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A. A. DATO

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METHOD OF LOWERING AND RAISING THE TEMPERATURE OF THE HUMAN BODY

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Fig. 1

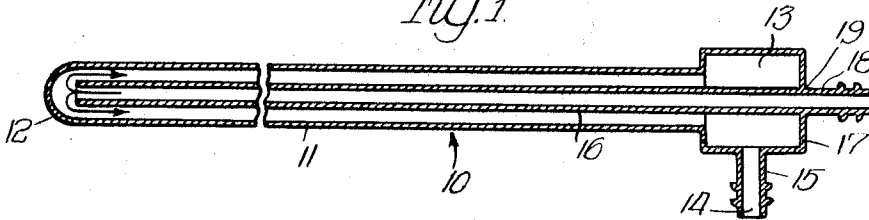


Fig. 2

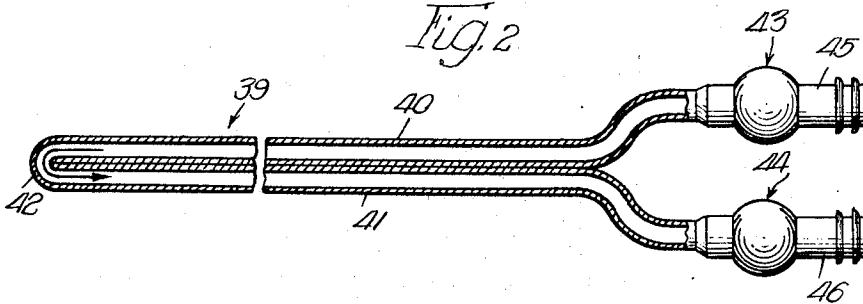
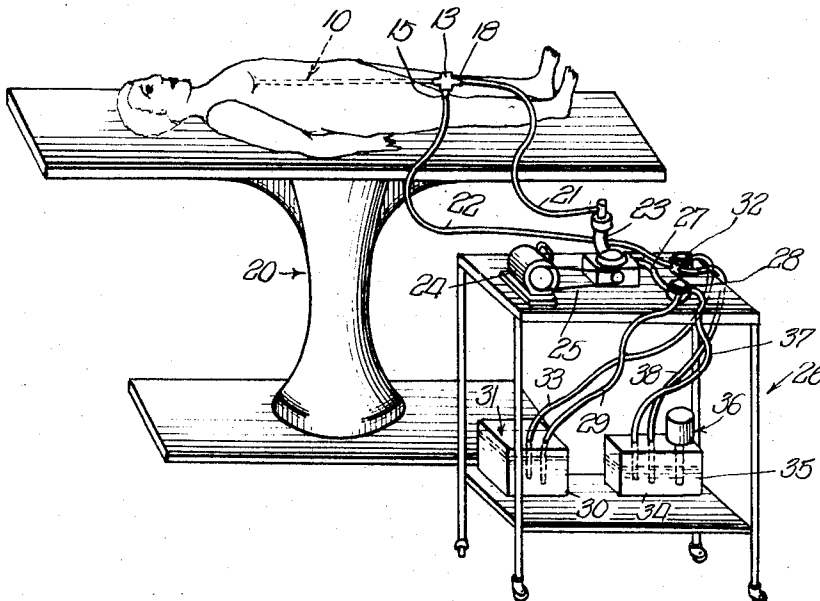


Fig. 3



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METHOD OF LOWERING AND RAISING THE TEMPERATURE OF THE HUMAN BODY

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9 Claims

ABSTRACT OF THE DISCLOSURE

A method for inducing moderate hypothermia in man through the use of a thermal exchange catheter adapted to be inserted within the flowing blood stream in the body. Fluid temperature changing means, together with valve and pump means, is provided to circulate the fluid through the catheter so as to achieve the desired rate of thermal exchange between the walls of the catheter and the blood flowing around the catheter.

