OCCLUSION DEVICE AND METHOD AND APPARATUS FOR INSERTING THE SAME

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ABSTRACT

A method of effecting the occlusion of a blood vessel by forming an access opening in the body of the patient communicating with the desired blood vessel, introducing an occlusion member in the vessel, moving the member to the desired point of occlusion, and thereat expanding the member to a size greater than the diameter of the vessel whereby the member is substantially immovably retained therein; the member comprising an expandable and contractable body, capable of disposition in a relatively contracted state in which it may be positioned at the desired point of occlusion, or in an expanded state, the body being constructed to contain the means for effecting such expansion; an example of apparatus for practicing the method comprising a catheter in the form of an elongated tubular conduit of a length to extend from said desired point of occlusion to said access opening and constructed at one end for operative connection with such an occlusion member and the other end for operative connection with actuating means cooperate with means disposed in the tubular conduit for effecting transition of said member from one of its states to the other of its states.

34 Claims, 14 Drawing Figures
1 OCCLUSION DEVICE AND METHOD AND APPARATUS FOR INSERTING THE SAME

This application is a continuation of pending application, Ser. No. 878,813, filed Nov. 21, 1969, now abandoned.

BACKGROUND OF THE INVENTION

The present invention pertains generally to the treatment of vascular conditions and more particularly to those involving thrombosis. Acute deep thrombophlebitis with secondary pulmonary embolism continues to be a very important clinical problem. In connection therewith, the management of the patient, at least in part, embodies principles and measures which are designed to prevent the spread of lower extremity venous clots to the lungs. Consequently, in certain patients with thromboembolic disease, it has become clinically accepted that interruption of the inferior vena cava becomes strongly indicated. The usual patient falling into this category is one who has experienced pulmonary embolism of a sublethal sort in spite of rigid application of clinical measures exclusive of surgery. For example, patients are encountered in whom there clearly is need for mechanical interruption of flow through the inferior vena cava and yet, for whom surgical caval ligation cannot be done at an acceptable or realistic risk.

As the singular purpose of inferior vena cava ligation is simply to mechanically obstruct the cava a comparable result could be obtained if it were possible to create a secure and, if desired, permanent obstruction within the blood vessel, for example at the inferior vena cava bifurcation. This would involve introduction of a suitable mechanical element at the selected point in the vascular system to enable controlled movement of the element to the desired point of occlusion and thereat firmly securing the same in place. This technique would enable suitable introduction of such mechanical element into the desired blood vessel by relatively minor surgery with the entire procedure taking place in a matter of minutes as compared with a normal vena cava ligation which would require a matter of hours. In addition to the utilization of such a mechanical element, it will be appreciated that the success of the operation also is dependent upon proper positioning of such mechanical element at the desired location in the particular blood vessel and that to insure this result means should be provided for accurately visually ascertaining the location of the mechanical element in the blood vessel.

The present invention proceeds from the concept of utilizing an expandable and contractable mechanical element as the obstructing member, which may be inserted, in contracted state, into the blood vessel, moved to the desired location therein and thereat suitably expanded, forming what might be termed an intraluminal balloon which will firmly and securely engage the walls of the vessel thereby to permanently secure and fix the obstruction at the desired location. Such a method would enable the element to be introduced, for example, through the venous system of the neck, thereby avoiding the use of lower extremity veins. Such obstruction would thereby effectively block the spread of venous clots in a lower extremity from spreading to the lungs.

The present invention may be initially considered under three aspects, the first being the evolvement of a practical method of achieving the desired results, the second, details surrounding the construction of the mechanical element which is to perform the blocking function, and third, the apparatus by means of which the mechanical element is to be disposed at the precise desired location in the particular blood vessel.

BRIEF SUMMARY OF INVENTION

The invention therefore has among its objects the development of a method of effecting the occlusion of a blood vessel which is relatively simple and readily performed, making use where possible of steps individually involving known techniques, and which may be practiced with various types of mechanical blocking elements and apparatus for effecting the insertion thereof.

A further object is the development of such a method which preferably will enable withdrawal of the element from the vessel in a reverse manner to its introduction.

Another object of the invention is the production of a mechanical element for disposition in a blood vessel to effect an occlusion thereof, which element is relatively simple in construction, capable of being selectively contracted and expanded, preferably being capable of contraction subsequent to its insertion in a blood vessel to permit withdrawal of the element from such a vessel when deemed necessary or desirable, and which will firmly and securely engage the adjacent walls of the blood vessel to insure positive and secure retention in the blood vessel at the desired location.

A further object of the invention is the production of apparatus for practicing the method with such a contractable and expandable mechanical element, which apparatus is relatively simple in construction, capable of being readily sterilized, etc. and which is completely compatible with the method of the invention as well as the particular mechanical elements employed. Likewise, such apparatus should be so constructed that a suitably constructed mechanical element may be inserted thereby into a blood vessel at a desired location, preferably under supervision by visual means such as X-ray or other equipment, and which preferably may be employed both for insertion of the element into the blood vessel and for withdrawal therefrom.

In the practice of the method of the invention, the blood vessel, for example the inferior vena cava, would be occluded by means of an expandable mechanical element by the steps of forming an access opening in the body of the patient, normally at a point remote from that at which the occlusion is to be located, for example, effecting an opening into the venous system of the neck, thereby avoiding use of lower extremity veins, inserting the occlusion member in such opening and moving the same by means of the apparatus to the desired location of occlusion, following which the occlusion member is expanded to a size greater than the inner diameter of the blood vessel whereby the member is substantially immovably retained therein.

