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(54) **Title**: RADIOFREQUENCY ABLATION CATHETER DEVICE

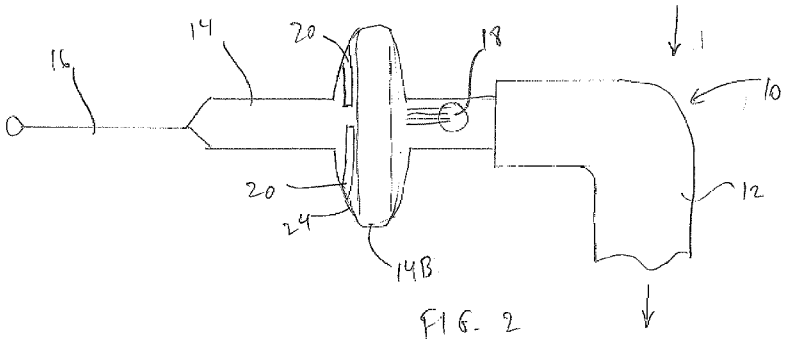

FIG. 2

(57) **Abstract**: A radiofrequency ablation catheter device has a balloon catheter that may be expanded at some portions along its length through inflation. The catheter may have one or more differently compliant sections along its length, or may have a generally noncompliant body with one or more separate compliant portions overlying it, which compliant sections/portions may be separately inflated. One section of the catheter is expanded into a disk-like configuration with a circular, somewhat planar surface that is oriented orthogonally to the direction of the guide wire and facing in a distal direction. The catheter bears one or more RF electrodes that are capable of conducting RF energy and may be positioned on the surface of the balloon catheter such that they take a circular configuration on the planar surface. The unexpanded balloon catheter is advanced longitudinally through the blood vessel to the relevant location within the body lumen, inflated and pushed distally. To contact the inner surface of the lumen such that the electrodes ablate the nerve activity circumferentially at the desired location, such as around the renal artery ostium of the aorta, to ablate the nerve activity that leads specifically to the kidney.

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RADIOFREQUENCY ABLATION CATHETER DEVICE

FIELD OF INVENTION

[0001] The present invention generally relates to a medical apparatus and method for treating vascular tissues through application of radiofrequency energy, and more particularly to an ablation apparatus for treating tissues in a patient by delivering therapeutic radiofrequency energy through a catheter and/or stent to a specific lesion site for nerve or atherosclerotic ablation.

BACKGROUND OF THE INVENTION

[0002] Arteries are the tube-shaped blood vessels that carry blood away from the heart to the body's tissues and organs and are each made up of outer fibrous layer, smooth muscle layer, connecting tissue and the inner lining cells (endothelium). Certain arteries comprise complex structures that perform multiple functions. For example, the aorta, which is a complex structure that performs multiple functions, houses a network of nerves that are helpful in maintaining vascular tone throughout the entire body and each individual organ, sodium and water excretion or reabsorption, and blood pressure control. The electrical activity to these nerves originates within the brain and the peripheral nervous system.

[0003] The kidneys have a dense afferent sensory and efferent sympathetic innervation and are thereby strategically positioned to be the origin as well as the target of sympathetic activation. Communication with integral structures in the central nervous system occurs via afferent sensory renal nerves. Renal afferent nerves project directly to a number of areas in the central nervous system, and indirectly to the anterior and posterior hypothalamus, contributing to arterial pressure regulation. Renal sensory afferent nerve activity directly influences sympathetic outflow to the kidneys and other highly innervated organs involved in cardiovascular control, such as the heart and peripheral blood vessels, by modulating posterior hypothalamic activity. These afferent and efferent nerves traverse via the aorta to their destination end-organ site.

[0004] Some studies suggest that conditions such as renal ischemia, hypoxia, and oxidative stress result in increased renal afferent activity. Stimulation of renal afferent nerves, which may be caused by metabolites, such as adenosine, that are formed during ischemia, uremic toxins, such as urea, or electrical impulses, increases reflex in sympathetic nerve activity and blood pressure.

[0005] An increase in renal sympathetic nerve activity increases renin secretion rate, decreases urinary sodium excretion by increasing renal tubular sodium reabsorption, and decreases renal blood flow and glomerular filtration rate. When nervous activity to the kidney is increased, sodium and water are reabsorbed, afferent and efferent arterioles constrict, renal function is reduced, and blood pressure rises.

[0006] Renin release may be inhibited with sympatholytic drugs, such as clonidine, moxonidine, and beta blockers. Angiotensin receptor blockers substantially improve blood pressure control and cardiovascular effects. However, these treatments have limited efficacy and adverse effects. In addition, many hypertensive patients present with resistant hypertension with uncontrolled blood pressure and end organ damage due to their hypertension.

[0007] Patients with renal failure and those undergoing hemodialysis treatment exhibit sustained activation of the sympathetic nervous system, which contributes to hypertension and increased cardiovascular morbidity and mortality. Signals arising in the failing kidneys seem to mediate sympathetic activation in chronic renal failure. Toxins circulating in the blood as a result of renal failure cause excitation of renal afferent nerves and may produce sustained activation of the sympathetic nervous system.

[0008] Abrogation of renal sensory afferent nerves and renal efferent nerves has been demonstrated to reduce both blood pressure and organ-specific damage caused by chronic sympathetic overactivity in various experimental models. Hence, functional denervation of the human kidney by targeting both efferent sympathetic nerves and afferent sensory nerves appears to be a valuable treatment strategy for hypertension and perhaps other clinical conditions characterized by increased overall nerve activity and particularly renal sympathetic nerve. Functional denervation in human beings may also reduce the potential of hypertension related end organ damage.

[0009] Destruction or reduction in size of cellular tissues in situ has been used in the treatment of many diseases and medical conditions, both alone and as an adjunct to surgical removal procedures. This procedure is often less traumatic than surgical procedures and may be the only alternative where other procedures are unsafe or ineffective. This method, known as ablative treatment, applies appropriate heat to the tissues and causes them to shrink and tighten. Ablative treatment devices have the advantage of using a destructive energy that is rapidly dissipated and reduced to a nondestructive level by conduction and convection forces of circulating fluids and other natural body processes.

[0010] In many medical procedures, it is important to be able to ablate the undesirable tissue in a controlled and focused way without affecting the surrounding desirable tissue. Over the years, a large number of minimally invasive methods have been developed to selectively destroy specific areas of undesirable tissues as an alternative to resection surgery. There are a variety of techniques with specific advantages and disadvantages, which are indicated and contraindicated for various applications.

[0011] In one technique, elevated temperature (heat) is used to ablate tissue. When temperatures exceed 60°C, cell proteins rapidly denature and coagulate, resulting in a lesion. The lesion can be used to resect and remove the tissue or to simply destroy the tissue, leaving the ablated tissue in place. Heat ablation can also be performed at multiple locations to provide a series of ablations, thereby causing the target tissue to die and necrose. Subsequent to heating, the necrotic tissue is absorbed by the body or excreted.

[0012] Electrical currents may be used to create the heat for ablation of the tissue. Radiofrequency ablation (RF) is a high temperature, minimally invasive technique in which an active electrode is introduced in the undesirable tissue and a high frequency alternating current of up to 500 kHz is used to heat the tissue to coagulation. Radiofrequency (RF) ablation devices work by sending alternating current through the tissue, creating increased intracellular temperatures and localized interstitial heat.

