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APPARATUS AND METHODS TO CREATE AND MAINTAIN AN INTRA-ATRIAL PRESSURE RELIEF OPENING

Abstract

The present disclosure relates to a method and a device for treating heart failure by normalizing elevated blood pressure in the left and right atria of a heart of a mammal. The present disclosure includes methods for creating and maintaining an opening in the atrial septum. Tools for making an opening and enlarging the opening are also disclosed. Use of the techniques and tools described herein prolongs the patency of an intra-atrial pressure relief opening.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS [0001] This application is a continuation of U.S. application Ser. No. 18/174,372, filed Feb. 24, 2023, which is a continuation of U.S. application Ser. No. 16/417,576, filed May 20, 2019, now U.S. Pat. No. 11,589,854, which is a continuation of U.S. application Ser. No. 13/905,638, filed May 30, 2013, now U.S. Pat. No. 10,292,690, which is a divisional of U.S. application Ser. No. 13/370,913, filed Feb. 10, 2012, now U.S. Pat. No. 8,882,697, which claims the benefit of U.S. Provisional Application No. 61/441,546, filed Feb. 10, 2011, each of which are herein incorporated by reference in their entirety.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are incorporated herein by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

[0003] The present disclosure relates to a method and a device for treating heart failure, more particularly to a method and a device for treating heart failure by reducing elevated blood pressure in a heart chamber by creating an intra-atrial pressure relief opening. Additionally, the present disclosure relates to a method and a device for maintaining or prolonging the patency of an intra-

atrial pressure relief opening.

BACKGROUND

[0004] Heart failure is a condition effecting millions of people worldwide. Heart failure includes failure of either the left side of the heart, the right side of the heart, or both. Left heart failure can lead to elevated pulmonary venous pressure, which may cause respiratory problems, including shortness of breath and exercise intolerance. Left heart failure may be ascribed to a number of causes, including valve disease, systolic failure of the left ventricle, and diastolic failure of the left ventricle. The adverse clinical result of each of these conditions is similar; the heart failure leads to elevated pressure in the left atrium and elevated pressure in the pulmonary veins, impeding proper flow of oxygenated blood through the blood supply. Therefore, there exists a need to treat the adverse effects of elevated pulmonary venous pressure on the body.

[0005] Heart failure has been further classified as either systolic heart failure or diastolic heart failure. Diastolic heart failure refers to heart failure that is present without the presence of major valve disease even while the systolic function of the left ventricle is preserved. More generally, diastolic heart failure is failure of the ventricle to adequately relax and expand in order to fill with blood, causing a decrease in the stroke volume of the heart. Presently, there exist very few treatment options for patients suffering from diastolic heart failure. Therefore there exists a need for methods and devices for treating elevated pulmonary venous pressures caused by diastolic heart failure.

[0006] A few techniques have been disclosed for reducing elevated pulmonary venous pressure; however these techniques all suffer from critical deficiencies. For example, U.S. Published patent application Ser. No. 09/839,643 by Keren et al discloses the use of a complex an intra-atrial pressure relief shunt including a stented valve. This approach suffers from several deficiencies. First, the proposed treatment requires the implantation of a complex implant device, which increases the risk of various clinical complications and adverse events. The implant resides partially in both the left atrium and right atrium, and poses a risk of generating thrombus and releasing emboli into the left or right circulation.

[0007] Releasing emboli into the left circulation could lead to a myocardial infarction or stroke. Additionally, the valve apparatus requires moving parts, which increases the risks associated with long term implant material fatigue and device fracture. A device fracture could in turn lead to embolization of all or part of the implant. Additionally, the valve incorporated into the shunt has the potential to fail acutely, possibly leading to a rapid increase in the load on the left heart. The patient could conceivably experience a significant acute circulatory pressure overload caused by sudden closure of the therapeutic shunt, potentially leading to severe complications. Therefore, there still exists a need for a simple and effective means of treating elevated pulmonary venous pressures caused by heart failure.

SUMMARY OF THE DISCLOSURE

[0008] In general, the present disclosure relates to a method and a device for treatment of heart failure by reducing both left atrial and pulmonary venous pressure which includes the creation of an intra-atrial pressure relief opening in the atrial septum. Furthermore, the method and the device disclosed herein provide treatment to the tissue near the intra-atrial pressure relief opening in order to maintain the long term patency of the opening.

[0009] The method and the device are particularly useful for treating the symptoms of left heart failure, and in particular diastolic heart failure, by reducing the pressure in the left atrium and pulmonary veins.

[0010] The present disclosure relates to a catheter device for treating heart failure. The catheter device includes an outer sheath having at least one lumen. The device also includes a penetrator for penetrating an atrial septum between a first high pressure chamber and a second low pressure chamber in a heart of a patient by creating an opening in the atrial septum and a dilator for enlarging the opening to a second substantially larger opening, thereby creating an intra-atrial

pressure relief opening in the atrial septum. The device also includes a mechanism suitable for treating the atrial septum substantially surrounding the intra-atrial pressure relief opening in order to avoid natural healing of the second substantially larger opening in the septum. The second substantially larger opening is large enough to allow blood flow through the intra-atrial pressure relief opening from the first high pressure chamber to the second low pressure chamber. This reduces the atrial pressure and pulmonary venous pressure without implanting a mechanical device in the atrial septum.

[0011] The present disclosure also describes a method for normalizing elevated blood pressure in a heart chamber. The method includes steps of penetrating an atrial septum present between a first high pressure chamber and a second low pressure chamber of a heart to create a first opening in the atrial septum; dilating the first opening to a second substantially larger opening of a desired size to create an intra-atrial pressure relief opening; delivering at least one treatment to the atrial septum surrounding the intra-atrial pressure relief opening, wherein the second substantially larger opening is made large enough to allow blood flow through the intra-atrial pressure relief opening from the first high pressure chamber to the second low pressure chamber, thereby reducing the atrial pressure and pulmonary venous pressure.

