Title: TULIP-SHAPED BALLOON CATHETER AND METHODS FOR PERICARDIOCENTESIS AND PERCUTANEOUS PERICARDIOTOMY

Abstract: The present subject matter describes a tulip-shaped balloon catheter and methods of using the tulip-shaped balloon catheter. The balloon catheter is particularly useful for pericardiocentesis and percutaneous pericardiotomy.
TULIP-SHAPED BALLOON CATHETER AND METHODS FOR PERICARDIOCENTESIS AND PERCUTANEOUS PERICARDIOTOMY

FIELD OF SUBJECT MATTER

This subject matter relates to the performance of pericardiocentesis and percutaneous creation of a pericardial window.

BACKGROUND OF THE SUBJECT MATTER

All publications herein are incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference. The following description includes information that may be useful in understanding the present subject matter. It is not an admission that any of the information provided herein is prior art or relevant to the presently claimed subject matter, or that any publication specifically or implicitly referenced is prior art.

Pericardiocentesis is a procedure wherein the fluid in the pericardium is aspirated. Fluid aspiration is necessary to relieve the pressure on the heart or to analyze the fluid surrounding the heart. Examples of indications for pericardiocentesis include but are not limited to cardiac tamponade, pericarditis, and pericardial effusion.

In instances wherein long term drainage is necessary, a cardiothoracic surgeon will create a pericardial window, in which an opening is made in the pericardium to drain the fluid. The procedure is known as a pericardiectomy or pericardiostomy.

Balloon dilation of the pericardium is currently performed with an aortic balloon valvuloplasty catheter. Percutaneous balloon pericardiectomy is a percutaneous procedure using a balloon catheter to produce a pericardial window, in effect, by tearing the pericardium in patients with pericardial effusion. The procedure is typically an alternative to conventional pericardiectomy to avoid surgery in patients with a poor prognosis. Percutaneous pericardiectomy procedures have been performed with a single or double balloon catheter. Generally, the procedure involves having the balloon
span across the pericardium and quickly inflating the balloon to create the pericardial window and is performed under fluoroscopic guidance to ensure that the balloon spans across the pericardium and that a pericardial window is created.

Nonetheless, these procedures require fluoroscopic guidance and a highly skilled interventional cardiologist. Thus, there exists a need in the art for a device and a method for percutaneous pericardiotomy that does not require the fluoroscopic guidance and that may be more simple to perform.

BRIEF DESCRIPTION OF THE FIGURES

Exemplary embodiments are illustrated in referenced figures. It is intended that the embodiments and figures disclosed herein are to be considered illustrative rather than restrictive.

Figure 1A depicts a deflated tulip-shaped balloon catheter in accordance with an embodiment of the present subject matter.

Figure 1B depicts a deflated tulip-shaped balloon catheter with second balloon in accordance with an embodiment of the present subject matter.

Figure 2A depicts an inflated tulip-shaped balloon catheter in accordance with an embodiment of the present subject matter.

Figure 2B depicts an inflated tulip-shaped balloon catheter with second balloon in accordance with an embodiment of the present subject matter.

Figure 3A depicts a tulip-shaped balloon catheter in a various stage of use in accordance with an embodiment of the present subject matter.

Figure 3B depicts an inflated tulip-shaped balloon catheter with second balloon in a various stage of use in accordance with an embodiment of the present subject matter.

DETAILED DESCRIPTION OF THE SUBJECT MATTER

All references cited herein are incorporated by reference in their entirety as though fully set forth. Unless defined otherwise, technical and scientific terms used
herein have the same meaning as commonly understood by one of ordinary skill in the art to which this subject matter belongs.

One skilled in the art will recognize many methods or materials similar or equivalent to those described herein, which could be used in the practice of the present subject matter. Indeed, the present subject matter is in no way limited to the methods or materials described.

The present subject matter relates to a "tulip-shaped" balloon catheter and percutaneous methods of using the balloon catheter for pericardiocentesis and pericardiotomy. The inventive balloon catheter does not require guidance by fluoroscopy and allows for the creation of a pericardial window with standard pericardiocentesis techniques. Furthermore, the inventive catheter may remain in the pericardium after balloon dilatation for further drainage of fluid from the pericardial space.

One embodiment of the present subject matter is a tulip-shaped balloon catheter. The tulip-shaped balloon catheter comprises: a catheter and a first inflatable balloon attached to the catheter, wherein the first inflatable balloon has an axis and comprises a first section proximal to the user being generally conical along the axis, and a second section distal to the user being generally half-spherical along the axis.