[0013] RF treatment exposes a patient to minimal side effects and risks, and is generally performed after first locating the tissue sites for treatment. RF energy, when coupled with a temperature control mechanism, can be supplied precisely to the apparatus-to-tissues contact site to obtain the desired temperature for treating a tissue. By heating the tissue with RF power applied through electrode tips emerging from a controlled radio-frequency (RF) instrument, the tissue is ablated.

[0014] The theory behind and practice of RF heat lesion has been known for decades, and a wide range of RF generators and electrodes for accomplishing such practice exist. RF therapeutic protocol has been proven to be highly effective when used by electrophysiologists for the treatment of tachycardia, by neurosurgeons for the treatment of Parkinson's disease, and by neurosurgeons and anesthetists for other RF procedures such as Gasserian ganglionectomy for trigeminal neuralgia and percutaneous cervical cordotomy for intractable pains.

[0015] Denervation of the kidney can be accomplished via the renal artery ostium of the aorta, namely the orifice of the branch off the aorta that opens into the renal artery. Ablation of nerve

activity at the renal artery ostium will not affect blood flow from the aorta into the renal artery but will cause the desired effect of denervation of the kidney. One problem in the art, however, is the providing of a treatment surface that can reach all of the desired treatment areas, such as the area circumferentially surrounding the renal artery ostium. While the use of a catheter to deploy energy may be known, it has been difficult to provide ablation about the entire opening of the ostium of an aortic branch blood vessel, such as the renal artery, so as to provide optimal uniform treatment.

[0016] There is an urgent need in the art to develop an approach to effectively ablate the nerve function within the kidney by means of disrupting nerve activity leading to the kidney. This mechanism may be accomplished by ablation of nerve activity at the level of the aorta and specifically at the level of the renal artery ostium. Such an approach would provide the advantage of improving volume status within the body and reducing blood pressure.

[0017] It is desirable to provide an apparatus and system for ablating the nerve function within the kidney by attacking the renal nerve via the renal artery ostium of the aorta.

SUMMARY OF THE INVENTION

[0018] In general, it is an object of the present invention to provide a method and an improved medical ablation apparatus for generating heat, to effectively ablate the nerve function directed to the kidney of a subject or patient.

[0019] It is another object of the present invention to deliver electrical energy, such as RF (radiofrequency) energy, to the inner layer of the aortic wall for ablation of aortic nerve activity.

[0020] It is a further object of the present invention to deliver electrical energy, such as RF (radiofrequency) energy, to the inner layer of the aortic wall, specifically at the renal artery ostium of the aorta, for ablation of aortic nerve activity specifically leading to the kidney.

[0021] It is a further object of the present invention to measure nerve activity at the level of the aorta and within the renal artery so as to determine the success of the ablation procedure.

[0022] The present invention is directed to a device, system and method for delivering radiofrequency energy, to the inner layer of a body lumen, particularly the aorta, specifically surrounding the renal artery ostium of the aorta, using a nonconductive catheter.

[0023] In one embodiment, the device comprises a balloon catheter, e.g., cylindrically shaped, that may be expanded at some portions along its length through inflation. In one embodiment, the balloon catheter is a noncompliant catheter that generally does not expand but has one or

more separate compliant portions overlying the noncompliant catheter, which compliant portions may be separately or individually expandable through inflation. In another embodiment, the balloon catheter is a noncompliant catheter that generally does not expand but has one or more different compliant sections along its length, with each section having a different level of compliancy, to allow certain portions thereof to be expanded through inflation more than other portions thereof. In a further embodiment, the balloon catheter is a noncompliant catheter that generally does not expand but has one or more different compliant sections along its length, with each section having a different levels of compliancy, to allow certain portions thereof to be expanded through inflation more than other portions thereof, and also has one or more separate compliant portions overlying the catheter, which overlying compliant portions may be separately or individually expandable through inflation.

[0024] The device is movable between a non-deployed position and a deployed position. In the non-deployed position, the balloon catheter is unexpanded. In its non-deployed position, the balloon catheter may be advanced longitudinally through the blood vessel, e.g., over a guide wire and through a tube-like guiding catheter, to the relevant location within the body lumen, such as within the aorta, and into the desired position within the inner circumference of the vessel, such as at the renal artery ostium of the aorta.

[0025] In one embodiment, the device bears one or more electrodes that are capable of conducting RF energy and that come in contact with the body tissue. In one embodiment, the one or more electrodes are positioned in a circular configuration on a portion of the balloon catheter when the device is in its deployed position. If more than one electrode is used, then the circularly configured electrodes can be positioned such that, when the device is in a deployed position, the electrodes together have a circular configuration or are oriented concentrically. The electrodes are to be contacted against the inner surface of the lumen, e.g., the aorta, for example, at the renal artery ostium, such that the electrodes ablate the nerve activity circumferentially around the renal artery ostium.

[0026] When the device is in its deployed position, the compliant segment of the balloon catheter, called the balloon segment, is expanded such that it has a disk-like configuration with a circular, somewhat planar surface that is oriented orthogonally to the direction of the guide wire and facing in a distal direction. The one or more electrodes having a circular configuration are situated on the balloon segment of the device when the device is in its deployed position, i.e., on the distally-facing surface of the expanded catheter segment. This distally-facing surface of the balloon segment can be pressed up against the renal artery ostium of the aorta, such that

electrodes that are positioned in a circular configuration may be made to contact the renal artery ostium of the aorta.

[0027] Heat is then generated to the electrodes by supplying a suitable RF energy source to the apparatus, and the ablation is performed for the ablation of nerve activity, e.g., at the renal artery ostium, such as nerve activity that leads specifically to the kidney. Positioning the circularly-configured RF elements such that they are situated circumferentially around the opening to the renal artery ensures improved delivery of the RF energy to the designated location at the level of the aortic wall. By including multiple RF elements in a single catheter system, more complete nerve ablation may ensue.

[0028] A mechanism may also be provided in the device design for positioning and securing the device at the desired location within the vessel, e.g., the aorta, such that the electrodes can operate at the precise location, namely around the renal artery ostium.

[0029] In one embodiment, the positioning mechanism comprises a guide wire and unexpanded section of the balloon catheter that is inserted at least partially into the entrance to the renal artery and remains there. If there is a guiding catheter overlying the expandable catheter, the guiding catheter is then withdrawn proximally, and the balloon catheter segment is then inflated. The sheath or a guiding catheter is then advanced distally such that its distal edge presses against the proximally-facing surface of the expanded catheter segment, thereby allowing the RF electrodes on the distally-facing surface of the expanded catheter segment to be positioned against the renal artery ostium so that they may perform their ablative function.

[0030] In another embodiment, the positioning mechanism comprises a separately compliant portion of the balloon catheter, namely a separately inflatable portion that is situated distally of the balloon segment that projects into the entrance to the renal artery, called the positioning segment. This positioning segment of the balloon catheter is inserted at least partially into the entrance of the renal artery and is then inflated, not to the extent of the balloon catheter segment but only approximately to the diameter of the renal artery, so as to prevent the balloon catheter from being moved distally or proximally relative to the renal artery, so as to allow the device to hold its position within the renal artery relative to the aorta. When the device is so positioned by virtue of the inflatable balloon in the positioning segment of the balloon catheter, the circular RF electrodes may be positioned against the renal artery ostium so that they may perform their ablative function. In one embodiment, before the positioning segment of the balloon catheter is expanded, the distal edge of the sheath or guiding catheter presses against the proximally-facing

surface of the expanded catheter segment, thereby allowing the RF electrodes on the distally-facing surface of the expanded balloon catheter segment to be positioned against the renal artery ostium

[0031] In yet another embodiment, the positioning mechanism comprises an imaging catheter at the distal end of the balloon catheter that allows the user to properly center and position the balloon catheter within the renal artery. The imaging catheter allows the user to view exactly where the renal artery ostium is located.