[0012] Another method according to the present disclosure is a method for normalizing elevated blood pressure in a heart chamber of a patient. The method includes steps of penetrating an atrial septum between a first high pressure chamber and a second low pressure chamber of a heart to create a first opening in the atrial septum. The method also includes a step of dilating the first opening to a second substantially larger opening of a desired size to create an intra-atrial pressure relief opening, extracting tissue separated from the atrial septum of the patient and delivering at least one treatment to the atrial septum surrounding the intra-atrial pressure relief opening, wherein the second substantially larger opening is made large enough to allow blood flow through the intra-atrial pressure relief opening from the first high pressure chamber to the second low pressure chamber without implanting a stent or a valve in the atrial septum.

[0013] In one of the embodiments of the present disclosure, the intra-atrial pressure relief opening is created in the atrial septum in the region of the septum generally near the fossa ovalis. The intra-atrial pressure relief opening is configured to allow a therapeutic amount of communication of blood between the left atrium and the right atrium, in order to reduce the negative clinical outcomes associated with elevated left atrial and pulmonary venous pressure. The said method delays the natural healing response of the septum tissues surrounding the intra-atrial pressure relief opening which would otherwise act to occlude the opening.

[0014] In exemplary embodiments of the present disclosure, dilation of the first diameter opening to a second substantially larger diameter opening to create an intra-atrial pressure relief opening is done by a conical distal tip of dilation catheter.

[0015] In some embodiments of the present disclosure, dilation of the first diameter opening to a second substantially larger diameter opening to create an intra-atrial pressure relief opening is done using a balloon catheter.

[0016] In some of embodiments of the present disclosure, the intra-atrial pressure relief opening may be treated with a treatment means, in order to treat the tissue in a manner that disrupts, slows, or reduces the body's ability to heal and occlude the therapeutic an intra-atrial pressure relief opening. The treatment means may include an energy delivery means, such as a means for delivering RF energy, ultrasound energy, laser energy, visible light energy or UV light energy to the tissue in the vicinity of the intra-atrial pressure relief opening.

[0017] In additional embodiments, the treatment means may include a means for delivering or removing thermal energy from the tissue, such as heating the tissue with steam, burning the tissue with heat generated by other means, or freezing the tissue with a cryogenically cooled heat transfer medium.

[0018] In still other embodiments the treatment means includes a means for physically or

mechanically abrading the tissue in the vicinity of the intra-atrial pressure relief opening, thereby inducing the formation of a thickened scar tissue in the vicinity of the opening, and slowing the healing response of the body.

[0019] In other embodiments the treatment means includes a means for fixing or gluing the tissue by secreting a fixative or adhesive to the tissue in the vicinity of the intra-atrial pressure relief opening. In still other embodiments the treatment means may include a catheter designed to ablate the tissue in the vicinity of the intra-atrial pressure relief opening by exposing the tissue to alcohol, thereby limiting the body's ability to heal and subsequently occlude the intra-atrial pressure relief opening.

[0020] In additional embodiments of the present disclosure, an intra-atrial pressure relief opening is created by piercing the atrial septum with a wire or other suitable device. A specially designed balloon catheter is then introduced into the newly created first diameter opening in the atrial septum. The balloon features a coating which incorporates at least one anti-proliferative drug or immunosuppressant drug. The balloon is then inflated, thereby simultaneously dilating the opening, creating an intra-atrial pressure relief opening, and depositing a coating of the drug onto the tissue in the vicinity of the intra-atrial pressure relief opening. In this way the normal healing responses of the body is disrupted and the long term patency of the intra-atrial pressure relief opening is increased.

[0021] In another embodiment, a medication is applied to an inner surface of tissue within a patient. In this method, a balloon is prepared with a medication on an outer surface of the balloon. In one variant, the medication is placed in an absorbent pad on the outer surface of the balloon. The balloon is deployed within the patient using a sheath, and the balloon is inflated to apply the medication in an inner surface of tissue within the patient. In one embodiment, the inner surface is an opening within an atrial septum. In one embodiment the medication is sirolimus, paclitaxel, zotarolimus, everolimus, silver nitrate, pyrimidine, methotrexate, azathioprine, dactinomycin, formalin, formaldehyde and ethanol.

[0022] The tools, apparatuses and methods disclosed herein provide many advantages. One advantage is reducing heart failure by reducing high pressure within a chamber of the heart and also by reducing pulmonary venous pressure. The intra-atrial pressure relief openings disclosed herein do not leave behind any complex, expensive or potentially hazardous implant. The treatments described herein also prolong or maintain the patency of an intra-atrial relief opening by preventing or substantially delaying natural healing processes of intra-atrial septum tissues present in the vicinity of the intra-atrial pressure relief opening. In addition, the methods and techniques described herein create a fail-safe intra-atrial pressure relief opening that is incapable of failing acutely, and which can become occluded only over an extended or clinically significant period of time. The devices and methods described herein create an intra-atrial pressure relief opening to allow blood to flow from the left atrium to the right atrium, thereby reducing pressure in the left atrium and in the pulmonary veins. The embodiments described herein accomplish this by treating tissue in the vicinity of the opening to prevent or substantially slow the healing response which would normally act to close the intra-atrial pressure relief opening.

[0023] The foregoing and other features and advantages of the present disclosure will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings, which are not to scale. The detailed description and drawings are merely illustrative of the disclosure, rather than limiting the scope of the disclosure being defined by the appended claims and equivalents thereof. Specific details are disclosed which would allow one with ordinary skill in the art to make and use the inventive devices and practice the inventive methods. It should be understood that various substitutions and additions can be made by those with ordinary skill in the art while still falling within the inventive features disclosed herein.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] FIG. 1 is a cross sectional side view of the device implanted in a human heart.

[0025] FIG. 2A is a side view of one embodiment depicting a catheter equipped with thin wire electrode as a means for delivering energy.

[0026] FIG. 2B is a side view of an embodiment depicting a catheter equipped with series of radio frequency electrodes as a means for delivering energy

[0027] FIG. 2C is a side view of an embodiment depicting a catheter with two semi-circular electrodes designed to carry bi-polar radio frequency energy.

[0028] FIG. 2D is a side view of an embodiment depicting a catheter equipped with piezoelectric ultrasound transducers arrays as a means for delivering energy.

