METHOD AND APPARATUS FOR PERFORMING HYPOThERMIA

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ABSTRACT OF THE DISCLOSURE

A method and apparatus for performing local hypothermia of the central nervous system by extracranial profusion, wherein liquid coolant which is cooled to a temperature of approximately 30°C to —30°C is circulated directly over a selected portion of the central nervous system through a supply catheter. The coolant is returned to the cooling system through a return catheter by means of a pump device which longitudinally compresses the exterior surface of the yieldable return catheter.

It has been found that cooling of the central nervous system provides many advantages in dealing with neuurosurgical problems. For example, it has been found that local or regional hypothermia of the spinal canal structure produces beneficial results in certain patients with spastic rigid quadriaparesis and severe mental deficiency, spinal cord trauma and surgical treatment of spinal cord tumors and vascular malformations. Beneficial results have also been obtained in local extra vascular profusion hypothermia of the intracranial canal structures in surgical treatment of certain brain tumors, cerebrovascular lesions such as aneurisms and hemangiomata, and head injuries. Hypothermia of the intracranial structures results in a decrease in brain volume, mainly as a result of systemic hypertension in diminished cerebral spinal fluid pressure, as well as arrest of cerebral edema when present. Furthermore, when the tissue of the central nervous system cools, there is a decrease in oxygen consumption and therefore, greater protection against anoxia, ischemic, or arrested circulation. In addition, the resistance of brain tissue to surgical trauma is markedly increased and surgical bleeding is easy to control. Thus, local or regional hypothermia of the central nervous system is effective as a therapeutic technique, per se, as a surgical aid and also as a post-operative technique.

Cerebral hypothermia in the past has been brought about by cooling the entire body (surface cooling and intravascular profusion) cooling the vasoclyse supply to the brain, regional hypothermia by extracorporeal intravascular profusion, or by the use of cold capsules or ice applied directly to the cerebral hemispheres. Hypothermia by intravascular profusion requires an additional major surgical procedure and carries with it a number of complications. A serious complication sometimes experienced through the use of systemic hypothermia, (surface or intracranial), is ventricular fibrillation and cardiac standstill which is attributable to the lowered temperature tolerance of heart neumuscular elements, as compared with central nervous system tissue.

A general object of this invention is to provide an apparatus and method for lowering the temperature in the central nervous system in an otherwise normothermic body thereby retaining the advantages of hypothermia while minimizing complications normally attributable to hypothermia.

A more specific object of this invention is to provide a method and apparatus for producing local or regional hypothermia of the central nervous system by extravascular profusion of a selected area of the brain or spinal cord, with cold nontoxic solutions.

These and other objects and advantages of this invention will more fully appear from the following description made in connection with the accompanying drawings wherein like reference characters refer to the same or similar parts throughout the several views, and in which:

FIG. 1 is a perspective view of the apparatus used in carrying out the novel method;

FIG. 2 is a cross-sectional view on an enlarged scale of certain parts of the apparatus taken approximately along line 2—2 of FIG. 1 and looking in the direction of the arrows;

FIG. 3 is a diagramatic view of the apparatus indicating the flow pattern of the coolant.

Generally, in carrying out the method of the present invention, a preselected area of the central nervous system is continuously bathed by controlled extravascular profusion of a cold solution which is nontoxic with respect to the body tissues. The instrument or apparatus used in carrying out this method comprises a supply catheter and a return catheter positioned in proximal relation with respect to the area which is to be continuously bathed or irrigated by the cold solution. A suitable pump means is provided for circulating the coolant, which is first cooled by a suitable cooling or refrigeration system prior to discharge of the liquid coolant over the surface of that selected region of the central nervous system to be cooled.

Referring now to the drawing, it will be seen that one embodiment of the apparatus for carrying out the novel method is there shown. This apparatus, designated generally by the reference numeral 10 comprises a generally rectangular shaped housing 11 preferably constructed of stainless steel or the like, including an upper portion 12 of reduced size, the front surface of which defines a control panel 13. The housing 11 is preferably provided with wheels or rollers 14 to permit the same to be easily moved from one location to another. The interior of the housing is hollow and houses the various components of the systems used in carrying out the novel method.