[0032] Once the device has been properly positioned, e.g., by one of the positioning means described above, the balloon segment of the balloon catheter is expanded. When the expanded balloon segment of the balloon catheter has been properly positioned, the distally-facing surface of the expanded balloon segment of the balloon catheter rests against the inside surface edges of the aorta, allowing the RF electrodes to be positioned against the aortic wall surrounding the renal artery ostium.

[0033] Also included in this design is a means to measure renal nerve afferent and efferent nerve activity prior to and following RF nerve ablation. By measuring renal nerve activity post procedure, a degree of certainty is provided that proper nerve ablation has been accomplished. Renal nerve activity will be measured through the same electrode mechanism as that required for energy delivery at the level of the renal artery ostium, but also along the renal artery positioning balloon.

[0034] In addition to the above noted functions, the device comprises a mechanism for cooling the aortic wall in order to limit potential damage to the endothelial surface of the aorta while ablative energy is effectively transmitted to the adventitial layer. This cooling mechanism is by means of chilled material used to inflate the device, thus providing protection to the aortic wall at the level of the energy delivery.

[0035] The present invention is also directed to a method for radio-frequency (RF) heat ablation of tissue through the use of one or more circularly-shaped RF electrodes, which are mounted on an expandable portion that is at the distal end of a catheter within a sheath. In a first step of the invention, the catheter may be inserted into the body via a natural orifice, a stoma or a surgically created opening that is made for the purpose of inserting the catheter, and insertion of the catheter may be facilitated with the use of a guide wire or a generic support structure or visualization apparatus. The catheter is advanced through the body to the relevant location, such as in the aorta at the location of the ostium of the renal artery.

[0036] In the next step, the device must be positioned at the renal artery ostium of the aorta. This positioning can be done via a positioning mechanism, as discussed herein. In one embodiment, a positioning member may assist the user in determining where the renal artery ostium is.

[0037] In the next step of the invention, once the catheter is at the relevant location, a portion of the catheter is expanded, and the expanded portion and the RF electrodes that are mounted thereon are positioned against the inner surface of the aorta, at the ostium of the desired branch artery. In one embodiment, the RF electrodes are positioned about the opening of the renal artery so as to surround the renal artery ostium.

[0038] In the next step of the invention, RF energy is applied to the RF electrodes that are mounted on the wire frame or stent in order to effect changes in the target tissue. Heat is generated by supplying a suitable energy source to the apparatus, which is comprised of at least one electrode that is in contact with the body tissues through the wire frame or stent. Additionally, coolant -- either stagnant or circulating -- may be employed to cool the inner surface of the vessel wall. This coolant function may provide a form of protection or insulation to the inner vessel wall surface during RF energy activation and heat transfer.

[0039] In one embodiment, the ablation is performed for the ablation of aortic nerve activity that leads specifically to the kidney.

[0040] Other features and advantages of the present invention will become apparent from the following detailed description examples and figures. It should be understood, however, that the detailed description and the specific examples while indicating preferred embodiments of the invention are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description

BRIEF DESCRIPTION OF THE DRAWINGS

[0041] Embodiments of the invention will be understood and appreciated more fully from the following detailed description in conjunction with the figures, which are not to scale, in which like reference numerals indicate corresponding, analogous or similar elements, and in which:

[0042] Figure 1 shows a side view of a first embodiment of a device for delivering radiofrequency energy to the renal artery ostium;

[0043] Figure 2 shows a side view of the first embodiment of the device for delivering radiofrequency energy to the renal artery ostium in a deployed position;

[0044] Figure 3 shows a front end view of the first embodiment of the device for delivering radiofrequency energy to the renal artery ostium in a deployed position; and

[0045] Figure 4 shows a side view of a second embodiment of a device for delivering radiofrequency energy to the renal artery ostium.

DETAILED DESCRIPTION OF THE INVENTION

[0046] As used herein, "proximal" refers to a portion of an instrument closer to an operator, while "distal" refers to a portion of the instrument farther away from the operator.

[0047] As used herein, the singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise. For example, the term "a wire" includes one or more wires and can be considered equivalent to the term "at least one wire."

[0048] The term "subject" or "patient" refers in one embodiment to a mammal including a human in need of therapy for, or susceptible to, a condition or its sequelae. The subject or patient may include dogs, cats, pigs, cows, sheep, goats, horses, rats, and mice and humans.

[0049] Figure 1 is a side view drawing of one embodiment of a device 10 for delivering radiofrequency energy to the walls of a body lumen. In one embodiment, radiofrequency energy is delivered to the walls of the renal artery or aorta. In one embodiment of the device 10, radiofrequency energy is delivered using a nonconductive catheter.

[0050] In one embodiment, the device 10 includes a substantially tubular catheter 12, called a guiding catheter, namely a long, thin, tube-like device, having proximal and distal openings, preferably constructed from a nonconductive material. The guiding catheter 12 can be any type of catheter, as are well known to those in the art, having a proximal end for manipulation by an operator and a distal end for operation within a patient. The distal end and proximal end preferably form one continuous piece. In a preferred embodiment, guiding catheter 12 is nonconductive. As will be discussed in greater detail below, guiding catheter 12 is used as a delivery system for delivering a balloon catheter bearing radiofrequency electrodes to the desired site for nerve ablation.

[0051] In one embodiment, device 10 also comprises a balloon catheter 14, e.g., cylindrically shaped, that is formed of a material, such as a polymer, as is well known in the art that allows it to be expanded at some portions along its length through inflation. In one embodiment, balloon

catheter 14, when in a non-deployed configuration, has an outer diameter that is smaller than the inner diameter of guiding catheter 12 so as to allow balloon catheter 14 to pass easily through guiding catheter 12 into the patient. In certain embodiments, balloon catheter 14 moves within and relative to guiding catheter 12 with low friction, such that guiding catheter 12 can be retracted from balloon catheter 14 at the appropriate time.

[0052] In another embodiment, balloon catheter 14, as is known in the art, has a small diameter annulus therethrough to allow it to be threaded over a guide wire 16 and advanced into the patient, e.g., through guiding catheter 12. In one embodiment, as is known in the art, guide wire 16, such as one having 0.035" thickness, may first be inserted into the patient's vascular system, e.g. through the groin, and advanced to the desired location. Next, tube-like guiding catheter 12 is inserted into the patient and threaded over guide wire 16 to the desired location. In preferred embodiments, device 10 is advanced to the desired location within the patient's vascular system with, e.g., a rapid exchange (RX) or over-the-wire wire (OTW) delivery system with a 0.035" or smaller guide wire 16 is employed for the device. Radiographic contrast media may be injected at the beginning of the procedure to assist in manipulation and positioning of the instruments.

[0053] Balloon catheter 14, in an unexpanded condition, is advanced longitudinally through the blood vessel, e.g., over guide wire 16, through guiding catheter 12 to the relevant location within the body lumen, such as within the aorta, and into the desired position within the inner circumference of the vessel, such as at the renal artery ostium of the aorta. Balloon catheter 14 in its unexpanded, non-deployed position may be positioned or encapsulated within a guiding catheter 12, which functions as a retractable sheath at the end of device 10.

