

[54] **DIALYSIS CONTROL SYSTEM AND METHOD**

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 149,905, June 4, 1971, Pat. No. 3,756,234.

[52] U.S. Cl. **128/214 R**, 128/214 E, 210/90, 210/321

[51] Int. Cl. **A61m 01/03**

[58] Field of Search 128/214 R, 214 B, 214 E, 128/214 F, 214.2, DIG. 3; 23/258.5; 210/90, 321

[56] **References Cited**

UNITED STATES PATENTS

2,721,732 10/1955 Melrose 128/DIG. 3

3,416,664 12/1968 Kume et al. 210/321 X
3,731,680 5/1973 Wright et al. 128/214 F

OTHER PUBLICATIONS

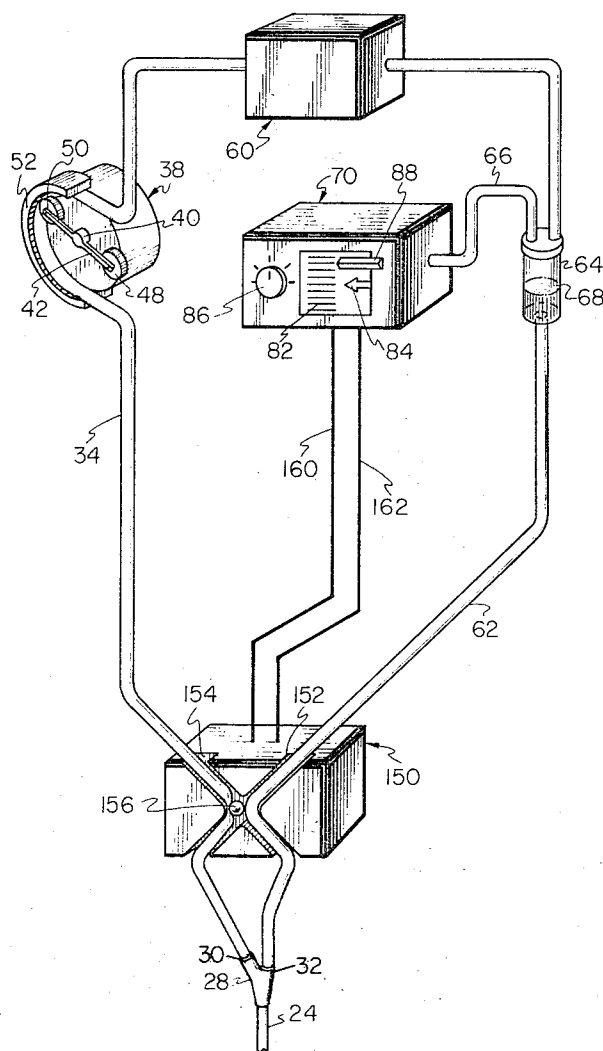
Twiss - Lancet - November, 1964, No. 7369 (p. 1106).

Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—H. Ross Workman

[57] **ABSTRACT**

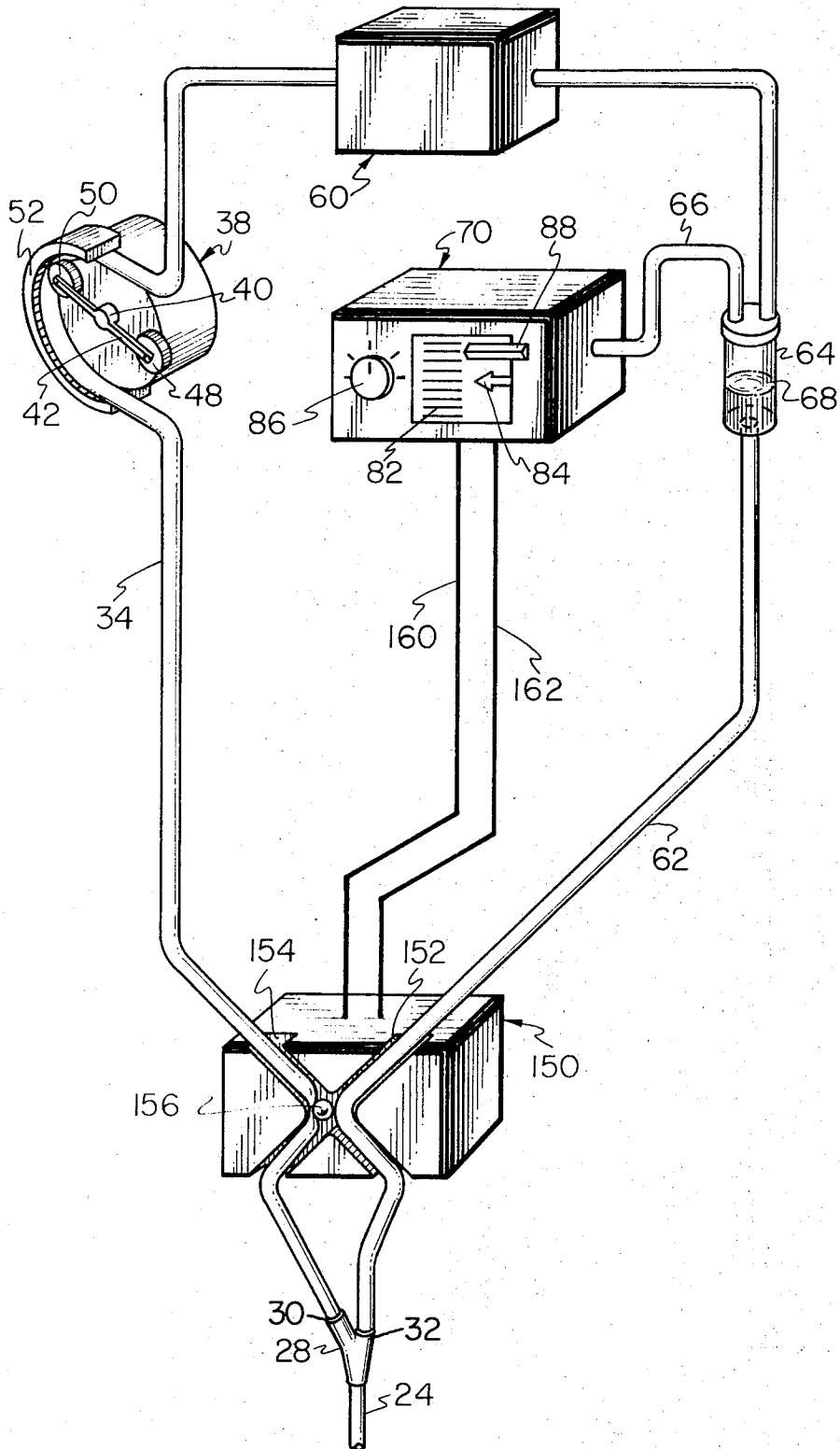
Method and apparatus for extracorporeally dialyzing the blood of a patient with only a single venipuncture including withdrawing blood from the patient through the venipuncture and forcing the blood along an arterial path to a dialyzer. Blood emerging from the dialyzer is then conducted along a venous path again to the patient. The pressure is monitored in the extracorporeal system to trigger occluding devices which alternately open and close the arterial and venous paths, the closure time being asynchronous so that undialyzed blood is taken from the patient at a flow rate which differs measurably from the flow rate that dialyzed blood is injected into the patient.

4 Claims, 1 Drawing Figure



PATENTED AUG 20 1974

3,830,234



DIALYSIS CONTROL SYSTEM AND METHOD

This application is a continuation-in-part of my co-pending application Ser. No. 149,905, filed June 4, 1971, now U.S. Pat. No. 3,756,234 issued Sept. 4, 1973.

BACKGROUND

1. Field of the Invention

The invention relates to extracorporeal hemodialysis and more particularly to method and apparatus for dialyzing a patient's blood with a single venipuncture or cannulation.

2. The Prior Art

The numerous advantages of extracorporeal hemodialysis through a single fistula are set forth in my co-pending patent application Ser. No. 149,905, filed June 4, 1971 now U.S. Pat. No. 3,756,234, dated Sept. 4, 1973, herein incorporated by reference. It has been found that the effectiveness of single fistula dialysis is remarkably improved by increasing the stroke volume of the dialyzing system. Stroke volume is herein defined as the blood flow rate (ml/min) divided by the number of cycles per minute of the flow control system. Increased stroke volume increases efficiency because it reduces the admixing so common in single-fistula dialysis.

Prior art systems have commonly employed pressure monitors or time-controlled clamps to control the flow of blood out of the patient into a dialyzer and then from the dialyzer into the patient again. Conventionally, care has been taken to assure that the blood flow rate out of the patient was essentially equal to the blood flow rate in the return line. Wherever the flow rate in the arterial line (away from the patient) and the venous line (toward the patient) are the same, the stroke volume cannot be maximized. This will be understood by recognizing that increase in blood flow rate according to the known prior art also requires a corresponding increase in cycles per minute of the flow control system.

