AMBULATORY HEMODIALYSIS APPARATUS

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References Cited

UNITED STATES PATENTS

3,373,876 3/1968 Stewart.......................... 210/321

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ABSTRACT

An ambulatory hemodialysis apparatus has a perfusion unit having multiple small internal diameter tubules secured at both tubule terminus in a pair of plastic header plates. The plate pair are secured in a rigid exchanger shell having an inlet and outlet dialysate conduit, forming a perfusion unit typically having 25 ml. blood and 25 ml. dialysate contained volumes, as scaled in size for an adult patient. Cellophane or de-acetylated cellulose triacetate tubules, of 0.2 mm to 2.0 mm internal diameter by 8 cm length, provide the blood residence volume for dialysis. A rigid exchanger shell, typically 8.5 cm long x 6 cm wide x 1 cm thick, provides the dialysate volume. A femoral arteriovenous cannulae positioned on the thigh provides an exteriorized artery cannula to the blood inlet conduit of the portable perfusion unit, and the blood outlet conduit of the unit is connected to the venous cannula. The required dialysate is circulated through two perfusion conduit connections to a portable patient-worn dialysate reservoir, and the dialysate is pumped by patient generated pulses, such as arterial and breathing pulses, utilizing a check-valve controlled diaphragm pumping means. Dialysed excreta is manually periodically voided from the dialysate reservoir by the patient, on periodic signal by a patient powered pulse counter. An orifice disposed in the blood outlet conduit of the perfusion unit can symmetrically increase blood pressure and accelerate water removal from the patient's blood.

10 Claims, 9 Drawing Figures
AMBULATORY HEMODIALYSIS APPARATUS

BACKGROUND OF THE INVENTION

Kidney perfusion chambers are classified under Class 128, Subclass 1, other subclasses include 214.

Maintenance hemodialysis has become an important technique for the treatment of chronic uremic patients. The kil kidney machine is well known and frequently used in hospitals and at home for the dialysis of the chronically uremic patient. The machine utilizes a semi-permeable cellulose membrane, 1 sq. m in area, over which the patient's blood is passed, where it is dialyzed against a prescribed saline solution, prior to returning the blood to the patient.

An artificial kidney utilizing capillary fibers is described by Stewart, Barreta, Cerny, and Mahon in Investigative Urology, Volume 3, No. 6, page 614 (1966). Capillary fibers extruded from cellulose triacetate and deacetylated by a saponification process are formed into a fluid exchange chamber, which are sealed in header plates in a fluid exchange shell. The perfusion unit provides means for impervious flow of patient blood into and out of the capillaries, and dialysis of the blood by the saline dialyse solution which circulates around the exterior of the capillary fibers. The deacetylated cellulose acetate provides a semi-permeable membrane which is substantially more permeable to water than cellophane, and when used in capillaries having a mean inside diameter of 90 micron and a wall thickness of 20 micron provides a satisfactory dialysate membrane.

By providing a permanent femoral shunt as first developed by Quimtron, Dillard and Scribner, reported in the Trans. Amer. Artif. Intern. Organs, 6:104, 1960 and later modified by Thomas, ibid. 15:288, 1969, a femoral shunt can lie comfortably on a patient's anterior thigh and is well hidden from observation by the patient's garment. A femoral shunt in conjunction with a bulky dialysis semi-permeable membrane unit and an electro mechanical pumping means can provide for the periodical dialysis of a patient's blood while lying in a bed.

This invention provides an ambulatory hemodialysis apparatus suitable for use by a patient during a reasonably normal ambulatory physical activity schedule. It is intended that the dialysis apparatus be worn continuously, awake and asleep. Means are provided for periodically renewing the dialysate by the patient, on periodic signal by a patient powered pulse counter.


McKirdy and La Torra in U.S. Pat. No. 3,212,498, disclose the art of simultaneous diffusion and blood dialysis, including a membrane arrangement contrived to oxygenate blood concurrently with the dialysis process for transporting certain electrolytes and organic entities across the membrane into a dialysis reservoir.

Gasca et al in U.S. Pat. No. 2,720,879, issued Oct. 18, 1955, discloses a dialyzer interposed in the blood circulation of the patient which is traversed by blood to clean the blood of toxic waste products, and includes a semipermeable membrane separating the blood from an isotonic saline solution.