In one embodiment, the length of the first section is shorter than the length of the second section. In another embodiment, the length of the first section is substantially equal to the length of the second section. In another embodiment, the length of the first section is longer than the length of the second section.

In various embodiments, the largest diameter of the first inflatable balloon is about 6 to 26 mm and the length of the first inflatable balloon is about 5 to 25 mm along the axis.

The catheters may be any size. One of skill in the art can readily determine sizes that are suitable for particular uses of the tulip-shaped balloon catheter. For
pericardiocentesis or pericardiotomy in a human subject catheter sizes 5 to 14 French, inclusive may be particularly useful.

The catheters may also be any type that is suitable for insertion into a body cavity. For pericardiocentesis or pericardiotomy in a human subject, a pigtail catheter or a straight catheter may be particularly useful. The catheter may optionally comprise drainage holes to allow fluid in the pericardial space to be removed through the catheter.

In an alternative embodiment, the tulip-shaped balloon catheter further comprises a second inflatable balloon adapted to secure and prevent the catheter from being pulled out of the pericardial space. The second inflatable balloon is distal to the first balloon. The second inflatable balloon may range in shape and size from being generally spherical to generally disk-shaped, where the length of the balloon along the axis is smaller than the diameter of the balloon. A range of additional shapes and configurations may be appropriate for the second inflatable balloon, so long as such shapes and configurations enable the second inflatable balloon to be used for securing and/or preventing the catheter from being pulled out of the pericardial space, as will be readily appreciated by those of skill in the art.

The first and the second inflatable balloons may be composed of any material that enables their inflation and deflation as well as materials compatible for medical use.

Examples of suitable materials include but are in no way limited to polyvinyl chloride (PVC), polyethylene terephthalate (PET), nylon, rubber, polyethylene and polyurethane.

The tulip-shaped balloon catheter is configured for inflating and deflating the first and/or the second balloon. For example, the configuration may be similar to those of aortic balloon valvuloplasty catheters. In various embodiments, the tulip-shaped balloon catheter may comprise one or more inflation lumens and/or one or more deflation lumens that are in fluid communication with the first and/or the second inflatable balloon. A gas or liquid can be introduced from an external inflation device to inflate the first and/or the second inflatable balloon. The inflation device may also be used to withdraw the gas or liquid to deflate the first and/or the second balloon. Inflation
devices can be any inflation device known in the art that is suitable for use for balloon catheters or dilation devices. In one embodiment, inflation of the tulip-shaped balloon catheter may be accomplished by utilizing a syringe configured to administer a pre-specified amount of air or fluid. The syringe is attached to the end of the catheter and depressed. This will force liquid or air through the catheter resulting in balloon inflation. The amount of air or fluid required for complete balloon inflation can be pre-determined such that a fixed volume can deployed each time. This technique will ensure that complete balloon inflation can be reliably and reproducibly performed. Further, a three-way stop cock can be utilized on the catheter to seal the inflated balloon.

As an example, figure 1A depicts a deflated tulip-shaped balloon catheter comprising a pigtail catheter 101, a tulip-shaped balloon in its deflated state 102 is along the axis A. Drainage holes 103 are also shown. Figure 1B shows a deflated tulip-shaped balloon catheter comprising a pigtail catheter 101, a tulip-shaped balloon in its deflated state 102 and a second balloon in its deflated state 104. Drainage holes 103 are also shown.

As an example, figure 2A depicts an inflated tulip-shaped balloon catheter comprising a pigtail catheter 201, a tulip-shaped balloon in its inflated state 202. Figure 2B shows an inflated tulip-shaped balloon catheter comprising a pigtail catheter 201, a tulip-shaped balloon in its inflated state 202 and a second balloon in its inflated state 203.

