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Kitrilakis et al.

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[54] **STEADY FLOW REGENERATIVE PERITONEAL DIALYSIS SYSTEM AND METHOD**

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[52] **U.S. Cl.** **128/213**, 128/348

[51] **Int. Cl.** **A61m 5/00**

[58] **Field of Search** ..... 128/213, 214 R, 348, 1 R; 210/321

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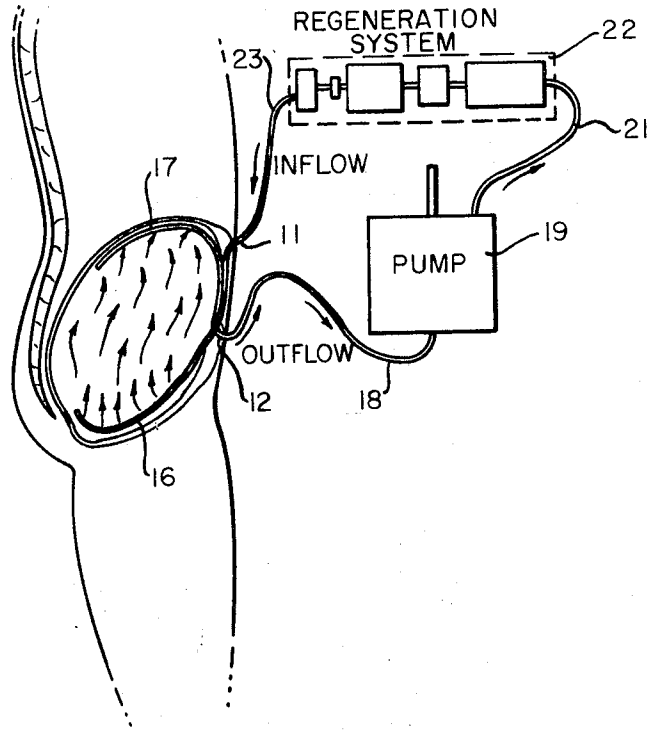
[57] **ABSTRACT**

A steady-flow regenerative peritoneal dialysis system and method making use of permanent percutaneous tubes extending into the abdominal cavity and means for circulating a dialysate through the abdominal cavity and reconstituting the dialysate.