[0054] In one embodiment, balloon catheter 14 is a noncompliant catheter that generally does not expand but has one or more different compliant sections along its length, with each section having a different level of compliancy, to allow certain portions thereof to be expanded through inflation more than other portions thereof. For example, as shown in Fig. 1, balloon catheter 14 has sections 14A, 14B and 14C along its distal end, with each of sections 14A, 14B and 14C having a different level of compliancy. In one embodiment, section 14B of balloon catheter 14 is formed of a very compliant material that may be expanded, while sections 14A and 14C of balloon catheter 14 are formed of a very non-compliant material that it essentially non-expandable. The materials of balloon catheter 14 sections 14A, 14B and 14C are bonded together to form one unitary balloon catheter device 14.

[0055] In another embodiment, the balloon catheter may be a noncompliant catheter that generally does not expand but has one or more separate compliant portions overlying, as a sleeve or overlay, the noncompliant catheter which compliant portions may be separately or individually expandable through inflation. In this embodiment, referring to Fig. 4, the entire balloon catheter 14' is formed of a very non-compliant material that is essentially non-expandable (although in this embodiment, the base catheter can no longer truly be referred to as a "balloon" catheter since it does not expand as a balloon does). However, balloon catheter 14' has a portion, i.e., section 14B' between sections 14A' and 14C', near its distal end, that is overlaid with an annular, sleeve-like balloon overlay 15, that is formed of a very compliant material and may be expanded.

[0056] In a further embodiment, the balloon catheter is a noncompliant catheter that generally does not expand but has one or more different compliant sections along its length, with each section having a different levels of compliancy, to allow certain portions thereof to be expanded through inflation more than other portions thereof, and also has one or more separate compliant portions overlying the catheter, which overlying compliant portions may be separately or individually expandable through inflation.

[0057] Balloon catheter 14 is selectively movable between a non-deployed, unexpanded condition and a deployed, expanded condition, and back to the non-deployed, unexpanded condition. In the non-deployed condition, as shown in Figs. 1 and 4, balloon catheter 14 of device 10 is unexpanded, i.e., in a collapsed configuration, and may be advanced longitudinally through the blood vessel, e.g., over guide wire 16 and through guiding catheter 12, to the relevant location within the body lumen, such as within the aorta, and into the desired position within the inner circumference of the vessel, such as at the renal artery ostium of the aorta. Once at the desired position, guiding catheter 12 may be retracted, revealing balloon catheter 14.

[0058] Balloon catheter 14, once guiding catheter 12 has been retracted, may be expanded into its deployed position for operation within the patient. In the deployed condition, as shown in Figs. 2 and 3, the expandable portions of balloon catheter 14 are expanded. Balloon catheter 14 may have a port 18, as is known in the art, through which air (or another gas) may be introduced to enable inflation of its inflatable portions.

[0059] The largest diameter of balloon catheter 14 in its deployed condition is larger than the inner diameter of guiding catheter 12, such that balloon catheter 14 cannot be expanded into its deployed condition while still encased within guiding catheter 12, and such that balloon catheter

14 in its deployed condition cannot be retracted back into guiding catheter 12. It is desirable for balloon catheter 14 to be deflated back to its non-deployed position for retraction back into the guiding catheter 12 after ablation is complete and when it is desired to withdraw the device from the patient.

[0060] In one embodiment, when balloon catheter 14 is in its deployed position, as shown in Fig. 2, the compliant segment of balloon catheter 14 (section 14B in Fig. 1), called the balloon segment, is expanded to have a much larger diameter than the non-compliant segments 14A and 14C, such that the balloon segment 14B has a disk-like configuration with a circular, somewhat planar surface 24 that is oriented orthogonally to the direction of guide wire 16 and facing in a distal direction. It is this distally-facing surface 24 of the expanded balloon segment 14B that provides the ablating surface when contacting the renal artery ostium of the aorta.

[0061] In another embodiment, shown in its non-deployed, unexpanded condition in Fig. 4, when balloon catheter 14' is expanded into its deployed position, similar to as shown in Fig. 2, separately compliant annular balloon portion 15 that overlays section 14B' of balloon catheter 14' in Fig. 4, called the balloon overlay, is expanded to have a much larger diameter than the non-compliant segments 14A' and 14C', such that the balloon overlay 25 has a disk-like configuration with a circular, somewhat planar surface that is oriented orthogonally to the direction of guide wire 16 and facing in a distal direction, similar to as shown in Fig. 2. It is this distally-facing surface of the expanded balloon overlay 25 that provides the ablating surface when contacting the renal artery ostium of the aorta.

[0062] In one embodiment, balloon catheter 14 of device 10 comprises one or more electrodes 20 that are capable of conducting RF energy and that come in contact with the body tissue. In one embodiment, one or more electrodes 20 are positioned in a circular configuration on a portion of balloon catheter 14 when device 10 is in its deployed position, such that electrodes 20 provide essentially 360° coverage at the renal artery ostium. If more than one electrode 20 is used, then electrodes 20 can be positioned such that, when device 10 is in a deployed position, electrodes 20 together have a circular configuration or are oriented concentrically, such that they together provide essentially 360° coverage around a target area.

[0063] When balloon catheter 14 is in its deployed position, one or more electrodes 20 are situated on the balloon segment 14B of device 10 when device 10 is in its deployed position, i.e., on the distally-facing surface 24 of the expanded balloon segment 14B (or of the expanded balloon overlay 15), as shown in Figs. 2 and 3. This distally-facing surface 24 of the balloon

segment 14B can be pressed up against and contacted with the inner surface of the aorta at the juncture of the renal artery, such that electrodes 20 that are positioned, e.g., in a circular configuration, would be situated about the renal artery ostium of the aorta. When electrodes 20 are contacted against the inner surface of the lumen, e.g., the aorta, for example, at the renal artery ostium, electrodes 20 ablate the nerve activity circumferentially around the renal artery ostium.

[0064] As shown in Fig. 1, RF electrodes 20 are attached to balloon catheter 14 as a means to deliver RF energy to the body lumen, as well as temperature and nerve activity sensing. In certain embodiments, device 10 has several RF electrodes 20 that are attached to the surface of balloon catheter 14 separately but that, when oriented together in a deployed configuration, are positioned in a circular configuration on the distally-facing surface 24 of the balloon segment 14B. In one embodiment, as shown in Fig. 3, device 10 has four arc-shaped electrodes 20. In one embodiment, electrodes 20 are attached to and positioned on the outside of balloon catheter 14 at segment 14B. In another embodiment, electrodes 20 are attached to and positioned on balloon overlay 15.

[0065] When balloon catheter 14 is in its non-deployed configuration, RF electrodes 20 lie substantially flat against the surface of balloon catheter 14 and have a relatively low profile thereagainst. Electrodes 20 can be attached to the surface of the balloon segment of the balloon catheter, e.g., by gluing, bonding, or a wire cage attachment. Thus, when balloon catheter 14 is advanced distally through guiding catheter 12 for use within the patient, or when balloon catheter 14 is advanced proximally through guiding catheter 12 for withdrawal from the patient, RF electrodes 20 do not interfere with or impede the progress of balloon catheter 14 through guiding catheter 12.

