TRANSSEPTAL LEFT ATRIAL ACCESS AND SEPTAL CLOSURE

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ABSTRACT
Methods, systems, and devices for transseptal access into the left atrium of a heart. In one embodiment an apparatus for transseptal left atrial access comprised of a catheter adapted for insertion into a vessel and one or more RF devices adapted to be extendable from the distal end of said catheter and configured for the penetration or sealing of septal tissue.
TRANSSEPTAL LEFT ATRIAL ACCESS AND SEPTAL CLOSURE

FIELD OF THE INVENTION

The present invention relates generally to the medical arts and specifically to transseptal methods, devices, and systems for accessing the left atrium of a patient's heart and for sealing closed an opening in the septum and/or for sealing septal tissue together.

BACKGROUND OF THE INVENTION

With recent advances in the cardiovascular arts, there's a renewed interest in finding safe and uncomplicated methods for accessing the left atrium of a patient's heart. Currently, a retrograde transseptal technique is most often and involves advancing a catheter through the aorta, into the left ventricle, accessing the left atrium from the left ventricle. However, this path into the left atrium is tortuous. A simple and more attractive alternative is accessing the left atrium directly from the right atrium by crossing the interatrial septum ("septum") that divides the two atrial chambers of the heart. The right atrium can be easily accessed and crossing the septum is the only requirement to entering the left atrium.

The left atrium can be accessed by puncturing across the septum of the heart at the fossa ovalis membrane, typically the thinnest part of the septum, with a needle-like device such as a Brockenbrough needle. While this technique has been widely known since the 1950's, it has not been used largely because the technique has not proven reliable or secure. Misalignment or the incorrect orientation of the needle against the septum, for example, may have severe consequences for the patient, including perforation of the left atrium or perforation of a patient's aorta. Inadvertent perforations of the inferior vena cava and the coronary sinus have also been reported as a possible complication of this technique. Therefore, rapid, precise and controlled methods and devices for crossing the interatrial septum are needed. The present invention meets these, as well as other, needs.

SUMMARY OF THE INVENTION

Broadly, the invention is directed at methods and radiofrequency (RF) devices for crossing an interatrial septum and sealing an opening in it closed.

In yet another aspect of the invention, methods, RF systems and devices for sealing septal tissue are provided.

In yet another aspect of the invention, methods, RF systems, and devices for sealing closed an naturally occurring opening in a heart is a provided.

These, as well as other additional embodiments and features of the invention, will appear in the following description in conjunction with the accompanying drawings.
(cooling or conductive) eluted from one or more ports located on a guide catheter. Alternatively, a fluid, coating or gel can be used on the RF probes 13, wires 17, or electrodes themselves to prevent tissue adhesion to the devices. In addition, one or more feedback sensors may be incorporated the present invention, preferably located adjacent to the RF penetration probes 13 to prevent unintended injury. The one or more feedback sensors can be configured to measure tissue impedances, temperatures, etc. as a means of preventing or controlling tissue heating, overheating or excessive tissue adhesion caused by heat generation.

[0015] FIG. 2 illustrates one embodiment of an RF penetration probe 13 for creating a slit-like opening 5 in the septum 1 of a patient’s heart. As shown, the RF probe 13 comprises a relatively straight wire 17 which is attached to a connection member 23, which secures it to the distal end 15 of the RF penetration catheter 11. A described above, RF wire 17 can be configured as a wire electrode or can be comprised of an electrode located preferably in the middle of wires 17 wherein the ends of wire are insulated as illustrated. The size of the RF wire 17 or the electrode will depend on the desired size of the septal opening 3; if a longer slit 5 is desired a larger RF wires 17 or electrode may be employed. Though not illustrated, RF wire 17 is operationally connected by lead wires, or other like means, to an RF generator or energy source (not shown).

[0016] FIG. 3 illustrates yet another embodiment of an RF penetration probe 13. In this embodiment, RF penetration probe 13 is comprised of a plurality of wires 17 radiating from center point 0. The wires 17 of the RF penetration probe 13, which are preferably straight, are secured to connection member at center point 0. This RF penetration probe 13 illustrated in FIG. 3 may be used to create the type of opening 7 depicted in FIG. 1B.