Referring now to FIG. 3 of the drawing, it will be seen that a tissue cooling system 15 and a refrigeration system 16 are diagrammatically illustrated to show the various components of each system. The tissue cooling system 15 includes a reservoir structure or supply receptacle 17 which is adapted to contain a supply of the liquid coolant used in cooling the central nervous system. Although many kinds of liquid coolants may be used, the coolant must be nontoxic to the tissue and such liquids may include saline and glycerin solutions, glucose solutions, and a physiologic irrigation solution, generally known in the trade as Tiss-U-Sol. The supply receptacle 17 is located exteriorly of the housing 11 and is preferably formed of a transparent material such as glass or the like to permit an operator to determine the volume of liquid coolant therein at any given time. Since the discharge of the liquid out of the supply receptacle 17 is preferably by action of gravity, such a supply receptacle may be supported in a well-known manner from a conventional stand.

The supply receptacle 17 will be provided with a suitable inlet through which the liquid coolant may be added from time to time, the inlet being closed by any conventional closure means.

One end of an elongate preferably flexible supply conduit 18 is connected to the discharge outlet of the supply receptacle 17 in communicating relation therewith, so that the liquid coolant will flow through the supply con-
duct by action of gravity. The other end of the flexible supply conduit 18 is connected to one end of an elongate cooling conduit which is preferably formed of metal and is wound into helical or coil form and positioned within a cooling receptacle 20. A heat exchange action takes place between the refrigeration liquid contained within the cooling receptacle 20 and the liquid tissue coolant, as it passes through the cooling coil 19.

One end of an elongate flexible supply catheter 21 is connected in communicating relation to the other end of the cooling coil 19, and the supply catheter 21 has a discharge end 22, which in the embodiment shown is branched as best shown in FIG. 3. The liquid coolant is discharged from the discharge end of the supply catheter so that the fluid may be distributed over a selected portion of the central nervous system. The use of a catheter having a branched discharge end permits wider distribution of the tissue coolant.

The supply receptacle 17 also has one end of an elongate flexible return catheter 23 connected in communicating relation therewith and it will be seen that the free or intake end 24 of the return catheter may be branched in the manner of the supply catheter 21. The intake end of the return catheter will be positioned in communicating relation with an intracranial or spinal canal structure in the manner of the supply catheter 21, and in close apposition thereto. The liquid coolant will therefore be returned through the return catheter 23 to the supply receptacle 17.

Means are provided for inducing flow of the liquid coolant into the return catheter 23 by suction, and this means comprises a pump device 25, which is positioned within the housing 11, and which is generally known in the trade as a Sigma motor pump. In this type of pump, the liquid coolant being pumped never comes into contact with any of the pump mechanism, and the material is moved through the catheter 23 by the wave-like action of rigid metallic fingers 26, which are diagrammatically illustrated in FIG. 3. These fingers progressively compress the tube in a direction away from its intake end, thus inducing a negative pressure or suction causing the liquid to be forced through the catheter 23 and into the supply receptacle 17.

Variable speed drive means 27 are provided and are interconnected by suitable drive linkage 28 to the pump device 25 to permit operation thereof to be variously adjusted. This variable speed drive mechanism may comprise any suitable power means such as an electric motor having a gear reduction system operatively connected therewith. The variable speed mechanism 27 is preferably of the type sold in the trade under the trademark "Varidrive" manufactured by Zero-Max Industries, Inc.

Means are also provided for permitting ready adjustment for the variable speed drive mechanism 27 and this means includes a double acting hydraulic cylinder 29 having a piston movable therein to which is connected a piston rod 30. The upper or outer end of the piston rod 30 is connected to a control or operating arm 31 of the variable speed drive mechanism 27 so that extension and retraction of the piston rod causes swinging movement of the operating arm 31.

Another cylinder 32 is interconnected in communicating relation with the cylinder 29 by a pair of conduits 33 so that fluid may circulate between the cylinders. The cylinder 32 is also provided with a piston which is movable therein and the piston has a piston rod 34 connected thereto for movement therewith. The piston rod 34 is connected by link 35 to a swinging foot pedal 36, the latter being pivotally mounted on any suitable support means by means of a pivot 37 for vertical swinging movement. A helical spring 38 normally resists depressive movement of the foot pedal 36. It will be seen that when the foot pedal 36 is depressed, the piston rod 34 will be moved from a retracted position to an extended position thus forcing the hydraulic fluid through one of the conduits 33 to thereby retract the piston rod 30 and to increase the speed of operation of the variable speed drive mechanism 27. The pump 25 will also be driven at a faster rate and fluid will be induced through the return catheter 23 at a greater rate. Thus, an operator may control the volume flow of the fluid coolant to the area of the nervous system being cooled by operation of the foot pedal 36. It will be appreciated that a foot pedal is used to permit an operator to have freedom of use of his hands.

