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(54) **IONTOPHORESIS DRUG DELIVERY SYSTEM AND METHOD FOR DENERVATION OF THE RENAL SYMPATHETIC NERVE AND IONTOPHORETIC DRUG DELIVERY**

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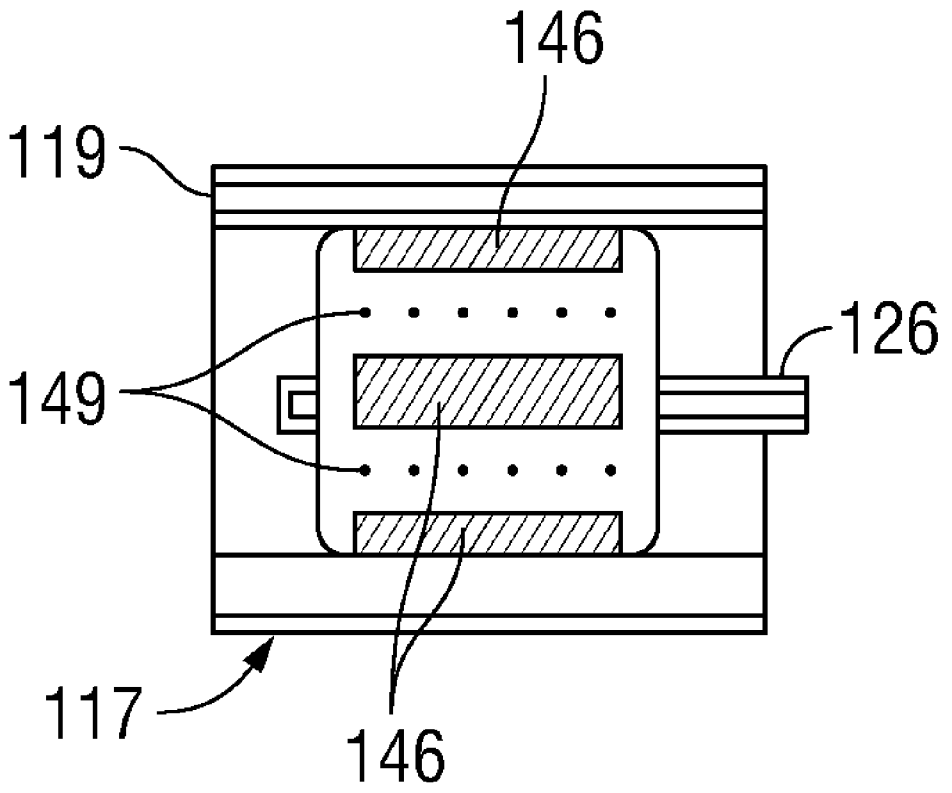
(57) **ABSTRACT**

A system for denervation of the renal sympathetic nerve and iontophoresis drug delivery includes an iontophoresis catheter fitted with a drug coated balloon. The balloon contacts the vessel wall when inflated. One or more electrodes are associated with a surface of the balloon, and may be disposed on an outer surface of the balloon. The electrodes are operably coupled to an energy source configured to produce a bipolar or monopolar electric field between two balloon electrodes and/or between one balloon electrode and another electrode placed in contact with the patient's body. The drug-delivery catheter produces an electric potential gradient within adjacent tissue, that, facilitates iontophoresis delivery of a drug. The catheter can also include a store of one or more drugs to be delivered to the targeted tissue.