9 Claims, 4 Drawing Figures



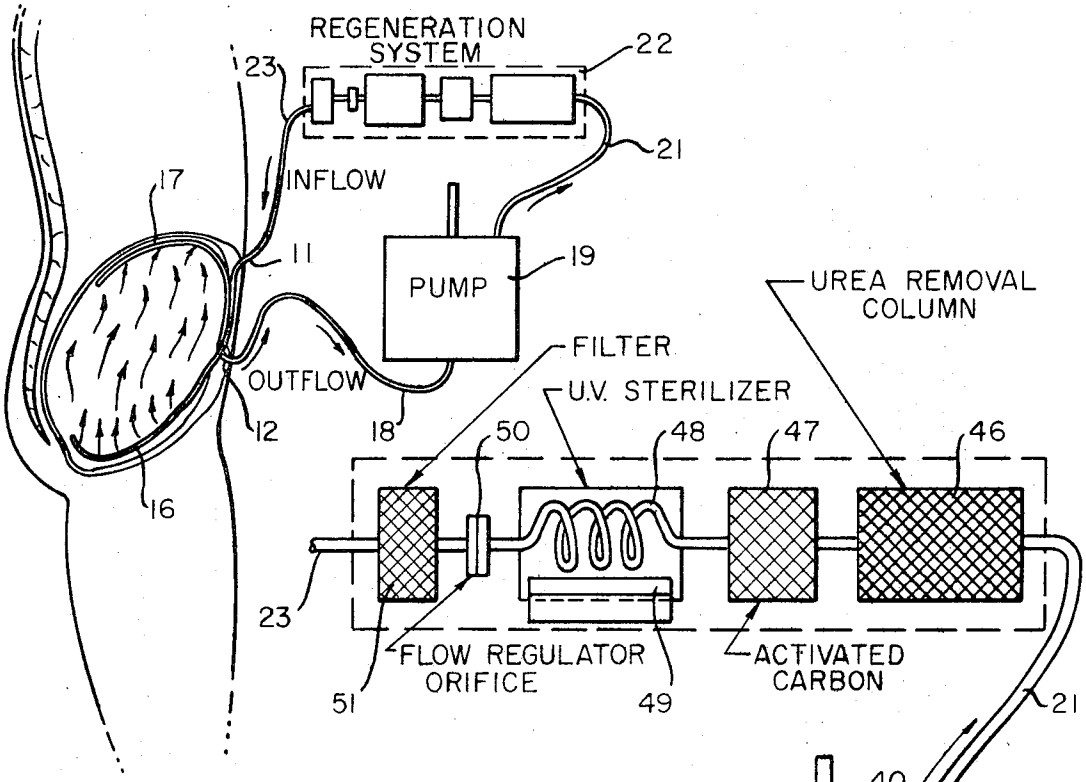


FIG. 1

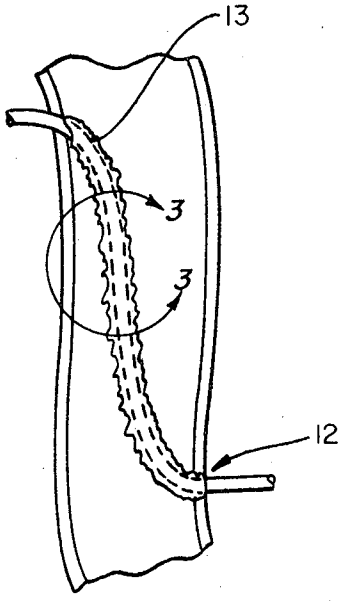


FIG. 2

FIG. 3

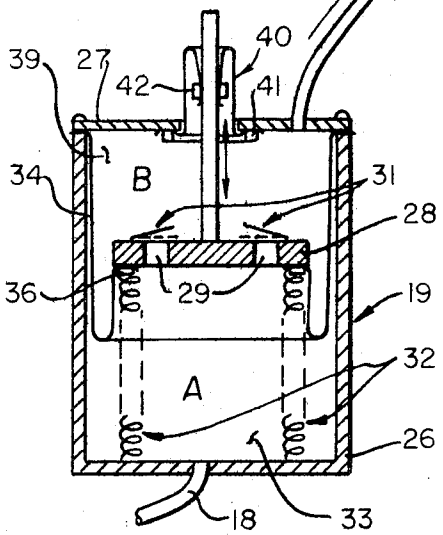


FIG. 4

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STEADY FLOW REGENERATIVE PERITONEAL DIALYSIS SYSTEM AND METHOD

BACKGROUND OF THE INVENTION

This invention relates generally to apparatus for treatment of chronic kidney disease and more particularly to a peritoneal dialysis system and method.

The dialysis process has become an effective means for treatment of chronic kidney disease. Two types of dialysis are currently in use; hemodialysis and peritoneal dialysis. In hemodialysis the blood is removed from an artery or vein, dialyzed in an artifical kidney machine external of the body and returned to a vein usually through cannulas in the arm or leg. This type if dialysis involves permanent connectors to major blood vessels for attachment of the device and also requires the handling of blood in an external prothesis.

The second type of dialysis which does not involve handling of blood directly in a prosthesis is peritoneal dialysis. In this method, dialysing fluid is introduced in the abdominal cavity either through a puncture in the abdominal wall or through a permanently installed percutaneous tube. The dialysate resides in the cavity for a period of time (20 minutes to 1 hour) and is then removed. While the fluid is in the cavity, it picks up urea and other metabolic wastes from the blood stream by diffusion through the walls of the blood vessels within the abdominal cavity. This scheme of dialysis avoids the requirement of handling the blood and invasion of the vascular system but requires the penetration of the abdominal wall. Both types of dialysis require that the blood stream be brought directly or indirectly in chemical equilibrium with a very large quantity of dialysate. In addition to the waste material picked up by the dialysate, a certain amount of proteins and inorganic constituents capable of diffusing through the hemodialysis membrane or the blood vessel walls are dissolved in the dialysate fluid and lost. The systemic replacement capacity for these substances may or may not be capable of maintaining physiologic levels. When certain of these materials are depleted by chronic dialysis over long periods of time, characteristic pathologic symptoms often appear. The depletion of important trace components is proportional to the total quantity of dialysate used.