This invention relates to method of lowering and raising the temperature of the human body and finds particular application in the technique of moderate hypothermia as an aid to surgery on the heart.

The lowering of the temperature of the human body within determined limits consists of the technique which has been called moderate hypothermia. This technique has opened important possibilities in the field of cardiovascular surgery by permitting surgery on the bloodless heart. For example, surgical corrections have been made in cases of pulmonary infundibular or valvular stenosis, in cases of atrial-septal defects, and in cases of rapid operations on the mitral valve.

Certain methods have heretofore been used in the technique of moderate hypothermia in man but none have been entirely satisfactory. One method consists in immersing the human body in a tub of cold water until the body temperature is reduced to the desired degree. This method has many disadvantages including the fact that the cooling is very slow and the cooling of the various body organs is not uniform. Furthermore, the temperature of the human body can not be easily controlled or changed during the surgical operation, and the operation must be fully completed before the warming of the human body can be commenced. In addition, there is danger of infection during the surgery due to the fact that the body is immersed in the water.

Another method heretofore used in the technique of moderate hypothermia consists in wrapping the human body with a double layer rubber cape through which the chilling fluid can be circulated. This method is slow and the cooling of the organs of the body is not uniform. Furthermore, the apparatus is costly and is a hinderance in the operating room.

A still further method which has heretofore been used in the technique of moderate hypothermia has been to bypass the blood from the superior vena cava to the inferior vena cava through a heat exchanger wherein the temperature of the blood can be raised or lowered. This method has a serious disadvantage in that the thorax is open for a long period of time to accommodate the connection to the venae cavae, and the cooling of the human body can only be commenced after the thorax has been opened and the apparatus connected. There are also certain disadvantages in that this involves dangers of hemolysis of the blood because of the additional operation on the heart.

Another method previously used in this technique has been to place the human body in an enclosure and to

circulate a chilling air stream over the body to cool the body. This apparatus is costly and the cooling is slow so that the method must be commenced several hours before the surgery is to be performed. It is also extremely inconvenient for the surgeon as he must work within the enclosure and there are dangers of infections due to the forced air circulation.

Thus, it seems apparent that though previous methods have been devised for the technique of moderate hypothermia in man, these methods have many inherent disadvantages. It is therefore an object of this invention to provide a method whereby moderate hypothermia in the human body can be conveniently and safely accomplished.

It is yet another object of the invention to provide a method of inducing moderate hypothermia in man whereby the temperature of the human body can be conveniently and quickly controlled at all times by the surgical team.

It is still yet another object of the invention to provide a method of inducing moderate hypothermia which can be used with a minimum amount of danger of infection to the human body.

Other objects and advantages of my method of inducing moderate hypothermia in man with a heat exchanger catheter will be apparent during the course of the following description.

In the accompanying drawings forming a part of this specification and in which like numbers are employed to designate like parts:

FIG. 1 shows a cross-sectional view of one form of a heat exchanger catheter used in combination with other elements of my device.

FIG. 2 shows a cross-sectional view of another form of a heat exchanger catheter that can be used in combination with the other elements of my device.

FIG. 3 is a perspective view showing, in dashed lines, a heat exchanger catheter according to the invention as received in the human body and connected to fluid circulating and control means.

Generally, the invention is directed to a method of inducing moderate hypothermia in a patient by using a metallic catheter with internal passageways through which a fluid, such as water, at a desired temperature, can be circulated by suitable valve and pump means connected to one end of the catheter. The other end of the catheter is closed and rounded so that the catheter can be inserted in a blood-carrying vessel of the human body. As an example, the catheter has been inserted through the femoral vein, isolated at the inguinal region, then through the inferior vena cava as far as the right atrium and the superior vena cava. Fluid refrigerated at about 0° C. is circulated through the catheter by means of a small pump to induce moderate hypothermia in the human body so that surgery can be performed. Valve means are provided so that fluid at a higher temperature of approximately 40° C. can be circulated through the heat exchanger catheter to restore the temperature of the human body to a normal temperature after the intra-cardiac operation is finished.