[0017] FIG. 4 illustrates yet another embodiment of the present invention wherein RF penetration probe 13 comprise a plurality of bisecting RF wires 17 that can be used to affect an opening 9 of the type illustrated in FIG. 1C. Each wire 17 in these embodiments may be configured as a wire electrode 17 or portions of the wire may be insulated 21.

[0018] Turning to FIGS. 5 and 6, yet another aspect of the invention, is provided. In this aspect, various RF tissue sealing devices or catheters 31 comprising a distally located RF sealing probe 33, are illustrated. The RF sealing probe 33 is comprised of one or more wires 17 arranged in a predetermined shape. Similar to the RF penetrating devices 11, the RF tissue sealing devices 31 can be separate catheter device insertable into a guide catheter, or alternatively, used to extend from the distal end of a guide catheter by use of a manipulator. For example, movement of a manipulator can control extension or retraction of both an RF penetrating device 11 and an RF sealing device 31 from the distal end of a guide catheter. To affect closure, RF wires 17, or electrodes of a RF sealing device 31, are configured to be operable at less intense modalities than the electrodes of an RF penetrating device 11 or probe 13. Specifically, the RF sealing probes 33 and the electrodes comprised therein are configured to heat, melt or coagulate tissues coming in contact with it. In addition, as provided in the art, heating of tissues at less intense parameters will trigger a healing response in the RF heated tissues, which will contribute and further promote closure of an opening and promote sealing of septal tissues.

[0019] Like the RF penetration probes 13, the RF sealing probes 33 of the present invention can be configured in a variety of shapes and sizes depending on the opening 3 to be closed. As illustrated in FIG, RF sealing probe 33 may be a circular wire 35 or a straight wire 37. Circular or straight type wires 35, 37 can be used to seal an opening 3 having several different patterns; for example, a circularly shaped RF sealing probe 35 can be used to seal a radial 7 or slit type 5 opening as illustrated in FIG. 1.

[0020] The various devices of the invention can be used similarly. The RF devices (including the tissue penetrating 11, 13 and sealing devices, catheters, probes 31, 33) can be delivered as a component of a catheter assembly system. The catheter assembly can comprise: a conventional guide or sheath catheter that can be introduced over a guidewire (not shown), an RF penetrating device 11 and/or an RF sealing device 31. First, the catheter assembly can be introduced into the right atrium from a number of access points using well known catheterization techniques. For example, to gain access to a patient’s vasculature and the right atrium of the heart, commercially available introducers can be inserted into a vessel such as into the femoral vein or artery. The introducer can be of a variety of sizes, 4-14 French. The guide catheter should be readily insertable into an introducer and extend from the access point to the septum; this will require use of a guide catheter about 80-120 cm long and about 4-14 French. The guide catheter can be manufactured in accordance with a variety of known techniques, including as an extrusion of an appropriate material, such as high density polyethylene (HDPE), polytetrafluoroethylene, nylons, polyether-block amides, polyurethanes, polyimides, polyolefin copolyester and the like. However, other catheter materials well known in the catheter art, as well as various braking techniques, may be employed depending on the desired catheter performance characteristics. In one embodiment, the guide catheter can be manufactured to be self-positioning to a desired location on a septum 3. For example, the guide catheter can be adapted so its distal tip preferentially locates to pre-determined position (such as at the fossa ovalis or above it), in which case the appropriate braking technique can be used to affect preferential positioning of the distal tip of the catheter. Other component of the catheter assembly, in addition to a guide catheter, can include one or more of the following: an RF penetrating device 11, an RF sealing device 31, a guidewire, imaging components and the like. These components can be configured to be inserted into and extend out of the distal end of a guide catheter. Alternatively, these components, such as the RF devices 11, 31 can be configured to be extendable from the distal tip of guide catheter via a manipulator or other like means located at a proximal end of the guide catheter. In addition, these devices 11, 31 can be configured to extend only to predetermined distances from the distal end of a guide catheter to ensure accurate penetration of the interatrial septum 1.