An additional serious difficulty with both types of dialysis is the danger of infection, either at the sites of cannulation of arteries and veins in the case of hemodialysis, or the penetrations through the abdominal wall, temporary or permanent, in the case of peritoneal dialysis. The large quantities of dialysate involved must be maintained sterile during preparation and throughout the diffusion process to avoid infecting the blood stream or the peritoneal cavity.

As a consequence, elaborate cleaning and sterilization procedures must be followed by hospital personnel or the patient himself while connecting the cannulas or percutaneous in-flow out-flow tubes to the dialysis equipment. Any laxities during the procedure can lead to serious infection.

The equipment involved in both types dialysis is bulky and expensive, primarily because of the large quantity of dialysing fluid and the handling of blood. In both types the patient must be attached to the equipment and remains essentially immobilized for the duration of the dialysis process. The complexity and high

risks associated with currently used dialysis equipment and methods have resulted in the administration of treatments as infrequently as possible, usually about 2–3 times weekly. In the time period between treatments the concentration of metabolic wastes in the patient's blood stream continuously increases reaching levels which normally cause discomfort and often debilitation prior to the next dialysis treatment.

The discomfort and incapacity prior and during treatments often impairs the patient's ability to lead a normal, productive life and may also lead to serious psychological problems.

OBJECTS AND SUMMARY OF THE INVENTION

It is a general object of the present invention to provide a steady-flow regenerative peritoneal dialysis system and method which overcomes a number of the drawbacks of presently used systems and methods.

It is another object of the present invention to provide a peritoneal dialysis system and method which employs a small amount of dialysate fluid which is circulated at low, steady flow rates through the peritoneal cavity via in-flow and out-flow tubes extending through the abdominal wall.

It is another object of the present invention to provide a regenerative peritoneal dialysis system and method wherein the fluid employed is regenerated and the amount retained in the abdomen is minimized whereby the abdominal cavity is not distended by a large amount of fluid and virtually no discomfort results from the presence of the fluid within the cavity.

It is a further object of the present invention to provide a peritoneal dialysis system and method in which the dialysis is performed at steady flow rates and approaches continuous use thereby eliminating excessive concentrations or urea and other metabolic wastes which would otherwise build up in the blood stream and thereby avoid abrupt changes in waste concentration resulting from present dialysis processes.

It is a further object of the present invention to provide a continuous regenerative peritoneal dialysis system and method in which the in-flow and out-flow tubes extending through the abdominal wall into the peritoneal cavity are permanently affixed and are formed whereby the tissue may readily grow to the surface of the tubes to form a living seal to prevent bacterial infection.

The foregoing and other objects of the invention are achieved by a dialysis system including in-flow and out-flow conduits extending through the abdominal wall and provided with a surface which permits the growing and attachment of tissue to the surface of the conduits. The conduits provide means for introducing and removing fluid from the peritoneal cavity which communicates with means for circulating the dialysate fluid through the cavity and regenerative means for regenerating the fluid. The cavity, associated conduits, and circulating and regenerating means are connected in a closed fluid system whereby the fluid is continuously reconstituted and circulated through the peritoneal cavity.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram of the regenerative peritoneal dialysis system in accordance with the

present invention shown connected to supply fluid to the cavity.

FIG. 2 is an enlarged view of the abdominal wall showing the skin, subcutaneous tissue and peritoneum together with a conduit anchored in the wall by tissue growth.

FIG. 3 is an enlarged view of the portion of the conduit of FIG. 2 showing the surface microcavities into which the tissue grows.

FIG. 4 is a detailed drawing of the fluid circulating flow control and regeneration means.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In accordance with one feature of the invention, two substantially identical permanent percutaneous tubes **11** and **12** are inserted through the abdominal wall. One tube, tube **12**, is shown in enlarged view in FIG. 2. The tube may be formed of silicone rubber material with an outer wall containing a plurality of irregular microcavities **13**. These microcavities may be formed in accordance with the method set forth in copending application Ser. No. 77,289 filed Oct. 1, 1970 to provide microcavities which have a depth in the range of 0.002 to 0.020 inches. These microcavities permit the subcutaneous tissue to grow around the outside walls and become permanently affixed or anchored to the walls. Thus, the track along the peritoneal penetrations is completely sealed by the tissue which grows into the microcavities and is nourished from adjacent cells.