[0029] FIG. 2E is a side view of an embodiment depicting a catheter equipped with concave-shaped piezoelectric ultrasound transducers arrays as a means for delivering energy.

[0030] FIG. 2F is a side view of an embodiment depicting a catheter with annular cavity carrying a heat transfer fluid for delivering energy.

[0031] FIG. 3 is a cross sectional side view of an embodiment showing a catheter device implanted in a human heart with a dilation balloon.

[0032] FIG. 4A is a cross sectional view of an embodiment depicting an inflated cylindrical dilation balloon coated with a drug.

[0033] FIG. 4B is a cross sectional view of an embodiment depicting a dilation balloon with an optical fiber for delivering visible light energy of a desired intensity.

[0034] FIG. 4C is a cross sectional view of an embodiment depicting a dilation balloon with optical fiber, covered with reflective coating at its distal end for delivering visible light energy.

[0035] FIG. 4D is a cross sectional view of one an embodiment depicting a dilation balloon with plurality of piezoelectric ultrasound transducer arrays as a means for delivering ultrasound energy.

[0036] FIG. 4E is a cross sectional view of an embodiment depicting a dilation balloon with two fluid passageways for delivering energy.

[0037] FIG. 4F is a transverse cross sectional view taken along line 4F-4F in FIG. 4E.

[0038] FIG. 5 is a side view of an embodiment depicting a catheter configured to abrade or scrape septum surrounding an intra-atrial pressure relief opening.

[0039] FIGS. 6A-6D depict partial cross-sectional view of a technique for making an additional opening in the patient's septal wall.

[0040] FIGS. 6E-6H depict additional partial cross-sectional views of an alternate way of making an initial opening in the patient's septal wall.

[0041] FIGS. 7A-7B depict a grasper suitable for removing separated septal-wall tissue.

DETAILED DESCRIPTION

[0042] Referring to FIG. 1, an embodiment is depicted for treating heart failure. FIG. 1 shows an atrial septum **100** which has been penetrated by a wire **102** thereby creating a first diameter opening and further dilated to second substantially larger diameter opening with aid of a dilation means **106**. The dilation means is a conical distal tip **106** of a dilation catheter **104** which is configured to allow for the user to dilate the first a diameter opening created by the wire **102**. The wire **102** and dilation catheter **104** extend from the right atrium **108** and into the left atrium **110**. The dilation catheter **104** is equipped with a treatment means **112** for delivering energy to the septum tissues in the vicinity of the first diameter opening being enlarged by the dilation means **106**. In FIG. 1 the means for delivering energy is depicted as a stipple-shaded region on the dilation catheter **104**. The treatment means **112** for delivering energy may be used to ablate the tissue near the second larger diameter opening created by the dilation means **106**, in order to improve the long term patency of the intra-atrial pressure relief opening created by the wire **102** and dilation means

106.

[0043] The crossing wire **102** of FIG. **1** may be any suitably stiff wire currently available for catheter procedures, or it may be custom made for the procedure. The wire **102** may include a sharpened tip in order to more easily penetrate the septum **100**. The wire **102** may be made of stainless steel, nitinol, or any other suitable material. After crossing the septum **100** the wire **102** may be withdrawn from the body, or may be left behind in order to facilitate the advancement of further devices and catheters into the body. In addition the wire **102** may feature a curved distal section in order to prevent the user from accidentally puncturing the wall of the left atrium **110**. In one embodiment, the guide wire **102** is a 0.9 mm (0.035") J-curve nitinol wire. In another embodiment, the guide wire **102** may be similar to the wires used in treating total coronary occlusions. The design, manufacture, and use of guide wires for penetrating tissue and lesions are well known in the art.

[0044] The dilation catheter **104** of FIG. **1** may be manufactured in a number of ways, and may be made of any suitable biocompatible material. A simple dilation catheter **104** might be made from LDPE, HDPE, or FEP and may feature a heat formed or over-molded conical tip. Another suitable dilation catheter **104** construction might include a PEBAX or nylon braided shaft with a specially designed conical cap **106**. The dilation catheter features a generally circular cross-section, however ridges or texturing may be employed in order to more efficiently dilate the septum by creating localized stress-concentration on the tissue near the ridges. In addition, the distal conical section **106** of the dilation catheter **104** may incorporate a number of cutting features, such as small metallic blades, or sharpened plastic protrusions, in order more effectively dilate the atrial septum **100**. The outer diameter (OD) of the dilation catheter **104** is designed to create an opening in the septum **100** that is large enough to allow enough blood to flow through the opening to substantially reduce the pulmonary vein and left atrial blood pressure. In some embodiments, the outer diameter of the dilation catheter **104** is roughly between 3 mm and 5 mm. The dilation catheter **104** may be configured to be advanced over a wire **102**, and as such it may have at least one wire lumen. Additional lumens might be used to allow for additional functionality, including lumens for secondary treatment devices and for injection of biocompatible dye. Furthermore, the dilator may include a stopping feature to prevent the user from advancing the dilation catheter so far into the left atrium **110** that the energy delivering means **112** is no longer in contact with the tissue of the intra-atrial septum **100**.

[0045] Still referring to FIG. **1**, the dilation catheter extends from an access point in the lower veins, and extends into the right atrium **108** through the inferior vena cava **114**. In alternative embodiments, the dilation catheter **104** may access the atrial septum **100** by other means, including from the jugular vein and through the superior vena cava **116**. In addition, access to the atrial septum **100** may be provided by other means, including through minimally invasive surgery, and through other major vessels in the body.

[0046] Referring now to FIGS. **2A** to **2F**, a series of exemplary energy delivering means are depicted. FIG. **2A** shows a crossing wire **102** extending from a dilation catheter **104**, featuring a conical distal tip **106**. A thin wire electrode **200** is depicted spiraling around the shaft of the dilation catheter **104** just proximal to the conical tip **102**. The path of the electrode **200** is tortuous, thereby maximizing the contact of the electrode **200** with the tissue. The electrode **200** is connected by a suitable means to an external power source, such as a DC power supply. When the power source pushes current across the electrode **200** the wire heats up due to the electrical resistance of the wire. The electrode **200** is electrically insulated from the body in order to prevent an adverse reaction to the current or a short circuit through the body. By carefully controlling the power being sent through the electrode **200** the surface temperature on the catheter shaft can be controlled. The electrical circuit may include a means for measuring or monitoring the temperature, and may also include an emergency circuit breaker, which could break the circuit if the temperature becomes too high. The heat energy is transferred from the dilator through to the tissue in order to ablate or

otherwise damage the tissue surrounding the intra-atrial pressure relief opening. By ablating the tissue in the vicinity of the intra-atrial pressure relief opening the healing process is impeded and the patency of the intra-atrial pressure relief opening over time is improved.