A number of constructive examples are disclosed herein which may be utilized in practicing such method. In general, the devices illustrated fall into two categories, one of which employs mechanical means for effecting contraction and expansion of the occlusion member, and the other of which utilizes a fluid to effect the expansion, with the occlusion member being constructed in either case to contain the means for ef-
fecting such expansion. Where fluid is employed as the actuating medium the occlusion member may be provided with suitable valve means to insure retention therein of the fluid, following expansion of the member, such valve means in the examples illustrated taking the form of one or more flap members, or a ball member, or may rely on part or entirely in the characteristics of the material forming at least a portion of the occlusion member to effect a seal upon withdrawal of the apparatus utilized to insert and actuate the member.

In one form of the invention, the fluid may be supplied to the occlusion member by means of a permanently connected tubular conduit which is suitably terminated and closed adjacent the point of insertion into the patient's body whereby such tube may be left therein.

Various types of apparatus may be employed in connection with the practice of the invention and those illustrated are utilizable with the respective general types of occlusion members disclosed. In general, such apparatus comprises a catheter in the form of an elongated tubular conduit of a diameter to be freely received in the blood vessel involved and of a length greater than the effective distance from the opening made in the patient's body for insertion of the occlusion member to the point in the blood vessel at which it is to be positioned. The tubular conduit is constructed at one end for operative connection with the occlusion member and adapted to receive means for effecting the transition of the occlusion member from one of its states to the other of its states whereby the occlusion member may be inserted in such a blood vessel in a contracted state, moved to the desired point and thereafter expanded. The opposite end of the tubular conduit is adapted to be operatively connected to actuating means for effecting movement of the transition-effecting means within the conduit.

Where mechanical means is employed to effect expansion of the occlusion member the transition-effecting means may comprise a wire-like element or such engageable with the occlusion member to effect a transition thereof to a relatively contracted state, in which it is to be inserted in a blood vessel, and in this case, to effect relative movement between the conduit and the stylet for effecting disconnection of the latter from the occlusion member, the actuating means may comprise a pair of manually engageable members, one of which is operatively connected to the outer or free end of the conduit, and the other operatively connected to the corresponding end of the stylet whereby relative movement between the two members will be reflected in relative movement between the conduit and the stylet.

Where fluid is employed as the transition-effecting means, the manually actuated members may be so constructed that the member connected with the conduit functions as a hollow cylinder communicating with the conduit interior and the second member functions as a piston slidably disposed within the cylinder, to form a syringe by means of which fluid may be forced through the conduit.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, wherein like reference characters indicate like or corresponding parts:

FIG. 1 is an elevational view of apparatus for effecting insertion and expansion of an occlusion member, illustrated at the end of a tubular conduit forming a part of the apparatus;

FIG. 2 is an enlarged longitudinal sectional view through the connected occlusion member of FIG. 1, schematically illustrated as being positioned within a blood vessel, with the occlusion member being disposed in a relatively contracted state;

FIG. 3 is a sectional view, similar to FIG. 2, illustrating the occlusion member in a relatively expanded state following disconnection of the inserting apparatus;

FIG. 4 is a sectional view, similar to FIG. 2, illustrating details of an occlusion member adapted to be expanded by the reception of fluid therein, and the adjacent portion of the inserting apparatus;

FIG. 5 is a sectional view, similar to FIG. 3, illustrating the occlusion member of FIG. 4 in expanded state following disconnection of the inserting apparatus therefrom;

FIG. 6 is a sectional view, similar to FIG. 4, illustrating details of an insertion apparatus constructed to permit subsequent reengagement thereof with the occlusion member of FIG. 4 for effecting withdrawal of the latter from the blood vessel;

FIG. 7 is a sectional view, similar to FIG. 4, illustrating a modified form of connection between the inserting apparatus and the occlusion member;

FIG. 8 is a sectional view, similar to FIG. 5, illustrating the occlusion member of FIG. 7 in an expanded state;

FIG. 9 is a sectional view, similar to FIG. 4, illustrating a modified form of occlusion member provided with a blood by-pass;

FIG. 10 is a sectional view, similar to FIG. 5, illustrating the occlusion member of FIG. 9 in expanded position with the by-pass operatively connecting the vessel interior at opposite sides of the occlusion member;

FIG. 11 is a sectional view, similar to FIG. 4, of a modified form of occlusion member utilizing a ball valve arrangement;

FIG. 12 is a sectional view, similar to FIG. 4, illustrating another form of occlusion member in its contracted state;

FIG. 13 is a sectional view, similar to FIG. 5, illustrating the occlusion member of FIG. 12 in its expanded state; and

FIG. 14 illustrates a further modification of the invention with the occlusion member illustrated in inserted position.

DETAILED DESCRIPTION OF INVENTION

In explaining the invention in detail, the construction of the occlusion members will be initially presented, followed by a detailed description of the apparatus for inserting such members, and finally the method of effecting the occlusion by use of such members and apparatus.

OCCUSION MEMBERS

Referring initially to FIGS. 2 and 3, the reference numeral 1 indicates generally an occlusion member, schematically illustrated as being disposed in a blood vessel 2 having side walls 3, the member 1 being illustrated in a relatively contracted form in which it has a configuration generally approaching an ellipsoid, i.e., having a longitudinal cross-sectional configuration, as viewed in FIG. 2, closely approaching an ellipse, and a transverse cross-sectional configuration which is substantially cir-
cular. As used herein the terms "contracted" or "expanded" have reference only to the transverse cross-sectional state of the occlusion members, i.e., the dimensions involved in effecting the occlusion.