The tubes are preferably very small in diameter, for example, 1 to 3 mm. in diameter, and are very flexible because of the very low flow rates required in steady flow dialysis in accordance with another feature of the present invention. Both of these characteristics greatly facilitate the permanent fixation of the tubes into the abdominal wall. The conduits **11** and **12** each have a portion **16** and **17**, respectively, which extend into the abdominal cavity. The other end of the conduit **12** is connected to means for removing the fluid from the abdominal cavity comprises a conduit **18** which, in turn, connects the pump **19** which serves to transport fluid from the upper portion of the abdominal cavity and pumps the fluid along the conduit **21** to the reconstitution system **22** which reconstitutes the dialysate fluid and forms a means for supplying the fluid to the abdominal cavity. The fluid then flows through the conduit **23** through the conduit **11** and into the lower portion of the abdominal cavity at the tube **16**. Thus, it is seen that there is formed a closed system in which the dialysate fluid is circulated and reconstituted.

The out-flow from the peritoneal cavity flows along the line **18** to the fluid pump **19**. The pump **19** may include a cup-shaped chamber **26** provided with a cap **27** which is suitably secured to the portion **26** as, for example, by screws. Piston **28** which includes a pair of spaced ports **29** provided with one-way valves **31** is disposed in the chamber **26**. The piston is urged in one direction by means of a pair of springs **32** which are suitably secured between the piston **28** and the bottom wall of the cup and serve to urge the piston in said one direction to draw fluid from the cavity into the chamber **33**. Chamber **33** is defined by the walls of the cup-shaped chamber **26** and the flexible membrane **34** which may have one end suitably secured to the piston as by a ring **36** and its other end suitably secured to the cup by being sandwiched between the cap **27** and the side walls **26**. Thus, fluid is drawn into the chamber **33** as the springs urge the piston in one direction. At the same time as fluid is being drawn into chamber **33**, the fluid in the upper chamber **39**, which is defined by the other side of the piston, the flexible seal membrane **34** and a second sealing membrane **40**, is moved through the conduit **21** into the reconstitution system. The upper chamber **39** is defined by the upper wall of the pump together with the flexible seal **36** which has one end affixed to the upper wall by means of a ring **41** and to the piston rod by means of a second ring **42**.

The reconstitution system may be one of two general types. In a first type, illustrated in FIGS. **1** and **4**, the fluid travelling along the conduit **21** passes through a urea removal column **46**, an activated carbon or charcoal column **47**, a transparent conduit portion **48** which is irradiated by an ultra-violet source **49**, and a conventional flow regulator **50** which regulates the flow and finally through a filter **51**. The reconstituted fluid leaving the reconstitution system is then applied along the conduit **23** to the in-flow conduit **11**. The rate of flow through the system is controlled by flow regulator **50**.

After the piston P reaches the top of the stroke, the chamber **33** is full and, of course, chamber **39** is basically empty. The piston is then depressed and fluid is transferred from the lower chamber **33** to the upper chamber **34**, through valve means **31**. When the piston reaches its lowest stroke, the piston is released and the springs urge the piston upwardly pumping fluid into the chamber and expelling fluid from the chamber **39**.

Although rolling diaphragms or seals are indicated and are preferable since there is minimal leakage and a reliable method of knowing the piston displacement and rate and minimal friction, it is, of course, apparent that other seals such as O-ring seals or the like could be employed. In any event, the pump is entirely sealed and remains sterile.

The urea removal column includes material which serves to absorb urea or converts the urea to ammonia enzymatically as with the enzyme, urease, and then absorbs the ammonia. Such columns are known.