[0047] Referring now to FIG. 2B, a dilation catheter **104** which features an elongate shaft and a conical tip **106** is depicted. A series of radio frequency (RF) electrodes **202** are exposed on the surface of the shaft, just proximal to the conical tip **106**. The electrodes **202** are designed to carry monopolar radio frequency energy and to transfer the energy to the tissue. The RF energy may be supplied by a suitable RF generator, the likes of which are available to hospitals and are often available in catheter labs. The electrodes may be connected to the RF generator by means of an insulated conduction wire or wires which run through the length of the catheter. A grounding pad may be attached to the patient's anatomy in order to represent a safe means for dissipating the electrical current after the tissue has been significantly ablated. The RF electrode array **202** therefore represents a means for delivering energy to the tissue surrounding the intra-atrial pressure relief opening in order to ablate the tissue.

[0048] Referring now to FIG. 2C, a dilation catheter **104** which features an elongate shaft and a conical tip **106** is depicted. Two semi-circular radio-frequency electrodes **204 206** are shown. The electrodes **204, 206** are designed to carry bi-polar radio frequency energy and to transfer the energy to the tissue. For example, RF electrode **206** might represent a return electrode, where the radio-frequency energy might travel from electrode **204**, through the tissue surrounding the dilation catheter **104**, and complete the circuit by conduction of the RF electrode **206**. The electrodes **204, 206** may be connected to an external RF generator in much the same way as the embodiment depicted in FIG. 2B. The use of RF energy to treat tissue is known in the art. For example, RF energy is employed in electrophysiology procedures for treating atrial fibrillation.

[0049] Referring now to FIG. 2D, a dilation catheter **104** is depicted with an energy delivering means **208** for treating tissue. The energy delivering means of FIG. 2D may be represented by two arrays of piezoelectric ultrasound transducers **210, 212**. As required, additional arrays of piezoelectric ultrasound transducers may be used, for example, four such arrays may be spaced around the circumference of the dilation catheter **104**. The ultrasound transducers **210, 212** are configured to emit high frequency focused ultrasonic energy when an appropriately phased alternating current is supplied to the transducers. This may be accomplished by connecting each transducer array to an electrical conduit **214, 216**, which in turn is connected to an external power supply. The electrical conduits **214, 216** may include a plurality of individually insulated conductive wires. Each wire is configured to deliver an alternating current to a different section of the transducer array. The electrical current in each wire is carefully controlled by the external power supply such that the ultrasonic energy emitted across the array is appropriately phased in order to direct the overall signal to a focused region of tissue surrounding the dilation catheter **104**.

[0050] Still referring to FIG. 2D, the phased transducer array works by a means well known in the art involving the use of waveform interference. The high intensity focused ultrasound emitted by the dilation catheter **104** in this way generates significant heat at the focal point of the ultrasound array. The array may be shaped to emit this focused ultrasound in a roughly circular pattern around the circumference of the shaft, thereby ablating the tissue in the vicinity of the dilation catheter **104**. In this way the ultrasound array represents a means of treating the tissue in order to slow or prevent the natural healing process of the body.

[0051] Referring now to FIG. 2E, a dilation catheter **104** which may be used to create an intra-atrial pressure relief opening is depicted with an energy treating means **208** for treating tissue. The energy delivering means is represented by two or more arrays of piezoelectric ultrasound transducers **210, 212**. Although two transducer arrays **210, 212** are shown, however any number of such arrays may be employed to produce a similar effect. In contrast to FIG. 2D the transducer arrays of FIG. 2E are shaped like a concave lens, and this allows the transducer to naturally emit focused ultrasonic energy. The transducer arrays of FIG. 2E therefore emit focused ultrasonic

energy without the need for separating elements of array into different phases. The transducer arrays are electrically connected to electrical conduits **214**, **216**, which are in turn connected to an external power supply. In this way alternating current can be generated by the power supply and eventually supplied to the ultrasound arrays **210**, **212** by the electrical conduits **214**, **216**. The focused ultrasonic energy that is emitted heats up the tissue near the focal point of the array. In this way the ultrasonic array **210**, **212** of FIG. 2E represents a means for damaging or ablating tissue in order to prevent or delay the natural healing process of the body, which would otherwise cause the intra-atrial pressure relief opening to close over time.

[0052] Referring now to FIG. 2F, a dilation catheter **104** which may be used to create a delivering means **208** for treating tissue surrounding the intra-atrial pressure relief opening. The energy delivering means is represented by an annular cavity **218** located inside the dilation catheter **104**. The annular cavity **218** is connected to an inlet lumen **220** and an outlet lumen **222**. A heat transfer fluid is pumped through the inlet lumen **220** and into the annular cavity **218**, where it transfers or absorbs heat energy from the surroundings. The fluid is then pumped out the outlet lumen **222**. In this way the heat transfer fluid is circulated throughout the annular cavity **218** of the dilation catheter **104**. The heat transfer fluid may be any number of fluids, including very cold or very hot saline or water, steam, or a cryogenic fluid. In addition, nearly any suitable fluid or gas may be pumped at an appropriate temperature to treat the tissue. In some embodiments, the heat transfer fluid is saline and is pumped through the dilation catheter at 55-65 degrees Celsius. In other embodiments, the saline is pumped through the catheter at roughly negative 10 degrees Celsius.