In FIG. 1 I have shown one form of heat exchanger catheter which is generally indicated at 10. The catheter is of elongated cylindrical shape and the material used in its construction is stainless steel. The dimensions of the catheter used in conjunction with my invention can, of course, vary to some extent. However, by way of example, in catheters which have been successfully used according to my invention, the length has been approximately 70 centimeters. The outside diameter of such catheters has ranged from those of approximately 2 millimeters in diameter for use in the case of children to approximately 6 millimeters in diameter for use in the case of adults. In all forms of my heat exchanger catheter

the wall thickness of the stainless steel material used therein has been approximately .1 millimeter.

Turning, then, to a specific description of the catheter shown in FIG. 1, the outside wall 11 of the catheter 10 is closed and rounded at one end 12. At the other end of the catheter 10 the wall 11 is enlarged to form a chamber 13 having a passageway 14 extending through a radially disposed nipple 15. A stainless steel tube 16 which is open at both ends is concentrically disposed within the outside wall 11 of catheter 10. One end of said tube 16 lies adjacent to, but spaced from, the closed rounded end 12 of catheter 10. The other end of tube 16 extends through a wall 17 that closes the end of chamber 13 and projects therebeyond as indicated at 18. Tube 16 is secured in a fluid-tight connection to wall portion 17 by means of solder 19.

Referring now to FIG. 3 of the drawings, a human body is shown on an operating table, generally indicated at 20. The catheter 10 is shown in the human body as by dashed lines, and a flexible hose 21 is attached to the projecting end 18 of tube 16 with a suitable fluid-tight connection. In the same manner, a second flexible hose 22 is attached through a fluid-tight connection to nipple 15.

A pump 23 that is driven by an electric motor 24 through belt 25, and other fluid circulating and valve means to be described later, are mounted on the top shelf of a wheeled cart, generally indicated at 26. The pump and electric motor are of the type commercially available and it is not thought necessary to describe the features of either the pump or the motor.

The flexible hose 21 leading from catheter 10 is connected to the outlet of pump 23, and the inlet on pump 23 is connected through a flexible hose 27 to a two-way valve, generally indicated at 28. A flexible hose 29 leads from the two-way valve 28 to a tank 30, on the lower shelf of cart 26, and into a fluid supply, generally indicated at 31. The flexible hose 22 from catheter 10 is connected to a second two-way valve, generally indicated at 32, and a flexible hose 33 leads from this second two-way valve 32 into the fluid supply 31 in tank 30. The two-way valves can be of well-known construction but are provided so that the fluid flow through the valve can be directed in either of two paths by manual control means.

The method of use of the heat exchanger catheter 10 and associated fluid circulating and valve mechanisms to achieve a state of moderate hypothermia in a human body is as follows. The patient, in general anesthesia, is placed on the operating table 20. The right femoral vein is exposed in the inguinal region through a small transverse incision in the vein so that the heat exchanger catheter 10 can be introduced through this vein to the inferior vena cava, into the right atrium, and into the superior vena cava. The procedure is relatively easy as a result of the fact that the anatomic location of these body parts is in approximately a straight line. Occasional obstacles to the advancement of the catheter through the body can be overcome by raising the lumbar region of the patient.

Assume, then, that the heat exchanger catheter 10 has been inserted in the human body as described above and that the electric motor 24 is driving the pump 23. Fluid from the fluid supply 31 is drawn through hose 29, two-way valve 28, hose 27, through pump 23, and through hose 21 into the tube 16. As indicated by the arrows within the tube 16, the fluid flow is to the end of tube 16 adjacent the rounded end 12 of the catheter 10 and returning through the passageway between the outer wall 11 and tube 16 to the chamber 13. From chamber 13 the fluid is discharged through passageway 14 and into hose 22. The flow from hose 22 is through the second two-way valve 32 and hose 33 back to the fluid supply 31 in tank 30.