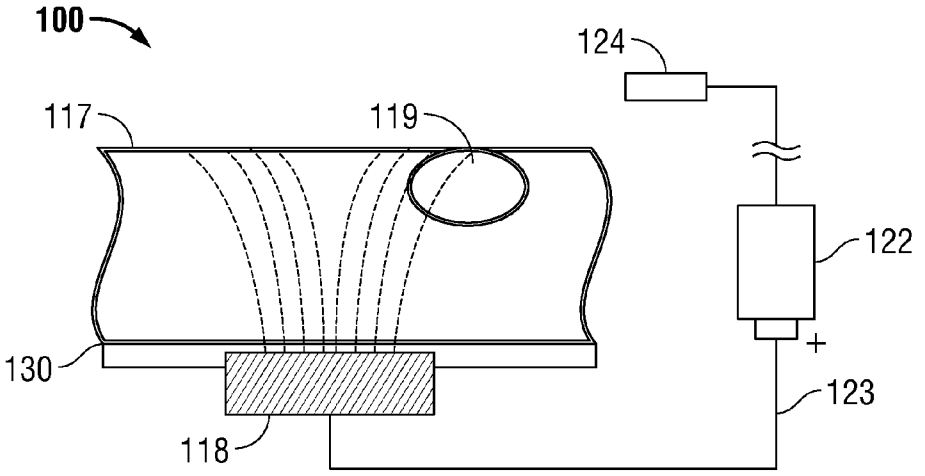


FIG. 1

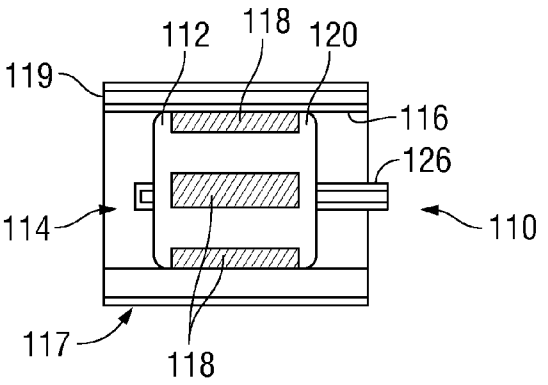


FIG. 2

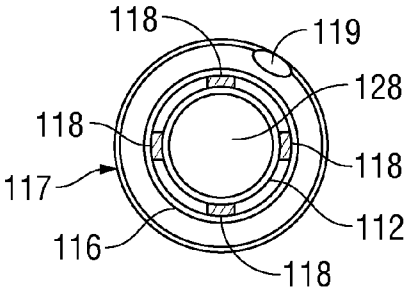


FIG. 3

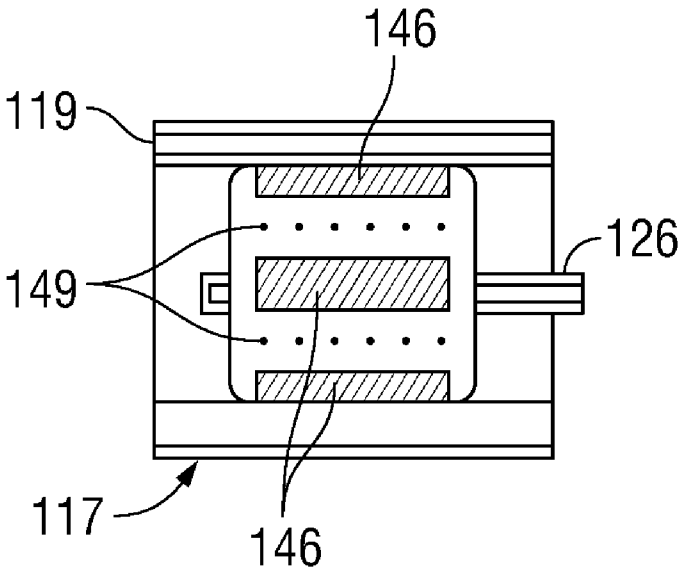


FIG. 4

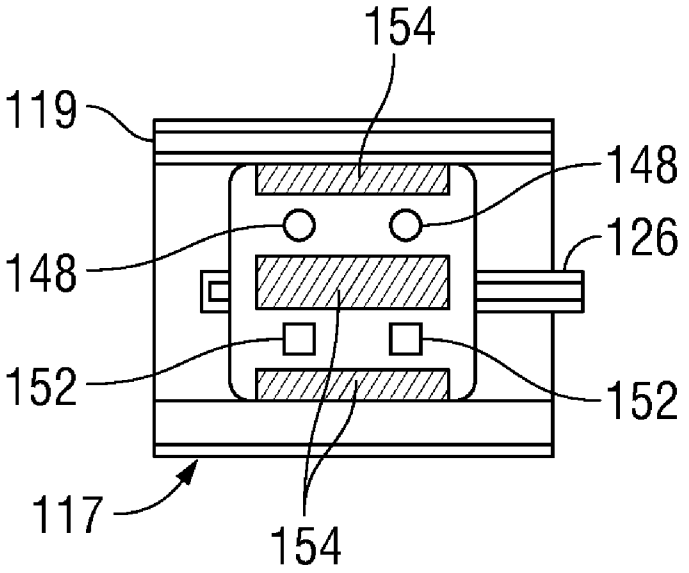


FIG. 5

IONTOPHORESIS DRUG DELIVERY SYSTEM AND METHOD FOR DENERVATION OF THE RENAL SYMPATHETIC NERVE AND IONTOPHORETIC DRUG DELIVERY