[0053] The annular cavity **218** of the dilation catheter **104** depicted in FIG. 2F may be surrounded by a material with especially high heat conductance, such as stainless steel or other metals. In this way pumping either a hot or cold fluid through the annular cavity **218** can chill or heat the tissue surrounding the dilation catheter **104** in order to ablate or otherwise damage the tissue. Therefore, the dilation catheter **104** with a cavity **218** for circulating a heat transfer fluid represents a means of treating the tissue near the intra-atrial pressure relief opening in order to slow or prevent the natural healing process of the body.

[0054] The energy delivery means depicted in FIGS. 2A to 2F are not intended to be an exhaustive list of the various energy delivery means for treating the tissue. In addition to the depicted energy delivery means, a variety of other mechanisms for delivering energy may be used. In other embodiments, for example, high intensity unfocused light may be channeled through an optical fiber in the catheter and directed towards the tissue surrounding the intra-atrial pressure relief opening. In other embodiments a focused beam of light, such as a laser, may be directed towards the tissue. In still other embodiments other forms of electromagnetic energy may be employed to treat the tissue, such as ultraviolet light or microwave radiation. In still other embodiments a combination of any of these methods for treating the tissue near the intra-atrial pressure relief opening may be employed.

[0055] In embodiments depicted in FIGS. 2A to 2F where multiple electrodes or transducers are depicted it should be understood that any suitable number of electrodes or transducers may be used. In some embodiments, for example, two, three, four, five, or more Radio frequency electrodes may be located around the circumference of the dilation catheter in order to treat the tissue.

[0056] In some embodiments, the dilation catheter may not incorporate an energy delivering means. In these embodiments a secondary catheter that is similar to the dilation catheter, but does not require the conical dilating tip may be used. This secondary treatment catheter may make use of any of the various energy delivery means that are disclosed herein in order to treat the tissue surrounding the intra-atrial pressure relief opening. In this way the tasks of dilating the opening in the atrial septum and treating the intra-atrial pressure relief opening thus created may be separate tasks performed using separate catheters and still fall within the scope of the disclosure depicted in FIGS. 2A to 2F.

[0057] Referring now to FIG. 3, additional embodiments are depicted. FIG. 3 shows a dilation

balloon **302** which has been advanced to the atrial septum **100** and inflated. The balloon may be configured to be advanced over a wire **102**, which has already penetrated the septum by conventional trans-septal wire delivery means, as are discussed earlier in this application. The opening in the atrial septum **100** may have been pre-dilated with a simple conical tip dilation catheter in order to make accessing the septum **100** with the balloon **302** easier. The balloon **302** is designed to dilate the opening in the atrial septum **100**, thereby creating or enlarging an intra-atrial pressure relief opening of the desired therapeutic size. In some embodiments, the balloon **302** may dilate the opening in the atrial septum **100** up to a size between 4 mm and 8 mm. The balloon **302** optionally incorporates a means for treating the tissue surrounding the intra-atrial pressure relief opening. In some embodiments, the treatment may include a means for delivering energy to the tissue. In other embodiments, the treatment includes delivering a medication or combination of medications to the tissue.

[0058] The dilation balloon **302** of FIG. **3** may be shaped with an hour glass type shape where the diameter at the center of the balloon is smaller than the diameter at either end. Alternatively, the balloon **302** could be a simple cylinder, or be spherical or any other suitable shape. The balloon **302** may optionally feature stress concentrating or cutting elements on the surface of the balloon **302**, in order to more easily dilate the opening in the septum **100**. The balloon **302** may be non-compliant or compliant. The balloon catheter may include radio-opaque marking features to allow the user to appropriately place the balloon **302** at the septum **100** in order to dilate the septum **100** while inflating the balloon **302**. Alternatively, the balloon **302** may be designed to be inflated entirely in the left atrium, and then may be drawn backwards by the user in order to position the balloon **302** and in order to dilate the septum **100**. Methods of manufacturing and inflating balloon catheters are well established in the art.

[0059] Still referring to FIG. **3**, where the balloon catheter is depicted as being advanced to the atrial septum **100** by tracking through the inferior vena cava **114**. In alternative embodiments, the dilation balloon may access the atrial septum by other means, including from the jugular vein and through the superior vena cava **116**. In addition, access to the atrial septum may be provided by other means, including through minimally invasive surgery, and through other major vessels in the body.

[0060] Referring now to FIGS. **4A-4E**, a series of balloon dilators featuring exemplary secondary treatment means are depicted. FIG. **4A** shows a cross-sectional view of an inflated cylindrical dilation balloon **402**. The dilation balloon **402** has crossed the atrial septum **100** by tracking over crossing wire **102**. Arrows **404** depict the pressure of the fluid used to inflate the balloon. The balloon **402** is coated in a drug **405** which acts to slow the healing process of the body, such as an anti-proliferative drug or an immunosuppressive drug. In some embodiments, the drug coating may be one or a combination of the following drugs, paclitaxel, everolimus, sirolimus (rapamycin), zotarolimus, temsirolimus, doxorubicin, cyclophosphamide, or similar compounds. These drugs may also be applied in any other medically appropriate manner using suitable applicators.

[0061] In one embodiment, as mentioned below, the balloon may have a central lumen, shown in FIG. **4A**, for deploying the balloon along a guide wire **102**. One or more points along the central lumen or other portions of the balloon may include an echogenic or radiopaque feature for pin-point location of the balloon with respect to the atrial septum and the first opening and second larger opening created in the atrial septum. A portion of the outside or outer surface of the balloon may be coated with a medication or drug, as mentioned above, so that when the balloon is inflated, the outer surface and the medication are pressed against the opening made in the atrial septum. The balloon will typically be deployed by pushing the balloon down the guide wire within sheath **104**. In some embodiments, the balloon itself will be deployed within a protective sheath (not shown) within outer sheath **104**. The protective sheath acts to protect both the balloon and the medication on the outer surface of the balloon until the inflation balloon is in place. The balloon is then ready for inflation. Inflation of the balloon will act to enlarge the opening in the atrial septum and will

also apply the medication to the now-exposed inner surface of the atrial septum (opening), which the balloon itself may have created. Alternatively, the enlarged opening in the atrial septum may be made by another method described below, while the balloon is used apply a medication. The medication, such as an anti-proliferative drug or an immunosuppressive drug, may be used to slow the healing process of the body. Examples of a drug include sirolimus, paclitaxel, zotarolimus, everolimus, silver nitrate, pyrimidine, methotrexate, azathioprine, dactinomycin, formalin, formaldehyde and ethanol.

