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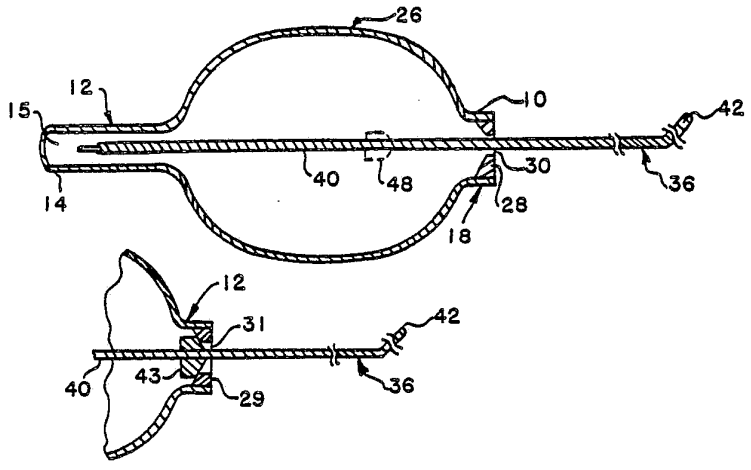
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(57) Abstract

A catheter device for accessing an internal body site along a small-diameter vessel path containing branch points in which the path may follow either the larger of smaller-diameter branch vessels. The device includes a catheter (12) having a distal-end inflatable balloon (26) and a distal-end aperture (30). A guidewire (36) in the device is designed to block, partially and/or completely, the aperture (30) at one or more axial wire positions, allowing the balloon to be inflated by fluid infusion into the catheter. In a catheter placement operation, the catheter is advanced along the vessel path toward the selected target site. When the leading end of the catheter encounters a branch point at which the path follows the larger-diameter vessel, the guidewire is moved to a position which partially or completely blocks the catheter aperture, and fluid is infused into the catheter to inflate the balloon. The catheter is then carried by hydrodynamic flow into the larger-diameter vessel.

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VALVED CATHETER DEVICE AND METHOD

1. Field of the Invention

This invention relates to catheter devices and methods for accessing internal body target sites along a small-vessel path.

2. Background of the Invention

Catheters are being used increasingly as a means for delivering diagnostic or therapeutic agents to internal target sites, and to perform mechanical functions on vasculatures that can be accessed through the circulatory system. For example, in angiography, catheters are designed to deliver a radiopaque agent to a target site within a blood vessel, to allow radiographic viewing of the vessel and blood flow characteristics near the release site. For the treatment of localized disease, such as solid tumors, catheters allow therapeutic agents to be delivered to the target site at a relatively high concentration, with reduction in drug delivery to non-target sites. Often the target site which one wishes to access is in a tissue, such as brain, liver or kidney, which requires catheter placement along a tortuous path through small vessels or ducts, such as arterial vessels or biliary ducts. Typically, the vessel path will include vessel branch points at which the path may follow either a

relatively larger-diameter, higher-flow branch vessel, or a relatively smaller, lower-flow branch vessel.

Heretofore, three general types of catheters have been developed for accessing internal target sites. One type is a torqueable catheter having relatively rigid tube construction and large-diameter lumen. In particular, the catheter tube may be formed as a braided fiber or wire laminate which has high torque properties. The distal portion of the catheter can be made narrower and more flexible by eliminating laminate windings or braid from this portion of the catheter, but this compromises torque transmission. Torqueable catheters of this type are generally too large in diameter and too rigid to be safely advanced through narrow, tortuous vessel or duct paths.

Another type of guidable catheter is a guidewire catheter which contains a single-lumen catheter used in conjunction with a flexible, torqueable, guidewire which can be moved axially within the catheter. In a typical catheter-placement operation, the wire is advanced along the vessel pathway, using wire torquing to orient the bent tip of the wire along the selected path, i.e., into and through selected branch vessels and/or regions of sharp bends. The catheter is then advanced along the wire with the wire held in place. The wire and catheter are alternately advanced in this manner until the target site is reached. Thereafter, the wire can be removed to allow fluid delivery through the catheter into the site. Since the wire can be both torqueable and quite flexible, and the catheter can be a thin-walled flexible tube, the catheter device is well suited for accessing sites via small-diameter tortuous paths.

Another general class of guidable catheters have a distal-end balloon which can be partially inflated to carry the catheter in the direction of highest blood flow,

and therefore along a vessel path having maximum blood flow. The balloon may be further inflated, at a selected target site, for purposes of occluding blood flow, or for anchoring the catheter end at the selected site. Extending the balloon to contact the walls of a blood vessel can also be useful in relaxing spasmodic vessel muscles, resulting in less vessel constriction. Balloon catheters thus have the advantage over guide-wire catheters in that they can take advantage of blood flow for advancing along a vessel pathway, and various advantages relating to balloon contact with vessel walls can be achieved.

One type of balloon catheter has a double-lumen construction, where one lumen communicates with the distal balloon, for transferring fluid to or from the balloon. The second lumen allows delivery of injected material, such as a radio-opaque tracer material or therapeutic agent, into the target site. One advantage of the double-lumen catheter is the ability to inflate the balloon to relatively high pressure, which is particularly useful when the balloon is used for stretching a vessel wall, in a catheter treatment for removing vessel plaque. Also, the catheter can be firmly anchored at the target site when the balloon is in a highly inflated state. The double-lumen balloon catheter, however, is not well suited for guidance along small-diameter, tortuous pathways, since the catheter typically has a relatively large outer shaft diameter, and these shafts are generally relatively inflexible. Alternatively, the two catheter lumens may be made relatively small, but here fluid passage through the lumens is slow and limited to low-viscosity agents. Also, since the catheter is guided by blood flow, the device is limited in use to vessel paths with highest blood flow.

