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3,520,298

PERITONEAL DIALYSIS APPARATUS

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FIG. 1

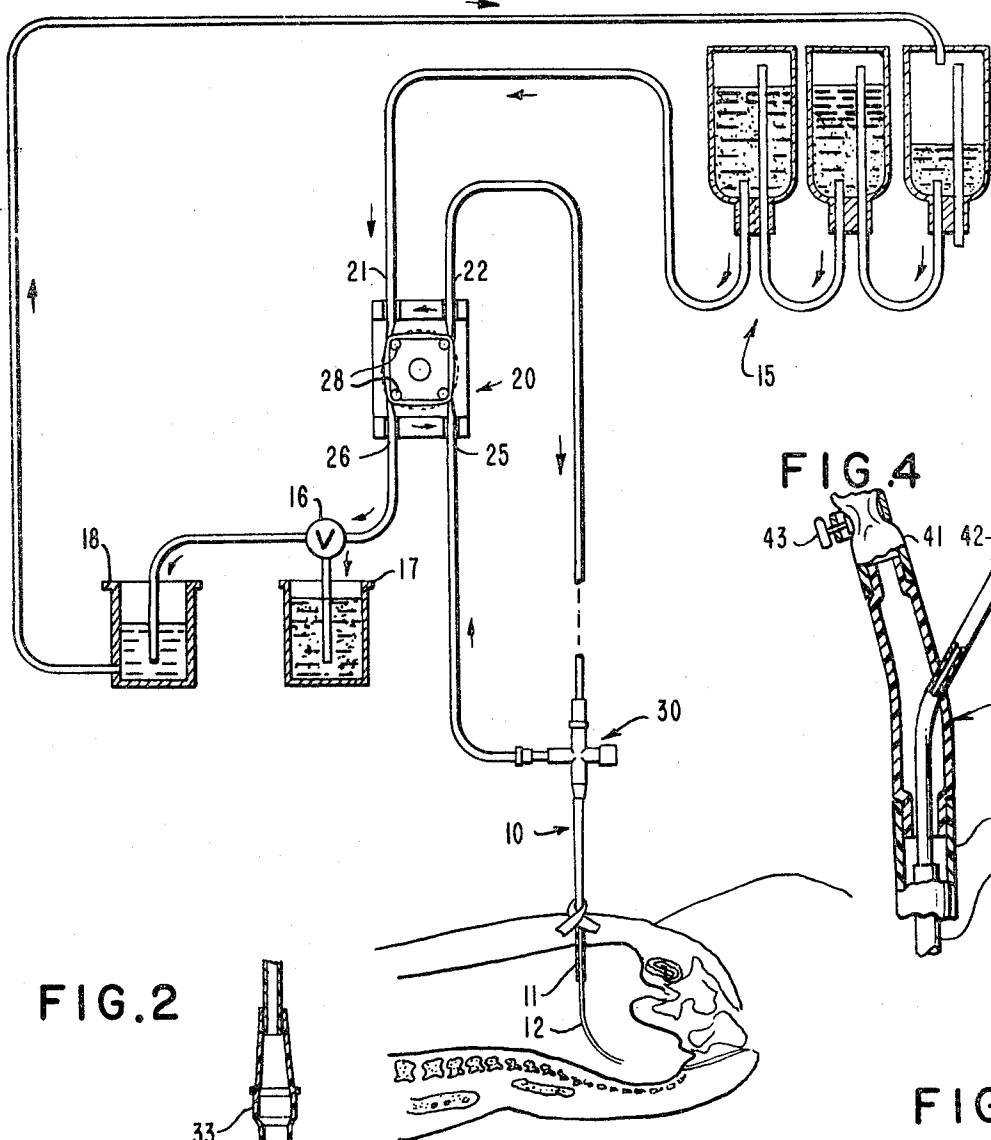


FIG. 4

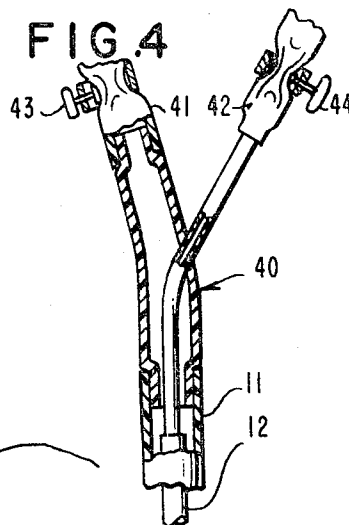


FIG. 2

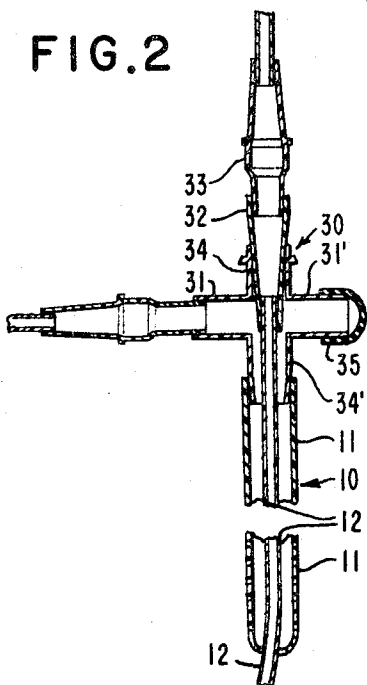
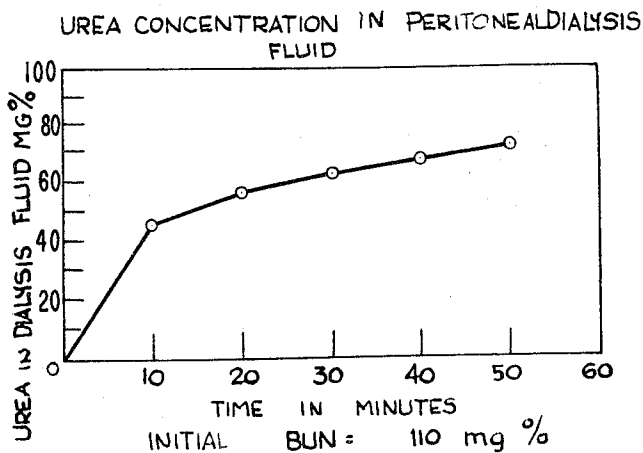


FIG. 3



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PERITONEAL DIALYSIS APPARATUS

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4 Claims

ABSTRACT OF THE DISCLOSURE

An equal volume supply-withdrawal arrangement supplies peritoneal dialysis fluid through the inner tube of a concentric catheter into the peritoneal cavity and from an outer tube, about one-third the length of the inner tube, within the patient; volume equalization may be by an equal volume supply-withdrawal pump; when the amount of fluid pumped into the peritoneal cavity and removed therefrom is equal, the difference in length of catheter tubes provides for efficient peritoneal dialysis with only a single wound for insertion.

The present invention relates to medical equipment, and more particularly to a peritoneal dialysis apparatus which is capable of continuous dialysis, with continuous exchange of fluid, yet requiring only one entrance of outside apparatus within the body of the patient.

It has been found that the removal of urea and other metabolites from the peritoneal cavity is most effective when the gradient of concentration between plasma and peritoneal fluid is highest. Of the urea removed during a one hour exchange of, for example 2,000 cc. of dialysis fluid, fifty to sixty percent are removed during the first twenty minutes. Thereafter, the removal rate is much lower due to the diminished gradient. Thus, when a method of removal of urea by intermittent filling and emptying of the