The tulip-shaped balloon allows for various functions. First, the tulip-shaped balloon can dilate a hole made in the pericardium. Second, the tulip-shaped balloon can prevent the catheter from being pulled out of the pericardial space. This may be particularly beneficial when the balloon catheter is left in the pericardial space for prolonged drainage of the fluid from the pericardial space. Third, a medical practitioner can pull the tulip-shaped balloon with the balloon inflated to slowly increase the hole in the pericardium (essentially by tearing the pericardium). As such, a pericardial window is created without the need for surgery, or the use of fluoroscopy to determine the
location of the catheter or the balloon or to determine whether a sufficient size hole in
the pericardium is made

Another embodiment of the present subject matter provides for a method of using
the tulip-shaped balloon catheter to perform pericardiocentesis. The method comprises
providing a tulip-shaped balloon catheter, advancing the balloon catheter into the
pericardial space, and draining fluid from the pericardial space of the subject. The fluid
may be drained through the small hole that is created by the tulip-shaped balloon
catheter into the chest cavity. Alternatively, the fluid may be drained by the tulip-shaped
catheter by withdrawing the fluid through the catheter. For example, about 100cc of
fluid may be drained from the pericardial space. The method may also comprise
inflating the tulip-shaped balloon to prevent the balloon from being pulled out of the
pericardial space. The method may further comprise deflating the balloon and removing
the tulip-shaped balloon catheter from the subject. Additionally, the method may
comprise using ultrasound to verify that the balloon catheter is in the pericardial space.

In embodiments wherein the tulip-shaped balloon catheter comprises a second
balloon, the method may further comprise inflating the second balloon to secure and
prevent the catheter from being pulled out of the pericardial space. The second balloon
may be deflated prior to removal of the catheter from the subject.

Advancing the tulip-shaped balloon catheter into the pericardial space may be
performed by implementing the use of a guidewire, whereas the catheter passes over
the guidewire and into the pericardial space. One of skill in the art will readily
appreciate methods for implementing the use of a guide wire in the present subject
matter for application in the pericardial space. For example, this may be performed by
making an incision, inserting a hollow needle through the incision, advancing the hollow
needle towards the pericardium and into the pericardial space, confirming that the
hollow needle is in the pericardial space, passing a guidewire through the hollow needle
into the pericardial space, and withdrawing the hollow needle. The catheter can now be
passed over the guidewire into the pericardial space.
Another embodiment of the present subject matter provides a method of using the tulip-shaped balloon catheter to perform a pericardiotomy on a subject. The method comprises providing a tulip-shaped balloon catheter, advancing the balloon catheter into the pericardial space, inflating the balloon, pulling the inflated balloon catheter back through the pericardium to slowly increase the size of the hole in the pericardium. For example, as seen in figure 3A, the inflated tulip-shaped balloon catheter comprising a catheter 301 and an inflated tulip-shaped balloon 302 is pulled 304 through the pericardium 305 where a small hole was made in the pericardium by the initial insertion of the catheter. Figure 3B depicts the inflated tulip-shaped balloon catheter comprising a catheter 301 and an inflated tulip-shaped balloon 302 pulled further 304a through the pericardium 305a where the size of the hole in the pericardium is increased. The catheter may be pulled until the entire inflated balloon is pulled out of the pericardial space to create the pericardial window. Alternatively, the catheter may be pulled until the desired size of the pericardial window is created, but prior to the entire inflated balloon being removed from the pericardial space. The method may further comprise deflating the balloon prior to removing the tulip-shaped balloon from the subject. The method may also further comprise using ultrasound to verify that the balloon catheter is in the pericardial space.

In embodiments wherein the tulip-shaped balloon catheter comprises a second balloon, the method may further comprise inflating the second balloon to secure and prevent the catheter from being pulled out of the pericardial space. The second balloon may be deflated prior to removal from the subject.

The tulip-shaped balloon catheter of the present subject matter may also be used for balloon atrial septostomy, also known as the Rashkind procedure. Balloon atrial septostomy is a catheter-based procedure that widens the atrial septal defect ("ASD"), which is a hole between the two upper chambers of the heart. The procedure is performed on an infant as a temporary solution to improve circulation until the underlying cardiac defect can be repaired. The method comprises advancing the tulip-shaped balloon catheter through the ASD, inflating the tulip-shaped balloon and pulling
the tulip-shaped balloon catheter back through the septal defect to widen the ASD. Widening the ASD allows oxygen-rich and oxygen-poor blood to mix and improve the availability and circulation of oxygen-rich blood until the underlying heart defect can be surgically repaired.

The present subject matter is also directed to a kit for withdrawing fluid from the pericardial space by pericardiocentesis for evaluation of the fluid for diagnostic purposes or to remove the excess fluid causing compression of the heart and a kit for pericardiotomy. The kit is an assemblage of materials or components, including at least one of the inventive tulip-shaped balloon catheters. The exact nature of the components configured in the inventive kit depends on its intended purpose. For example, some embodiments are configured for the purpose of performing pericardiocentesis. In other embodiments, the kits are configured particularly for the purpose of performing percutaneous pericardiotomy. In one embodiment, the kit is configured particularly for the purpose of treating mammalian subjects. In another embodiment, the kit is configured particularly for the purpose of treating human subjects. In further embodiments, the kit is configured for veterinary applications, treating subjects such as, but not limited to, farm animals, domestic animals, and laboratory animals.