In a second balloon-catheter construction, the catheter has a single-lumen tube which communicates with a slow-leak balloon at the distal tube end. In operation,

fluid is supplied through the tube at a slow controlled rate, to maintain the balloon at an inflated condition which promotes fluid-directed movement through the vessel path. The single lumen tube can have a small-diameter, highly flexible construction which permits movement along a small-diameter, tortuous vessel path. The ability to guide the catheter, however, is limited to vessel or duct branches with greater flow, as above, so the catheter is not generally useful for accessing a site against the direction of flow, or along a pathway which includes relatively low-flow branches. Another limitation of the single-lumen catheter is that the slow-leak principle of balloon inflation does not allow for high-flow delivery of fluid material or delivery of particulate suspension at the target site.

A third balloon catheter construction has a single-lumen catheter which communicates with a sealed balloon. The catheter is able to access small-vessel tortuous paths and allows relatively high balloon inflation pressures. The catheter is limited, however, to vessel paths of highest blood flow, and of course cannot be used to deliver fluid to the target site.

3. Summary of the Invention

It is a general object of the invention to provide an improved catheter device for accessing a target site along a small-vessel tortuous path.

A related object of the invention is to provide such a device which overcomes or reduces above-discussed problems and limitations associated with prior art guidable catheters.

A more specific object of the invention is to combine advantages of balloon catheters and guide-wire catheters in a single device.

The catheter device of the invention includes a catheter having (a) an inner lumen extending between proximal and distal catheter ends, (b) an inflatable balloon at the distal catheter end which communicates with the inner lumen, and (c) an aperture disposed distally of the communication between lumen and balloon. The balloon may be carried at the distal end of catheter, or along a distal end section of a catheter tube, or formed as an intermediate inflatable section of a catheter tube. The device further includes a guidewire which is designed for axial sliding movement within the catheter lumen. The guidewire and catheter aperture define a valve structure effective to block the aperture at one or more selected wire positions, to permit the catheter balloon to be inflated by supplying fluid through the catheter lumen. The valve structure may be designed for blocking the valve structure partially and/or completely.

In one general embodiment, the catheter aperture is defined by an annular ring mounted in the distal end of the catheter. The ring aperture is dimensioned to receive a distal end segment of the guidewire freely therethrough, with limited wire clearance. Where the catheter is formed of a tube having an inflatable distal end balloon, the ring is positioned at the distal end of the balloon. Where the balloon is disposed along an end section of the catheter tube, the ring is disposed distal to the balloon end section or distal to an opening communicating the catheter tube with the balloon. The guidewire may additionally include a radial enlargement which, when positioned against the annular ring, acts to block the ring aperture completely.

In a second general embodiment, the catheter balloon is an inflatable sleeve carried on a distal end segment of the catheter tube, where the catheter lumen communicates with the inflatable sleeve through an opening

in the catheter tube. The guidewire in this embodiment has an enlargement which is dimensioned to be moved freely through the catheter with limited clearance, to partially block the interior walls of the catheter lumen. The balloon can be inflated by moving the guidewire enlargement to a position within the catheter tube, just downstream of the opening communicating the lumen and the balloon, and supplying fluid through the tube.

The invention also includes a method for accessing an internal body site along a narrow-vessel tortuous path which includes some branch points in which the path follows the larger-diameter of two branch vessels, and some in which the path follows the smaller diameter of two branch vessels. The method employs a catheter device of the type described in which a single-lumen balloon catheter and a guidewire movable therein define a valve structure which can be manipulated to partially or completely block the distal end of the catheter, for purposes of supplying fluid to and inflating the balloon.

In the accessing method, the guidewire and catheter are advanced along the vessel pathway toward the target site. When a branch point at which the vessel path follows the larger-diameter of two branch vessels is reached, the guidewire is placed in a position to partially (or completely) close the balloon valve, and the balloon is inflated, allowing the distal end of the catheter is carried by fluid flow into larger-diameter vessel. When a branch point at which the vessel path follows the smaller diameter of two branch vessels is reached, the guidewire can be torqued to orient the guidewire tip in the direction of the smaller-diameter vessel, and the catheter then advanced into the smaller vessel, with the catheter balloon preferably in an uninflated state.

The catheter can also be manipulated for balloon inflation at a position along a vessel pathway where vessel constriction is encountered, or to anchor the catheter at the target site.

These and other objects and features of the invention will become more fully apparent when the following detailed description of the invention is read in conjunction with the accompanying drawings.

Brief Description of the Drawings

Figure 1 shows a catheter device constructed according to one embodiment of the invention;

Figure 2 is an enlarged sectional view taken along line 2-2 of Figure 1;

Figure 3A shows the enlarged distal end section of the Figure 2 catheter device with the balloon in an inflated condition;

Figure 3B is an enlarged, fragmentary view of a modified valve structure;

Figures 4-6 are enlarged sectional views of the distal end sections of catheter devices constructed according to various alternative embodiments of the invention;

Figure 7 shows a portion of a small-vessel tortuous path in a target tissue;

Figure 8 shows a branch junction region from Figure 7, in which the path of the catheter follows the larger-diameter of two branch vessels; and

Figure 9 shows a branch junction region from Figure 7, in which the path of the catheter follows the smaller-diameter of two branch vessels.