Other objects and advantages of this invention are taught in the following description and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

A description of this invention is to be read in conjunction with the following drawings:

FIG. 1 is an elevational perspective view of the ambulatory hemodialysis apparatus worn by a patient.

FIG. 2 is a plan view of an ambulatory perfusion unit as worn by a patient.

FIG. 3 is a cross sectional view taken through the planar view FIG. 2.

FIG. 4 is a cross sectional view through 4-4 of FIG. 2.

FIG. 5 is a perspective elevational partial cross sectional view of a diaphragm circulatory pump useful in circulating dialysate in the hemodialysis apparatus.

FIG. 6 is a plan view of a patient worn dialysate reservoir illustrated in perspective in FIG. 1.

FIG. 7 is an elevation cross sectional view through 7-7 of FIG. 6.

FIG. 8 is a perspective elevational view of the fluid control means for modifying the composition of the dialysate.

FIG. 9 is a cross sectional view through 9-9 of FIG. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1 in detail, the ambulatory hemodialysis apparatus 10 is shown disposed in a typical operational position on a human torso 11. The hemodialysis perfusion unit 12 is disposed on the patient's anterior thigh, and a dialysate reservoir 13 is shown secured on the patient's side. A diaphragm pump means 14 is shown secured on the torso by a nonelastic pump torso belt 23. A dialysate exchange unit 15 is shown disposed adjacent to the perfusion unit 12 and is connected to the unit 12 by the conductive tubing 29. A dialysate voiding valve 16 is shown typically disposed below the dialysate reservoir 13. Conductive tubing 17 connects the valve 16 and the dialysate exchange unit 15. The conductive tubing 18 connectively conducts dialysate flow 30 from the perfusion unit 12 to the diaphragm pump means 14. The conductive tubing 19 connects the dialysate flow 30 from the pump means 14 to the dialysate reservoir 13. The femoral artery cannula 20 and the femoral venous cannula 21 provide a peripheral arteriovenous exteriorized loop which is conductively connected to the perfusion unit 12. A pulse counter 22 is disposed underneath the nonelastic pump torso belt 23, cooperatively reacting with the diaphragm pump 14 to provide a mechanical count of the diaphragmatic pulses of the patient's torso 11, which provide the energy required to operate the pump 14. Periodically, as is required by the patient's medical regime, the counter 22 can be set to ring a mechanical alarm bell or operate a like sensor input signalling the patient to void dialysate which has been collected in the dialysate reservoir 13, utilizing the voiding valve 16.

Adjustable torso harness straps 24, secure the armored conductive tubing 17 and 18, in suitable anatomical positions. The pair of torso harness straps 25 and 26 secured on the reservoir 13 in a selected position on the torso 11, the straps 25 and 26 being adjustably secured to the straps 23 and 24. A pair of shoulder straps
27 and 27' secure the nonelastic torso belt 23 in the desired position on the patient's torso 11. Belt 23 provides the necessary position for pump 14 on the patient's diaphragmatic perimeter, to operate the diaphragm pump 14 at the required pump flow rate. An elastic strap bandage 28, which has been removed to show the apparatus clearly, is conventionally applied around the patient's thigh to secure and protect the artery shunt 20, the venous shunt 21, the perfusion unit 12, and the dialysate exchange unit 15.

Referring to Figs. 2, 3 and 4 together in detail, the perfusion unit 12 is shown in Fig. 2 in plan view, having an arterial blood conduit 40 and a venous blood conduit 41. A dialysate inlet conduit 42 and a dialysate outlet conduit 43 are oppositely disposed on two sides of the perfusion unit 12. The perfusion unit 12 has a rigid case wall 44 to which the conduits 40, 41, 42 and 43 are integrally, fluid imperviously secured. The unit 12 has a typically flat, rigid exterior case structure. As illustrated in Fig. 3, a first header plate 45 and a second header plate 46 are oppositely disposed in fluid impervious sealed means inside the case 12, having multiple, equal length dialysis tubules 47 fluid imperviously secured therein. The multiple dialysis tubules 47 can be typical regenerated cellulose or cellophane, and alternatively can be a partially deacetylated grade of cellulose triacetate. Typically the dialysis tubules range in size from 0.2 mm to 2 mm in diameter, having a typical length of 7-8 centimeters. Typically for an adult blood flow rate of 500 ml/min in the femoral shunt, approximately 340 tubules are imperviously secured in the first header plate 46 and the second header plate 47. The header plates 46 and 47 can be a polyurethane resin or other nontoxic resin which can be used in contact with the fluid involved.