peritoneal cavity is used, a large part of the time during which the fluid is within the patient's body is wasted, or, in the alternative, the patient must be disturbed frequently. If one adds the time of rather inefficient removal, to the time required for filling and emptying of the peritoneal cavity, the total effectiveness per unit time is substantially reduced further.

It is an object of the present invention to provide a peritoneal dialysis apparatus which has a high removal rate of urea and other toxic substances and requires but one penetration of the body cavity.

SUBJECT MATTER OF THE INVENTION

The apparatus of the present invention provides a flow control arrangement for dialysis fluid arranged in such a manner that the fluid supply rate to the patient is the same as that for removal of contaminated fluid from the peritoneal cavity. Preferably, an equal-volume pump is used, with one inlet-outlet combination acting as a supply and another inlet-outlet combination providing suction for withdrawal of the peritoneal dialysis fluid. The flow control arrangement, which may be gravity fed, or pumped, is connected to a double catheter formed of a pair of concentric tubes, the inner one being smaller than the inner diameter of the outer tube so that fluid can be withdrawn from between the two tubes. One of the catheter tubes is much longer than the other, so that fluid introduced into the longer tube (or withdrawn therefrom) is circulated within the body cavity. If a pump is used, one of the tubes is connected to the supply inlet-outlet combination and the other to the drawal inlet-outlet combination of the pump, so that continuously circulating fluid will be supplied to the body cavity, with equal supply and withdrawal rates; if gravity feed is used, clamps on connecting tubes are regulated to equalize flow rates.