The occlusion member may be constructed of any suitable material which is capable of the desired contraction and expansion and which is inert to body fluids and materials. Silicone compositions which possess such characteristics are particularly efficient for this purpose and are currently used for materials and elements to be inserted in the human body. As illustrated in FIG. 2, the opposite end portions 4 of the member are of considerably greater thickness than the intermediate connecting portion 5 whereby such end portions are substantially form-retaining in either the contracted state illustrated in FIG. 2 or the expanded state illustrated in FIG. 3, thus substantially concentrating any expansion at the intermediate portion 5 of generally tubular configuration.

Extending between and having its free ends anchored in the enlarged end portions 4 is a helical tension spring 6 which is in a relatively expanded or tensioned condition when the occlusion member is in the retracted position illustrated in FIG. 2 or is in a contracted position to draw the ends 4 toward one another when the occlusion member is in its expanded position, as illustrated in FIG. 3. Thus, in this construction the occlusion member, under the action of the spring 6, tends to assume its operatively expanded position as illustrated in FIG. 3 and the inserting apparatus must be suitably constructed to move the respective end portions 4 without stretching said vessel to the operatively retracted position illustrated in FIG. 2, in which position the occlusion member may be inserted in the blood vessel involved.

It will be particularly noted that in this construction the relatively heavy end portions 4 tend to concentrate the lateral expansion to the thin wall intermediate portion 5, and at the same time, provide a firm and secure anchorage for the ends of the spring 6.

As discussed in greater detail in connection with the apparatus for inserting this occlusion member, the occlusion member is brought into the operatively contracted configuration illustrated in FIG. 2 by exerting oppositely directed axial forces on the end portions 4 in opposition to the action of the spring 6, to separate the end portions 4 sufficiently to bring the intermediate portion 5 into the configuration illustrated in FIG. 2. Upon release of the respective end portions 4 the spring 6 will draw such end portions into the positions illustrated in FIG. 3 resulting in expansion of the intermediate portion 5 to effect engagement with and sufficient outward expansion of the walls 3 of the blood vessel 2 to ensure a firm retention of the member at its location of initial expansion in the blood vessel.

FIGS. 4 to 14 illustrate forms of occlusion members which employ a liquid to produce the desired expansion of the occlusion member within the blood vessel involved, such fluid being suitably discharged into the occlusion member, with the means for effecting the supply of fluid to the occlusion member being disconnectable in all cases but that illustrated in FIG. 14, and in some instances are constructed for reconnection to the occlusion member in the event it is desired to effect a withdrawal thereof from the blood vessel. In all of these forms, the occlusion member, while generally constructed similar to that illustrated in FIGS. 1 and 2, is formed with an initial configuration corresponding substantially to the retracted position of the member illustrated in FIG. 2, and which thus represents the retracted state of the member in which it is introduced into the desired blood vessel, following which fluid is supplied to the interior of the member operative to effect an expansion of the intermediate portion 5 thereof to a position similar to that illustrated in FIG. 5 and corresponding to the expanded state of the member illustrated in FIG. 3.

In this construction the spring 6 is omitted and the end portion 4' of increased thickness, is provided with a fluid inlet defined by an internally threaded sleeve 7 embedded in the end portion 4' and extending therethrough. The sleeve 7 may be suitably assembled with the body of the member 1, as for example, at the time of fabrication of the latter, whereby the sleeve is firmly secured in leak-proof relation to the portion 4'. In this particular embodiment the inner end of the inlet formed by the sleeve 7 is adapted to be closed, under action of fluid within the member, by a valve member in the form of a flap or leaf, which may be suitably fabricated from such material as the member 1, for example, a suitable silicone composition, and is suitably secured to the member, as indicated at 9, to permit the flap to move to an open position as illustrated in FIG. 4 or to a closed position as illustrated in FIG. 5. In the construction of FIGS. 4 and 5 the transition of the occlusion member from such contracted state to such expanded state is adapted to be effected by fluid supplied to the member through a tubular conduit 11 which is of suitable flexible material such as one of the synthetic materials now employed in various types of catheters, and is provided at the end thereof with a tubular fitting 12 having an externally threaded portion 13 extending axially outward beyond the end of the conduit 11 and threadedly engageable with the internal threads of the sleeve 7, whereby the end of the conduit 11 may be suitably connected with the member 1 by screwing the threaded end 13 into the sleeve 7. As fluid is discharged from the conduit 11, such flow will move the flap into open position and upon receipt of sufficient fluid within the member 1 the fluid pressure in the conduit 11 may be relieved whereby the internal fluid pressure within the member 1 will move the flap 8 to its closed position as illustrated in FIG. 5. The threaded end 13 of the conduit 11 may then be unscrewed from the sleeve 7, permitting withdrawal of the conduit, the occlusion member remaining stationary during this operation as a result of its engagement with the vessel walls.

FIG. 6 illustrates a modified conduit structure for use with the occlusion member of FIG. 4 whereby the member can be returned to its original contracted state and thus enable withdrawal thereof from the blood vessel. In this embodiment, the member 13' has an effective length which is greater than the corresponding thickness of the end portion 4' whereby the member 13' may be threaded a sufficient distance into the sleeve 7 to protrude thereby beyond, lifting the flap 8, as illustrated in FIG. 6, to open the valve formed thereby and permit fluid to be withdrawn from the expanded member through the conduit 11 permitting the latter to return to its original contracted state in which it may be withdrawn from the blood vessel. To facilitate engagement of the threaded portion 13' with the threads of the sleeve 7, the end of the latter preferably is flared as...
indicated at 14 (FIG. 5) and in like manner the extreme end of the portion 13 is preferably tapered as indicated at 14'.