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of, and priority to, U.S. Provisional Patent Application No. 61/473,569 filed on Apr. 8, 2011, the entire contents of which are incorporated by reference herein for all purposes.

BACKGROUND

[0002] 1. Technical Field

[0003] The present disclosure is related to renal denervation and endovascular drug delivery. More particularly, the present disclosure is related to an iontophoretic catheter system and method for denervation of the renal sympathetic nerve and iontophoretic drug delivery.

[0004] 2. Description of Related Art

[0005] Chronic elevated blood pressure, or hypertension, is a significant cause of heart disease and death and afflicts millions worldwide. Generally, one having chronic blood pressure of over 140 mm Hg systolic and 90 mm Hg diastolic is classified as suffering from hypertension. It is believed that renal sympathetic nerve activity initiates, and sustains, the elevation of blood pressure. The renal nerves are bundled around the renal artery, which is readily accessible via the femoral artery. Renal denervation has been found to reduce blood pressure.

[0006] There exist several disadvantages of conventional methods of renal denervation for the treatment of hypertension. Conventional methods involve the application of intense heat to several discrete sites of the renal artery, which can be very painful to the patient and increase recovery times. Additionally, the application of intense heat may produce flow limiting stenosis. Another disadvantage has to do with not knowing the exact location of the nerve bundle within the artery wall. Therefore, multiple sites must be treated in order to increase the probability that the renal nerve function will be attenuated.

[0007] Another disadvantage includes the difficulty in maintaining apposition with the blood vessel wall during treatment. Also, conventional renal denervation treatment systems and methods require moving the catheter longitudinally as well as rotating the catheter after the treatment of each site to avoid the creation of flow-limiting stenosis. Therefore, systems and methods for renal nerve denervation which overcome the disadvantages of conventional renal nerve denervation systems and methods would be a welcome advance.

SUMMARY

[0008] According to the present disclosure there is provided an iontophoresis drug delivery system and method for denervation of the renal sympathetic nerve and iontophoresis drug delivery. The system includes an iontophoresis catheter configured to be placed interventionally within a patient. In some embodiment, the iontophoresis catheter is configured to be placed in the lumen of the renal artery between the descending aorta and/or the one or more renal artery branches adjacent to the kidney. The drug delivery catheter includes a balloon near its distal tip or end that, when inflated, contacts the vessel wall circumferentially.

[0009] One or more electrodes are associated with a surface of the balloon, and in some embodiments, the electrodes are disposed on an outer surface of the balloon. The electrodes are operably coupled to an energy source. The energy source is configured to produce a bipolar or monopolar electric field between two balloon electrodes (e.g., bipolar mode) and/or between one balloon electrode and another electrode placed in contact with a part of the patient's body, such as, without limitation, the skin, a blood vessel, and so forth (e.g., monopolar mode). The energy source may include a control system that is configured to regulate and monitor energy delivery and/or monitor a related parameter (tissue impedance, contact temperature, tissue temperature, and the like). In some embodiments, the energy source provides constant-current direct current (DC) energy.

[0010] The electric field may be continuous or pulsed direct current. During use, the disclosed catheter produces an electric potential gradient within adjacent tissue (e.g., blood vessel wall, nerves, and surrounding tissues), that, in turn, facilitates iontophoresis delivery of a drug.

[0011] The disclosed catheter can also include a store of one or more drugs to be delivered to the targeted tissue. In embodiments according to the present disclosure, the drugs can be provided as a coating on the outer surface of the balloon. In some embodiments according to the present disclosure, the balloon is perforated (e.g., a weeping balloon) such that administration of the drug to the balloon lumen causes its transfer to the outer surface of the balloon adjacent to the electrode(s).