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The structure, organization, and operation of the invention will now be described more specifically with reference to the accompanying drawings, wherein:

FIG. 1 is a schematic diagram of the apparatus of the present invention, applied to a patient, shown in highly schematic form;

FIG. 2 is a connecting element for use in connection with the present invention;

FIG. 3 is a diagram illustrating the effectiveness of peritoneal dialysis methods with respect to time; and

FIG. 4 is a partly cross-sectional schematic view of a type of fluid connector and flow control arrangement.

Referring now to the drawings, and first to FIG. 3, it will be seen that the curve illustrating removal of urea has a sharp bend or knee in the region of approximately ten minutes. Thus, for a treatment period of one hour, the major portion (as has been referred to before) of removal of toxic substances occurs initially. In accordance with the present invention, fluid is continuously circulated so that the concentration of toxic substances within the dialysis fluid is always low and the removal rate stays below the bend of the knee of the curve, that is in the removal rate range of the zero to ten minute portion of the curve of FIG. 3.

Based on the considerations of the removal rate as illustrated in FIG. 3, the present invention provides apparatus for an automatic, continuous, high-flow rate dialysis. It has previously been suggested to introduce two catheters at different locations into the peritoneal cavity and to feed fluids through one by gravity and empty at the other at a distant point, again by gravity. This method requires two wounds, which is undesirable, and further, does not insure complete removal of dialysis fluid after the treatment.

In accordance with the present invention, a short, peritoneal nylon catheter tube 11, which may be disposable, of about 20 cm. length, with an outer diameter of about 4.7 mm. and an inner diameter of 4 mm., with an indwelling trocar, is introduced into the peritoneal cavity. This catheter tube 11 has numerous perforations extending upwardly from its far end by about 3 cm. After its introduction into the body, the trocar is withdrawn and a connector, for example a plastic cross 30, is connected by means of stub 34' to its free end. Any one of the other branches of the cross, 34 or 31, 31' are then connected to a source of dialysis fluid, the remaining two openings of the cross being plugged by rubber caps. About 2,000 cc. of dialysis fluid are then rapidly introduced in the peritoneal cavity, either by gravity or by a pump. Immediately thereafter, a nylon catheter tube 12 of about 37 cm. length, having an outer diameter of 2.12 cm. and an inner diameter of 1.4 mm. is introduced through the cross and through the catheter 11, (FIG. 2), deeply into the peritoneal cavity into the area of the cul de sac. This catheter tube 12 is tightly sealed into the cross by means of a reducing bushing 32 extending through branch 34 of cross 30, and then connected to the inflow tubing coming from a pump 20. One of the cross branches, 31' (FIG. 2), is plugged by a rubber cap and the other cross branch, 31, connected by means of a reducing bushing through the suction inlet of another branch of the pump as best seen in FIG. 1.

One of the inflow sides of pump 20, connection 21, is connected to a source of dialysis fluid 15. The outflow side of the same branch, 22, connects with bushing 33 and therethrough to the long inner tube 12 of the catheter 10. The second inflow side of the pump, 25, connects to the branch 31 of cross 30 and thus to the short catheter tube 11, for withdrawal of fluids containing toxic substances, and the outflow side 26 of the withdrawal portion of the pump is then connected to a valve 16 selectively settable to lead the spent dialysis fluid to a waste recep-

table 17, or to a recovery and re-circulating unit only generally indicated at 18 and well known in the art by itself, for recycling and re-introduction into dialysis supply unit 15.

The pump 20 is a special pump, and it is important that the rate of pumping from the supply inlet-outlet side 22 and from the withdrawal inlet-outlet sides, 25, 26 is substantially equal. A pump which has been found acceptable is made by the Holter Company of Philadelphia; its speed can be regulated. The pump generally has a head with a peristaltic rotor; as commercially supplied, three rollers squeeze deformable "Silastic" tubing to force fluid from one direction (inlet side) to another (outlet side). It has been found that the use of 4 or more rollers 28 rather than three (FIG. 1) is preferable in order to maintain equal pumping of both the supply, as well as of the withdrawal fluid circuit. By the very nature of the arrangement, both the supply as well as the withdrawal channel will move the same amount of fluid per unit time, so that the inflow and outflow into and from the peritoneal cavity will be equal. Due to the high pressure produced by the pump, clogging of the inflow catheter from which the fluids spurt in a strong stream has not been found to occur. Similarly, the numerous openings at the end of catheter tube 11, pointing in all directions circumferentially, prevent clogging of the withdrawal side. It has been found that, with a flow rate of 4 litres per hour, the inflow and outflow differ by not more than 200 cc. in 12 hours.