[0062] In still other embodiments, the coating contains a radiation source similar to that used in brachytherapy. In some embodiments, the balloon **402** may be shaped in order to maximize the surface contact between the medicinal coating **405**, as shown in FIG. **4A**, and the intra-atrial pressure relief opening created by the balloon **402**. In some embodiments, the balloon **402** featuring the medicinal coating **405** may also feature ribs, protrusions, or other cutting elements in order to further increase the surface area available to be treated by the coating. In some embodiments, the balloon is inflated in the septum **100** and then drawn back proximally or advanced distally or simply rotated in order to encourage the adhesion of the medicinal coating **405** onto the tissue surrounding the intra-atrial pressure relief opening.

[0063] FIG. **4B** shows a dilation balloon **406** is configured to create an intra-atrial pressure opening by dilating an opening created in the atrial septum **100** by conventional means. In FIG. **4B**, the balloon **406** is depicted with a plug **408** closing off the distal end, and therefore is not delivered over a wire. As disclosed above, and in alternative embodiments, the dilation balloon may also be configured with a central through lumen and be designed to be delivered over the wire. The balloon catheter is shown nested inside an optional delivery sheath **410**, which may be used to maintain the proper position of the devices relative to the opening in the atrial septum.

[0064] The balloon **406** includes an energy delivering means, incorporating a flexible optical fiber **412**, which may be used to transmit visible light of a desired intensity. The visible light is represented by the dashed lines **414** in FIG. **4B**. The optical fiber **412** is positioned in a center passageway that does not communicate with the annular passageway **416** for the inflation fluid. In some embodiments, the inflation fluid is chosen which has an especially high light transmission. In some embodiments, the inflation fluid is distilled water, de-ionized water, or a gas, for example, air or nitrogen. The optical fiber **412** emits the light energy inside the balloon **406** in a direction that is substantially axial to the treatment device. A 3-dimensionally curved mirror **418** is positioned in line with the optical fiber **412**. The curved mirror **418** is configured to reflect the light energy in a radial direction. The curved mirror **418** is also configured to focus the light into a thin band in the axial direction by acting as a lens. The light source and the curved mirror **418** therefore direct significant light energy to the tissue surrounding the atrial septum **100** generating considerable heat, thereby ablating or otherwise damaging the tissue near the intra-atrial pressure relief opening.

[0065] FIG. **4C** depicts a dilation balloon **406** configured to create an intra-atrial pressure opening by dilating an opening created in the atrial septum **100** by conventional means. The balloon **406** is similar to the balloon which is depicted in FIG. **4B** except that the distal end **420** of the balloon is covered by a reflective coating **422**. The balloon **406** is further configured so that when fully inflated the distal end of the balloon is shaped like a concave lens. The lens shape coupled with the reflective coating **422** turns the dilation balloon **406** itself into a means for reflecting and focusing light. The light is supplied by an optical conduit **424** which may be a single optical fiber or a cable of optical fibers. The path the light takes is depicted by a series of dashed lines **426** which roughly approximate the shape of the wave of light being emitted by the optical fibers. The light can be described as exiting the optical fiber and traveling to the reflective distal end, where it bounces and is focused in an angular fashion towards the tissue surrounding the intra-atrial pressure relief opening. After being reflected at the distal end of the balloon **406**, the light can further be described as a hollow cone of ever increasing intensity. In this way the dilation balloon **406** of FIG. **4C** represents a means of ablating tissue in the vicinity of the intra-atrial pressure relief opening by

means of focusing high intensity light at the tissue.

[0066] Turning now to FIG. 4D a dilation balloon 406 is shown having been inflated and having dilated an opening in an atrial septum 100. As with other embodiments, the original puncture in the atrial septum 100 can be created by conventional means described herein and also well known in the art. In addition, the original puncture in the atrial septum 100 may be pre-dilated by a simple dilation catheter prior to inserting the dilation balloon 406 and applying treatment. The balloon 406 is configured to be delivered over a crossing wire 102, although in alternative embodiments the balloon 406 may be delivered without the aid of a crossing wire 102.

[0067] Incorporated in the balloon of FIG. 4D is a plurality of piezoelectric ultrasound transducer arrays 428, 429 which are similar to the transducer arrays discussed above and illustrated in FIG. 2E. The transducer arrays 428, 429 are configured to emit high intensity focused ultrasonic energy in a generally radial direction across most of the circumference of the balloon 406. The ultrasonic energy is depicted as a series of curved lines 430. In alternative embodiments, the ultrasound transducer arrays may be arranged so as to comprise a phased array in order to focus the ultrasonic energy. A similar phased array is also disclosed above, and is depicted in FIG. 2D. The transducer array represents a means for delivering energy to the tissue in order to ablate or otherwise destroy the tissue and slow down the natural healing process of the body.

[0068] Turning now to FIG. 4E another dilation balloon 406 is depicted. The balloon 406 is configured to be advanced to a small puncture opening in the atrial septum 100 and inflated as shown. The balloon 406 is further configured to be advanced over a crossing wire 102. Once inflated the balloon 406 defines an annular space 431, which is configured to allow fluid to flow around the circumference. Proximal to the balloon 406 the catheter features a shaft with a three lumen cross section 432, as shown in the cross sectional detail of FIG. 4F. FIG. 4F is a cross sectional view taken along line 4F-4F in FIG. 4E. The location of the cross-sectional detail on the proximal shaft is represented by a dotted line 434. In this cross-sectional view the center lumen 436 is configured to accept the crossing wire. One lobed region 438 represents an inlet passage for the inflation fluid, while the other lobed region 440 represents an outlet passage for the inflation fluid. The two fluid passageways are separately connected on the proximal end to an external pump.