BRIEF DESCRIPTION AND OBJECTS OF THE INVENTION

The present invention, including novel method and apparatus, reduces patient trauma and tissue damage by accommodating extracorporeal hemodialysis by providing for variations in stroke volume to maximize the efficiency of hemodialysis. While this invention may have application in a variety of extracorporeal systems, it presently appears most significantly advantageous in dialysis through a single venipuncture. Generally, once the venipuncture has been performed, blood is conducted away from the venipuncture site through the arterial branch of a bifurcated blood path at a pressure which is low enough to prevent collapsing the arterial branch or the patient's blood vessel. The bifurcation is located next to the needle connector to keep the resulting deadspace as small as possible. The blood is then forced to the extracorporeal hemodialyzer under pressure while the venous branch is occluded. Thereafter, the venous branch of the bifurcated flow path is opened for a predetermined time to return blood again to the venipuncture site. The time of the return in the venous branch is controlled so that the return flow rate differs from the flow rate in the arterial branch. The method using the single venipuncture is made possible by alternating the blood flow into and out of the patient

at the venipuncture site. A unidirectional pulsatile blood flow through the dialyzer is established by, for example, drawing the blood from the patient at a pressure which will not collapse the patient's blood vessel or arterial branch. In the interim, the venous branch is occluded so that substantial pressures are developed in the dialyzer. In a preferred example, at a predetermined pressure limit, the venous occlusion is opened for a predetermined time, allowing the blood to return to the patient at a flow rate substantially greater than the rate of withdrawal.

It is, therefore, a primary object of the present invention to provide an improved method of extracorporeal hemodialysis.

It is another primary object of the present invention to provide improved apparatus facilitating extracorporeal hemodialysis with a single venipuncture.

Another valuable object of the present invention is to provide an improved system for single needle dialysis for providing variable stroke volume to improve the efficiency of an extracorporeal dialyzer.

One still further and no less important object of the present invention is to provide a novel method of varying the blood flow rate in the venous branch of an extracorporeal system with respect to the flow rate in the arterial branch.

These and other objects and features of the present invention will become more fully apparent from the following description and appended claims taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The FIGURE is a schematic perspective illustration of a presently preferred system for dialyzing a patient's blood using a single venipuncture.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference is now made to the preferred embodiments of the invention as illustrated in the FIGURE. A hollow cannula 24 is adapted to be situated within a blood vessel of a patient. Preferably, the cannula has been placed according to any suitable technique such as venipuncture. The cannula 24 may be of any suitable type and may be made of any desirable material such as radiopaque Teflon. One suitable cannula has been found to be the Angiocath intravenous placement unit manufactured by Deseret Pharmaceutical Company, Inc., Sandy, Utah. A 14-gauge catheter having a length of between 1 and 2 inches has been found to be most effective. Nevertheless, it is also presently preferred to use a hollow needle or any other suitable hollow instrument which can be effectively placed within a vein. In this specification, cannula means any hollow tubing which can be placed in a patient's blood vessel.

In the illustrated embodiment, the cannula 24 is bifurcated at coupling 28. Coupling 28 has an arterial branch 30 and a venous branch 32, arterial branch 30 being attached in conventional manner to a rubber or plastic tube 34. Tube 34 will hereinafter be referred to as the arterial line 34.

Arterial line 34 is situated over the face 36 of a blood pump generally designated 38. Blood pump 38 is conventional and normally includes a rotatable shaft 40 upon which is mounted a transverse bar 42. The bar 42, has, at its respective ends 44 and 46, rotatable cylinders 48 and 50.

Approximately one-half of the circular path traversed by the cylinders 48 and 50 is bordered by a semi-circular track 52. The arterial line 34 is caused to follow the inside surface 54 of the track 52. Thus, as the cylinders 48 and 50 traverse their circular path about the axis of shaft 40, the arterial line 34 will be squeezed between the respective cylinders and the track 52. Conventionally, the bar 42 rotates clockwise around the shaft 40 so that the squeezed portion of the arterial line 34 is developed between the cylinder and the track 52 at the leading end 56 of the track and progresses over the entire inside surface 54 of the track to the trailing end 58 thereof. As the squeezed portion of the arterial line 34 progresses over the inside surface of the track 52, blood in the arterial line 34 is forced to the dialyzer generally designated 60. It can be appreciated that when the cylinder 48 reaches the trailing end 58 of the track 52, the cylinder 50 will engage the arterial line 34 at the leading end 56 so that a constant forward pressure is exerted on the blood to move from the blood vessel 22 to the dialyzer 60 as long as the pump is in operation.

