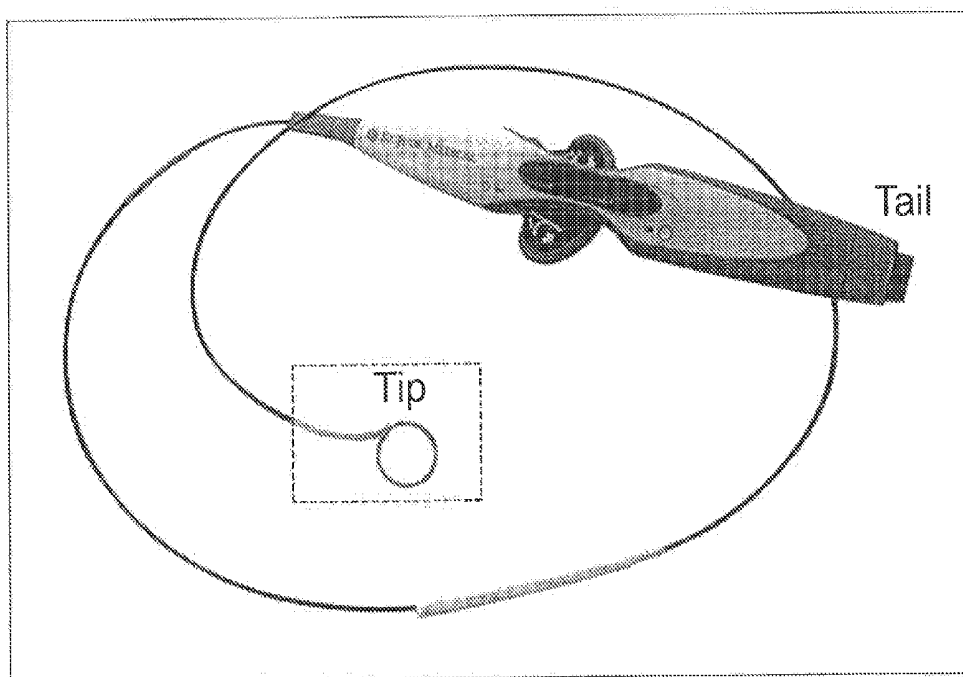


Fig 2a PRIOR ART



Fig 2b PRIOR ART

Ring type
electrodes

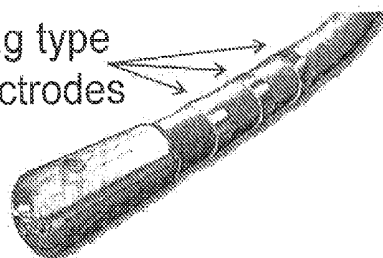


Figure 3

The electrodes can be circular, oval or other types

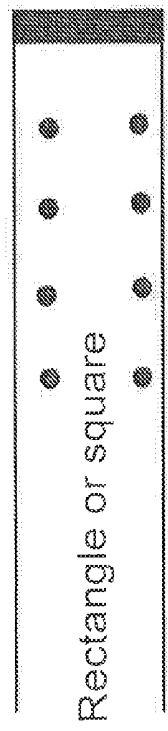
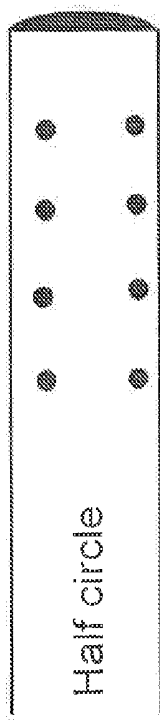
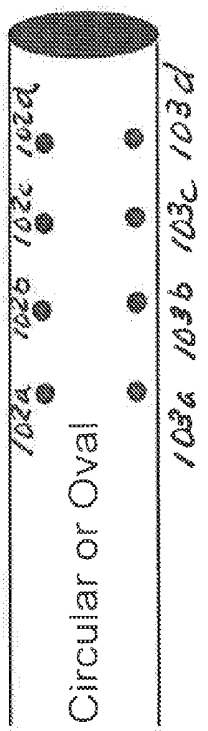