FIGS. 7 and 8 illustrate a further embodiment of the invention in which the end portion 4' is provided with an inwardly directed extension 15 in the form of a block of gum rubber, the inner end of which carries the flap valve 8. This embodiment has a normal configuration corresponding to that illustrated in FIG. 7 in which the member is in its relatively contracted state and adapted to be expanded to a position such as illustrated in FIG. 8. The supply conduit 11 in this construction is provided with a hollow needle-like discharge fitting 12", the free end 13" of which is of a length to be inserted through the end portion 4' and block 15, pivoting the flap valve 8 into the position illustrated in FIG. 7, in which condition the occlusion member may be inserted into the blood vessel involved and fluid subsequently supplied to the interior of the member to expand the same to the position illustrated in FIG. 8. Following expansion, the needle-like extension 13" may be withdrawn from the member with the flap 8 initially sealing the opening in the block 15 as soon as the free end of the needle 13" passes into the block, and as the needle is withdrawn from the latter, the gum rubber will resume its original form to provide a self-sealing action supplementing that effected by the flap valve 8.

FIGS. 9 and 10 illustrate a further modification employing an occlusion member of a construction similar to that illustrated in FIGS. 4 - 6 but omitting the threaded sleeve 7 and utilizing a pair of flap valves 8 and 8' to seal the inlet opening formed by the insertion of the needle-like end 13" of the fitting 12' illustrated in FIG. 7. In this construction two flaps are utilized to ensure an efficient seal. This embodiment also illustrates an additional feature of the provision of a passageway 16 extending completely through the occlusion member. The passageway 16 is illustrated as being formed by a tubular member 17 having sufficient wall rigidity to permit passage of blood from one end of the expanded occlusion member to the opposite end thereof by-passing the same and at the same time possessing sufficient resilience to permit proper expansion or contraction of the member 17 as transition is effected from one state to another. This construction thus permits the flow of a limited amount of blood in the vessel, which may be desirable in some applications.

FIG. 11 illustrates a further embodiment of an occlusion member of a construction similar to that hereinafore described, in which the principal difference is in the valve structure, the flap valve 8 of the previous forms being replaced by a ball valve member 8" which is retained in operative position adjacent the fluid inlet 7' by a suitably formed retaining cage 9' or the like. This embodiment is adapted to receive fluid from the conduit 11 through a fitting 12' similar to that illustrated in FIGS. 7 and 9, but in which the length of the outwardly extending portion 13" is less than the thickness of the adjacent end portion 4' whereby the member 13" when fully inserted into the end portion will not engage the ball 8'.

FIGS. 12 and 13 illustrate a further embodiment of an occlusion member according to the invention. This construction employs an elongated generally cylindrical body member 18 having enlarged end portions 19 and 21, connected by a hollow intermediate portion 22 which is provided with transversely extending openings 23 in the side walls thereof. Secured to the portions 19 and 21 and disposed in substantially concentric relation with respect to the intermediate portion 22 is a relatively thin walled tubular or sleeve-like member 24 having its end edges secured to the respective members 19 and 21 whereby the portion of the member 24 extending between the members 19 and 20 forms the expandable side wall of the member. In this construction at least the portion 21 of the body member 18 is of gum rubber and has a relatively long axial length so that the self-sealing action thereof provides all the seal necessary to retain the expanding fluid within the member. This construction may utilize the same conduit 11, fitting 12' and needle-like extension 13" for supplying fluid to the occlusion member, the extension 13" being inserted through the end portion 21 whereby the open end of the member 13" is disposed within the chamber defined by the intermediate portion 22 of the body 18 so that the entering fluid may flow into such chamber through the openings 23 and exert an expanding force on the tubular member 24. Upon withdrawal of the needle 13" from the portion 21, following expansion thereof in the blood vessel involved, the self-sealing action of such portion will effectively seal the interior of the member.

APPARATUS FOR EFFECTING INSERTION AND EXPANSION OF OCCLUSION MEMBERS

The apparatus for effecting the insertion and expansion of the respective occlusion members can be substantially identical for all of the various types of occlusion members illustrated with the exception of the particular means for effecting the transition from one state to the other of the occlusion members. Thus where the occlusion member utilizes mechanical means for expansion, for example, that illustrated in FIGS. 2 and 3, the means for effecting the transition likewise will normally be mechanical, whereas for the remaining forms illustrated utilizing fluid means this apparatus may employ a liquid as the transition effecting means. Consequently, the apparatus illustrated in FIG. 1, while including mechanical means for effecting such transition, may be readily utilized with the other forms of occlusion member by merely omitting the mechanical transition effecting means and substituting a fluid therefor, with the end of the conduit 11 being modified as hereinafore described to accommodate the particular type of occlusion member with which it is to be employed.

The manually actuable members in either form of the apparatus may be of substantially identical construction corresponding, for example, to the construction of a hypodermic syringe, and in the embodiment illustrated in FIG. 1 such manually actuable members may comprise a hypodermic body or cylinder and plunger. Thus, the tubular conduit 11 is illustrated as being connected at one end to the occlusion member and at the opposite end suitably connected to the body or cylinder 31 of a syringe which is provided with a cooperate plunger 32, the body 31 having a manually engageable flange or lip 33 and the plunger a like flange or lip 34. Thus by suitable manual actuation thereof relative insertion and withdrawal of the plunger 32 may be effected with respect to the body 31. Connection of the conduit 11 to the body 31 may be achieved by any suitable means as for example a suit-
able fitting indicated generally by the numeral 35 which is of known construction and currently utilized in connecting catheters and the like to cooperable syringes.