[0012] In some embodiments according to the present disclosure, the drugs are provided within wells associated with the outer surface of the balloon. The wells are covered with a covering layer that is disrupted when the balloon is inflated, thereby releasing the drug inside the well into the vicinity of the electrode(s). Other embodiments for providing one or more drugs to the outer surface of the balloon are envisioned within the teachings of the present disclosure. Therefore, the methods described herein are provided as example methods and are not to be construed as limiting.

[0013] According to an aspect of the present disclosure, there is provided an iontophoresis drug delivery system. The system includes an energy source; a catheter; a balloon disposed at a distal end of the catheter; at least one electrode disposed on a surface of the balloon and operably coupled to the energy source; and a drug supply operatively associated with the balloon. The drug supply is configured to selectively release a drug. The drug supply includes at least one drug. The at least one drug is selected from the group consisting of guanethidine, epinephrine, dimethyl sulfoxide (DMSO), and combinations thereof. The energy source is configured to deliver direct current to the at least one electrode.

[0014] In some embodiments, an outer surface of the balloon includes at least one well for storing the drug supply. The at least one well includes a covering layer configured for being disrupted.

[0015] In some embodiments, the balloon includes a plurality of perforations in fluid communication with an interior of the balloon.

[0016] In some embodiments, the drug supply is a coating provided on an outer surface of the balloon.

[0017] According to another aspect of the present disclosure, there is provided an iontophoresis drug delivery system.

The system includes an energy source; a catheter; an expandable member disposed at a distal end of the catheter; at least one electrode disposed on the expandable member and operably coupled to the energy source; and a drug supply operatively associated with the expandable member. The drug supply is configured to selectively release the drug. The drug supply includes at least one drug. The at least one drug is selected from the group consisting of guanethidine, epinephrine, dimethyl sulfoxide (DMSO), and combinations thereof. The energy source is configured to deliver direct current to the at least one electrode.

[0018] The expandable member is selected from the group consisting of a balloon and a frame. An outer surface of the balloon includes at least one well for storing the drug supply. The at least one well includes a covering layer configured for being disrupted. The balloon includes a plurality of perforations in fluid communication with an interior of the balloon. The drug supply is a coating provided on an outer surface of the balloon.

[0019] According to still another aspect of the present disclosure, there is provided an iontophoresis drug delivery catheter. The catheter includes a balloon disposed at a distal end of the catheter; at least one electrode disposed on a surface of the balloon and operably coupled to an energy source; and a drug supply operatively associated with the balloon. The drug supply is configured to selectively release the drug. The drug supply includes at least one drug. The at least one drug is selected from the group consisting of guanethidine, epinephrine, dimethyl sulfoxide (DMSO), and combinations thereof.

[0020] An outer surface of the balloon includes at least one well for storing the drug supply. The at least one well includes a covering layer configured for being disrupted. The balloon includes a plurality of perforations in fluid communication with an interior of the balloon. The drug supply is a coating provided on an outer surface of the balloon.

[0021] According to yet another aspect of the present disclosure, there is provided a method for the treatment of renal hypertension. The method includes placing a drug-delivery catheter in to the lumen of the renal artery; producing an electric potential between the catheter and the nerves adjacent to the renal artery wall; and administering a drug to the nerves via the electric potential to attenuate the activity of said nerves.

[0022] According to another aspect of the present disclosure, there is provided a method to determine if a hypertensive patient may benefit from a renal denervation procedure. The method includes measuring blood pressure of the hypertensive patient; administering guanethidine to the hypertensive patient; determining whether the blood pressure of the hypertensive patient changed subsequent to guanethidine administration; comparing a change in blood pressure to a predetermined value; and performing a renal denervation procedure on the hypertensive patient if the change in blood pressure exceeds the predetermined value.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other advantages will become more apparent from the following detailed description of the various embodiments of the present disclosure with reference to the drawings wherein:

[0024] FIG. **1** is a block diagram of an iontophoresis catheter system for denervation of the renal nerve having an iontophoresis catheter according to an embodiment of the present disclosure wherein the catheter is fitted with a drug coated balloon having one or more electrodes;

[0025] FIG. **2** is an enlarged view of the distal end of an iontophoresis catheter of the iontophoresis catheter system in accordance with an embodiment of the present disclosure;

[0026] FIG. **3** is a cross-sectional view of the distal end of the iontophoresis catheter shown in FIG. **2**;

[0027] FIG. **4** is an enlarged view of the distal end of an iontophoresis catheter in accordance with another embodiment of the present disclosure; and

[0028] FIG. **5** is an enlarged view of the distal end of iontophoresis catheter in accordance with yet another embodiment of the present disclosure.