Any suitable conventional dialyzer can be used with the present system. An example of one suitable dialyzer which could be used is described in U.S. Pat. No. 3,723,305 and manufactured by Vital Assists, Inc. of Salt Lake City, Utah. Another suitable dialyzer is the Coil EX-01 manufactured by Extracorporeal, Inc. Blood emerges from the dialyzer 60 in the venous line 62 which is attached in a conventional way to the branch 32 of the coupling 28. Preferably, a bubble trap 64 is interposed in the venous line 62 to prevent bubbles from passing through the cannula 24 into the blood vessel 22. The bubble trap 64 may be any suitable conventional bubble trap such as that used with blood infusion apparatus.

A pressure conductor 66 is connected into the venous line, preferably at the bubble trap 64 above the surface level 68 of the blood. Thus, pressure within the bubble trap 64 and venous line 62 can be transmitted through the conductor 66 to a controller generally designated 70. The controller 70 includes (a) a pressure monitor which may be of any suitable type such as is manufactured by Cambridge Instrument Corporation of Great Britain, and (b) a time circuit which may be of any suitable type such as is manufactured by Eagle Signal Company, a Division of E. W. Bliss Co. of Davenport, Iowa.

The controller 70 has a calibrated bezel 82 with indicia thereon representing, for example, millimeters of mercury. An indicator 84 is controlled by venous line pressure in conductor 66 so that when the venous line pressure in conductor 66 rises, the indicator 84 rises to indicate the pressure in millimeters of mercury (mm Hg). Similarly, when the pressure in conductor 66 drops, the indicator 84 drops to represent the decreasing pressure in millimeters of mercury. A manually adjustable set point is determined by the position of marker 88. For example, marker 88 sets the upper limit of blood pressure in the venous line 62 as will now be more fully described.

The set point 88 represents a pressure maximum in the venous line 62 which, when reached, actuates clamp 150 to open the venous line 62 and close the arterial line 34 as will be hereinafter more fully described. Venous line 62 will again be closed after the expiration of a predetermined time increment. The

time increment is determined by positioning dial 86 on the controller 70. Although any suitable time range could be included, increments between 0.5 second and 1.5 seconds have been found adequate for most signal fistula systems.

In the illustrated embodiment, a double clamp 150 is provided. The clamp 150 has intersecting channels 152 and 154 through which the venous and arterial lines 62 and 34, respectively, pass. The clamp 150 has a detent 156 situated between the channels 152 and 154, the detent 156 being selectively actuated alternately into channel 152 or 154 to occlude and clamp off the arterial and venous lines. Control of the detent is provided through electrical conductors 160 and 162 connecting the clamp 150 to the controller 70.

The Method

Initially, the set point on the controller 70 is adjusted by moving the marker 88 to represent the desired venous pressure. The arterial and venous lines are primed by filling the lines with isotonic saline. When a single venipuncture or cannulation has been performed, the saline in the arterial and venous lines 34 and 62 is replaced with blood.

The pump 38 operates continuously to force blood toward the dialyzer 60. The speed of the blood pump is selected to be at a maximum rate which will not collapse the arterial line 34 of the patient's blood vessel.

Assuming that the venous line 62 is occluded by clamp 150, blood is withdrawn from the patient's blood vessel 22 through the cannula 24 and arterial line 34 into the dialyzer 60. Continued pumping by the pump 38 causes the pressure in the venous line 62 to increase because of the occlusion of the venous line in the channel 152. As the pressure rises, the indicator 84 will rise to the set point determined by marker 88. When the set point is reached, clamp 150 will be actuated to open the venous line 62 and to occlude, essentially simultaneously, the arterial line 34.

Importantly, the arterial line 34 is occluded for a predetermined time increment which is selected at dial 86 to be just long enough to reduce venous pressure by injecting blood into the patient through the cannula 24. It has been found that the time required to return a quantity of blood through the venous line to the patient is proportional to the pressure developed on the blood in the venous trap 64. Accordingly, higher pressure settings by marker 88 accommodate shorter time increments for opening the venous line. According to this embodiment of the invention, it is presently preferred that the time increment during which the venous line is open be less than the time increment during which the venous line is closed. In a preferred embodiment, for example, the open time of the arterial line compared to the venous line was advantageously maintained in a ratio of 2:1. The flow rate through the venous line to the patient will depend upon the pressure developed in the venous trap 64 while the line is occluded.