Encircling the conduit 11 is a tubular sheath 36 of suitable construction, which likewise may be of a type commonly employed in the medical field, the end thereof adjacent the occlusion member 1 having an opening 37 therein while the opposite end is suitably secured to a standard type of fitting 38 which in turn is connected to a Y-fitting 39 having a fluid inlet stem 41. The latter is constructed to receive and retain a suitable tube or conduit from which a contrast medium may be injected into the passageway formed between the outer face of the conduit 11 and the inner face of the conduit 36 and ejected through the opening 37 into the blood vessel adjacent the occlusion member 1, to enable visual ascertaining of the location of the occlusion member 1 in the blood vessel by suitable means such as X-ray equipment or the like.

In the embodiment of the apparatus illustrated in FIG. 1, constructed for use with occlusion members of the type illustrated in FIGS. 2 and 3, the actuating means is mechanical and in the form of a wire-like element 42 corresponding generally to styles or the type employed in catheters and the like to maintain their shape and prevent clogging, etc. In the present instance, however, the adjacent end of the element 42 is firmly secured to the inner end of the plunger 32, for example by means of a suitable connecting member 43, in which the end of the stylet is rigidly clamped, with the member 43 being suitably secured to the plunger end.

The element 42, as clearly illustrated in FIG. 2, is of such a length that the free end thereof may be inserted through the one end portion 4 of the occlusion member and engage the inner face of the opposite end portion 4, whereby separating forces may be applied to the two end portions, in opposition to the action of the spring 6, and thereby effect transition from the expanded state to the contracted state of the occlusion member, as illustrated in FIG. 2. It might be pointed out that in this construction the tension exerted by the spring 6 tending to draw the two end portions 4 into the position illustrated in FIG. 3 is so adjusted as to merely ensure that the spring will exert sufficient force to effect the desired expansion of the occlusion member. Under such conditions the free end of the stylet 42 may be seated on the adjacent end portion 4 of the occlusion member with the latter having sufficient rigidity to provide an adequate seat therefor, even when the spring is in its expanded position as illustrated in FIG. 2, without puncturing such end portion. Likewise, the piercing of the end portion 4 adjacent the conduit 11 by this stylet and engagement of the latter therewith will result in sufficient frictional forces between the stylet and such end portion that the occlusion member will be effectively retained in its contracted position until withdrawal of the stylet therefrom. Withdrawal of the stylet may be effected by outward movement of the plunger 32 with respect to the cylinder 31, thereby withdrawing the free end of the stylet into the conduit 11 with the adjacent free end of the conduit 36, possibly supplemented by the free end of the conduit 11, being engaged with the adjacent end portion 4 whereby movement of the latter is prevented while the stylet is being withdrawn from the occlusion member. Such withdrawal thereby permits the spring 6 to effect transition to the expanded state of the occlusion member, as illustrated in FIG. 3.

Where an occlusion member is employed which utilizes a fluid as the actuating means for transition of the occlusion member from one state to the other, the same general apparatus illustrated in FIG. 1 may be employed, merely eliminating the stylet 42 and connecting member 43 and providing the free end of the conduit 11 with a suitable fitting 12, as previously described, to enable operative connection of the conduit 11, now employed as a fluid supply line, to the associated occlusion member, for example the fitting 12 previously described with respect to the occlusion member illustrated in FIGS. 4–6.

In some cases it may be desirable to form the fluid conduit 11 integrally with the occlusion member. Such a construction is illustrated in FIG. 14, in which the occlusion member 1 is of a construction similar to FIG. 11 but omits the valve structure 8", 9" and the fitting 12", with the adjacent end of the conduit 11 being integrally connected to the adjacent end portion 4" of the occlusion member. In this construction, as illustrated in FIG. 14, the conduit 11 would not be removed from the patient but merely terminated and closed just inside the opening through which it was inserted into the patient's body and such opening suitably sutured as indicated at 44.

**METHOD OF INSERTING AND EXPANDING OCCLUSION MEMBERS**

The practice of the present method will be generally the same irrespective of the particular occlusion member employed or the particular apparatus utilized therewith.

Assuming that the occlusion member involved is constructed in accordance with the disclosure of FIGS. 2 and 3, and the apparatus constructed as illustrated in FIG. 1, the plunger 32 is moved inwardly in the cylinder 31 a sufficient distance to expose the free end of the stylet 42. Such free end is then inserted in the adjacent end portion 4 of the occlusion member 1, feeding the stylet through such portion into the interior of the occlusion member. Continued insertion of the stylet will result in engagement of the free end thereof with the inner face of the opposite end portion 4 and effect separating movement of the latter with respect to the other end portion, resulting ultimately in the occlusion member being disposed in its relatively contracted state as viewed in FIG. 2. As previously mentioned, the pierced end portion 4 of the occlusion member will frictionally engage the adjacent inserted portion of the stylet and provide adequate frictional engagement to ensure retention of the occlusion member in the desired contracted state. An access incision is then made into the body of the patient, extending into the venous system at a point from which the occlusion member may be moved to the desired location of occlusion. For example, where such occlusion member is to be positioned within the inferior vena cava it may be introduced into the venous system of the neck, thereby avoiding use of a lower extremity vein. The occlusion member may then be moved through the blood vessel in which it has been inserted, in a manner similar to that employed with other catheters, utilizing the conduit 11, and/or the conduit 36 as the motivating member until the desired location has been reached. Obvi-
usually the length of the respective conduits and the stylet must be such that they have a length somewhat greater than the effective distance from the point of insertion into the body of the patient to the location at which it is desired to effect the occlusion. When it is desired to ascertain the progress of the occlusion member a desired amount of a suitable contrast medium may be introduced through the Y-member 39 and discharged from the opening 37 to a point initially adjacent to the occlusion member. Such contrast mediums contain materials which are relatively opaque to the particular radiation to be employed therewith, whereby such material will be relatively opaque under the action of such radiation, readily enabling visual observation of the location of the occlusion member. Such materials are currently in common medical use, materials of this type being known, for example, under the tradenames RENOVI ST and HYPAQUE which may be termed radiopaque dyes and may, for example, contain a percentage of iodine as the dye medium. Such materials are usually designated by percentages, for example, HYPAQUE 90 percent and HYPAQUE 50 percent, the percentage indicating how much iodine is contained therein and thus how much radiation will be required to provide a suitable visual effect.