DETAILED DESCRIPTION

[0029] Particular embodiments of the present disclosure are described hereinbelow with the accompanying notes and drawings; however, it is to be understood that the disclosed embodiments are merely examples of the disclosure, which may be embodied in various forms. The terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting Well-known and/or repetitive functions and constructions are not described in detail to avoid obscuring the present disclosure in unnecessary or redundant detail. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present disclosure in virtually any appropriately detailed structure.

[0030] As used herein, the term "proximal," as is traditional, shall refer to the end of the instrument that is closer to the user, while the term "distal" shall refer to the end that is farther from the user. As used herein, terms referencing orientation, e.g., "top", "bottom", "up", "down", "left", "right", "o'clock", and the like are used for illustrative purposes with reference to the figures and corresponding axes and features shown therein. It is to be understood that embodiments in accordance with the present disclosure may be practiced in any orientation without limitation. As used herein, the term "iontophoresis" refers to a drug delivery method in which an electrical current is used to stimulate drug-carrying ions to pass through intact tissue, such as a vessel wall. Like reference members may represent elements which may perform the same, similar, or equivalent functions.

[0031] In embodiments in accordance with the present disclosure, iontophoresis drug delivery systems and methods are provided. Each drug delivery system includes an iontophoresis catheter which may be introduced into a body lumen to deliver a drug, medicament, or other therapeutic substance to targeted tissue via iontophoresis. In one non-limiting example, the disclosed catheter may be introduced into the femoral artery, advanced into the renal artery, and positioned adjacent to the renal nerve bundle. Advantageously, an iontophoresis catheter in accordance with the present disclosure may enable the attenuation of renal sympathetic nerve function for the treatment of hypertension by targeted delivery of guanethidine to the renal nerve bundle. Other applications and other drugs are also envisioned.

[0032] With reference to FIGS. **1**, **2** and **3**, there is shown an example embodiment of a iontophoresis drug delivery system for denervation of the renal nerve having an iontophoresis catheter fitted with a drug coated balloon in accordance with the present disclosure. The iontophoresis drug delivery sys-

tem is designated generally by reference numeral **100**. The system **100** includes the iontophoresis catheter **110** that is configured to be placed in the lumen of the renal artery between the descending aorta, and/or the one or more of the renal artery branches adjacent to the kidney.

[0033] In the embodiment shown by FIG. **1**, the catheter **110** includes an expandable member or balloon **112** at or near its distal end **114** that, when inflated, circumferentially contacts the vessel wall **116**, such as the wall of the renal artery **117** in proximity to the renal nerve **119**. One or more electrodes **118** are associated with a surface of the balloon **112**. In the present embodiment, the electrodes **118** are disposed on an outer surface **120** of the balloon **112**. The electrodes **118** are operably coupled to an energy source **122** via at least one wire **123**. The energy source **122** is configured to produce a bipolar or monopolar electric field between two balloon electrodes **118** (e.g., bipolar mode) and/or between one balloon electrode **118** and another balloon electrode **118** placed in contact with a part of the patient's body, such as without limitation, the skin, a blood vessel, etc. (e.g., monopolar mode).

[0034] The energy source **122** may include a control system that is configured to regulate and monitor energy delivery and/or monitor a related parameter (tissue impedance, contact temperature, tissue temperature, and so forth). In some embodiments, the energy source **122** provides constant-current DC energy. A return electrode **124** may be included as shown in FIG. **1**.

[0035] The electric field generated by the system **100** and illustrated by the broken lines in FIG. **1** may be continuous or pulsed direct current. The electrodes **118** may be positioned in any pattern on the outer surface **120** of the balloon **112** to provide particular configurations of the electric field. The electrodes **118** may be positioned in a equally spaced pattern as shown by FIGS. **2** and **3**, and/or the electrodes **118** can be positioned in random locations on the outer surface **120** of the balloon **112**.