The fluid supply 31 being circulated through the heat

exchanger catheter 10 in the manner described in the preceding paragraph is chilled to a temperature of approximately 0° C. The fluid can be as desired, but as an example, a mixture of alcohol, water, and chipped ice has been used in tank 30 to provide a chilling fluid. Cooling of the human body is obtained by direct contact between the outside wall 11 of the heat exchanger catheter 10 and the circulating venous blood. The cooling is rapid because the heat gradient between the outside wall 11 of the catheter 10, at approximately 0° C., and the blood is very high. I have found that to lower the temperature of the body to approximately 29° to 30° C., twelve to fifteen minutes are needed in the case of children and twenty to thirty minutes in the case of adults.

During the time that the catheter 10 is being used to lower the temperature of the human body, the surgeon performs thoracotomy to expose the heart and principal vessels. When the temperature of the human body has reached approximately 30° C., the catheter is withdrawn to a level to allow the closure of both the superior and the inferior venae cavae. The heart becomes bloodless so that the right atrium or ventricle and the pulmonary artery can be opened to permit the correction of atrial-septal defects or pulmonary infundibular or valvular stenosis. At the temperature of 29° to 30° C. of the human body the circulatory arrest can not exceed eight to ten minutes and the surgeon must operate during this time.

After the surgeon has finished the intra-cardiac operation, the heat exchanger catheter 10 is replaced in its former position in the right atrium or in the superior vena cava. When this has been done the warming of the human body toward a more normal temperature is commenced, and the apparatus forming part of my device which is used for this purpose will now be described. As seen in FIG. 3 of the drawings, there is a second tank 34 on the lower shelf of cart 26. This tank is adapted to hold a supply of fluid 35, such as water, which is maintained at a temperature of approximately 40° C. by a thermostatically controlled immersion type electric heater, generally indicated at 36, that is in contact the fluid 35. This electric heater can be of any well-known commercial type and it is not thought necessary to describe the heater in detail here. A flexible hose 37 leads from the supply of fluid 35 to the two-way valve 28 and a flexible hose 38 leads to the second two-way valve 32.

The fluid flow path or circulation from the two-way valve 28 through pump 23 catheter 10, and returning to the second two-way valve 32 has already been described in conjunction with the use of the chilled fluid supply 31 and it is not believed necessary to repeat this description. It should be clear, however, that if the two-way valves 28 and 32 are manually operated to stop the flow of fluid from tank 30 and permit the flow of the warming fluid from the second tank 34, then the warming fluid from the supply of fluid 35 will be circulated through the catheter 10 in the same manner as was the chilled fluid. Thus, the surgical team can manually operate the two-way valves 28 and 32 to direct either chilled fluid from the tank 30 or heated fluid from the tank 34 through the catheter 10.

During the time that the patient is being rewarmed by the circulation of the heated fluid from the second tank 34, the thoracic wall is closed, and by the time the surgeon has finished, the temperature of the human body will normally have reached approximately 35° C. The catheter is then removed and the incision on the femoral vein is closed.

While the above description of the use of my device indicates that the catheter 10 can be introduced into the human body through the femoral vein, it should be understood that this is not the only manner of insertion of the catheter 10 into the human body. For example, in three cases of surgery the catheter 10 was introduced through

the femoral artery, the aorta, to the origin of the left carotid artery. The results were similar to the cases in which the femoral vein was employed, and my device has been successfully employed in 131 cardiac operations.