Detailed Description of the Invention

I. Catheter Device Construction

Figures 1-3 show a catheter device 10 constructed according to one embodiment of the invention. Device 10 includes a catheter 12 composed of a flexible, thin-walled tube 14 having an inner lumen 15 extending between proximal and distal catheter end regions 16, 18, respectively. The proximal catheter end is provided with a syringe fitting 20 through which fluid can be supplied to the catheter lumen through a port 22. The fitting includes an axially extending port 24 also communicating with the catheter's inner lumen. Tube 14 preferably has an inner diameter of approximately 15-60 mils and walls that are approximately 3-15 mils thick. The total tube length is preferably between about 50-300 cm.

With reference now to Figures 2 and 3, the distal end of the catheter is provided with an inflatable balloon 26 which forms an intermediate section of the distal end region of tube 14. The balloon is preferably about 0.5 to 2 cm in length, and has a wall section which can be inflated by fluid supply through the catheter lumen, when the distal end of the tube is partially blocked in a manner to be described below. The balloon wall section is preferably formed integrally with the tube, according to known extrusion methods for producing a thin walled-extruded tube with a more flexible distal-end wall section. In particular, the balloon may be formed by inflating the balloon section in a heated condition, then deflating when the balloon wall section has cooled. Alternatively, the balloon may be formed from a sleeve of elastomeric material, such as silicon rubber, and attached at its opposite sleeve ends to relatively more rigid tube sections. The region along the length of the balloon is also referred to herein as means communicating the

catheter lumen with the balloon. The catheter tube adjacent the balloon is preferably provided with a radio-opaque band for X-ray imaging during use.

Disposed in the distal end of the catheter tube is an annular plug or ring 28 defining an aperture 30 formed axially in the ring. The ring, which is also referred to herein as means defining aperture 30, is positioned downstream of (on the distal side of) the means communicating the catheter lumen with the inflatable balloon, i.e., distal with respect to the balloon. The ring has an inwardly tapered, frustoconical wall section which acts to guide the guidewire through the central aperture in the ring. The diameter of the aperture is typically about 40-80% of the lumen diameter. The ring may be made of a suitable metallic or nonmetallic material, and can be attached to the catheter tube by heat shrinking, solvent bonding or the like.

The catheter device also includes an elongate, torqueable guidewire 36 which is constructed to extend through the catheter for axial sliding therein. The length of the guidewire is typically at least about 10-50 cm longer than the catheter, such that the distal end of the guidewire, seen in Figures 2 and 3, can be extended at least several centimeters beyond the distal end of the catheter, while allowing the proximal end of the wire to be manipulated, such as by torquing, adjacent the proximal end of the catheter. The proximal end of the wire is equipped with a handle 38, such as a pin vice, for applying torque to the wire during a catheter operation.

The guidewire may have a variable or step diameter along its length, typically including a larger-diameter, stiffer proximal region, and one or more smaller-diameter, more flexible distal end regions, giving the wire good torqueability in its more proximal region, and better flexibility and maneuverability along its more

distal region where the wire is advanced along small-diameter tortuous pathways. Typical wire dimensions, for a catheter having an lumen diameter of between about 20-50 mils, are a proximal segment extending along all but the last 20-50 cm of wire and having a diameter of between about 18-40 mils, and one or more reduced diameter segments 20-50 cm in length having diameters of between about 8-18 mils.

In addition the distal end portion of the wire may have a substantially constant taper, down to a final wire thickness of about 1-5 mils, for greater distal-end flexibility. This tapered region is preferably encased in a constant-diameter platinum coil, such as coil 40 seen in Figures 2 and 3. The guidewire terminates in a bent tip 42 which can be oriented by torquing.

The guidewire is preferably made of stainless steel such as is commercially available from Wytech or National Standard. The tapered tip may be made by a suitable technique, such as by grinding. In the embodiment shown, guidewire 36 is 8-20 mils at its proximal end and tapers down to a 2 mil distal tip over about a 10-20 cm length. The coil is made conventionally of wound 3 mil platinum, tungsten or other suitably radiopaque wire commercially available, e.g., from California Fine Wire Company or Sigmund Cohn. This coil preferably has an inner diameter of 7 mils and a length of approximately 2-20 cm. The coil is attached to guidewire 12 by an appropriate technique, such as soldering or brazing.

The diameter of the distal end section of the wire, including wire coil 40, is preferably about 0.5-2 mils less than that of aperture 30, allowing a distal end portion of the wire to be moved freely (with clearance) through the aperture. At the same time, the limited clearance between the guidewire and aperture forms a valve structure which is effective to partially block the

aperture, such that fluid supplied through the catheter will inflate the catheter balloon. The limited clearance between the guidewire is selected so as to allow the balloon to be inflated to a greater (smaller clearance) or lesser (larger clearance) balloon pressure, and/or to allow a desired leakage rate from the balloon in the inflated state.

The guidewire may optionally include an axial enlargement, such as shown in dotted lines at 48 in Figure 2, which is effective to completely block the catheter aperture, when the guidewire is moved to position the enlargement against the aperture ring. This modification is useful where it is desired to inflate the balloon to a relatively high pressure, such as where the catheter device is used for stretching a vessel for purposes of plaque compression.

Figure 3B shows a modification of the Figure 3A valve structure. The modified catheter device, like device 10 shown in Figure 3A, includes a catheter tube 12, a balloon 26, and a guidewire 36. An annular plug or ring 29 disposed at the axial end of the catheter tube defines an aperture 31 whose diameter is greater than that of aperture 30 in device 10. In particular, the clearance between the aperture and the guidewire is such as to allow relatively free flow of fluid through the catheter, with the wire in the position shown in the figure. The portion of the ring defining the aperture is tapered at its inwardly facing side, as shown.