[0066] When balloon catheter 14 is in its non-deployed configuration, as shown in Fig. 1, the four arc-shaped electrodes 20 are in an overlapping relationship with respect to each other. Then, when balloon catheter 14 is expanded into its deployed configuration, the four arc-shaped electrodes 20 slide or glide past each other and become oriented into a circular configuration, as shown in Fig. 3. In this configuration, Electrodes 20 may also have an attachment means that loosely connects them to the surface of balloon catheter 14 and assists in rearranging them back into their resting configuration when balloon catheter 14 is deflated into its non-deployed configuration. The attachment also insures proper fixation of electrodes 20 to the surface of balloon catheter 14. In one embodiment, as shown in Fig. 3, the attachment means may be a

shape memory wire 26 that helps reposition electrodes 20 to the surface of the balloon segment 14B of balloon catheter 14 with respect to each other when balloon catheter 14 is deflated.

[0067] In one embodiment, there are one or more elongated wires (not shown) that run along the side of balloon catheter 14 to which RF electrodes 20 are attached to conduct RF energy from an external RF control unit to RF electrodes 20. In one embodiment, all RF electrodes 20 are attached to the same wire such that they are made to operate together. The electrodes 20 may also have wires that loosely connect them, in order for them to be connected electrically. In another embodiment, there are multiple wires, each of which is attached to as few as one electrode 20 so as to conduct RF energy from the RF control unit to the individual RF electrodes 20. The RF electrodes 20 can deliver their energy simultaneously or can deliver energy in a sequential or other desired pattern.

[0068] When balloon catheter 14is changed into its deployed position by inflation, electrodes 20 that are positioned on the surface of balloon catheter 14 become situated on the distally-facing surface 24 of the balloon segment 14B. The purpose of positioning electrodes 20 on one side of the distally-facing surface 24 of the balloon segment 14B is so that electrodes 20 could be positioned or pressed up against the renal artery ostium, for more effective ablation of, e.g., the renal nerve. Guiding catheter 12 is advanced distally such that its distal edge presses against the proximally-facing surface of the expanded balloon segment 14B, thereby allowing RF electrodes 20 on the distally-facing surface 24 of the expanded balloon segment 24 to be pushed distally and positioned against the renal artery ostium so that they may perform their ablative function. When electrode-bearing distally-facing surface 24 of the balloon segment 14B is pressed up against the renal artery ostium of the aorta, electrodes 20 that are positioned in a circular configuration may be made to contact the renal artery ostium of the aorta. Heat is then generated to electrodes 20 by supplying a suitable RF energy source to device 10, and the ablation is performed for the ablation of nerve activity, such as nerve activity that leads specifically to the kidney.

[0069] In one embodiment, device 10 has a positioning element or mechanism for positioning and securing device 10 at the desired location within the vessel, e.g., the aorta. Such a mechanism is necessary so that electrodes 20 can operate at the precise location, namely around the renal artery ostium. Otherwise, if device 10 is not properly positioned, electrodes 20 can ablate tissue that is not intended to be harmed, causing irreversible damage. In the embodiment wherein RF electrodes 20 are circularly configured, the positioning mechanism should properly

center electrodes 20 circumferentially around the renal artery ostium, namely the opening to the renal artery.

[0070] In a first embodiment, the positioning mechanism comprises guide wire 16 and the distal, unexpanded section 14A of balloon catheter 14 that is inserted at least partially into the entrance to the renal artery and remains there. Once this is done, guiding catheter 12 overlying balloon catheter 14 is withdrawn proximally, and balloon segment 14B of balloon catheter 14 is then inflated. Guiding catheter 12 is then advanced distally such that its distal edge presses against the proximally-facing surface of expanded balloon segment 14B, thereby allowing RF electrodes 20 on the distally-facing surface 24 of expanded balloon segment 14B to be positioned against the renal artery ostium so that they may perform their ablative function.

[0071] In another embodiment, the positioning mechanism comprises a separately compliant portion of balloon catheter 14, namely the section 14A of balloon catheter 14 that is situated distally of balloon segment 14B. In this embodiment, section 14A of balloon catheter 14 is separately inflatable, and, because it projects into the entrance to the renal artery, is called the positioning segment. This positioning segment 14A of balloon catheter 14 is inserted at least partially into the entrance of the renal artery and is then inflated, not to the extent of the balloon segment 14B but only approximately to the diameter of the renal artery, so as to prevent balloon catheter 14 from being moved distally or proximally relative to the renal artery, so as to allow device 10 to hold its position within the renal artery relative to the aorta. When device 10 is so positioned by virtue of the inflatable balloon in positioning segment 14A of balloon catheter 14, circularly configured RF electrodes 20 may be positioned against the renal artery ostium so that they may perform their ablative function. In one embodiment, before positioning segment 14A of balloon catheter 14 is expanded, the distal edge of guiding catheter 12 presses against the proximally-facing surface of the expanded balloon segment 14B, thereby allowing RF electrodes 20 on the distally-facing surface 24 of expanded balloon segment 14B to be positioned against the renal artery ostium.

[0072] In certain embodiments, the positioning mechanism may comprise both an unexpanded section of balloon catheter 14 at its distal end and a separately inflatable portion that is situated distally of the balloon segment. The unexpanded section of balloon catheter 14 may be inserted at least partially into the entrance to the renal artery to help guide the device to the correct location in the aorta, and the separately inflatable portion of balloon catheter 14 may be inflated within the renal artery so to hold the device in its position within the renal artery relative to the aorta.

[0073] In one embodiment, the positioning mechanism includes an imaging catheter at the distal end of balloon catheter 14 that allows the user to view exactly where the renal artery ostium is and to properly position the device within the renal artery, through use of visual means. In one embodiment, the imaging catheter comprises a proximal end that is external to the patient and manipulated by the user along with the operating end of the device, and also comprises a distal end that is situated at the distal end of balloon catheter 14.

[0074] In these embodiments, the positioning element or mechanism operates to position balloon catheter 14 within the renal artery so that the circularly-configured RF electrodes 20 can be pressed against the renal artery ostium, and specifically around the opening to the branch renal artery off the ostium. This is accomplished by insertion of the unexpanded distal end of balloon catheter 14 or the distal end of the imaging catheter at least partially into the entrance of the renal artery so as to serve, either by itself or by inflation of a balloon that is exposed from within, as an anchor for device 10 within the aorta so that RF electrodes 20 can perform their ablative function.

[0075] At the proximal end thereof, device 10 includes at least one port 18 for connection to a source of radiofrequency (RF) power. Device 10 can be coupled to a source of Radiofrequency (RF) energy, such as RF in about the 300 kilohertz to 500 kilohertz range. The electrodes are electrically coupled to the RF energy source through this port. Device 10 can be coupled to a source of air for inflation of the inflatable portions of balloon catheter 14. Device 10 may also be connected to a control unit for sensing and measurement of other factors, such as temperature, conductivity, pressure, impedance and other variables, such as nerve energy.

[0076] Device 10 may also be connected, either through port 18 or through a second port, to an air or fluid source. This port can be pneumatically or hydraulically coupled to a pump or other apparatus for inflation and deflation of the inflatable portions of balloon catheter 14. The port may also be used for inflation and deflation of the balloon overlay of balloon catheter 14', when it is present. The port may further be used for inflation and deflation of a balloon used in a positioning mechanism. There may be one port for all balloons or separate ports for one or more balloons. This same port may be used to circulate coolant to the inside of the balloon for the purpose of cooling the balloon during RF energy activation.