[0036] The electrodes **118** may be arranged in a manner such that the majority of the electric field generated penetrates the renal nerve **119** for optimum denervation of the renal nerve **119**. The electrodes **118** can also be arranged as shown in FIG. **1**, such that a tail end of the electric field generated penetrates the renal nerve **119**. As such, according to the present disclosure the electrodes **118** can be positioned on the outer surface **120** of the balloon **112** in accordance with the amount of electric field desired to penetrate the renal nerve **119**.

[0037] The balloon **112** or distal end **114** of the catheter **110** may also be moved along the interior of the vessel, such as the renal artery **117**, by pushing and pulling the catheter shaft **126**. The balloon **112** can be moved along the interior of the vessel prior to activation of the electrodes **118** or during activation of the electrodes **118**. The balloon **112** may also be moved along the interior of the vessel while it is fully inflated, partially inflated or deflated.

[0038] The balloon **112** and/or catheter, such as the catheter shaft **126**, can include one or more lumens to allow blood to flow from one side of the balloon **112** to the other in order to maintain kidney perfusion during denervation of the renal nerve and/or iontophoresis drug delivery. The one or more lumens, such as lumen **128** shown in FIG. **3**, allow the balloon **112** to be kept inflated for as long as needed to complete the denervation procedure, or any other desired procedure. Additionally, the depth of drug penetration in iontophoresis drug delivery is dependent in part upon the duration of the applied current.

[0039] During use, the disclosed catheter **110** produces an electric potential gradient within adjacent tissue (e.g., blood vessel wall, nerves, and surrounding tissues), that, in turn, facilitates iontophoresis delivery of a drug.

[0040] The disclosed iontophoresis drug delivery systems also include a store of one or more drugs to be delivered to the targeted tissue. Preferably, at least one drug is in an ionic form. For example, and without limitation, guanethidine is a drug known to attenuate the function of sympathetic nerves by inhibiting the release of norepinephrine (also known as noradrenaline). Guanethidine may be formulated in an ionic form with a +2 charge. Additionally or alternatively, other drugs may be utilized. For example, and without limitation, a drug may be combined with one or more secondary drugs to improve the speed of drug uptake (e.g. penetration or permeation enhancers such as dimethyl sulfoxide (DMSO)) or to prolong the local drug effect (e.g., vasovasorum constrictors such as epinephrine).

[0041] In some embodiments, the catheter **110** includes a supply of a drug (e.g., prior to drug delivery) and may be configured to facilitate the release thereof for iontophoresis delivery into a body lumen and/or surrounding tissue. In some embodiments, additionally or alternatively to other embodiments, the drug may be incorporated into a coating **130** (FIG. **1**) surrounding the outer surface **120** of the balloon **112**.

[0042] Additionally or alternatively to other embodiments, a balloon **140** of the iontophoresis drug delivery system **100** can be perforated (e.g., a weeping balloon), as shown by FIG. **4**, such that administration of the drug to a balloon lumen **142** from a drug supply via, for example, the catheter shaft **126**, causes a transfer of the drug from the inner volume of the balloon **140** to the outer surface **144** at or adjacent to the electrode(s) **146** via a plurality of perforations **149**. The drug supply may be external or outside the patient.

[0043] In the embodiment shown by FIG. **4**, the catheter shaft **126** can be sized to have approximately the same diameter as the inner surface of the balloon **140**. The inner surface of the balloon **140** includes at least one opening in fluid communication with an inner lumen **141** of the shaft **126**. The drug is delivered under pressure through the shaft **126** to the balloon **140** via the at least one opening (not explicitly shown). The drug is then forced out of the plurality of perforations **149** to the outer surface of the balloon **140**. The drug can also be delivered to the balloon **140** through a lumen other than the catheter shaft **126**.

[0044] In some embodiments, additionally or alternatively to the other embodiments, with reference to FIG. **5**, the drug is stored in one or more wells **148** disposed on the surface of a balloon **150**, each of which is covered by a covering layer **152**. When this covering layer **152** is disrupted, the drug inside the wells **148** is released into the vicinity of the electrode(s) **154**. The covering layer **152** may be disrupted by mechanical action (e.g., pressure applied by the balloon pressing against the blood vessel wall) or the application of heat (e.g., a metallic covering is melted by resistive heating through the application of electrical energy from the electrode(s) **154**).