The refrigeration system 16 includes the cooling receptacle 20 which is preferably formed of metal and has a cover 39, the entire receptacle 21 being covered with a suitable insulating material 40, as best seen in FIG. 3. The interior 41 of the receptacle 20 defines a cooling zone or chamber in which the cooling coil 19 is positioned. The refrigeration system 16 includes a compressor 42, a condenser 43 and a fan mechanism 44 which serves to cool the condenser 43. The compressor, condenser and fan mechanism are all conventional in many well known refrigeration systems and a detailed description of these components is thought to be unnecessary for the instant application.

A fluid refrigerant, preferably Freon 12, is supplied through a conduit 45 which intercommunicates the cooling receptacle 20 and a condenser 43. Thus, the conduit 45 constitutes a main supply conduit for supplying the fluid refrigerant to the receptacle 20 to permit a heat exchange action to take place between the liquid coolant and the cooling coil 19. The fluid refrigerant is returned to the condenser from the receptacle 20 by means of a conduit 46. It will be noted that the compressor 42 is interposed in flow controlling relation in the conduit 46 although a bypass line may be provided which may include a temperature responsive solenoid valve structure (not shown) to allow the refrigerant to circulate freely through the compressor without having to pass through the condenser. The refrigeration system also includes a dryer 47 and an expansion valve 48 which units are also conventional in refrigeration systems.

During operation of the refrigeration system, the liquid refrigerant will be circulated through the system including the cooling receptacle 20 so that a very effective heat exchange action takes place between the coolant within the coil 19 and the liquid refrigerant within the receptacle 20. Thus, the coolant which is used to irrigate or bathe a selected portion of the central nervous system will be very effectively cooled just prior to discharge of the coolant over the selected portion of the central nervous system.

Although a number of electrical components are used in conjunction with the refrigerant and tissue cooling systems, it is felt that it is unnecessary to show the simple circuitry associated therewith. Electrical current for operating the various electrical components of the respective systems may be supplied through suitable electrical conductors (not shown) which conductors will be provided with a conventional bayonet type male socket for insertion into the conventional female outlet fitting.

The control panel 13 is provided with a switch 49, which is interposed in circuit controlling relation in the circuit for the refrigeration system and permits the electrical components of the refrigeration system to be energized. Another switch 50 is provided which controls operation of the electrical components of the tissue cooling system and a third switch 51 comprises a master switch which controls operation of the circuitry for both the refrigeration system and the tissue cooling system. The master switch 51 must be closed prior to closing either of the switches to the refrigeration or tissue cooling systems.

The control panel also includes a variously adjustable temperature control switch 52 which actually comprises a variable potentiometer which may be adjusted to control the temperature of the liquid coolant of the refrigeration-
tion system. Although not shown in the drawing, the temperature control switch mechanism will be provided with a probe which extends into the cooling receptacle to sense the temperature of the coolant circulating through the refrigeration system, and when the temperature reaches a preselected setting, the coolant will be bypassed with respect to the compressor. An indicator valve is also provided to permit a ready determination of the temperature of the refrigeration system.

In carrying out the novel method of extravascular profusion hypothermia of the central nervous system by the apparatus described hereinabove, the supply catheter and return catheter will have their respective discharge and intake ends positioned to cool a preselected portion of the central nervous system. For example, when the intake and discharge ends of the catheters may be positioned in the subdural space of the brain in communication with the ventricles thereof to achieve hypothermia of a selected portion of the brain or to cool substantially the entire brain. The tissue coolant may be introduced into the intradural, subdural, epidural spaces with respect to the brain or spinal cord. Segmental spinal cord epidural or subdural cooling by extravascular profusion may also be readily accomplished by the instant apparatus.