[0077] In one embodiment, RF electrodes 20 operate to provide radiofrequency energy for heating of the desired location during the nerve ablation procedure. Electrodes may be

constructed of any suitable conductive material, as is known in the art. Examples include stainless steel and platinum alloys.

[0078] RF electrodes 20 may operate in either bipolar or monopolar mode, with a ground pad electrode. In a monopolar mode of delivering RF energy, a single electrode is used in combination with an indifferent electrode patch that is applied to the body to form the other electrical contact and complete an electrical circuit. Bipolar operation is possible when two or more electrodes are used, such a two concentric electrodes. Electrodes 20 can be attached to an electrode delivery member, such as the wire frame, by the use of soldering or welding methods which are well known to those skilled in the art.

[0079] In the embodiment wherein the one or more arc-shaped RF electrodes 20 are oriented in a circular configuration, the diameter of the circular or arc-shaped RF electrodes 20 is determined by the width of the aortic artery branch for which denervation is desired. If the diameter of the RF electrode is smaller than the diameter of the aortic artery branch for which denervation is desired, the RF electrode would not actually be in contact with tissue, and no ablation would occur. For example, when aortic denervation is desired at the level of the renal artery ostium, which is approximately 6-7 mm in diameter at the ostium of the aorta, the diameter of the circular RF electrodes must be at least that distance, i.e., 7 mm, in order to properly provide ablation surrounding the renal artery ostium. In another embodiment, the length of each of four arc-shaped electrodes 20 is approximately 2-3 mm.

[0080] In another embodiment, the diameter of RF electrodes 20 may be calculated with reference to the renal artery ostium. For example, if it is desired that the RF energy be applied at least approximately 2 mm from each edge of the renal artery ostium, the RF electrodes that surround the imaging catheter may have a 10-14 mm diameter surrounding the renal artery ostium.

[0081] Each electrode 20 can be disposed to treat tissue by delivering Radiofrequency (RF) energy. The radiofrequency energy delivered to the electrode has a frequency of about 5 kilohertz (kHz) to about 1 GHz. In specific embodiments, the RF energy may have a frequency of about 10 kHz to about 1000 MHz; specifically about 10 kHz to about 10 MHz; more specifically about 50 kHz to about 1 MHz; even more specifically about 300 kHz to about 500 kHz.

[0082] In a preferred embodiment, electrodes 20 can be operated separately or in combination with each other as sequences of electrodes disposed in arrays. Treatment can be directed at a single area or several different areas of a vessel by operation of selective electrodes.

[0083] An electrode selection and control switch may include an element that is disposed to select and activate individual electrodes.

[0084] RF power source may have multiple channels, delivering separately modulated power to each electrode. This reduces preferential heating that occurs when more energy is delivered to a zone of greater conductivity and less heating occurs around electrodes that are placed into less conductive tissue. If the level of tissue hydration or the blood infusion rate in the tissue is uniform, a single channel RF power source may be used to provide power for generation of lesions relatively uniform in size.

[0085] RF energy delivered through the electrodes to the tissue causes heating of the tissue due to absorption of the RF energy by the tissue and ohmic heating due to electrical resistance of the tissue. This heating can cause injury to the affected cells and can be substantial enough to cause cell death, a phenomenon also known as cell necrosis. For ease of discussion for the remainder of this application, cell injury will include all cellular effects resulting from the delivery of energy from the electrodes up to, and including, cell necrosis. Cell injury can be accomplished as a relatively simple medical procedure with local anesthesia. In one embodiment, cell injury proceeds to a depth of approximately 1-5 mms from the surface of the mucosal layer of sphincter or that of an adjoining anatomical structure.

[0086] In certain embodiments, balloon catheter 14 comprises an insulation pad that is situated between each RF electrode 20 and the surface of balloon catheter 14, for example so as to protect balloon catheter 14 from the direct effects of the RF energy. In another embodiment, balloon catheter 14 may contain a circulating coolant so as to cool the balloons and protect it from the direct effects of the RF energy.

[0087] Also included in this design is a means to measure renal nerve afferent activity prior to and following RF nerve ablation. By measuring renal nerve activity post procedure, a degree of certainty is provided that proper nerve ablation has been accomplished. Renal nerve activity will be measured through the same mechanism as that required for energy delivery and electrodes on the renal artery placed positioning balloon.

[0088] Nerve activity may be measured by one of two means. Proximal renal nerve stimulation will occur by means of transmitting an electrical impulse to the catheter positioned

within the proximal segment of the renal artery. Action potentials will be measured from the segment of the catheter situated within the more distal portion of the renal artery. The quantity of downstream electrical activity as well as the time delay of electrical activity from the proximal to distal electrodes will be provide a measure of residual nerve activity post nerve ablation. The second means of measuring renal nerve activity will be to measure ambient electrical impulses prior to and post nerve ablation within a site more distal within the renal artery.

[0089] In another embodiment, RF electrodes 20 operate to provide radiofrequency energy for both heating and temperature sensing. Thus, in this embodiment, the RF elements can be used for heating during the ablation procedure and can also be used for sensing of nerve activity prior to ablation as well as after ablation has been done.

[0090] Each electrode 20 may be coupled to at least one sensor or control unit capable of measuring such factors as temperature, conductivity, pressure, impedance and other variables. For example, the device may have a thermistor that measures temperature in the lumen, and a thermistor may be a component of a microprocessor-controlled system that receives temperature information from the thermistor and adjusts wattage, frequency, duration of energy delivery, or total energy delivered to the electrode.

[0091] The device 10 can be coupled to a visualization apparatus, such as a fiber optic device, a fluoroscopic device, an anoscope, a laparoscope, an endoscope or the like. In one embodiment, devices coupled to the visualization apparatus are controlled from a location outside the body, such as by an instrument in an operating room or an external device for manipulating the inserted catheter.

[0092] In another embodiment, device 10 may be constructed with markers that assist the operator in obtaining a desired placement, such as radio-opaque markers, etchings or microgrooves. Thus, device 10 may be constructed to enhance its imageability by techniques such as ultrasounds, CAT scan or MRI. In addition, radiographic contrast material may be injected through a hollow interior of the catheter through an injection port, thereby enabling localization by fluoroscopy or angiography.

[0093] The invention herein also comprises a method for ablation of renal artery nerve function within the aorta using the device described hereinabove. The method is performed by a system including a device 10 and a control assembly (not shown). Although the method is described serially, the steps of the method can be performed by separate elements in conjunction

or in parallel, whether asynchronously, in a pipelined manner, or otherwise. There is no particular requirement that the method be performed in the same order in which this description lists the steps, except where so indicated.

[0094] At flow point a, electrical energy port is coupled to a source of electrical energy. The patient is positioned on a treatment table in an appropriate position for the insertion of a catheter.

[0095] At step b, the visualization port is coupled to the appropriate visualization apparatus, such as a fluoroscope, an endoscope, a display screen or other visualization device. The choice of visualization apparatus is responsive to judgments by medical personnel.

[0096] At step c, the therapeutic energy port is coupled to the source of RF energy.

[0097] In step d, suction and inflation apparatus is coupled to the irrigation and aspiration control ports so that the catheter balloon may be later be inflated.

[0098] At step e, guide wire 16 and guiding catheter 12 or tube are lubricated and introduced into the patient. Insertion may be percutaneous or through a surgically created arteriotomy or during an open surgical procedure.