In FIG. 2 I have shown another form of heat exchanger catheter which is generally designated by the number 39. In this particular form, a section of tubing is bent in U-shape with parallel and lengthwise extending tubular portions 40 and 41 in contact with each other. The end 42 of the heat exchanger catheter 39 is closed and rounded, and at the opposite end the tubular portion 40 and 41 diverge in a Y-shape having arms leading to chambers, generally indicated at 43 and 44. Nipples 45 and 46 extend from chambers 43 and 44, respectively, and are adapted to receive flexible hoses 21 and 22 in fluid-tight connections in a manner similar to the connection of these hoses to the heat exchanger catheter 10. The arrow within the heat exchanger catheter 39 indicates the direction of flow of the fluid in the catheter, and it will be appreciated that the catheter functions in the same manner as the heat exchanger catheter 10 previously described.

My device for inducing moderate hypothermia in man has many advantages in its use over previously used methods. Among these advantages is the fact that the device is not expensive or unwieldy for use in an operating room and is available for immediate use even though such use was not contemplated when surgery was commenced. Furthermore, the cooling and warming of the body is uniform since the circulating blood in the body is cooled or warmed directly. In addition, the temperature control of the body under the direction of the surgical team is continuous, easy, and sure. A further advantage in the use of my device lies in the fact that the duration of the operation can be shortened since thoracotomy and the suture can be done during cooling and rewarming of the body respectively.

While the above description of my device has been in connection with its use for inducing moderate hypothermia in the human body so as to permit open heart surgery, the device is not limited to this field. For example, the device can be used in cases of intractable hypothermia. Also, the device has been successfully used with smaller catheters than those above described and illustrated in FIGS. 1 and 2 of the drawings for insertion in the smaller blood vessels to produce hypothermia in various body organs.

In compliance with the requirements of the patent statutes, I have here shown and described the preferred embodiments of my invention.

I claim:

1. A method for lowering and raising the temperature of a human body including the steps of inserting a catheter to lie within the flowing blood stream in a blood-carrying vessel of the body and then lowering or raising the temperature of the wall surface of the catheter in contact with the blood flowing around said catheter so as to provide for a heat flow between said catheter and said blood.

2. A method for inducing moderate hypothermia in a human body which comprises the steps of inserting a catheter having walls permitting a heat transfer there-through into a flowing blood stream within a blood-carrying vessel of the body, urging said catheter through said blood-carrying vessel into the human heart and then lowering the temperature of the catheter surface in inti-

mate contact with the flowing blood in the blood-carrying vessel and the heart to a temperature much below that of the normal temperature of the blood in the human body so that said blood can be cooled to a desired temperature.

3. The method as defined in claim 2 wherein the blood-carrying vessel is a vein of the human body.

4. The method as defined in claim 2 wherein the blood-carrying vessel is an artery of the human body.

5. The method as defined in claim 2 wherein the catheter surface is lowered to a temperature of approximately 0° C.

6. The method of lowering the temperature of a human body comprising the steps of inserting a metallic catheter to lie in the blood stream flowing within the femoral vein of the human body, pushing said catheter through said vein to the human heart, lowering the temperature of the catheter wall surface in contact with the flowing blood in the vein and heart to a predetermined temperature lower than that of the human blood in said vein and heart, and maintaining said catheter wall surface at such predetermined temperature for a time sufficient to lower the temperature of the human blood by an appreciable amount through the heat transfer between said catheter and said flowing blood.

7. The method as defined in claim 6 wherein said predetermined temperature is approximately 0° C.

8. The method of control of the temperature of a human body including the steps of inserting a catheter in a flowing blood stream within the human body, lowering the temperature of the surface of the catheter in contact with the blood flowing around said catheter in the blood stream to a predetermined temperature so as to cool the blood, maintaining the surface of the catheter at this predetermined temperature for a period of time and then raising the temperature of the surface of the catheter in contact with the blood to another predetermined temperature so as to warm the blood.

9. The method as defined in claim 8 where said predetermined temperature of the surface of the catheter to cool the blood is approximately 0° C. and said another predetermined temperature of said surface for warming the human blood is approximately 40° C.

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DALTON L. TRULUCK, *Primary Examiner*.

U.S. Cl. X.R.

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