When arrival at the desired location has been ascertained, manual forces are applied to the plunger 32 to move the same outwardly with respect to the cylinder 31 thereby applying withdrawing forces to the stylet 42 which will initially result in expansion of the occlusion member under the action of the spring 6 until it has assumed the position illustrated in FIG. 3, following which continued withdrawal movement of the stylet will result in withdrawal thereof from the pierced end portion 4 of the occlusion member and disconnection of the occlusion member from the inserting apparatus, which may then be withdrawn from the patient. As previously mentioned, the self-sealing characteristics of the material of the end portion 4, such as s a silicone, will result in a resealing of the puncture therein made by the stylet, insuring an effective sealing of the interior of the occlusion member.

Where the occlusion member is adapted to be expanded by the introduction of a suitable fluid therein, the occlusion member is initially connected to the end 13 of the cooperable fitting 12. Depending upon the relative rigidity of the occlusion member in its rest or contracted state of this type of occlusion member, as illustrated in FIG. 4, the device may be initially filled with the expanding fluid, inserting sufficient fluid to merely fill the member when the latter is in its rest state, following which introduction into the body of the patient is made in the same manner as previously described. When the occlusion member has reached its desired location additional fluid may be discharged from the supply conduit 11 into the occlusion member to effect expansion thereof to the state illustrated in FIG. 5. Withdrawal of the fitting 12 from the occlusion member may then be effected, the flap valve 8 or other valve means effectively sealing the interior of the occlusion member and preventing leakage of fluid therefrom. Following disconnection of the conduit 11 from the occlusion member the inserting apparatus may be removed from the body of the patient and the original incision suitably sutured.

In this type of operation various different fluids may be employed as the expanding means. In many cases it may be desirable to utilize a liquid contrast medium, such as that previously described, as the expanding means and at least partially filling the retracted member therewith in which case it may be unnecessary to employ a separately inserted contrast medium as previously described in connection with the use of mechanical expansion means. However, in some instances it may be desirable to utilize other materials as for example a suitable silicone, which may be inserted into the occlusion member in liquid form and which will subsequently harden therein, thereby eliminating any possibility of subsequent deflation of the occlusion member.

In the event the material employed as the expansion means does not possess sufficient inherent opacity to function as a contrast medium, a suitable contrast medium may be employed, injecting the same through the Y-fitting 39 in the same manner as previously described in connection with the mechanical expanding means.

Where an occlusion member, such as illustrated in FIG. 14, is employed, in which the fluid supply conduit for effecting expansion of the occlusion member is integrally connected with the latter, the same general sequence of steps may be performed. However, in this case the occlusion member and its associated conduit 11 is inserted in the cooperative conduit 36 and its free end connected in suitable manner to the fitting 35 or its equivalent, following which introduction into the body of the patient and disposition to the desired location is effected in the same manner as previously described, utilizing a contrast medium as the expanding fluid or utilizing a separate contrast medium as previously described. Assuming that such occlusion member does not contain an internal valve, the conduit 11 may be suitably tied off or sealed adjacent its outer end, and following disconnection from the syringe, the outer conduit 36 may be withdrawn from the patient. The conduit 11 is then closed off, forming the sole closure, and the excess conduit cut off to provide a termination of the closed conduit within the patient's body, following which the original incision may be suitably sutured.

With this arrangement the occlusion member may be subsequently removed by merely effecting a reopening at the point of insertion, bringing the end of the conduit 11 to the exterior, opening the free end of the latter and permitting the expanding fluid to be discharged therefrom. Upon return of the occlusion member to its original contracted state it may be readily withdrawn from the patient's body, utilizing the conduit 11 as the means for effecting such withdrawal.

In the event this type of occlusion member contains suitable valve means such as a valve flap 8, following expansion of the occlusion, the conduit 11 is disconnected from the actuating syringe and the outer conduit 36 withdrawn, the conduit 11 severed at the desired point and the open end thereof suitably sealed, after which it is disposed as illustrated in FIG. 14 and the insertion incision sutured. Retraction of this type of member could be effected with suitably unobstructed conduit by insertion of a valve opening stylet in the conduit.

Where a fluid is employed as the expanding medium and such fluid is of such character that it will supply an adequate opacity for visual examination, it may be desirable in some cases to so construct the conduit 11 that it will provide adequate stiffness or rigidity to facilitate insertion and movement of the occlusion member within the blood vessel involved, whereby the outer
3 conduit 36 may be omitted, this arrangement being capable of usage under suitable conditions with any of the occlusion members illustrated.

It will be noted from the above description that we have produced a novel method of effecting occlusion of a blood vessel together with novel means for forming such an occlusion, as well as a novel apparatus for practicing the method, the method being exceedingly simple and yet capable of ready practice with occlusion members of relatively simple construction and apparatus which is simple in design and readily operated, utilizing techniques with which the surgeon is normally completely familiar.