Instructions for use may be included in the kit. "Instructions for use" typically include a tangible expression describing the technique to be employed in using the components of the kit to effect a desired outcome, such as to perform pericardiocentesis or to perform a percutaneous pericardiotomy. Optionally, the kit also contains other useful components, such as, one or more needles, scalpels, alligator clips, ECG connector wires, three-way stop cock with lock nut, guide wires, drainage bags, syringes, local anesthetics (e.g., lidocaine), disinfectants (e.g., iodine), sutures, gauze, bandaging materials or other useful paraphernalia as will be readily recognized by those of skill in the art.

The materials or components assembled in the kit can be provided to the practitioner stored in any convenient and suitable ways that preserve their operability.
and utility. The components are typically contained in suitable packaging material(s).

As employed herein, the phrase "packaging material" refers to one or more physical structures used to house the contents of the kit, such as inventive compositions and the like. The packaging material is constructed by well known methods, preferably to provide a sterile, contaminant-free environment. The packaging materials employed in the kit may be those customarily utilized in pericardiocentesis kits. As used herein, the term "package" refers to a suitable solid matrix or material such as glass, plastic, paper, foil, and the like, capable of holding the individual kit components. The packaging material generally has an external label which indicates the contents and/or purpose of the kit and/or its components.

Various embodiments of the subject matter are described above in the Detailed Description. While these descriptions directly describe the above embodiments, it is understood that those skilled in the art may conceive modifications and/or variations to the specific embodiments shown and described herein. Any such modifications or variations that fall within the purview of this description are intended to be included therein as well. Unless specifically noted, it is the intention of the inventors that the words and phrases in the specification and claims be given the ordinary and accustomed meanings to those of ordinary skill in the applicable art(s).

The foregoing description of various embodiments of the subject matter known to the applicant at this time of filing the application has been presented and is intended for the purposes of illustration and description. The present description is not intended to be exhaustive nor limit the subject matter to the precise form disclosed and many modifications and variations are possible in the light of the above teachings. The embodiments described serve to explain the principles of the subject matter and its practical application and to enable others skilled in the art to utilize the subject matter in various embodiments and with various modifications as are suited to the particular use contemplated. Therefore, it is intended that the subject matter not be limited to the particular embodiments disclosed for carrying out the subject matter.
While particular embodiments of the present subject matter have been shown and described, it will be obvious to those skilled in the art that, based upon the teachings herein, changes and modifications may be made without departing from this subject matter and its broader aspects. It will be understood by those within the art that, in general, terms used herein are generally intended as "open" terms (e.g., the term "including" should be interpreted as "including but not limited to," the term "having" should be interpreted as "having at least," the term "includes" should be interpreted as "includes but is not limited to," etc.).
CLAIMS

WHAT IS CLAIMED IS

1. An apparatus, comprising:
   a catheter, and
   an inflatable tulip-shaped balloon attached to the catheter,
   wherein the inflatable tulip-shaped balloon has an axis and comprises a first section proximal to the user being generally conical along the axis, and a second section distal to the user being generally half-spherical along the axis

2. The apparatus according to claim 1, wherein the length of the first section is shorter than the length of the second section

3. The apparatus according to claim 1, wherein the length of the first section is longer than the length of the second section

4. The apparatus according to claim 1, wherein the length of the first section is substantially equal to the length of the second section

5. The apparatus according to claim 1, wherein the inflatable tulip-shaped balloon has a diameter of 5 to 30 mm when fully inflated and a length of 5 to 30 mm when fully inflated

6. The apparatus according to claim 1, wherein the catheter size ranges from 5 to 15 French.

7. The apparatus according to claim 1, further comprising at least one drainage hole in the catheter
8. The apparatus according to claim 1, further comprising a second inflatable balloon distal to the tulip-shaped balloon.

9. The apparatus according to claim 8, wherein the second inflatable balloon is disk-shaped.

10. The apparatus according to claim 8, wherein the second inflatable balloon has a maximum inflated diameter smaller than the maximum diameter of the tulip-shaped balloon, when inflated.