[0021] An RF penetrating device or catheter 5 can then be advanced into the guide catheter 43 and an RF penetrating probe 13 extended from its distal end. The RF penetration probe 43 should be placed into contact against the septum 1, and the electrodes energized to affect penetration. Pressure exerted on the proximal end of the RF penetration device or catheter 11 can used to ensure contact of septal tissue and the RF penetration probe 13. Other possible implementations include configuring the guide catheter to include a vacuum
or suction port to help immobilize septal tissue against the RF penetration probe 13 during septal penetration.

[0022] Once a desired opening 3 has been created, the RF penetrating device or catheter 11 can be withdrawn from the guide catheter and replaced with other diagnostic or therapeutic devices or catheters. Once the left atrium has been sufficiently accessed and the other devices and catheters withdrawn, the closing or sealing procedure can be initiated using the RF sealing device or catheter 31 of the present invention. To affect closure or sealing of an atrial opening 3, a RF sealing probe 33 should be delivered into the right atrium and the RF wire or electrodes 17 energized. As previously described, activation of the RF sealing probe 33 will cause tissue and collagen melting, as well as coagulation, around the tissue flaps 1 of a septal opening 3. In addition, a heat-induced healing process, including scar formation and cell proliferation, will further contribute to the septal closure and adhesion of the septal tissues.

[0023] As will be readily appreciated by one skilled in the art, the RF sealing devices and catheters 31 may be configured and used not only to seal actively created openings 3 but also those that occur naturally (ASDs, PFOs, floppy or aneurysmal septums or PFOs). In one method of treatment, the distal end of an RF treatment catheter can be delivered adjacent an aneurysmal or floppy PFO and RF energy applied to tighten the loose or septal tissue.

[0024] While this invention has been described in terms of specific embodiments, other embodiments will become apparent to those skilled in the art. Accordingly, the scope of the present invention is not intended to be limited by the specific embodiments disclosed herein, but rather, by the full scope of the claims.

We claim the following:

1. A method for crossing an interatrial septum of a patient’s heart, said method comprising:
   (a) advancing a catheter having an elongated shaft with a proximal portion, a distal portion, and at least one lumen, into a right atrium of the heart;
   (b) locating a fossa ovalis membrane;
   (c) advancing an RF penetrating probe comprising one or more electrodes adjacent to the fossa ovalis;
   (d) energizing the one or more electrodes and creating an opening of a desired pattern and size through the fossa ovalis.

2. The method of claim 1, further comprising the step of: providing an imaging apparatus.

3. The method of claim 1, wherein a user applied force to a proximal end of the catheter causes contact between the one or more electrodes and the fossa ovalis.

4. The method of claim 1, further comprising: applying a suction against the atrial septum to cause one or more of the following: immobilization of the interatrial septum or direct contact between the one or more RF electrodes.

5. The method of claim 1, wherein a grasping member is provided to stabilize of the distal end of the catheter against the fossa ovalis.

6. The method of claim 5, wherein the grasping member is disposed on the penetrating member.

7. The method of claim 1, further comprising the step of: eluting a fluid from the distal end of the catheter.

8. The method of claim 7, wherein the fluid is electrically conductive.

9. The method of claim 8, wherein the fluid is a cooling fluid.

10. The method of claim 11, wherein the RF penetrating probe is extendable through a distal port located at the distal end of the catheter.

11. The method of claim 10, wherein the penetrating probe is extendable to a pre-determined distance beyond the distal end of the guiding catheter.