Having thus described our invention it will be obvious that various materials may be used and modifications may be made in the same without departing from the spirit of our invention, hence we do not wish to be understood as limiting ourselves to the exact method, construction, form and arrangement of parts herein shown and described or usage mentioned.

What is claimed is:

1. A device for effecting the occlusion of a blood vessel comprising an elongated hollow body element having a wall of resilient material, being of a cross-section permitting ready passage through a blood vessel to a desired point of occlusion and inflatable to have a cross section larger than that of said vessel, the distal and proximal end portions of said body element being substantially less deformable than said resilient wall, at least a portion of the proximal end portion being constituted by a perforable body of self-sealing material, and insertion means having a length sufficient to extend from an access opening in the body of the patient to the desired point of occlusion, said means being traversed throughout its length by an inflation lumen and terminating distally in a needle-like element projected through the proximal end of the body of self-sealing material, and adapted to be withdrawn therefrom, whereby the hollow body element may be advanced through the blood vessel to the desired point of occlusion, inflated by fluid introduced through the inflation lumen and deposited in the vessel by disengagement of said needle-like element from said proximal end and withdrawal of said inserting means from such a vessel, with said hollow body element being in operatively self-sustaining fixed engagement with the vessel sidewalls throughout a circumferential band, distributing resulting outwardly directed pressure forces over a substantially unbroken area of the vessel sidewalls, thereby protecting the latter from concentrated puncturing or rupturing forces.

2. A device according to claim 1, wherein said body element is provided with a longitudinally extending passageway which extends therethrough and is not in communication with the hollow interior of said body, forming a bypass between the ends of the latter.

3. A device according to claim 1 which includes a one-way valve in a position to cooperate with the body of self-sealing material to prevent deflation of the inflated body element.

4. A device according to claim 1 wherein said valve comprises at least one flap in a position to rest against the distal end of a perforation through the self-sealing material.

5. A device according to claim 1 wherein said body comprises an elongated base structure of relatively fixed length and said wall is an expandable tubular member disposed in concentric relation with respect to said base structure, and having its end edges connected in fluid-tight relation to said base structure, the latter having a chamber therein communicating with the interior of said expandable tubular member, the latter in its unexpanded state having an outer diameter approximately equal to the maximum diameter of said base structure.

6. A device according to claim 5 wherein said tubular member is secured at its respective ends to said base structure adjacent opposite ends of the latter.

7. In a device for insertion in and effecting the occlusion of a blood vessel, particularly where occlusion is to be for an indefinitely long period, if not permanently, in which an expandable member is adapted to be transported through a blood vessel to a desired point of occlusion by an insertion device constructed to extend from an access opening in the body of the patient to the desired point of occlusion and to detachably support such member at the distal end of such insertion device, whereby the body element forms the lead member of the structure with expansion of the member being effected by actuation of means carried by the insertion device, the improvement in the expandable member including an elongated hollow, fluid-tight relatively smooth-walled body element having a tubular, expandable intermediate wall portion of resilient material and of a non-expanded cross section permitting ready passage through a blood vessel to a desired point of occlusion and expandable to form and operatively maintain an axially extending circumferential band having a cross section larger than that of such a vessel, the distal and proximal end portions of said body element being substantially less deformable than said resilient wall portion, the proximal end portion having means constructed for detachable engagement with and releasable support by the distal end of such an inserting device, said body element upon expansion and disengagement from the distal end of such insertion device, being adapted to be retained in operative self-sustaining fixed engagement with the vessel sidewall throughout such axially extending circumferential band whereby outwardly directed pressure forces are distributed over a substantial area of the vessel sidewall, thereby protecting the latter from concentrated puncturing or rupturing forces.

8. A member according to claim 7 wherein said body is provided with expansion means permanently disposed therein.

9. A member according to claim 7 wherein said body is adapted to receive means therein for effecting such expansion.

10. A member according to claim 7 wherein said body is provided with a longitudinally extending passageway which extends therethrough and is not in communication with the hollow interior of said body, forming a bypass between the ends of the latter.

11. A member according to claim 8, wherein said expansion means comprises a resilient member disposed in and secured to said hollow body and arranged to exert forces thereon urging said body into its expanded position.

12. A member according to claim 9 wherein said expansion means comprises a coiled spring having its ends secured to said end portions of greater thickness and is operative to urge such end portions toward one another.
13. A member according to claim 11 wherein said body is constructed to receive means for exerting expansion forces thereon in opposition to said resilient means, to effect contraction of the body.

14. A member according to claim 12, wherein said body is constructed to detachably receive elongated relatively rigid means carried by said insertion means for effecting such contraction of the body.

15. A member according to claim 7 wherein said body is constructed for detachable engagement with a fluid conduit whereby the latter may communicate with the interior of the body element for discharging fluid therefrom to effect said expansion.

16. A member according to claim 15 wherein said body is provided with a port therein constructed to receive the adjacent end of such a fluid conduit, and a valve member disposed in said body, operative to permit entry of fluid into said body interior, but normally prevent fluid flow from said body.

17. A member according to claim 16 wherein said valve member comprises a flap extending across the inner end of said port.

18. A member according to claim 16 wherein said valve member comprises a ball disposed in said body and adapted to close said port, and means carried by said body to retain said ball in cooperative relation adjacent the inner end of said port.

19. A member according to claim 16 wherein said port of the body is provided with internal threads for engagement with cooperative threads on such a fluid conduit.

20. A member according to claim 16 wherein said body has means thereon for aligning the adjacent end of such a conduit with said body for operative engagement therewith.