The Figure 3B valve structure further includes a radial enlargement 43 carried on the guidewire. The enlargement is dimensioned to move freely through tube 12 and to form a sealed valve closure with ring 29, when the wire is advanced to place the enlargement against the ring. The outer edge of the enlargement is tapered inwardly, as shown, to center the enlargement on the ring

for sealing. The reduced-diameter aperture in the valve structure could alternatively be formed by a smaller-diameter catheter tube section, distal to the balloon.

The valve structure just described allows the catheter balloon to be inflated to greater pressure by virtue of complete valve closure. The device also allows for relatively high fluid delivery through the catheter with the guidewire positioned such that the wire enlargement is within the catheter balloon, as shown.

In operation, the guidewire in device 10, or in the Figure 3B embodiment, is placed in the catheter through port 24 in fitting 20, and threaded through the catheter until the wire's distal end extends from the distal end of the catheter, as shown in Figure 1. During a catheter placement operation, as will be described in Section II below, it will be advantageous to operate the catheter in an uninflated condition during some phases of operation, and in an inflated operation at other times. To inflate the balloon, in the Figure 3A device, the guidewire is moved axially into and through aperture 30, to partially block the valve aperture, and fluid is supplied through the lumen through port 22 in fitting 20, acting to fill and inflate the balloon. Once the balloon is inflated, material is supplied through the catheter under slight pressure to offset fluid leakage through the partially blocked valve. To inflate the balloon in the Figure 3B embodiment, the guidewire is first positioned for complete valve closure.

To deflate the balloon, the guidewire is retracted, to unblock the aperture and cause the fluid in the balloon to leak out the distal end of the catheter, with progressive balloon deflation. Alternatively, the balloon can be deflated by withdrawing fluid from the catheter through port 22.

Figure 4 illustrates a catheter device 50 in which the catheter, indicated at 52, has an inflatable balloon 54 which is formed by an inflatable sleeve 56 secured at its opposite ends to a thin-walled, flexible catheter tube 58. The balloon sleeve may be formed of a thin polymer material, and preferably an elastomeric, stretchable material, such as silicon or latex rubber, or alternatively, a non-stretchable film material, such as polyethylene. Attachment of the sleeve ends to the catheter tube is tube by gluing, heat sealing, or the like, also according to known methods. The advantage of an elastomeric sleeve is that it tends to remain flush with the tube in an uninflated state, and also tends to resist balloon inflation. Therefore, the balloon will tend to deflate itself when fluid pressure in the tube is released.

An opening 60 formed in the catheter tube provides means communicating the balloon with the catheter lumen. Distal to this opening is a ring 62, which defines an aperture 61 in the catheter tube. A guidewire 66 in the device has an outer diameter which, as above, is dimensioned to partially block the aperture when the wire is moved through the ring. This wire thus forms with the ring valve structure for partially blocking the catheter lumen downstream of opening 60. The guidewire may have substantially the same construction as guidewire 36 in device 10. The operation of device 50, in balloon inflating and deflating operations, is substantially identical to that of device 10.

The guidewire in device 50 may be additionally provided with a radial enlargement, shown in dotted lines at 67 in Figure 4. This enlargement is dimensioned to allow free guidewire movement through the catheter tube, and to form a sealed valve closure with ring 62, when the wire is advanced to place the enlargement against the

ring. Like the device shown in Figure 3B, the ring in device 50 may have a greater clearance with the guidewire, to facilitate fluid flow through the catheter, with the guidewire positioned as shown, when the guidewire is provided with a radial enlargement for complete valve closure. That is, the device may be designed for partial and/or complete valve closure.

Figure 5 shows a similar type of catheter device 70 having a distal-end balloon 72 which is attached to and extends from the distal end of the catheter tube, indicated at 74. The distal end of the catheter thus provides means communicating the balloon with the catheter lumen. The balloon is formed of a membranous or elastomeric sac having a distal opening 76 which is dimensioned to receive the distal end of a guidewire 78 freely therethrough, with limited clearance. The opening is reinforced by a plug 80 whose inner bore with the same diameter as opening 76. This plug, which is preferably a flexible elastomeric material, may be formed integrally with the balloon, or attached to the balloon as by gluing. The opening and plug form a ring which defines a central aperture 81 in the catheter.

Guidewire 78 in the device has an outer diameter which is dimensioned to be received through aperture 81, to partially block the lumen of the catheter tube, when the wire is moved through the tube. The wire and aperture formed in the distal end of the balloon collectively form valve structure for use in inflating the balloon, as above. The guidewire may be provided with an enlargement, as above, where complete valve closure is desired. Where it is desired to produce complete valve closure, the guidewire may be provided with a radial enlargement as above. Alternatively, the opening at the distal end of the balloon can be dimensioned to form an elastomeric seal with the guidewire.

In Figure 6, a catheter device 90 has a catheter 92 whose tube and distal balloon construction is substantially the same as that of catheter 52 in Figure 4, where the balloon communicates with the catheter tube lumen through an opening 94 in the catheter tube. Here, however, the aperture is defined by the lumen itself, in the region between opening 94 and the distal end of the catheter tube. This region or aperture is indicated generally at 96 in the figure.

A guidewire 98 in the device has an enlargement 100 which is tapered on either side, as shown, and whose outermost rim 102 is dimensioned to slide freely within the lumen, with a clearance which is effective to partially block the lumen. With the enlargement positioned within the aperture of the catheter, i.e., between opening 94 and the distal end of the catheter tube (solid lines in the figure), the enlargement and aperture form valve structure for partially blocking the aperture. At this position, supplying fluid through the lumen inflates the balloon. With the guidewire moved slightly in a proximal or upstream direction, to place the enlargement at the position shown at 104, the lumen remains partially sealed, but fluid can leak from the balloon, for deflating the balloon.