[0099] In step f, the most distal end of balloon catheter 14 is lubricated and introduced into the patient. In a preferred embodiment, the balloon is completely deflated during insertion. Balloon catheter 14 may be inserted into the body lumen through its outer surface and is threaded through the vessel until the balloon portion is situated adjacent to the vessel to be treated.

[00100] In step g, the position of the device 10 is checked using visualization apparatus coupled to the visualization port. This apparatus can be continually monitored by medical professionals throughout the procedure.

[00101] At step h, a positioning mechanism, if used, is positioned such that it protrudes into the ostium of the renal or another artery.

[00102] At step i, guiding catheter 12 is retracted, allowing balloon catheter 14 to be expanded.

[00103] In step j, the irrigation and aspiration control ports are manipulated so as to inflate the balloon of the positioning mechanism, causing device 10 to be rendered stable in its position within the lumen, and so as to inflate the balloon segment 14B of balloon catheter 14.

[00104] In step k, guiding catheter 12 is advanced distally so that its distal-most edge presses against the proximally-facing surface of the expanded balloon segment 14B and pushing the distally-facing surface 24 of the expanded balloon segment 14B against the renal artery ostium.

[00105] In a step l, electrodes 20 on the distally-facing surface 24 of the expanded balloon segment 14B are selected using the electrode selection and control switch. In a preferred embodiment, all electrodes 20 are deployed at once. In another preferred embodiment, electrodes 20 may be individually selected. This step may be repeated at any time prior to step l.

[00106] In a step m, the therapeutic energy port is manipulated so as to cause a release of energy from electrodes 20. The duration and frequency of energy are responsive to judgments by medical personnel. This release of energy creates a circular pattern of lesions at the renal artery ostium.

[00107] In a step n, the irrigation and aspiration control port is manipulated so as to cause the positioning device balloon and balloon segment 14B to deflate.

[00108] In a step o, guiding catheter 12 is advanced over deflated balloon catheter 14.

[00109] In a step p, the positioning device, balloon catheter 14 is withdrawn from the renal artery ostium, into guiding catheter 12.

[00110] In a step q, guiding catheter 12 is withdrawn from the patient.

[00111] Having described preferred embodiments of the invention with reference to the accompanying drawings, it is to be understood that the invention is not limited to the precise embodiments, and that various changes and modifications may be effected therein by those skilled in the art without departing from the scope or spirit of the invention as defined in the appended claims.

CLAIMS

1. A nerve ablation device, comprising:

a balloon catheter having at least one inflatable portion, which, when inflated, has a larger diameter than when not inflated and has a distally facing planar surface; and

at least one radiofrequency electrode positioned on an outer surface of the at least one inflatable portion of the balloon catheter, said at least one radiofrequency electrode being positioned such that said at least one radiofrequency electrode assumes a circular configuration on said distally facing planar surface of said inflatable balloon catheter portion when said inflatable balloon catheter portion is inflated.

2. The nerve ablation device according to claim 1, wherein each said at least one inflatable portion has a different level of compliancy than an adjoining inflatable portion and is separately inflatable.

3. The nerve ablation device according to claim 1, wherein each said at least one inflatable portion comprises an inflatable balloon overlying a non-inflatable portion of said balloon catheter and is separately inflatable.

4. The nerve ablation device according to claim 1, wherein said device is movable between a non-deployed position and a deployed position.

5. The nerve ablation device according to claim 4, wherein said balloon catheter is not inflated when said device is in said non-deployed position, and wherein said balloon catheter is inflated when said device is in said deployed position.

6. The nerve ablation device according to claim 5, wherein when said device is in said non-deployed position, said balloon catheter may be advanced longitudinally to a desired position within a body lumen over a guide wire and through an annular guiding catheter.

7. The nerve ablation device according to claim 6, wherein once said device is in the desired position within a body lumen, said guiding catheter may be retracted to reveal said balloon catheter.

8. The nerve ablation device according to claim 7, wherein once said inflatable portion of said balloon catheter is expanded, said at least one radiofrequency electrode on said distally facing planar surface may be contacted against body tissue.

9. The nerve ablation device according to claim 7, wherein said at least one inflatable portion of said balloon catheter when inflated has a proximally facing surface, and wherein said annular guiding catheter can be pushed distally against said proximally facing planar surface so

as to force contact between said at least one radiofrequency electrode on said distally facing planar surface and said body tissue.

10. The nerve ablation device according to claim 1, wherein said at least one radiofrequency electrodes are capable of conducting RF energy to a body tissue which they contact.

11. The nerve ablation device according to claim 1, wherein said at least one radiofrequency electrodes may be affixed to the outer surface of the at least one inflatable portion of the balloon catheter by a shape memory material.

12. The nerve ablation device according to claim 1, wherein said at least one radiofrequency electrodes are positioned in an overlapping relationship with one another on the outer surface of said inflatable portion of the balloon catheter when said inflatable balloon catheter portion is not inflated and are movable to said circular configuration on said distally facing planar surface when said inflatable balloon catheter portion is inflated.

13. The nerve ablation device according to claim 1, further comprising a positioning mechanism.

14. The nerve ablation device according to claim 13, wherein said positioning mechanism comprises an expandable balloon.

15. The nerve ablation device according to claim 14, wherein said expandable balloon comprises a second inflatable portion of said balloon catheter, situated distally of said at least one inflatable portion.

16. The nerve ablation device according to claim 1, further comprising at least one port, said at least one port is used to for balloon inflation and/or for connection to a control unit.

17. A method for performing ablation of a nerve at an artery ostium of the aorta in a subject in need thereof, comprising:

inserting into said aorta a balloon catheter having (a) at least one inflatable portion that when inflated has a larger diameter than when not inflated and has a distally facing planar surface, and (b) at least one radiofrequency electrode positioned on an outer surface of the at least one inflatable portion such that said at least one radiofrequency electrode assumes a circular configuration on said distally facing planar surface when said inflatable balloon catheter portion is inflated;

inflating said inflatable portion of said balloon catheter;

positioning said circularly configured at least one radiofrequency electrode about the artery ostium of the aorta; and

delivering radiofrequency energy through at least one radiofrequency electrode to a designated location within the renal arterial wall.

18. The method of claim 17, further wherein inflating said inflatable portion comprises inflating an inflatable balloon overlying a non-inflatable portion of said balloon catheter.

19. The method of claim 17, further comprising advancing said balloon catheter longitudinally to a desired position within a body lumen over a guide wire and through an annular guiding catheter.

20. The method of claim 19, further comprising retracting said guiding catheter to reveal said balloon catheter before said step of inflating said inflatable portion of said balloon catheter.