As illustrated in Figs. 2 and 3, the inlet blood flow 48 through the arterial blood conduit 40 is in to the blood inlet manifold aperture 50, thence through the multiple dialysis tubules 47, into the blood outlet manifold aperture 51 and out through the venous blood conduit 41 in the venous flow direction 49. The dialysate inlet flow 53 is into the dialysate manifold aperture 54, provides a counter-current flow to the blood flow and out through the dialysate outlet conduit 43 in the direction 55. The counter-current flow of the dialysate and the blood provide for perfusion of dialysate fluid through the thin walls of the dialysis tubules 47 in the conventional manner to remove by diffusion the waste products conventionally removed by a kidney dialysis device. Fig. 4 illustrates in further detail the construction of the dialysis unit 12, illustrating the inner plate 46 imperviously secured in the unit 12 dividing 51 and 54 and having the multiple dialysis tubules 47 secured therein. The rigid case 44, somewhat oval in shape, provides a protective covering for the device, preventing crushing of the fragile tubules 47. Applicant is not restricted to the precise dimensions of the dialysis unit 12 which are given as typical examples. The size of the unit can be dimensionally scaled upward or downward to meet the medical requirements of the patient using the apparatus. An orifice plate 56 having an orifice 57 disposed in the blood outlet conduit 41 of the perfusion unit can systematically increase blood pressure and accelerate water removal from the patient's blood.

It is intended that the patient generate and supply the energy required to pump the dialysate circulating through the apparatus 10. This energy can be conveniently supplied by the breathing pulses of the patient. The diaphragm pump 14 operated at a typical breath inhalation rate of 18/minute can provide the typical flow rate of dialysate. For an adult blood flow rate of typically 500 ml/min a dialysate flow rate can range from 500 to 225 ml/min. Thus at 18 breaths/min, a single breath pulse must supply approximately 30 ml of periodic dialysate flow. By positioning the diaphragm pump 14 on the patient's torso near the base of the patient's rib cage, sufficient patient diaphragmatic expansion and contraction can be provided to satisfactorily operate a small flexible bellows pump or an equivalent bulb pump, typically providing an effective bellows volume change of 30 ml per breath. By utilizing a bellows pump 14 secured in the correct operative position on the patient's torso 11, the nonelastic belt 23 is shown in FIG. 5 securing a protective pump cover 60 permanently secured to and disposed over a bellows pump 61. The pump can be pure gum rubber, high density polyethylene or an equivalent elastomeric material. The protective pump cover 60 is directly secured to the belt 23, the belt 23 having a length conventionally adjusted for the required value of the patient's torso perimeter. The belt 23 is supported in position by the pair of shoulder straps 27 and 27'. Thus when the pump 14 is secured on the patient's torso 11, the base 69 of the bellows pump 61 rests on the patient's skin. A distance 71 is provided between the terminus 70 of the short wall 62 and the patient's skin, which can allow for proper adjustment of the belt 23. Thus, when the terminus 70 of the wall 62 is substantially in contact with the patient's skin during the minimum contraction of the patient on the breathing cycle, the belt 23 can be adjusted to fit. The expansion and contraction distance measured by 71 can provide a simple means of determining the pumping volume of the diaphragm pump 14 on each breath contraction and expansion of the torso. Typical expansions of the adult patient's thorax can range from one-fourth-three-eighths inch. Since water retention by a uremic patient produces a generally higher breath pulse rate, the pumping rate of dialysate will be automatically increased, with a hopefully automatic increase in the rate of water permeation and removal by the hemodialysis apparatus 10.

The bellows pump 61 has a pump inlet conduit 63 and a pump outlet conduit 64, providing dialysate inlet flow direction 65 and dialysate outlet flow direction 66. The pump bellows as illustrated has a compression and expansion axis 67 which can be adapted to provide the required change in pump volume 68, as the pump bellows base 69 is disposed on the patient's skin of torso 11. An arterial cuff, effectively filled with water, and disposed around a femoral artery, or other anterior artery, can provide arterial pulse power. A check valve disposed adjacent the cuff can operate to produce unidirectional dialysate flow 30. The arterial cuff is effectively equivalent to the breast powered pump 14, operating instead at a pulse rate of typically 72-80 pulses/min.