II. Catheter Accessing Method

The method of accessing an internal body site along a small-vessel, tortuous vessel or duct path, according to the method of the invention, will now be described with reference to Figures 7-9. Figure 7 shows a region of soft tissue 130, such as brain or liver tissue, containing a target site 132 which is to be accessed. The small-vessel path within this tissue region which leads to the target site is shown by arrows in the figure and includes three branch points, indicated at 134, 136, and

138, all supplied by a trunk vessel 140. Each branch point diverges into two branch vessels, such as branch vessels 142 and 144, diverging from vessel 140, and branch vessels 146 and 148 diverging from vessel 142. Often at a branch point along the vessel path, one of the two branch vessels, such as vessels 142 and 146, will have a relatively larger diameter and greater blood volume flow than the other branch vessel, such as vessels 144 and 148.

The method employs a guidewire catheter device of the type described above in which an inner-lumen balloon catheter balloon catheter and a guidewire movable therein define a valve structure which can be manipulated to block the distal end of the catheter, for purposes of supplying fluid to and inflating the balloon. In a typical operation involving a target site accessed through a vascular system, the catheter device is threaded as a unit from an external access site through the vasculature to a region adjacent, but not into the tortuous path region of the target tissue. This is done, in the usual case where the catheter must pass through the cardiac aorta, by first placing a relatively large diameter guiding catheter (e.g., about 40 mils inner diameter) from the access site through the aorta and toward the target site. The present catheter and guidewire are then threaded through the guiding catheter past the aorta, where large-vessel diameters and high blood flow volumes make it difficult or impossible to control the movement and position of the catheter. Once beyond the guiding catheter, the catheter and guidewire can be independently controlled to move toward the target site. In general, the path from the access site to the region adjacent the tissue is easily accessible, in that sharp bends, small-lumen vessels, and or soft tissue structure are not encountered.

The distal end of the device is now advanced into the target tissue along the selected path until

branch points in the vessels or ducts making up the small-vessel path are encountered, as illustrated in Figure 7. For purposes of illustration, it is assumed that the catheter has been moved along the path until branch point 134 in Figure 7 is encountered. Since the selected path follows the larger-diameter, greater-flow branch vessel 142, the catheter can be guided by blood flow, by inflating the catheter balloon and allowing the distal catheter end to flow into the larger vessel, as illustrated in Figure 8, which shows the catheter device being guided into and through vessel 142. The balloon is inflated, before the branch point is reached by the procedure mentioned above, which involves first moving the guidewire in the device to block the catheter aperture, then supplying fluid through the catheter until a desired degree of inflation is reached. The valve structure may be designed for partial and/or complete valve closure, as discussed above. After the catheter's distal end has been carried into the larger-diameter branch vessel, the wire may be further manipulated to open the valve structure, and/or fluid can be withdrawn from the catheter, to deflate the balloon.

Following the path illustrated in Figure 9, the next branch point encountered is at 136, where the vessel path follows the smaller-diameter branch vessel 148, as illustrated in detail in Example 9. Here the balloon is in a preferably non-inflated state, to reduce the tendency of the catheter end to be carried in to the larger-diameter vessel. At this branch point, the guidewire is torqued to orient the wire's bent tip in the direction of vessel 148, and the wire is then advanced, preferably independently of the catheter, into the smaller vessel. The catheter may now be threaded along the guidewire, and the device advanced as a unit until the next branch point is reached. Further catheter advance is achieved by guidewire

or balloon-flow guidance, as above. It will be appreciated that the guidewire may be used to advance the catheter through branch points in which the selected path may follow either a larger or smaller-diameter branch vessel. That is, balloon-assisted flow guidance need not be used for accessing a larger-diameter branch vessel. Of course, with smaller-diameter branch vessels, the guidewire must generally be employed.

The method of the invention may also include the use of the balloon catheter to dilate a constricted vessel, particularly, where the constriction is encountered along a vessel path, and makes advance along the path more difficult. This is done simply by locating the balloon at a region of spastic constriction, and manipulating the device to inflate the balloon.

Once the target site is reached, the guidewire may be removed in order to open the inner lumen of the catheter, and thereby increase the rate of supply to the target site of a therapeutic, vasoocclusive, and/or radiopaque material. Alternatively, where the purpose of the targeting is to dilate the vessels or ducts at the target site, for example, to widen the lumen of a narrowed target vessel, either for angioplasty or spasm relaxation, the catheter device may be manipulated to inflate and deflate the balloon repeatedly. As indicated above, it may be advantageous to provide for complete valve closure at a selected guidewire position, to allow for greater balloon inflation pressure.

From the foregoing, it will be appreciated how various objects and features of the present invention are met. The catheter device takes advantage of both guidewire and balloon-flow guidance for movement along small-diameter tortuous vessel or duct paths, to allow more efficient and in some cases more versatile catheter targeting to a tissue site.

The balloon in the device can also be used for relaxing spasmodic vessel walls, and for vessel wall therapies, such as plaque compression requiring balloon inflation. In this application, the catheter allows access to tortuous-path soft tissue target sites, and the ability to inflate the balloon to moderately high pressures, in contrast to prior-art slow-leak balloon catheters. Alternatively, where the catheter device is used to deliver a fluid agent to the target site, the guidewire can be withdrawn to increase the lumen cross section.