[0045] The covering layer **152** is shown in a non-disrupted state for the bottom two wells in FIG. **5**, while the covering layer **152** for the top two wells has been disrupted, for illustrative purposes. In operation, all covering layers **152** are

likely to be disrupted at or about the same time during operation of the drug delivery system.

[0046] When the drug to be delivered is situated adjacent to the electrodes **118**, **146**, **154**, an electric field is applied between two or more electrodes. The ionic charge of the drug causes the drug molecules to follow the electric field, thereby entering the tissue at a faster rate than would occur by, e.g., simple diffusion. Rapid uptake of drug into the tissue may be enhanced by electroporation, whereby one or more high-voltage pulses are applied to open temporary pores in the tissue that, in turn, facilitate accelerated drug uptake. Additionally or alternatively, the direct current used for iontophoresis may be pulsed, since tissue impedance decreases with the frequency of the applied current. The delivery of current is primarily direct current, since the direction of ionic migration is dependent upon the polarity of the applied electric field. In some embodiments, an iontophoresis catheter in accordance with the present disclosure may advantageously be used to remove undesirable compounds, drugs, and toxins from targeted tissue.

[0047] The aforementioned embodiment describes a balloon catheter. Additional or alternative methods of producing approximately circumferential vessel wall apposition are also envisioned within the scope of the present disclosure. For example, and without limitation, in some embodiments the electrodes **118**, **146**, **154** may be mounted on an expandable wire frame resembling an umbrella frame. In some embodiments, the electrodes **118**, **146**, **154** may be mounted on a stent-like expandable member or frame.

[0048] Also disclosed is a method for the treatment of renal hypertension. The method includes placing a drug delivery catheter, such as the catheter **110** shown in FIG. **2**, into the lumen of the renal artery **117**. The method further includes producing an electric potential between the catheter and the nerves adjacent to the renal artery wall. The method further includes administering a drug, such as the drugs mentioned above, to the nerves via the electric potential, thereby attenuating the activity of the nerves.

[0049] Also disclosed is a method to determine if a hypertensive patient is likely to benefit from a renal denervation procedure. It is based upon the established properties of guanethidine, which may suppress sympathetic nerve function. The method include the steps of: (1) measuring a patient's blood pressure; (2) administering guanethidine to the patient, for example, oral tablet, injection, or intravascular delivery; (3) measuring changes in the patient's blood pressure following guanethidine administration; (4) comparing the change in blood pressure to a pre-determined value; and (5) performing a renal denervation procedure if the change in blood pressure exceeds the predetermined value.

[0050] The drug delivery systems and catheters in accordance with the present disclosure have at least the following advantages: (1) there is no heat produced and therefore the patient experiences no pain; (2) they do not produce flow-limiting stenosis; (3) the treatment is circumferential, and therefore only one application is needed to guarantee treatment of the renal nerve; and (4) the systems and catheters maintain apposition with the vessel wall during treatment.

[0051] The described embodiments of the present disclosure are intended to be illustrative rather than restrictive, and are not intended to represent every embodiment of the present disclosure. Further variations of the above-disclosed embodiments and other features and functions, or alternatives thereof, may be made or desirably combined into many other different systems or applications without departing from the spirit or scope of the disclosure as set forth herein and/or in the following claims both literally and in equivalents recognized in law.

What is claimed is:

1. An iontophoresis drug delivery system, comprising:
an energy source;
a catheter;
a balloon disposed at a distal end of the catheter;
at least one electrode disposed on a surface of the balloon and operably coupled to the energy source; and
a drug supply operatively associated with the balloon.

2. The iontophoresis drug delivery system in accordance with claim **1**, wherein the drug supply is configured to selectively release a drug.

3. The iontophoresis drug delivery system in accordance with claim **1**, wherein the drug supply includes at least one drug.

4. The iontophoresis drug delivery system in accordance with claim **3**, wherein the at least one drug is selected from the group consisting of guanethidine, epinephrine, dimethyl sulfoxide (DMSO), and combinations thereof.

5. The iontophoresis drug delivery system in accordance with claim **1**, wherein the energy source is configured to deliver direct current to the at least one electrode.