Referring to Figs. 6 and 7 together in detail, the dialysate reservoir 13 is shown to have a rigid protective cover 80 secured to the exterior face 92 of the dialysate reserve bag 81, disposed opposite the patient's body. The reserve bag 81 has a dialysate inlet conduit 82 and a dialysate outlet conduit 83 integrally secured to the bag. A flexible inlet downspout 93 is integrally conduc-
A supplementary fluid volume dialysate control means 15 can be provided in the dialysate fluid circuit which can be utilized to add a specific chemical concentration to the dialysate or to remove a specific chemical composition from the dialysate in a chemical exchange reaction, as has been established in studies of the uremic patient. The dialysate control means 15 of FIG. 8 has an inlet conduit 100 and an outlet conduit 101 for the dialysate 88. The dialysate enters in the flow direction 102 and exits in the flow direction 103 from the unit 15. A first porous header plate 104 supports a dialysate fluid volume control composition 105 which chemically modifies the chemical composition of the dialysate 88 as it is circulated through the control composition 105. A second porous header plate 106 is disposed in the unit 15 providing a spaced volume between 104 and 106 for the control composition 105. The dialysate fluid volume control composition 105 provides a means of adding a chemical component to the dialysate, or for removing a chemical component from the dialysate 88 by a chemical absorption reaction or an ion exchange process, as is conventionally known. Because of the large volume of urine that is excreted in 24 hours, and the relatively small volume of the dialysate 88 which is provided to be circulated in the hemodialysis unit, amounting to typically 200-250 ml, it is desirable that the patient void urine periodically through the void valve 16. The exchange unit 15 cannot remove the typical 60 grams of solids which will accumulate in the patient's dialysate over a 24 hour period, unless the urine is voided periodically in the form of a dilute dialysate 88. This concurrently would require the addition of make-up fresh dialysate of the prescribed composition for a uremic patient, and would require also that the make-up be added periodically after each voiding period.

Since the hemodialysis apparatus is to be worn continuously by the patient during both waking and sleeping periods, it is desirable to provide an armored protective cover 111 for the conductive tubing, typically 17, 18, 19 and 29. As shown in FIG. 9, the typical tubing 18 can have an armored protective cover 111 disposed around a flexible plastic tubing 110. This provides protection during the sleeping and sitting periods for the conductive tubing 18, preventing the supply of dialysate from being cut by a pinch or compression of the tubing 18.

In treatment of the uremic patient, the ambulatory self-contained hemodialysis apparatus 10 has a femoral arteriovenous shunt positioned on the patient's thigh to provide an exteriorized artery cannula 20 to the blood inlet conduit 40 of the hemodialysis unit 12 and the blood outlet conduit 41 is connected to the venous cannula 21. The prescribed chemical composition dialysate 88 is circulated through perfusion unit 12 dialysate conduits 42 and 43 while the patient's blood circulates through the pair of conduits 40 and 41. The dialysate 88 is pumped through the armored conductive tubing 17, 18, 19 and 29 by the diaphragm pump 14 which is secured on the patient's thorax. The diaphragm pump 14 operated by the patient's breathing pulses provides circulation of the dialysate 88 at the required rate through the hemodialysis apparatus 10 as the patient's thorax contracts and expands. Check valves 86 and 87, which can be disposed in a suitable position dialysate circuit, provide for unidirectional counter-current circulation flow 30 of the dialysate 88 and the patient's
blood. Dialyzed excreta is manually periodically voided from the dialysate reservoir 13 by the voiding valve 16 on periodic signal, as by a pulse powered pulse counter 22 which can be set to signal the patient at the required periodic time interval as required by the patient's medical needs. When dialyzed excreta is voided from the dialysate reservoir, a like volume of a fresh dialysate fluid is added to the reservoir 13. Heparin treatment can be required during the operation of the apparatus 10.