Fig 3A

Fig 3B

Fig 3C

Fig 3D

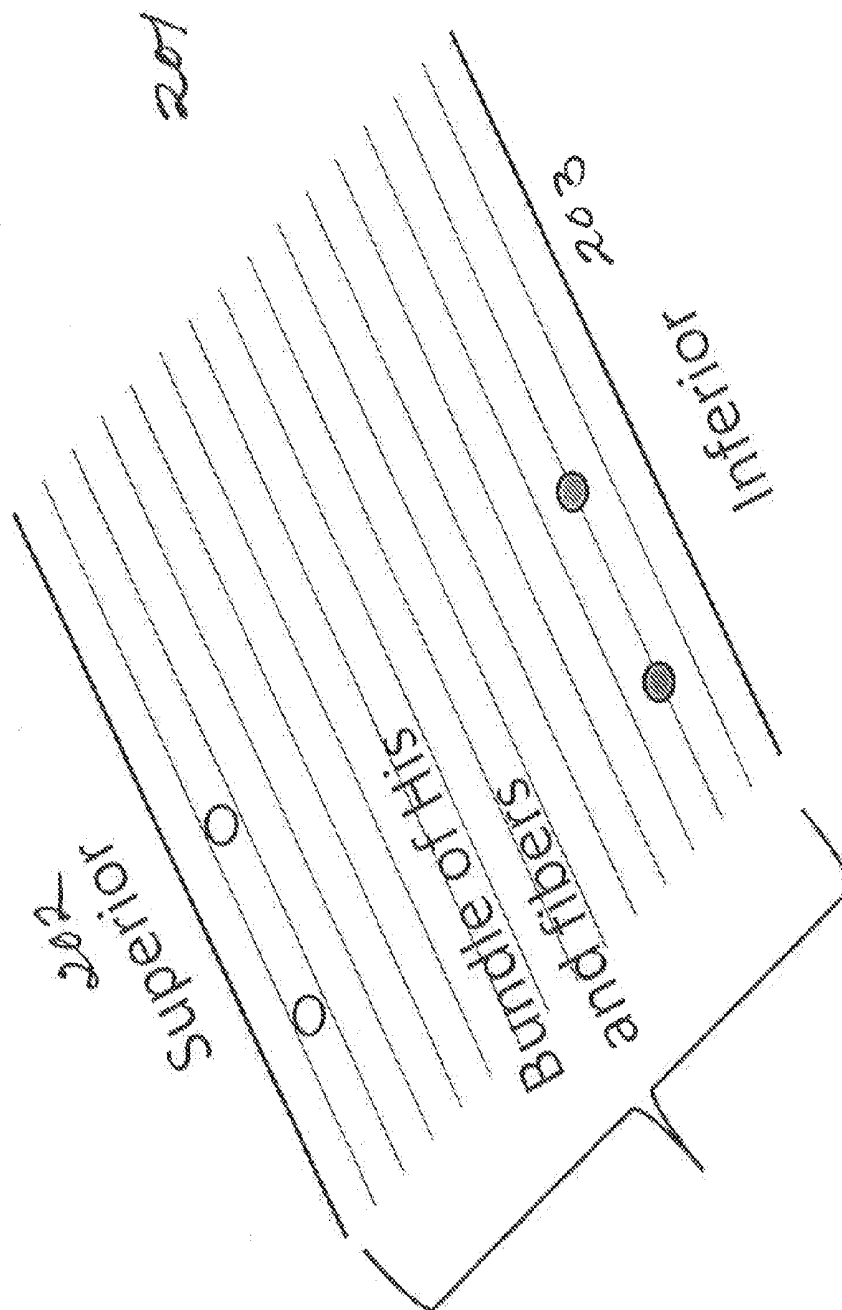


Fig 4

CATHETER FOR USE IN RECORDING HIS ELECTROGRAM ALTERNANS AND APPLICATION TO VARIOUS CONDITIONS

RELATED APPLICATION

[0001] This application claims priority from U.S. Provisional Application No. 62/056,902 filed Sep. 29, 2014, incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] The invention relates to an apparatus useful in determining an electric signal from cardiac tissue. More specifically, it relates to a catheter probe useful in determining electrical signals from the cardiac tissue referred to as the His bundle, or “bundle of His”.