At the end of the procedure, the inlet tube is clamped, and the peritoneum is emptied by the pump, especially when the patient is put into a position that the draining catheter comes close to the lowest point of the peritoneal cavity.

A suitable rate of flow is about 4 litres per hour for the average patient, although a somewhat lower rate can be used. After initial insertion of the catheter assembly 10, no further supervision by a physician is necessary and only minimal nursing supervision is required, to hang new bottles with dialysis solutions or to check on proper operation of recovery unit 18. The discomfort experienced by the patient from repeated distension and contraction of the peritoneum, as was previously the case with single fillings in the intermittent methods, is avoided. The actual length of the tubes 11, 12 of the catheter 10 within the body of the patient varies in the ratio of preferably about 1 to 3, with 1 to 2 being the lower limit and about 1 to 5 being the upper, if the patient is very large.

Dialysis fluid can also be introduced, and removed from the patient by gravity. To regulate inflow and outflow, a tube 41 connected with the outer, perforated tube 11 of the catheter 10 is provided with an adjustable clamp 43, while a tube 42 connected with the inner tube 12 of catheter 10 is provided with an adjustable clamp 44. Dialysis fluid is introduced, as before, through tube 42 to a Y-connector 40, which in turn connects with both tubes 11 and 12 of catheter 10. Y-connector 40, which may be in the form best seen in FIG. 4, may be one integral piece of plastic molding. In operation, the supply of dialysis fluid 15, connected to tube 42, and thence under tube 12 is fed by gravity, and removal is likewise by gravity through tube 11 and tube 41. The flow is controlled to be equalized by the combination of clamps 43, 44. Tube 41, of course, connects to valve 16 and thence either to waste or to the recovery unit 18.

It has been proposed, for chronic patients, to provide an implanted button closure so that insertion of the catheter within the body will not, repeatedly, cause new wounds. Such closures have not yet been completely perfected; the apparatus of the present invention would, however, be suitable for use therewith.

The "Y" connector 40 (FIG. 4) can, of course, be used

with the pumping arrangement illustrated in FIG. 1; and the cross connector can be used in the gravity arrangement discussed in connection with FIG. 4. Other connectors may, of course, be used, the cross 30 (FIG. 2) having been found particularly suitable and easy to keep clean and sterile.

I claim:

1. Peritoneal dialysis apparatus for use with a source of peritoneal dialysis fluid and means for receiving used dialysis fluid comprising

a double catheter (10) having a pair of concentric tubes (11, 12) sealed at one end with respect to each other;

fluid circuit means conducting dialysis fluid from the source of fluid to said one end of one of said tubes (12) and from said one end of the other tube (11) of said catheter (10) to the means receiving used dialysis fluid;

the inner tube (12) being of lesser outer diameter than the inner diameter of the outer tube (11) to permit passage of fluid between the inner (12) and the outer (11) tube, the inner tube extending beyond said outer tube and having a length of from twice to five times the length of the outer tube, said outer tube having fluid circulation openings in the other end thereof; and

forced means connected into said fluid circuit and automatically equalizing inflow from said source through one of said catheter tubes and outflow from the other of said tubes to said means receiving used dialysis fluid.

2. Apparatus as claimed in claim 1 wherein the inner tube is about three times as long as the outer tube.

3. Apparatus as claimed in claim 1 wherein said forced flow means includes an equal volume supply withdrawal pump (20) having a supply inlet (21) and outlet (22) and a withdrawal inlet (25) and outlet (26); and

the fluid means conducts dialysis fluid to the pump supply inlet (21) and thence from the supply outlet (22) to one of said tubes (12) of said catheter (10) and from the other tube (11) of said catheter (10) to the withdrawal inlet (25) and thence for removal from the withdrawal outlet (26) of said pump (20).

4. Apparatus as claimed in claim 1 wherein said fluid circuit includes a coupling connection (30) having a first fluid path (34-34') and a branching fluid path (31-31'); a fitting (32) included in one of said fluid paths, said fitting (32) having an outer diameter to accept and to be connected to said inner tube (12); said outer tube (11) being arranged over said inner tube (12) and connected to the first fluid path and said branching path (31) being connected to the means receiving used dialysis fluid.

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