An activated carbon column may be used to absorb creatinine, uric acid and other toxic substances. The ultraviolet sterilizer is used to sterilize the dialysate and prevent bacterial growth. The filter may be of a type which can or cannot pass bacteria depending upon the effectiveness of the ultra-violet sterilizer and sterilizing procedures. It, of course, will trap larger particles and prevent them from entering into the abdominal cavity where they may be a source of tissue irritation and adhesions. The filter, flow regulator, sterilizer, transparent window and reconstitution columns form a self-contained package which may or may not include the pump and which can easily be replaced. The fact that a very small amount of dialysate is used, of the order of one liter or less, and the fact that this same amount of dialysate is continuously reconstituted permits use of a steady flow and possibly a continuous dialysis process. Further, the system is of relatively small size because of the small volume of dialysate fluid being used which makes it possible to devise a system which can be made portable and worn in the vicinity of the patient's waist.

Thus, the patient can be completely rehabilitated by wearing such a system. He can continue to perform his normal tasks while dialysis is taking place. This is very much like a physiologic process performed by the kidneys.

In a second type of reconstitution system, not shown, which is conventional in the dialysis field, essentially all of the material removed from the abdominal cavity is non-selectively eliminated from the dialysate fluid. Those components removed during dialysis which are desirable to replace, such as glucose, the ions of sodium, calcium and potassium are supplied to the in-flow conduit from a source external to the reconstitution system. Such systems include the electrolytic type as described in S. B. Tuwiner, "Research Design and Development of an Improved Water Reclamation System for Manned Space Vehicles" (April 1966), Report No. NASA CR66323, and the ion exchange type as described in R. D. Fall et al., "Feasibility of Microcapsule System for Artifical Kidney Applications," Annual Report by Battelle Memorial Institute (Dec. 1968).

A simplified technique for supplying dialysate fluid to the abdominal cavity and removing the fluid from the same eliminates the need for any reconstitution system. In this technique the dialysate fluid is supplied from a fresh external source along with the aforementioned desirable components removed during dialysis. The fluid removed from the abdominal cavity is directed to a waste sink.

In summary, the features that make this system possible and of considerable advantage over prior art systems are the use of the permanently implanted conduits which allow fluid to be introduced and removed from the peritoneal cavity, the reconstitution system which permits the same fluid to be recycled after the waste that is picked up in the peritoneal cavity has been removed, and the simple system for sterilizing and pumping the fluid through the regeneration system and back to the abdominal cavity.

The use of small amounts of fluid which are recycled has added advantages. Many of the abnormal side effects resulting from either hemodialysis or peritoneal dialysis with large volumes of fluid are avoided since this same fluid can be saturated with all those constituents which are normally depleted from the blood stream when a large amount of dialysate is used. Low flow rate also permits effective ultra-violet sterilization and ultrafiltration to be accomplished.

We claim:

1. A steady flow peritoneal dialysis system including in-flow and out-flow conduits adapted to extend through the abdominal wall into the abdominal cavity whereby dialysate fluid may be introduced into and removed from the cavity, each of said conduits including an external surface portion at the interface between the abdominal wall and the conduits which is compatible with the skin, subcutaneous tissue and other tissue, said surface including a plurality of adjacent substantially discrete pockets having openings which face in the direction of said skin and tissue, the walls of said pocket extending inwardly to a depth in the range of 0.002 to 0.020 inches and being of such shape and size as to provide means to accommodate a number of living cells sufficient to provide anchoring but not so large as to prevent essentially normal transfer of nutrients to the living cells in said pockets from adjacent skin and tissue, means for supplying the dialysate fluid to said in-flow conduit, means for causing the dialysate fluid to flow through the cavity, and means for removing the dialysate fluid from said out-flow conduit.

2. A system as in claim 1 in which said means for causing fluid to flow comprises a sealed pump.

3. A system as in claim 1 in which said supply and removal means includes a flow regulator.

4. A system as in claim 1 in which said supply means includes a dialysate fluid source and said removal means includes a sink.

5. A system as in claim 1 in which said supply and removal means includes means for reconstituting the dialysate fluid connected by fluid conduits to said in-flow and out-flow conduits.

6. A system as in claim 5 in which said reconstitution means includes a column for the removal of uric acid and creatinine.

7. A system as in claim 5 including means for irradiating the circulatory fluid with ultra-violet radiation.

8. A system as in claim 7 in which said reconstitution means includes a filter adapted to receive the fluid flowing from the irradiation means.

9. A system as in claim 5 in which said system is a closed self-contained fluid system.

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