Many modifications and variations of the improvements in an ambulatory hemodialysis apparatus can be made in the light of these teachings. It is therefore understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

1 claim:

1. An ambulatory self contained hemodialysis apparatus, in combination comprising:

an ambulatory hemodialysis perfusion unit having equal length multiple small internal diameter dialysis tubules disposed in an opposed pair of header plates, said header plates secured in the interior of a rigid boundary case in a fluid exchanger configuration, said boundary case having a pair of opposed dialysate conduits secured thereto and a pair of blood conduits manifolded to said opposed pair of header plates;

an ambulatory dialysate reservoir having each one of an opposed pair of reservoir conduits secured to each one of a pair of dialysate tubular conductors, each one of said dialysate tubular conductors separately secured to one of said dialysate conduits, the inlet conduit of said reservoir having a flexible, gravity positionable downspout conductively secured thereto inside said reservoir, the downspout length adapted to provide dialysate circulation in upright or reclining reservoir position, said reservoir having a dialysate additive inlet and addition inlet closure, said reservoir adapted to securing to the body of a patient;

valve means conductively secured to said dialysate tubular conductors providing dialysate unidirectional flow;

an ambulatory pump means conductively secured to said dialysate reservoir, said pump means displacing dialysate in unidirectional flow, said pump means actuated by patient generated pulses; and

an ambulatory voiding valve conductively secured to said dialysate conduction circuit, providing dialysate removal.

2. In an ambulatory hemodialysis apparatus of claim 1, the modification wherein said dialysate reservoir and said pump means are each covered by a rigid protective cover disposed on said reservoir and said pump means exteriorly distant from the torso of said patient.

3. In an ambulatory hemodialysis apparatus of claim 1, the modification wherein said pump means has a compressible elastomeric bellows diaphragm pump of the required volumetric displacement secured on a nonelastic harness belt secured on said patient's torso, said pump adapted to compress and displace a unidirectional flow of said dialysate, on a patient generated breath displacement.

4. In an ambulatory hemodialysis apparatus of claim 1, the modification wherein a dialysate modification means is conductively disposed in the dialysate circulation flow stream, providing means of chemically maintaining the required dialysate composition value range.

5. In an ambulatory hemodialysis apparatus of claim 4, the dialysate modification means combination comprising:

a disposable adsorption cartridge providing removal of organic and inorganic waste products from said dialysate circulated by said pump; and

a pulse counter means, providing an adjustable patient alarm actuated by a pre-set number of patient generated pulses.

6. An ambulatory self contained hemodialysis apparatus, in combination comprising:

an ambulatory hemodialysis perfusion unit having equal length multiple small internal diameter dialysis tubules disposed in an opposed pair of header plates, said header plates secured in the interior of a rigid boundary case in a fluid exchanger configuration, said boundary case having a pair of opposed dialysate conduits secured thereto and a pair of blood conduits manifolded to said opposed pair of header plates;

an ambulatory opposed pair of cannulae conductively permanently secured to said hemodialysis perfusion unit, one said cannula adapted to conductively securing one said blood conduit to the artery and one said cannula adapted to conductively securing one said blood conduit to the vein of a patient;

an ambulatory dialysate reservoir having each one of an opposed pair of reservoir conduits secured to each one of a pair of dialysate tubular conductors, each one of said dialysate tubular conductors separately secured to one of said dialysate conduits, the inlet conduit of said reservoir having a flexible, gravity controlled downspout conductively secured thereto inside said reservoir, the downspout length adapted to provide dialysate circulation in upright or reclining reservoir position, said reservoir having a dialysate additive inlet and addition inlet closure, said reservoir adapted to securing to the body of said patient;

valve means conductively secured to said dialysate tubular conductors providing dialysate unidirectional flow;

an ambulatory pump means conductively secured to said dialysate reservoir, said pump means displacing dialysate in unidirectional flow, said pump means actuated by patient generated pulses; and

an ambulatory voiding valve conductively secured to the dialysate conduction circuit, providing dialysate removal.

7. In an ambulatory hemodialysis apparatus of claim 6, the modification wherein said dialysate reservoir and said pump means are each covered by a rigid protective cover disposed on said reservoir and said pump means exteriorly distant from the torso of said patient.

8. In an ambulatory hemodialysis apparatus of claim 6, the modification wherein said pump means has a compressible elastomeric bellows diaphragm pump of the required volumetric displacement secured on a nonelastic harness belt secured on said patient's torso, said pump adapted to compress and displace a unidirectional flow of said dialysate, on a patient generated breath displacement.

9. In an ambulatory hemodialysis apparatus of claim 6, the modification wherein a dialysate modification means is conductively disposed in the dialysate circulation flow stream, providing means of chemically maintain-
9. In an ambulatory hemodialysis apparatus of claim 9, the dialysate modification means combination comprising:
a disposable adsorption cartridge providing removal of organic and inorganic wastes from said dialysate
circulated by said pump; and,
a pulse counter means, providing an adjustable patient alarm actuated by a pre-set number of patient generated pulses.

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