21. A member according to claim 15 wherein at least a portion of the proximal end of said body is constructed of a self-sealing material which will permit penetration by such a conduit means, and effect a sealing thereof upon disengagement of said conduit means thereof.

22. A member according to claim 7 wherein said body comprises an elongated base structure of relatively fixed length and said wall is an expandable tubular member disposed in concentric relation with respect to said base structure, and having its end edges connected in fluid-tight relation to said base structure, the latter having a chamber therein communicating with the interior of said expandable tubular member, the latter in its unexpanded state having an outer diameter approximately equal to the maximum diameter of said base structure.

23. A member according to claim 22 wherein said tubular member is secured at its respective ends to said base structure adjacent opposite ends of the latter.

24. In a device for depositing an occlusion member in a blood vessel, particularly where occlusion is to be for an indefinitely long period, if not permanently, in which an occlusion member is adapted to be detachably connected to the distal end of an inserting device to form a detachable lead structure for guiding the insertion device as it is advanced through a blood vessel to the desired point of occlusion and with the occlusion member being adapted to the expanded at the point of occlusion whereby such occlusion member, upon disengagement from the inserting device may be operatively deposited in self-sustaining fixed engagement throughout a circumferential band of the vessel sidewall, the improvement in the inserting device comprising an elongated tubular structure having a length sufficient to extend from an access opening in the body of the patient to the desired point of occlusion and terminating distally in a mounting element adapted to be connected to and detached from the adjacent proximal end portion of said occlusion member to be employed therewith, and means disposed within the tubular structure adapted to effect the expansion of such a body element when mounted thereon, and manually actuable means at the proximal end of the insertion device for effecting actuation of said expansion-effecting means.

25. A member according to claim 24 wherein said expansion effecting means comprises a wire-like element extending through said tubular structure engageable at its distal end with such an occlusion member operative to effect a transition thereof to a relatively contracted state for insertion in such a blood vessel.

26. A member according to claim 25 wherein said actuating means comprises a manually engageable member connected to the proximal end of said elongated tubular structure, and a second manually engageable member, movable relative to said first member and operatively connected to the proximal end of said wire-like element.

27. A member according to claim 25 wherein said elongated tubular structure is disposed within a second concentrically disposed conduit, defining a fluid passageway therebetween, said second conduit having an opening therein adjacent the distal end thereof, and means adjacent the proximal end of said second conduit for introducing a contrast medium into said passageway for facilitating ascertainment of the location of the occlusion member in such a blood vessel by, for example, X-ray means.

28. A member according to claim 25 wherein said expansion effecting means comprises a fluid conductible through said elongated tubular structure, engageable with such an occlusion member for introducing such fluid into the latter to effect a transition thereof from a relatively contracted state to relatively expanded state.

29. A member according to claim 28 wherein said actuating means comprises a fluid-receiving cylinder and a manually actuable piston disposed in said cylinder, movement of said piston relative to said cylinder being operative to effect fluid movement in said conduit.

30. A member according to claim 29 wherein the end of said elongated tubular structure constructed for connection to such an occlusion member, is provided with a connection fitting having external threads thereon adapted to mate with complementary internal threads on such an occlusion member.

31. A member according to claim 29 wherein the end of said elongated tubular structure constructed for connection to such an occlusion member, is provided with a needle-like fitting adapted to be inserted through the proximal end of such an occlusion member.

32. A device for effecting the occlusion of a blood vessel, particularly where occlusion is to be for an indefinitely long period, if not permanently, comprising an elongated hollow, fluid-tight, relatively smooth-walled body element and insertion means therefor, the body element having a tubular-shaped intermediate wall portion of resilient material and of a cross section perm-
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Ting ready passage through a blood vessel to a desired point of occlusion and expandable to form and operatively maintain an axially extending circumferential band having cross-section larger than that of said vessel, the distal and proximal end portions of said body element being substantially less deformable than said resilient wall portion, the proximal end portion being constructed for mounting on and support by said insertion means, the latter having a length sufficient to extend from an access opening in the body of the patient to the desired point of occlusion, said insertion means terminating distally in a mounting element connectible to and disengageable from cooperating means carried by the proximal end of the body element and including means for expanding the latter, with said body element extending distally of said insertion means and forming the lead structure for guiding the insertion means as the body element is advanced thereby through the blood vessel to the desired point of occlusion, expanded by aid of said means for expanding and deposited by disengagement of the insertion means therefrom, in operatively self-sustaining fixed engagement throughout a circumferential band of the vessel sidewalls to distribute resulting outwardly directed pressure forces thereon over a substantial area and thereby protect the vessel sidewall from concentrated puncturing or rupturing forces.

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33. A structure according to claim 32, wherein said hollow body contains a coiled tension spring having its ends so connected to the respective end portions that said spring is operative to urge said body into its expanded state, said insertion means including a wire-like element having one end extending through the proximal end portion of said body adjacent the connection of one end of said spring and bearing on the distal end portion of said body adjacent the connection of the other end of said spring to maintain said body in its contracted state, in opposition to the action of said spring, the opposite end of said wire-like element being operatively connected to actuating means therefor.

34. A structure according to claim 32, wherein said insertion means comprises a fluid conduit, the distal end of which is connected to said body and communicates with the interior of the latter, and said inserting means includes a syringe structure having a movable plunger, with the proximal end of said conduit connected to said syringe structure and communicating with the interior thereof, said expansion effecting means comprising a liquid disposed in said syringe, said conduit and said body, whereby movement of said plunger will force such liquid into said body to expand the same.

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