BACKGROUND AND PRIOR ART

[0003] In 2001, Zhang et al., *Circulation*, 104:832-838 (2001), the disclosure of which is incorporated by reference, described a phenomenon termed “His electrogram alternans,” or “HE alternans.” It was observed that by recording HE alternans, the clinician may visualize atrioventricular (AV) nodal dual pathway conduction. In addition to Zhang, supra, see Zhang, et al., *Circulation*, 107:1059-1065 (2003); Zhang, et al. *Cardiovascular Research*, 61:45-55 (2004); Zhan, et al., *J. Cardiovasc. Electrophys.*, 22:1256-1262 (2011); Zhang, et al., *Int. J. Cardiology*, 171:259-264 (2014); and Zhang, et al., *J. Interv. Card. Electrophysiol.*, 40:99-103 (2014); all of which are incorporated by reference.

[0004] The concept of dual pathway AV node electrophysiology was developed, initially, to explain AV nodal re-entrant tachycardia (AVNRT), which is the most common type of paroxysmal supraventricular tachycardia. Prior to the observation described supra, also called Zhang’s Phenomenon, there were no tools or values available which could be used to monitor dual pathway conduction with the exception of a “sudden jump” in the AV node conduction curve. This “sudden jump” was defined as a sudden increase of AV conduction time, of 50 mseconds (ms) or more with premature beats shortened in 10 ms steps. While it was believed that this sudden jump resulted from a switch of AV conduction from fast to slow pathway conduction, not every patient was, or is, seen to exhibit this jump. An additional issue is that this jump is only revealed when the whole AV conduction curve is studied. No methodologies were available, before the discovery of Zhang’s phenomenon, to monitor dual pathway AVN conduction on a beat-by-beat basis. Prior to the invention, dedicated means for determining it were not available. It is now believed that dual pathway AV node conduction may exist in all patients, and determining HE alternans can be used in routine clinical cardiac electrophysiology in order to monitor dual pathway AV conduction. The phenomenon is especially useful during catheter ablation of atrioventricular nodal reentrant tachycardia, or any AV node modification approach involving dual pathway AVN conduction, including AVN modification to slow ventricular rates during atrial fibrillation.

[0005] At present, His electrogram recording is done, routinely, during clinical cardiac electrophysiology examination. It is only used as a marker of electrical excitation reaching the His bundle. In other words, it is used to measure AV conduction time intervals, and His ventricular intervals. It is not used as an index of dual pathway AV nodal conduction.

[0006] It is a purpose of this invention to facilitate the measurement of this phenomenon by way of an easily manufactured, easily used device.

[0007] The medical arts are replete with various catheter probes which are used either to receive information from tissue, such as cardiac tissue, or to deliver signals, such as electrical charges. An exemplary, but by no means exhaustive list of references showing various embodiments of catheters includes EP 499 491; U.S. Pat. No. 4,649,924; PCT/US94/03768; U.S. Pat. No. 4,974,588; U.S. Pat. No. 5,063,932; U.S. Pat. No. 5,184,620; U.S. Pat. No. 8,777,851; Published U.S. Patent Application 2014/0128935, and Published U.S. Patent Application 2012/0108993.

[0008] Even a cursory review of this sampling of the literature will show that for catheters “form follows function.” In other words, the shape of the catheter, including the catheter tip or probe, and the extended member which leads to the tip or probe, will change, depending upon the intended function of the catheter. Similarly, while all of these catheters incorporate electric poles, some, such as pace maker type devices are designed to discharge an electrical signal, while others include poles which receive and transmit an electrical signal.