It will be appreciated from Figure 2 that the guidewire, when provided with a radial enlargement, can also be advanced against the catheter aperture to maintain the flexible balloon in an uninflated, somewhat stretched condition. The guidewire and catheter can then be advanced as a unit along a vessel path, overcoming the problem of balloon buckling due to its inherent flexibility.

It will be clear from the foregoing that various changes and modifications in both the catheter device and tissue accessing method of the invention can be made without departing from the invention.

IT IS CLAIMED:

1. A catheter device for accessing an internal tissue site along a vessel path from an external body access site, comprising

a catheter having an inner lumen extending between proximal and distal ends, an inflatable balloon disposed adjacent the distal end, means communicating the catheter lumen with the balloon, and means defining an aperture disposed distally to said communicating means such that when the aperture is blocked, fluid supplied through the lumen is forced into the balloon,

a guidewire having proximal and distal ends and carried in said catheter for axial sliding movement therein, and

valve structure defined by said aperture and guidewire designed to block, partially and/or completely, the aperture at one or more selected guidewire positions, to permit the catheter balloon to be inflated by supplying fluid through the catheter lumen at a rate greater than fluid escape through the partially blocked aperture.

2. The device of claim 1, wherein said catheter aperture is defined by an annular ring mounted in the distal end of the catheter, and is dimensioned to receive a distal end segment of the guidewire freely therethrough, with a clearance which is effective to partially block the aperture, when the wire is advanced through the ring.

3. The device of claim 1, wherein said catheter aperture is defined by an annular ring mounted in the distal end of the catheter, and the guidewire includes a radial enlargement effective to completely block said

aperture at a selected guidewire position within the catheter.

4. The device of claim 2, wherein the catheter is formed of a tube which has an intermediate inflatable section forming said balloon, and said ring is positioned within the tube, distal to said inflatable section.

5. The device of claim 4, wherein the guidewire includes a radial enlargement effective to completely block said aperture at a selected guidewire position within the catheter.

6. The device of claim 2, wherein the catheter is formed of a tube having an inflatable distal end section which forms said balloon, and said ring is positioned within the inflatable end section.

7. The device of claim 1, wherein the inflatable balloon is disposed along a distal end region of a catheter tube, the balloon communicates with the inner lumen of the catheter through an opening in the tube which is adjacent the tube's distal end, but proximal thereto, and the valve structure includes an annular enlargement carried on the guidewire which is dimensioned to be moved freely through the catheter lumen with a clearance which is effective to partially block the catheter lumen.

8. The device of claim 1, which further includes means attached to the proximal end of the guidewire for torquing the wire along its axis, to orient the distal end of the wire in a selected direction.

9. A method of accessing an internal body site along a narrow-vessel tortuous path which includes some

branch points in which the path follows the larger-diameter of two branch vessels, and some in which the path follows the smaller diameter of two branch vessels, said method comprising,

providing a catheter device composed of (a) a catheter having an inner lumen extending between proximal and distal ends, an inflatable balloon disposed adjacent the distal end means communicating the catheter lumen with the balloon, and means defining an aperture disposed distally to the communicating means such that when the aperture is blocked, fluid supplied through the lumen is forced into the balloon, (b) a guidewire having proximal and distal ends and carried in said catheter for axial sliding movement therein, and (c) valve structure defined by said aperture and guidewire designed to block, partially and/or completely, the aperture at one or more selected guidewire positions, to permit the catheter balloon to be inflated by supplying fluid through the catheter lumen at a rate greater than fluid escape through the partially blocked aperture,

advancing the wire along the path,

when a branch point at which the vessel path follows the larger-diameter of two branch vessels is reached, placing the guidewire axially in a position effective to block said aperture, and infusing fluid through the catheter to inflate the balloon, whereby the distal end of the catheter can be carried by fluid flow into larger-diameter vessel, and

when a branch point at which the vessel path follows the smaller diameter of two branch vessels is reached, torquing said guidewire to orient the guidewire tip in the direction of the smaller-diameter vessel, and advancing the guidewire and catheter into such vessel.

10. The method of claim 9, which further includes inflating said balloon when the catheter distal end encounters a region of vessel constriction, thereby to extend and relax the constricted vessel region and facilitate movement of the catheter device therethrough.

11. The method of claim 9, wherein the valve structure in the catheter is defined by a ring mounted in the distal end of the catheter and defining said aperture therein, said aperture being dimensioned to receive the guidewire freely therein, with a clearance which is effective to partially block the aperture.

12. The method of claim 9, wherein the valve structure is effective to completely block the aperture.

13. The method of claim 9, wherein the balloon forms a distal end portion of the catheter, and said guidewire includes a radial enlargement for completely blocking the valve aperture.

14. The method of claim 13, wherein the guidewire is positioned to place the balloon in a stretched uninflated condition, and the guidewire and catheter are moved as a unit along such path.