[0069] The dilation balloon catheter of FIGS. 4E-4F is used in two stages. First the balloon 406 is inflated by closing off the outlet channel 440 and forcing a heat transfer fluid through the inlet channel 438, thereby inflating the balloon 406. When the balloon is satisfactorily inflated the atrial septum 100 puncture is dilated and an intra-atrial pressure relief opening is thereby created. After fully inflating the balloon 406 the heat transfer fluid is forced to circulate through the annular space 431 of the balloon 406. This is accomplished by forcing additional heat transfer fluid through the inlet lumen 438, and allowing sufficient fluid to flow through the outlet lumen 440. The backpressure on the outlet lumen 440 is controlled by the external pump, for example, by means of a gear pump with friction clutch. In this way sufficient pressure to keep the balloon 406 inflated is supplied while there is still considerable fluid flow through the balloon 406. The heat transfer fluid circulating through the balloon 406 may be any of the same fluids disclosed above. The heat transfer fluid flowing through the balloon allows for the transferring of energy to or from the tissue in order to damage or ablate the tissue surrounding the atrial an intra-atrial pressure relief opening. In this way the dilation balloon catheter of FIG. 4E represents a means of creating an intra-atrial pressure relief opening and treating the tissue surrounding the opening in order to prolong the patency of the opening.

[0070] The various embodiments for applying a treatment to the tissue surrounding the intra-atrial pressure relief opening as depicted in FIGS. 4A-4F are not intended to be an exhaustive list of the treatment options available. For example, in additional embodiments, a balloon may be configured with a microwave energy emitter. In other embodiments the balloon may incorporate a network of electrodes for heating the tissue surrounding the intra-atrial pressure relief opening. In other embodiments a balloon may include a coating on the internal diameter which when mixed with the

inflation fluid undergoes a highly exothermic or endothermic reaction, thereby heating or cooling the tissue. Examples of these fluids include water and saline. In other embodiments, the balloon may be coated in a fixative or biocompatible glue, which fixes the tissue and impedes the normal healing response of the body. Examples include pyrimidine, methotrexate, azathioprine and dactinomycin. In still other embodiments, the balloon includes pores designed to exude a small amount of ethyl alcohol, thereby ablating the tissue surrounding the intra-atrial pressure relief opening.

[0071] Turning now to FIG. 5A, additional embodiments are depicted. A dilation catheter **502** including a conical distal tip **503** is shown. The catheter **502** is shown having already dilated a punctured opening in an atrial septum **100**, thereby creating an intra-atrial pressure relief opening. Incorporated in the dilation catheter shaft **508** is a textured or ribbed cylindrical section **504**, which is rotatably coupled to the catheter shaft **508**. The ribbed section of the catheter shaft **508** is configured to abrade or scrape the tissue surrounding the intra-atrial pressure relief opening in order to encourage the formation of thickened scar tissue. In alternative embodiments the ribbed section of the catheter shaft **508** may instead be replaced by a section of catheter shaft **508** which has an abrasive material fixed to it, such as crimped stainless steel wires or sharpened glass beads. [0072] Still referring to FIG. 5, the ribbed section of the catheter shaft **508** is coupled to a torque transmission member **506**. The torque transmission member **506** may be any suitably flexible elongate member which is capable of transmitting torque over the length of the catheter shaft **508**. In some embodiments, the torque transmitting member **506** is a tri-filar drive shaft, where each layer of filars is turned in opposing directions. The torque transmission member **506** may be coupled to an external drive source, or it may instead be rotated manually by the user, in order to abrade the tissue surrounding the intra-atrial pressure relief opening. The abrasion and the friction between the ribbed sections of the catheter **502** together encourage the formation of a thick scar tissue, which in turn slows down the healing process of the body and helps to maintain the patency of the pressure related opening. In this way dilation catheter **502** represents a means for creating an intra-atrial pressure relief opening and prolonging its patency.

[0073] In alternative embodiments as depicted in FIG. 5, the textured section of the shaft may be fixed relative to the rest of the catheter shaft **508**. In this case the user may simply advance and retract the catheter device **502** axially in rapid succession, thereby abrading the tissue near the intra-atrial pressure relief opening. An external drive source may be used to actuate the catheter **502** in this way, or the user may simply actuate the catheter **502** by hand.

[0074] Other techniques may also be used for creating an opening in the atrial septum of a patient in order to provide intra-atrial pressure relief. One such technique is depicted in FIGS. 6A-6H. In this technique, a wire guide is advanced to the area of interest near the location where the atrial septum opening is desired. As is well known to those having skill in the art, the wire guide may be equipped with a radiopaque tip or echogenic features (not shown) for better visibility by monitoring equipment and medical personnel during the procedure. Some wire guides have a rounded distal end in order to prevent trauma to the patient, some have a penetrating end, such as the one discussed above with respect to FIG. 1. The initial penetration, as described further with respect to FIG. 1 may then be followed up with cutting instruments to enlarge the opening.

[0075] In the cross-sectional view of FIG. 6A, the wire guide **102** in sheath **104** has penetrated the atrial septum **100**, creating an initial opening **118**. FIG. 6B is a plan view that depicts the relative size of the initial opening **118** in the atrial septum **100**, as seen from a viewing point in the left atrium. In FIG. 6C, the opening has been expanded sufficiently to allow insertion of a retaining and reaction device **120** with legs **122** via sheath **104**. FIG. 6D again depicts the deployed legs **122** from a viewing point in the left atrium. The reaction and retaining device **120** may comprise a series of struts **124** and apices **126**, in a manner very similar to the legs depicted in U.S. Pat. No. 8,043,360, assigned to the assignee of the present application and incorporation herein by reference in its entirety. The intention of the procedure is to prepare an opening in the atrium septum of