[0009] Typically, electrophysiology catheters have essentially the same form, with a body, “tail,” and “tip,” as is shown in FIG. 1. To the extent that these “EP” catheters differ, they differ in the tip. FIG. 2a shows various types of prior art tips, and FIG. 2b, “ring type” electrodes, which are common.

[0010] In order to carry out functions as described herein, a catheter must be designed such that it can be placed in a blood vessel, e.g., a vein or an artery, which leads to cardiac tissue, such as cardiac muscle, the His bundle in particular. Further, the catheter tip or probe must be designed to fit precisely on the targeted cardiac tissue, i.e., the His bundle.

[0011] As will be shown in the disclosure which follows, the inventor has developed a catheter means which fulfills the requirements discussed supra. The details thereof will be elaborated upon in the disclosure which follows.

BRIEF DESCRIPTION OF THE FIGURES

[0012] FIG. 1 labeled PRIOR ART shows a commercially available electrophysiology catheter.

[0013] FIG. 2a labeled PRIOR ART shows various types of electrophysiology catheter tips.

[0014] FIG. 2b labeled PRIOR ART shows typical ring type electrodes as used in the field.

[0015] FIGS. 3a-3d show different embodiments of the invention.

[0016] FIG. 4 shows a schematic view of the His bundle its fibers, and preferred placement of electrode pole onto the superior (open circles) and inferior (closed circles) bundle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0017] Referring now to the drawings, one example of a preferred embodiment of the invention is shown, in FIG. 3. In FIG. 3, one sees different configurations a, b, c, and d, of the tip of a catheter in accordance with the invention. The different configurations of the tip of the catheter are shown, so as to depict geometries which are useful in determining HE alternans. The tip of the catheter must be configured so as to rest stably on the cardiac structure known as the His bundle. Shown in FIGS. 3a-3c, respectively, are circular oval, and rectangular (square) configurations. These embodiments are

all bilaterally symmetrical. The configurations can also be other shapes, such as semi-circles, squares, or rectangles.

[0018] Configurations shown in FIGS. 3A, 3B, and 3C all show two rows of parallel, receiving electric poles. These are shown by 102a, b, c, and d and 103a, b, c, and d in FIG. 3A, and these indicia apply for each figure. The poles are positioned at the end of the catheter, and the distance between any two poles in a horizontal row is the same for all others in that row. Similarly, the vertical distance between two corresponding poles is the same for all corresponding poles. Finally, the distance between terminal pole and the end of the catheter is always the same in a given catheter.

[0019] As the His bundle is a relatively small structure, the electric receiving poles are small, preferably from about 1 mm to 2 mm in diameter. Spacing of the electric receiving poles in a row from each other is about 2-4 mm.

[0020] The catheter tip of the invention may vary in size, however, as it must be inserted through a peripheral blood vessel into the chamber of the heart where the His bundle is located, preferably the tip is from about 3-5 mm wide (or, from about 3-5 mm in diameter if a circular or semicircular configuration is used). The tip is from about 6 to about 10 cm in length, and may present receiving poles along its full length, or part of its length. If the poles are only presented along a position of the length, it is preferred that they be at the distal end of the tip, relative to the catheter lead. Poles should be presented as close to the edges of the tip as possible. The poles can be configured in the shapes discussed supra.

[0021] The materials used to make the catheter tip are the standard materials used to make catheters, and these will be readily familiar to those of ordinary skill in the art. Exemplary materials for the body of the tip are polyurethanes, with platinum, iridium, or alloys thereof being used to manufacture the receiving poles. Other materials will be known to the skilled artisan and need not be provided here.

[0022] Each row should contain the same number of electric receiving poles, when the catheter employs two rows. Each row must contain at least two poles, but preferably contains at least 4-8.

[0023] In a further embodiment of the invention, depicted in FIG. 3d, the catheter only records one of the two HE values (SHE or IHE, i.e., superior or inferior His electrogram alternans). In this embodiment, the requirements of parallel rows are not present; however, the other dimensionalities apply here as well.