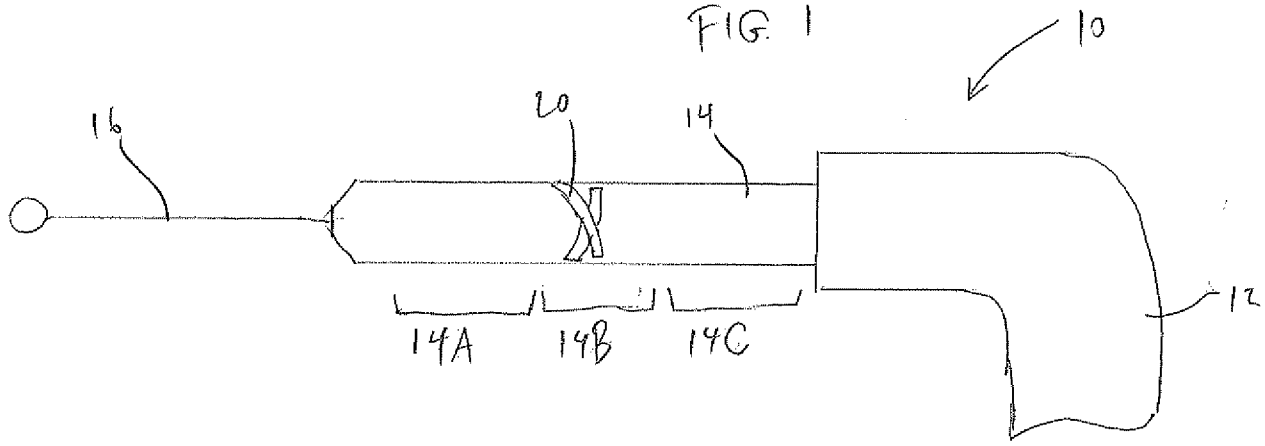
21. The method of claim 17, further comprising, wherein once said inflatable portion of said balloon catheter is expanded, contacting said at least one radiofrequency electrode on said distally facing planar surface against body tissue at the artery ostium of the aorta.

22. The method of claim 21, wherein said at least one inflatable portion of said balloon catheter when inflated has a proximally facing surface, and wherein said step of contacting comprises pushing said guiding catheter distally against said proximally facing planar surface so as to force contact between said at least one radiofrequency electrode on said distally facing planar surface and said body tissue.

23. The method of claim 17, further comprising positioning said balloon catheter in the aorta prior to inflating said inflatable portion.

24. The method of claim 17, wherein said positioning comprises inflating a second inflatable portion of said balloon catheter, situated distally of said at least one inflatable portion, within the aorta.

FIG. 1



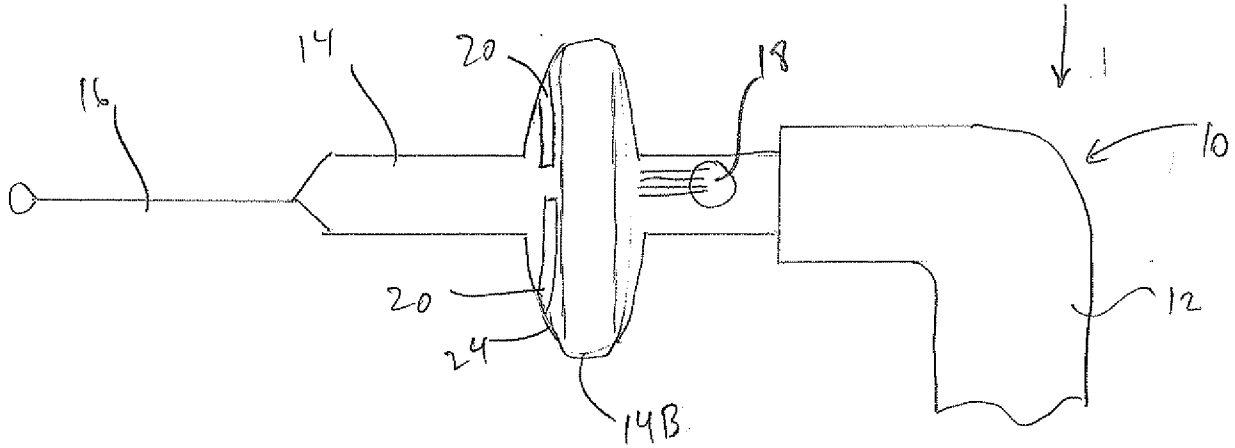


FIG. 2

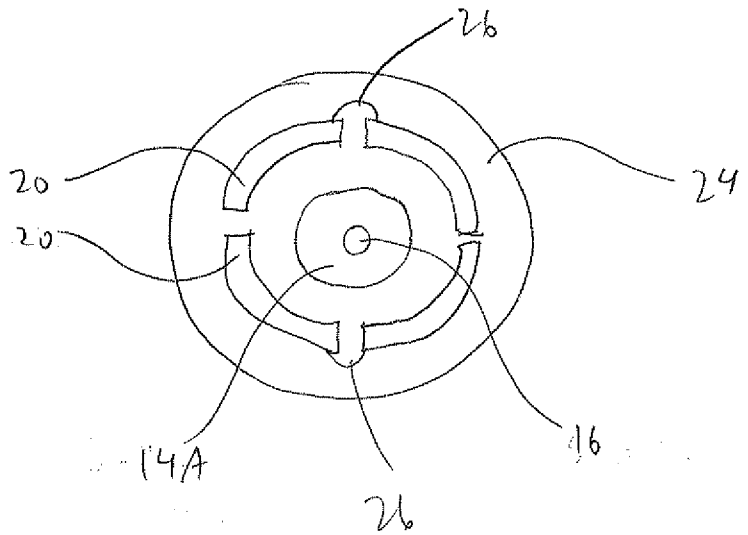
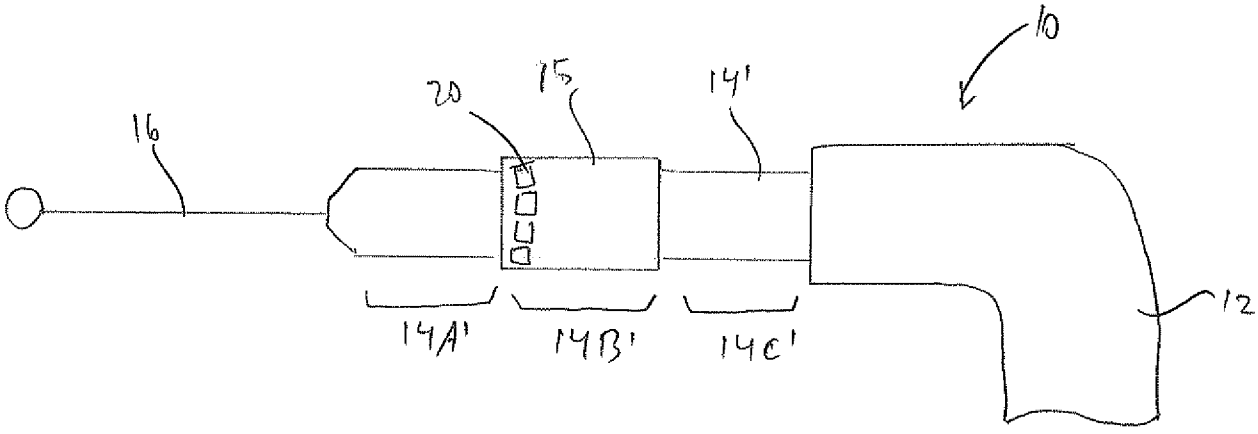


FIG. 3

FIG. 4



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/042664

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 18/14 (2012.01)
USPC - 606/33
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)
IPC(8) - A61B 18/14, 18/18 (2012.01)
USPC - 606/33, 41, 101

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2005/0165388 A1 (BHOLA) 28 July 2005 (28.07.2005) entire document	1-5, 10, 12-18, 21, 23-24 --- 6-9, 11, 19, 20, 22
Y	US 2004/0215186 A1 (CORNELIUS et al) 28 October 2004 (28.10.2004) entire document	6-9, 19, 20, 22
Y	US 2003/0074039 A1 (PUSKAS) 17 April 2003 (17.04.2003) entire document	11

☐ 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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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 August 2012	01 OCT 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)