diameter **128**, as seen in FIG. 6F. Diameter **128** may be from about 5 mm to about 10 mm, depending on instructions from the patient's physician or health care provider. The legs **122** should extend a little less than the intended final diameter or dimension of the opening **128**. As will be recognized by those having skill in the art, the legs will act to retain the tissue which is removed from the septal wall. In some techniques, the wire guide **102** will be left in place to also retain the tissue. While wire guide **102** will generally not be sufficient for removal of the tissue, the wire guide will act to prevent movement of the tissue away from the general area of the septal wall. [0076] Once the legs are in place, an RF probe is inserted into the area of interest near the septal wall using sheath **104**, as shown in FIG. 6E. RF probe **130** is connected to a source of power via wire **132**, in a manner similar to that discussed above for FIG. 2A. FIG. 6F depicts a plan view of the situation, again from a viewing point in the left atrium. The legs with struts **124** and apices **126** are deployed within a roughly circular area **128**, which is the area from which tissue is to be removed. The RF probe **130** may be a circular probe as depicted in the figure. The probe is energized to ablate tissue and to separate the tissue from the atrial septum. Alternatively, the probe may comprise an arc or a short length. In this situation, the probe is sequentially moved or rotated through the roughly circular pattern until the ablation has been completed and the tissue is ready for removal. In one embodiment, the system is unipolar and is designed to shut down when ablation has proceeded sufficiently that when RF current or voltage reaches legs **124**. In other techniques, there may be a delay after current or voltage is detected, to insure that penetration through the tissue is complete. This technique has the advantage that the location of 5-10 mm diameter-sized tissue is in the control of the surgeon and the surgical team at all times during the procedure. [0077] As noted above, the RF probe may be unipolar, with the patient protected by a grounding pad. Alternatively, a bi-polar technique may be used, with a grounding electrode on the left atrial side of the patient or externally on the patient. In one technique, the RF probe (first electrode) and the grounding probe (second electrode) may be positioned on opposite sides of the atrial septum. Their locations may then be verified before the probe is energized and ablation begins. This technique may be used for a circular RF probe or for a smaller probe, in the general form of an arc or a short length. The procedure continues until ablation is completed and the tissue is ready for removal.

[0078] When ablation is complete, the separated or removed tissue **134** may be retained by device **120** and legs **122** for removal or extraction from the patient, as shown in FIG. 6G. FIG. 6H depicts the removed tissue. In one embodiment, device **120** is sufficient for extraction, and tissue **134** with initial opening **118** may be extracted from the patient by retracting device **120** through sheath **104**. In other embodiments, tissue **134** may be retained by wire guide **102** and a grasper advanced through sheath **104** to grasp and extract the tissue, as disclosed in U.S. patent application Ser. No. 12/954,468, co-owned by the assignee of the present application, and incorporated by reference in its entirety.

[0079] An example of a suitable grasper **140** with retaining prongs **144** is depicted in FIGS. 7A-7B. The grasper **140** is advanced through sheath **104** to the area of interest, near the septal wall. The grasper is deployed when sufficiently near the tissue **134** by advancing the grasper from grasper sheath **142** so that tips **146** are spread and are able to grasp the tissue which has been separated from the patient's atrial septum. The tips **146** engage tissue **134** when they are sufficiently close that when the tips are retracted into grasper sheath **142**, the tips **146** engage the tissue and are able to securely retain the tissue. The separated tissue is then extracted or removed from the patient through sheath **104**.

[0080] In addition to the above disclosed embodiments, the tissue may be treated by any combination of the above discussed treatment options. In these embodiments, the steps of dilating the puncture opening in the atrial septum and treating the tissue to slow down the healing process of the body may be spread out over a series of similar devices.

[0081] In another embodiment, a method is provided for treating elevated pulmonary venous

pressure and elevated left atrial pressure caused by heart failure. The method includes creating an intra-atrial pressure relief opening by using any of the devices or means disclosed herein. The method further includes treating the tissue in the vicinity of the intra-atrial pressure relief opening with a treatment operation. The secondary treatment operation includes any of the above mentioned treatment means or devices, including the use of energy to ablate the tissue or drugs to delay the healing response of the body.

[0082] While reference has been made to various drawings and embodiments, it should be understood that certain substitutions, additions, and exchanges may be made by those skilled in the art while still remaining within the scope of the invention. The scope of the invention should therefore be defined by the attached claims:

[0083] The use of the terms “a” and “an” and “the” and similar referents in the context of describing the invention (especially in the context of the following claims) is to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms “comprising,” “having,” “including,” and “containing” are to be construed as open-ended terms (i.e., meaning “including, but not limited to,”) unless otherwise noted. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., “such as”) provided herein, is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

[0084] Embodiments are described herein, including the best mode known to the inventors for carrying out the invention. Variations of those embodiments may become apparent to those of ordinary skill in the art upon reading the foregoing description. Skilled artisans will use such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the claims unless otherwise indicated herein or otherwise clearly contradicted by context.

Claims

1. A method for normalizing elevated blood pressure in a heart chamber, the method comprising: penetrating an atrial septum between a left atrium and a right atrium of a heart and creating an opening in the atrial septum having a first diameter; inserting a tissue retaining device through the opening into the left atrium; engaging the atrial septum with the tissue retaining device; ablating and separating tissue with a treatment mechanism to form an intra-atrial pressure relief opening; and permitting blood to flow from the left atrium to the right atrium through the intra-atrial pressure relief opening to reduce left atrial pressure.
2. The method of claim 1, further comprising advancing a dilation catheter over a guide wire through the opening to radially expand the opening to a second diameter, wherein the second diameter is larger than the first diameter.
3. The method of claim 1, further comprising delivering RF energy, ultrasound energy, laser energy, visible light energy, or UV light energy to the tissue using the treatment mechanism.
4. The method of claim 1, wherein the treatment mechanism has a circular probe.
5. The method of claim 1, wherein the tissue retaining device has a plurality of graspers, wherein

the graspers engage the atrial septum from the left atrium.

6. The method of claim 1, wherein the tissue retaining device has a plurality of legs, wherein the legs engage the atrial septum from the left atrium.

7. The method of claim 1, further comprising delivering medication or a combination of medications to ablated tissue around the intra-atrial pressure relief opening.

8. The method of claim 1, further comprising delivering an anti-proliferative or immunosuppressive medication to tissue around the intra-atrial pressure relief opening.

9. The method of claim 1, wherein the intra-atrial pressure relief opening has a diameter of 5 mm to 10 mm.

10. The method of claim 1, wherein the intra-atrial pressure relief opening has a diameter of 4 mm to 8 mm.

11. The method of claim 1, further comprising applying an adhesive, a fixative, or an adhesion prevention substance to tissue around the intra-atrial pressure relief opening.