11. The apparatus according to claim 8, wherein the inflatable tulip-shaped balloon and second inflatable balloon are each composed of a material independently selected from the group consisting of polyvinyl chloride, polyethylene terephthalate, nylon, rubber, polyethylene and polyurethane.

12. The apparatus according to claim 1, further comprising at least one lumen in communication with the catheter for inflation and/or deflation of the inflatable tulip-shaped balloon and/or second inflatable balloon.

13. The apparatus according to claim 1, further comprising a syringe affixed to the catheter for inflation and/or deflation of the inflatable tulip-shaped balloon and/or second inflatable balloon.

14. The apparatus according to claim 1, further comprising a stop-cock affixed to the catheter for sealing the inflatable tulip-shaped balloon and/or second inflatable balloon.

15. The apparatus according to claim 1, further comprising a guide wire for placement of the apparatus during operation.
The apparatus according to claim 1 further comprising an ultrasound for viewing of the apparatus during operation

A method, comprising
providing an apparatus, comprising
a catheter, and
an inflatable tulip-shaped balloon attached to the catheter,
wherein the inflatable tulip-shaped balloon has an axis and
comprises a first section proximal to the user being generally conical along the axis, and a second section distal to the user being generally half-spherical along the axis,
advancing the apparatus into a pericardial space,
inflating the tulip-shaped balloon to encompass the pericardial space, and
draining the fluid from the pericardial space

The method according to claim 17, wherein the apparatus further comprises a ultrasound device for viewing catheter placement

The method according to claim 17, further comprising pulling the inflated tulip-shaped balloon and catheter through the pericardium to enlarge the pericardial space, to be performed prior to draining the fluid

The method according to claim 17, further comprising deflating the inflated tulip-shaped balloon and removing the apparatus from the pericardial space, to be performed prior to draining the fluid
21. The method according to claim 17, wherein the apparatus further comprises a second inflatable balloon attached to the catheter and distal to the tulip-shaped balloon.

22. A method according to claim 21, further comprising inflating the second inflatable balloon to secure and prevent the catheter from being pulled out of the pericardial space, to be performed prior to draining the fluid.

23. The method according to claim 21, further comprising pulling the inflated balloon catheter back towards the pericardium to enlarge the pericardial space, to be performed prior to draining the fluid.

24. The method according to claim 21, further comprising deflating the inflated tulip-shaped balloon and second inflatable balloon, and removing the apparatus from the pericardial space, to be performed prior to draining the fluid.

25. A kit for pericardiocentesis comprising:
   - a catheter for draining the pericardial space;
   - an inflatable tulip-shaped balloon attached to the catheter, for enlarging the pericardial space; and
   - a second inflatable balloon attached to the catheter, for securing the catheter.

26. A kit for pericardiocentesis comprising:
   - a catheter for draining the pericardial space; and
   - an inflatable tulip-shaped balloon attached to the catheter, for enlarging the pericardial space.
INTERNATIONAL SEARCH REPORT

A CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 25/10 (2009.01)
USPC - 604/509, 101.01
According to International Patent Classification (IPC) or to both national classification and IPC

B FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC - 604/509, 101 01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 604/500, 506-510, 96 01, 97 01, 99 01, 103 03

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB, USPT, EPAB, JPAB), Google, PubMed

catheter, balloon, conical, tulip, inflate, stopcock, drain, pericardial, effusion, double

C DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No</th>
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</thead>
<tbody>
<tr>
<td>Y</td>
<td>US 4,575,371 A (Nordqvist et al.) 11 March 1986 (11 03 1986) Especially Fig 3, abstract</td>
<td>1-4, 5-26</td>
</tr>
<tr>
<td>Y</td>
<td>US 2004/01 16888 A1 (Forman et al.) 17 June 2004 (17 06 2004) Especially Fig 2, abstract, para [0011], [0016], [0018], [0041], [0042], [0050], [0054], [0068], [0069], [0064], [0074]</td>
<td>5, 6, 8-26</td>
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<tr>
<td>Y</td>
<td>US 5,900,433 A (Igo et al.) 04 May 1999 (04 05 1999) Especially Fig 1, col 10, in 26-30</td>
<td>7</td>
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</table>

I I Further documents are listed in the continuation of Box C

- Special categories of cited documents
  - "A" document defining the general state of the art which is not considered to be of particular relevance
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Date of the actual completion of the international search
24 February 2009 (24 02 2009)

Date of mailing of the international search report
06 MAR 2009

Name and mailing address of the ISA/US
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Facsimile No 571-273-3201

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