As pointed out above, only extravascular profusion hypothermia of the central nervous system capable of achieving all those advantages of systemic hypothermia with blankets and ice baths as well as intravascular hypothermia techniques, but many of the complications associated with systemic hypothermia are avoided with extravascular profusion. Thus, extravascular profusion hypothermia is useful as a therapy per se as well as an aid to neurosurgical procedures. For example, hemostasis is made much easier through the use of extravascular profusion hypothermia of the central nervous system, since even light bleeding shows as a red streak moving through a clear blue fluid. The source of such bleeding may be readily discovered by merely tracing the streak to its source.

Another highly desirable advantage of extravascular profusion hypothermia of the central nervous system is that it may be used with great advantage as a post-operative technique. As pointed out above, extravascular profusion will minimize cerebral edema.

It is preferred that the coolant in the tissue cooling system be cooled to a temperature of about 30°C to about 35°C and preferably approximately about 0°C before it is discharged by extravascular profusion into the central nervous system. However, the temperature may be readily adjusted by adjusting the temperature control switch, and the operator may readily vary the rate of flow by control of the foot pedal. Thus, the operator has a relatively wide range of adjustment with respect to rate of flow and temperature although maintaining the temperature of the tissue coolant at approximately 0°C has been found to be extremely beneficial in clinical experience.

From the foregoing description, it will be seen that a novel method and apparatus for extravascular profusion hypothermia of the central nervous system has been provided which is capable of functioning in a more efficient manner than any heretofore known comparable apparatus and system.

It will, of course, be understood that various changes may be made in the form, details, arrangement and proportions of the various parts without departing from the scope of my invention.

What we claim is:

1. Apparatus for providing local hypothermia of the central nervous system by extravascular profusion of a coolant, said apparatus comprising a receptacle containing a predetermined amount of coolant therein, an elongate supply catheter having a discharge end, means connecting the other end of said supply catheter in communicating relation with said receptacle, a return catheter separated from said supply catheter which is formed of yieldable somewhat rigid material and having one end thereof connected in communicating relation with the said receptacle and having an intake end, said discharge and intake ends of said catheters being adapted to be positioned in communicating relation with a selected portion of the central nervous system which is to be cooled, whereby liquid coolant passed through the supply catheter will be discharged therefrom to bathe and cool the selected portion of the central nervous system by extravascular profusion, pump means engaging the exterior surface of said return catheter for progressively compressing the return catheter longitudinally thereof in a direction away from the intake end thereby inducing the flow of coolant through the return conduit by suction, a cooling chamber having a liquid refrigerant therein, a refrigeration unit, conduits communicating said refrigeration unit with said cooling chamber, said refrigeration unit including means for cooling and circulating the liquid refrigerant through said conduits and the cooling chamber, said connecting means including a coiled conduit extending into said cooling chamber whereby the liquid coolant is cooled to a temperature within the range of 30°C to —30°C prior to discharge from said supply catheter.

2. The apparatus as defined in claim 1 having a foot pedal control mechanism for controlling speed of operation of said pump means, whereby the rate and volume of the coolant circulating through the supply and return catheters may be readily adjusted.

3. The apparatus as defined in claim 1 wherein said supply and return catheters each have a plurality of openings in the respective discharge and intake ends thereof.

4. A method of performing local hypothermia of the central nervous system by extravascular profusion, said method comprising the steps of, positioning the discharge end of a supply catheter and the intake end of a return catheter in communicating relation with a selected portion of the central nervous system which is to be cooled, said catheters being connected in communicating relation with a source of liquid coolant, said liquid coolant being selected from the group comprising saline and glycerin solutions, glucose solution, and physiologic irrigation solution, first passing the coolant through a cooling medium to cool the liquid coolant to a temperature within the range of 30°C and —30°C and passing the liquid through the supply catheter to discharge the coolant therefrom whereby the selected portion of the central nervous system is bathed with and cooled by extravascular profusion of the coolant, progressively compressing the return catheter longitudinally thereof in a direction away from the intake end thereof to induce the flow of the coolant through the return conduit by suction, then returning the coolant to the cooling medium to again cool the coolant.

5. The method as defined in claim 1 wherein the coolant is discharged from the supply catheter at a temperature of approximately 0°C.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,504,674

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It is certified that error appears in the above identified patent and that said Letters Patent are hereby corrected as shown below:

Column 6, line 54, the claim reference numeral "1" should read -- 4 --.

Signed and sealed this 22nd day of December 1970.

(SEAL)

Attest:

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