6. The iontophoresis drug delivery system in accordance with claim **1**, wherein an outer surface of the balloon includes at least one well for storing the drug supply.

7. The iontophoresis drug delivery system in accordance with claim **6**, wherein the at least one well includes a covering layer configured for being disrupted.

8. The iontophoresis drug delivery system in accordance with claim **1**, wherein the balloon includes a plurality of perforations in fluid communication with an interior of the balloon.

9. The iontophoresis drug delivery system in accordance with claim **1**, wherein the drug supply is a coating provided on an outer surface of the balloon.

10. An iontophoresis drug delivery system, comprising:
an energy source;
a catheter;
an expandable member disposed at a distal end of the catheter;
at least one electrode disposed on the expandable member and operably coupled to the energy source; and
a drug supply operatively associated with the expandable member.

11. The iontophoresis drug delivery system in accordance with claim **10**, wherein the drug supply is configured to selectively release the drug.

12. The iontophoresis drug delivery system in accordance with claim **10**, wherein the drug supply includes at least one drug.

13. The iontophoresis drug delivery system in accordance with claim **12**, wherein the at least one drug is selected from the group consisting of guanethidine, epinephrine, dimethyl sulfoxide (DMSO), and combinations thereof.

14. The iontophoresis drug delivery system in accordance with claim **10**, wherein the energy source is configured to deliver direct current to the at least one electrode.

15. The iontophoresis drug delivery system in accordance with claim **10**, wherein the expandable member is selected from the group consisting of a balloon and a frame.

16. The iontophoresis drug delivery system in accordance with claim **15**, wherein an outer surface of the balloon includes at least one well for storing the drug supply.

17. The iontophoresis drug delivery system in accordance with claim **16**, wherein the at least one well includes a covering layer configured for being disrupted.

18. The iontophoresis drug delivery system in accordance with claim **15**, wherein the balloon includes a plurality of perforations in fluid communication with an interior of the balloon.

19. The iontophoresis drug delivery system in accordance with claim **15**, wherein the drug supply is a coating provided on an outer surface of the balloon.

20. An iontophoresis drug delivery catheter, comprising:

a balloon disposed at a distal end of the catheter;

at least one electrode disposed on a surface of the balloon and operably coupled to an energy source; and

a drug supply operatively associated with the balloon.

21. The iontophoresis drug delivery catheter in accordance with claim **20**, wherein the drug supply is configured to selectively release the drug.

22. The iontophoresis drug delivery catheter in accordance with claim **20**, wherein the drug supply includes at least one drug.

23. The iontophoresis drug delivery catheter in accordance with claim **22**, wherein the at least one drug is selected from the group consisting of guanethidine, epinephrine, dimethyl sulfoxide (DMSO), and combinations thereof.

24. The iontophoresis drug delivery catheter in accordance with claim **20**, wherein an outer surface of the balloon includes at least one well for storing the drug supply.

25. The iontophoresis drug delivery catheter in accordance with claim **24**, wherein the at least one well includes a covering layer configured for being disrupted.

26. The iontophoresis drug delivery catheter in accordance with claim **20**, wherein the balloon includes a plurality of perforations in fluid communication with an interior of the balloon.

27. The iontophoresis drug delivery catheter in accordance with claim **20**, wherein the drug supply is a coating provided on an outer surface of the balloon.

28. A method for the treatment of renal hypertension, comprising:

placing a drug-delivery catheter in to the lumen of the renal artery;

producing an electric potential between the catheter and the nerves adjacent to the renal artery wall; and

administering a drug to said nerves via said electric potential to attenuate the activity of said nerves.

29. A method to determine if a hypertensive patient may benefit from a renal denervation procedure, comprising:

measuring the blood pressure of a hypertensive patient;

administering guanethidine to the hypertensive patient;

determining whether the blood pressure of the hypertensive patient changed subsequent to guanethidine administration;

comparing a change in blood pressure to a predetermined value; and

performing a renal denervation procedure on the hypertensive patient if the change in blood pressure exceeds the predetermined value.

30. A method for treating hypertension comprising:

placing a drug delivery catheter into a lumen of the renal artery;

producing an electric potential between the catheter and nerves adjacent a wall of the renal artery; and

administering a drug to the nerves via the electric potential, thereby attenuating the activity of the nerves.

* * * * *