15. A method of accessing an internal body site along a narrow-vessel tortuous path, comprising,

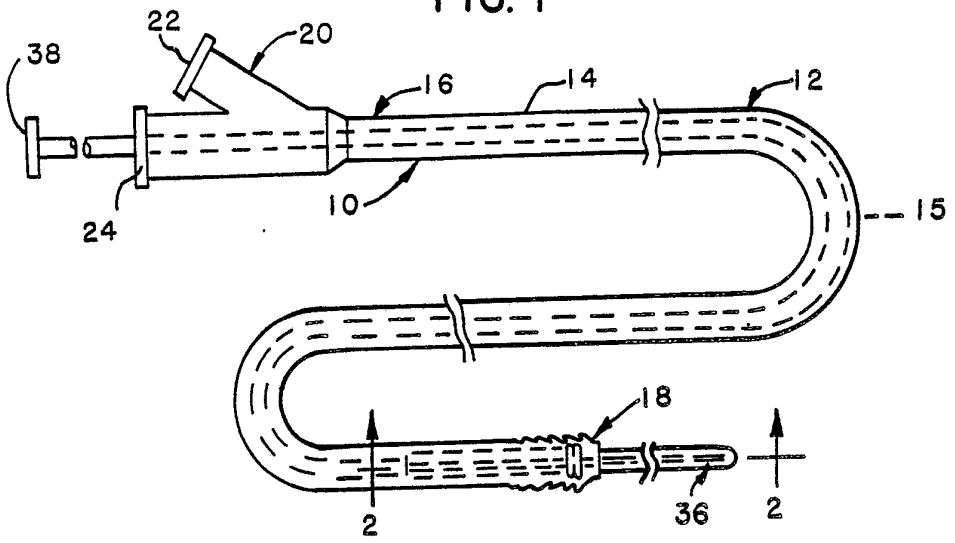
providing a catheter device composed of (a) a catheter having an inner lumen extending between proximal and distal ends, an inflatable balloon disposed adjacent the distal end means communicating the catheter lumen with the balloon, and means defining an aperture disposed distally to the communicating means such that when the aperture is blocked, fluid supplied through the lumen is

forced into the balloon, (b) a guidewire having proximal and distal ends and carried in said catheter for axial sliding movement therein, and (c) valve structure defined by said aperture and guidewire designed to block, partially and/or completely, the aperture at one or more selected guidewire positions, to permit the catheter balloon to be inflated by supplying fluid through the catheter lumen at a rate greater than fluid escape through the partially blocked aperture, including an enlargement on the guidewire which allows guidewire movement through the catheter, but is effective to block said aperature, when the enlargement is moved against the aperture-defining means,

advancing the wire to a position in which the wire enlargement is placed against the aperture-defining means, to hold the balloon in a stretched, uninflated condition, and

moving the guidewire and catheter as a unit along such path.