While the above described embodiment emphasizes the value of improving a high pressure dialysis system by developing greater flow in the venous line 62 than the arterial line 34, it is sometimes desirable to maintain very low pressures in the dialyzer 60. In that circumstance, it is more desirable that the velocity of the outflow blood through the arterial line 34 be greater than through the venous line 62. This can be easily ac-

complished when using a low pressure dialyzer merely be selecting a greater time increment on dial 86 to, for example, up to as much as several seconds, allowing the blood to return more slowly. The small pressure gradient in the venous line 62 resulting from the low pressure dialyzer will assure that the blood return flow rate is less than the blood withdrawal flow rate.

It is observed that the speed of pump 38 should be controlled so that blood 18 is not withdrawn so quickly from the patient that the arterial line or the patient's vein collapses. However, a greater blood return flow rate incurs no risk of collapse of the venous line or the patient's vein and the greater flow rate return is advantageous to maximize the efficiency of the system.

From the foregoing, it can be appreciated that improved dialysis of a patient's blood can be obtained with a single venipuncture where the stroke volume is increased by withdrawing blood from the patient at a comparatively slow rate and injecting the return blood at a comparatively rapid rate. A surprising and advantageous improvement has also been demonstrated by this system: admixture of blood at the bifurcated coupling 28 is noticeably reduced. This surprising result is presently believed to be due to the greater flow rate of the returning blood.

The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive and the scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed and desired to be secured by United States Letters Patent is:

1. A method of dialyzing the blood of a patient in an extracorporeal hemodialyzer, the steps of:

cannulating a blood vessel of a patient with a single hollow cannula, the cannula being bifurcated extracorporeally into an arterial branch and a venous branch, the hemodialyzer being situated therebetween;

closing the venous branch for a first variable time increment and simultaneously aspirating blood out of the patient blood vessel through the arterial branch toward the dialyzer until blood in the venous branch reaches a predetermined elevated pressure;

closing the arterial branch and opening the venous branch for a second predetermined time increment, the second time increment being less than the first, so that the elevated pressure causes the blood in the venous line to be conducted to the patient at a flow rate which is greater than the rate at which the same quantity of blood is withdrawn from the patient.

2. A method of controlling an extracorporeal hemodialysis system comprising an arterial line conducting blood away from a patient, a venous line conducting blood toward the patient, a dialyzer situated between the arterial and venous lines and a blood pump for uni-

directionally displacing the blood, the steps of:

aspirating blood from the patient through the arterial line at a flow rate which will not collapse blood-conducting conduit;

closing the venous line while continuing to aspirate the blood until a predetermined elevated pressure is reached in the venous line;

thereafter opening the venous line and essentially simultaneously closing the arterial line for a predetermined time increment to inject the blood under pressure into the patient; and

insuring that the duration of a venous line opening is less than the duration of the arterial line opening.

3. A system for controlling the dialysis of blood comprising an arterial line conducting blood away from a patient, a venous line conducting blood toward the patient, and a dialyzer situated between the arterial line and venous line, the improvement comprising:

means for pumping blood unidirectionally from the patient through the open arterial line at a pressure which will not collapse blood-conducting conduit;

means for closing the venous line while the blood is being pumped until a predetermined elevated blood pressure is reached in the venous line, said closing means comprising pressure-responsive control means adjustable to maintain the closure of the venous line independent of time;

means for opening the venous line and essentially simultaneously closing the arterial line, said opening means comprising time-responsive control means adjustable to maintain the venous line open independent of pressure in the line for a predetermined time increment to inject the blood under pressure to the patient, the duration of the closure of the arterial line being less than the duration of the venous line closure.

4. A system for controlling the dialysis of blood comprising an arterial line conducting blood away from a patient, a venous line conducting blood toward the patient, and a dialyzer situated between the arterial line and the venous line, the improvement comprising:

means for pumping blood unidirectionally from the patient through the open arterial line at a pressure which will not collapse blood-conducting conduit;

means for closing the venous line while the blood is being pumped, said closing means comprising a first independently variable control means maintaining closure of the venous line until a predetermined blood pressure is reached in the system;

means for opening the venous line and essentially simultaneously closing the arterial line, said opening means comprising a second independently variable control means allowing accumulated pressure of the blood to inject the blood to the patient for a predetermined time increment, the duration of the closure of the arterial line being greater than the duration of the venous line closure.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,830,234

Dated August 20, 1974

Inventor(s) KLAUS F. KOPP

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

Column 3, line 63, "actautes" should be --actuates--;

Column 4, line 4, "signal" should be --single--;

Column 4, line 49, "ine" should be --line--;

Column 5, line 2, "be" should be --by--.

Signed and sealed this 29th day of October 1974.

(SEAL)

Attest:

McCOY M. GIBSON JR.
Attesting Officer

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Commissioner of Patents