[0024] In operation, the catheter of the invention functions in a manner set forth in FIG. 4. FIG. 4 shows a rough schematic of the His bundle, 201. It can be seen that the His bundle has superior inferior positions 202 and 203. In operation, the end of the catheters shown in FIG. 3 are configured to fit precisely on top of the His bundle, such that the receiving poles record both the superior His electrogram value, and the inferior His electrogram value. The catheter end depicted in 3d is used to record one or the other of these values. Fitting of the catheter tip onto the His bundle can be accomplished via, for example, using an external control mechanism to curve the tip to the degree necessary.

[0025] The skilled artisan will recognize that this catheter tip or probe is integrally connected to a flexible, elongate member, which is suitably small so as to pass easily through a blood vessel, e.g., a vein leading to a heart.

[0026] Other embodiments of the invention will be clear to the skilled artisan and need not be set forth herein.

[0027] The terms and expression which have been employed are used as terms of description and not of limitation, and there is no intention in the use of such terms and expression of excluding any equivalents of the features shown and described or portions thereof, it being recognized that various modifications are possible within the scope of the invention.

We claim:

1. An apparatus useful in receiving an electrical signal from cardiac tissue, said apparatus comprising a catheter probe at one end and a flexible elongate member at the other end, wherein said catheter probe comprises a plurality of receiving poles positioned in a row at a first edge of said probe, said poles positioned equidistant from each other, wherein said catheter probe is from about 6 cm to about 10 cm in length, and from about 3 mm to about 5 mm in width or diameter, and said elongate member is capable of moving through a human blood vessel.

2. The apparatus of claim 1, further comprising a second row of receiving poles positioned at a second edge of said catheter probe opposite said first edge, wherein said second row of receiving poles are equidistant from each other, distance between said poles in said second row being identical to distance between said poles in said first row.

3. The apparatus of claim 1, wherein said receiving poles are from about 1 mm to about 2 mm in diameter.

4. The apparatus of claim 1, wherein said receiving poles are positioned from about 2 mm to about 4 mm from each other.

5. The apparatus of claim 1, comprising at least 2 electric receiving poles.

6. The apparatus of claim 5, comprising from 4-8 electric receiving poles.

7. The apparatus of claim 2, wherein each of said first and second row of receiving poles comprises from 2 to 8 electric receiving poles, each of which has a diameter of from about 1-2 mm, and each receiving pole in said row is positioned from about 2 mm to about 4 mm from the receiving pole to which it is closest.

8. The apparatus of claim 1, wherein said apparatus is constructed of polyurethane.

9. The apparatus of claim 1, wherein said receiving poles are constructed of platinum, iridium, or mixtures thereof.

10. A method for determining an electric signal from cardiac tissue, comprising inserting the apparatus of claim 1 through a blood vessel which leads to the heart, positioning said catheter probe on cardiac tissue, which generates an electric signal, and receiving said electric signal via said receiving poles.

11. The method of claim 10, wherein said cardiac tissue is an His bundle.

12. The method of claim 11, wherein said electric signal is SHE (superior His electrogram alternans) or IHE (inferior His electrogram alternans).

13. The method of claim 10, wherein said blood vessel is a vein.

14. The method of claim 10, wherein said blood vessel is an artery.

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专利名称(译)	导管用于记录他的电图交替和应用于各种条件		
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当前申请(专利权)人(译)	纽约理工大学		
[标]发明人	ZHANG YOUHUA		
发明人	ZHANG, YOUHUA		
IPC分类号	A61B5/042 A61B5/00 A61M25/00		
CPC分类号	A61B5/0422 A61M2210/125 A61B5/6859 A61M25/00 A61B5/6852 A61B2562/046 A61M25/0082 A61M2230/04 A61B5/6869		
优先权	62/056902 2014-09-29 US		
其他公开文献	US10383538		
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摘要(译)

本发明涉及在记录他的电描交替有用的导管。该导管包括含有接收定位在导管探测器，彼此等距间隔的边缘磁极中的至少一个行的导管探针。