FIG. 1



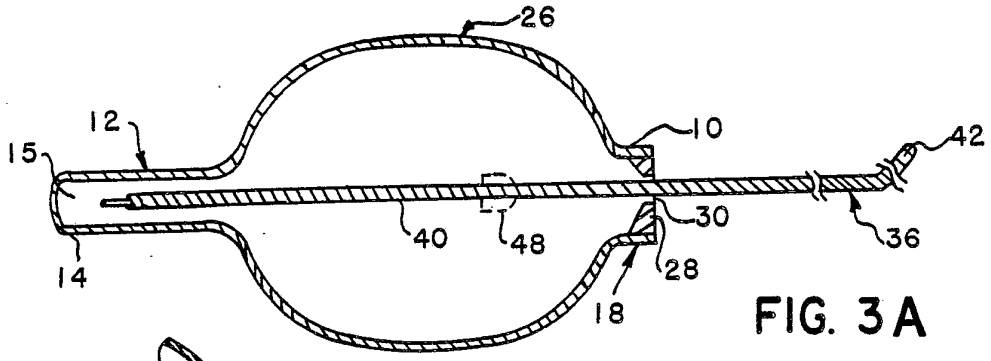


FIG. 3A

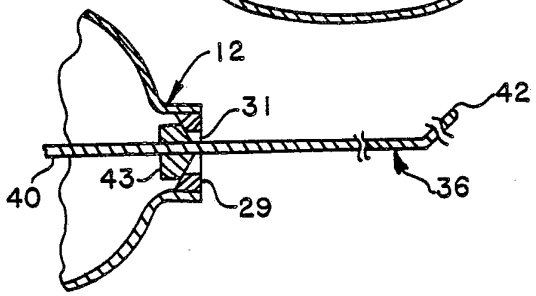


FIG. 3B

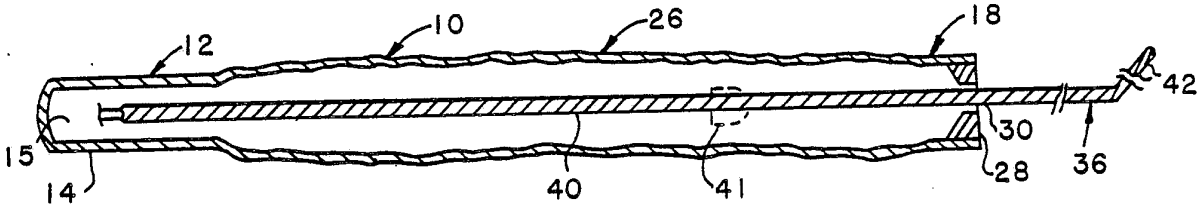


FIG. 2

FIG. 4

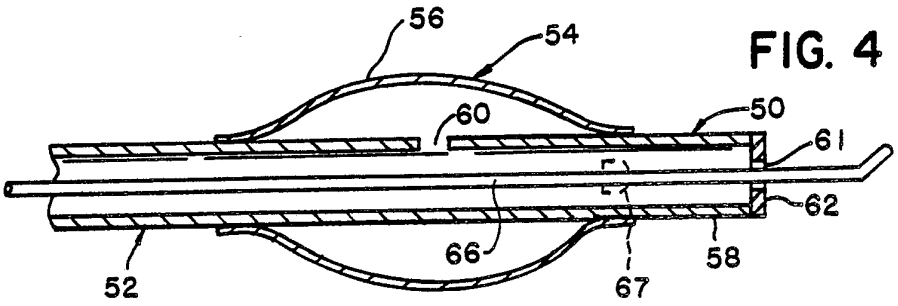


FIG. 5

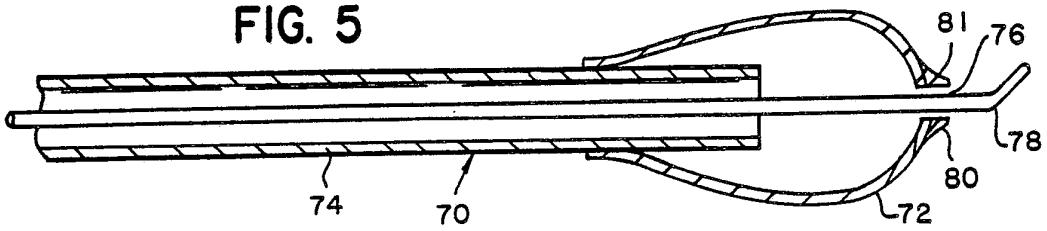


FIG. 6

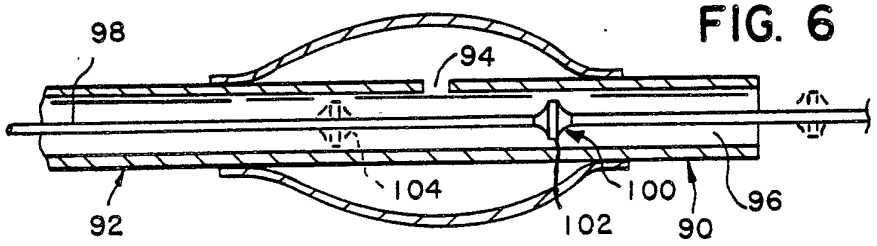


FIG. 7

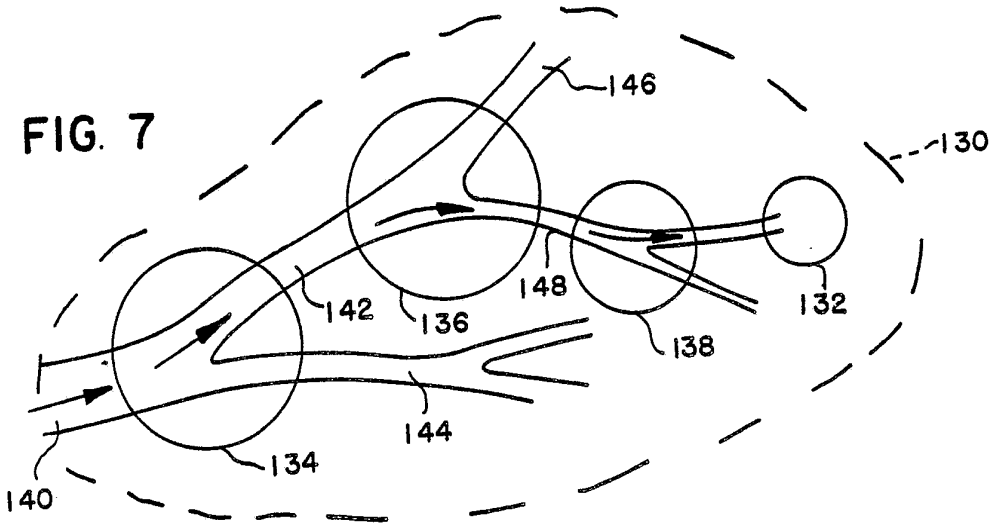


FIG. 8

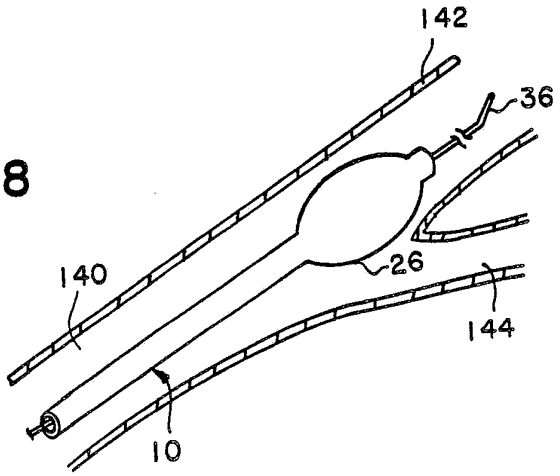
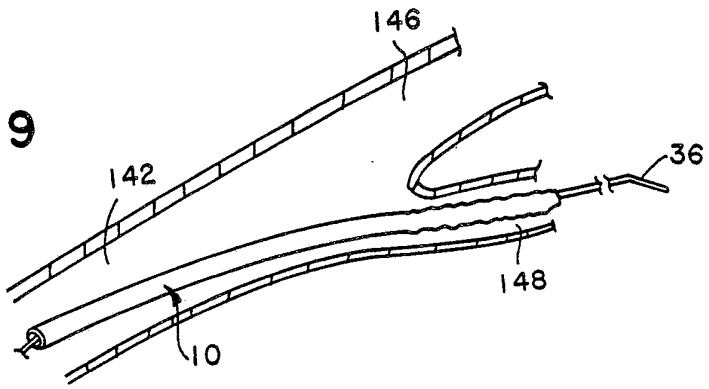


FIG. 9



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US88/02656

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(4) : A61M 29/00
U.S. Cl. 604/99

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
US	604/96-103 128/325,344,348.1,207.15,1D

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	US, A, 3,402,717 (DOHERTY) 24 September 1968 (see entire document)	1,8,12-15

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"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

"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

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
30 November 1988	04 JAN 1989
International Searching Authority	Signature of Authorized Officer
ISA/US	J. Yasko

Form PCT/ISA/210 (second sheet) (Rev.11-87)