12. The method of claim 18, wherein the RF penetrating probe is comprised of at least one wire electrode.

13. The method of claim 12 wherein the wire electrode is made of a shape memory material.

14. The method of claim 13, wherein the wire electrode is made of a metal.

15. A method for penetrating and closing an opening in a atrial septum, said method comprising:
   (a) advancing a catheter having an elongated member with a proximal portion, a distal portion, and one or more lumens, into a right atrium of a patient’s heart;
   (b) presenting an RF penetrating probe configured to penetrate tissue and having one or more RF penetrating electrodes disposed thereon;
   (c) energizing the one or more RF penetrating electrodes and creating an opening of a desired pattern and size in the septum;
   (d) presenting an RF sealing probe configured to melt and coagulate tissue and comprising one or more RF sealing electrodes disposed thereon; and
   (e) energizing the one or more RF sealing electrode and joining septal tissues cut in step (c) at one or more locations.

16. The method of claim 15, further comprising the step of: providing an imaging apparatus.

17. The method of claim 15, wherein the RF penetrating electrodes are in direct contact with septal tissue at a fossa ovalis.

18. The method of claim 17, wherein a user applied force at a proximal end of the catheter causes contact between the first RF penetrating electrodes and the RF sealing electrodes and the septum.

19. The method of claim 15, further comprising: applying a suction against the atrial septum to cause one or more of the following: immobilization of the interatrial septum or direct contact between the one or more RF electrodes and the septum.

20. The method of claim 19, wherein a grasping member is provided to stabilize of the distal end of the catheter against the septum.

21. The method of claim 15, further comprising the step of: eluting a fluid from the distal end of the catheter.

22. The method of claim 21, wherein the fluid is electrically conductive.

23. The method of claim 22, wherein the fluid is a cooling fluid.

24. The method of claim 15, wherein the RF penetrating probe and the RF sealing probe are extendable to a predetermined distance beyond the distal end of the catheter.
25. A method for penetrating an atrial septum from the right atrium of a patient’s heart, said method comprising:
   (a) advancing a distal end of a catheter into a superior vena cava until a distal end of a catheter is resting against a wall of the superior vena cava;
   (b) applying a force to a proximal end of the catheter whereby the distal end of the catheter is moved from the superior vena cava against a wall of the right atrium;
   (c) detecting a movement on the proximal end of the catheter signifying placement of the distal end of the catheter adjacent a fossa ovalis membrane;
   (d) presenting an RF penetrating member comprising one or more RF penetrating electrodes adjacent the fossa ovalis; and
   (e) energizing the one or more RF penetrating electrodes thereby creating an opening of a desired pattern and size in the fossa ovalis.

26. A method for closing a patent foramen ovale (PFO) or other cardiac defects located on an interatrial septum of a patient’s heart, said method comprising:
   (a) locating a fossa ovalis membrane;
   (b) crossing the interatrial septum at the fossa ovalis;
   (c) presenting an RF sealing probe comprising one or more RF sealing electrodes; and
   (d) energizing the one or more RF sealing electrodes.

27. A method for treating an aneurysmal interatrial septum, said method comprising:
   (a) locating a treatment position on the septum from a right atrium of the heart;
   (b) presenting a distal end of a RF treatment device comprising one or more RF electrodes one or more electrodes adjacent the treatment location;
   (c) energizing the one or more electrodes; and
   (d) delivering sufficient energy to the treatment location to cause a heat mediated tissue modification whereby the septum is tightened.

28. A system for penetrating an atrial septum separating right and left atriums of a heart, said system comprising:
   (a) a catheter configured for delivering an RF penetrating probe into the right atrium and adjacent the septum;
   (b) an RF generator operationally coupled to the RF penetrating probe;
   and wherein the RF penetrating probe configured to deliver sufficient RF energy to tissues of the atrial septum to allow penetrating thereof.

29. A system for penetrating an atrial septum separating right and left atriums of the heart, said system comprising:
   (a) a catheter configured for delivering an RF penetrating probe and an RF sealing probe into the right atrium and adjacent the septum;
   (b) an RF generator operationally coupled to the RF penetrating probe and the RF sealing probe; and
   wherein the RF penetrating probe configured to deliver sufficient RF energy to tissues of the atrial septum creating an opening therethrough; and the RF sealing probe configured to deliver sufficient RF energy to the tissues adjacent to the opening to cause coagulation and sealing of the adjacent tissues thereby sealing the opening.