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Developing a Device for Automated Peritoneal Dialysis

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Abstract

Background: Peritoneal dialysis (PD) is an efficient alternative for hemodialysis. Removal of waste metabolites and excess water from the blood circulation are the two main tasks done during dialysis. These are done by using a filter; in PD, the naturally semi-permeable peritoneal membrane acts as the filter. Automated PD machines control intelligently the operations to enhance the efficiency and survival of patients. Available PD devices, however, have several limitations.

Objective: To develop a novel portable automated PD device to be worn by patients.

Methods: The developed device has a peristaltic pump to produce a steady dialysate flow, two flowmeters to measure the volume of dialysate, and a servomotor-actuated triway valve to conduct the dialysate to the right path. Moreover, to disinfect the permanent tubes inside the device an external steam sterilizer was designed. Electrical power of the device is supplied by rechargeable batteries.

Results: Tests of a 16×12.5×6 cm^3 device revealed that the three phases of dialysis, *i.e.*, injection, dwelling, and drainage, were efficiently performed, and the alarms acted properly.

Conclusion: This newly designed automated PD can surmount the social isolation dilemmas of either children or adults, and notably improve their life quality

Keywords

Renal disorders; end-stage renal disease; peritoneal dialysis; hemodialysis

Introduction

End-stage renal diseases can be treated by kidney transplantation, hemodialysis, or peritoneal dialysis (PD). Although it is the most efficient option, renal transplantation is not always possible for several reasons including availability of a matched transplant. Therefore, kidney transplantation is not common [1]. Hemodialysis is an artificial maintenance therapy for end-stage renal disease. In hemodialysis, the blood is drawn from an artery, usually in the forearm, passed through an artificial filter where mass transfer takes place with a counter-current dialysate flow, and pumped back to the venous system. Hemodialysis, though highly efficient is associated with numerous side effects including disequilibrium syndrome. It also has several disadvantages including problems with availability of the filter, being stuck to the machine several hours, three times a week with subsequent waste of time and money that lead to low quality of life. Furthermore, there are reports indicating that hemodialysis is not an appropriate treatment for those patients with diabetes and children [2, 3]. The third therapeutic option, PD, is on the

Figure 1: Peristaltic pump used for both injection and drainage of the dialysate

other hand, associated with lesser side effects and satisfactory efficiency [4, 5].

The main objectives of dialysis are removal of accumulated waste metabolites and excess water from the body. When the dialysate becomes in vicinity to a semi-permeable membrane (peritoneum in PD) particles move through the membrane according to their concentration gradient the rate of which can be described by the following equation [6]

$$J = -D\frac{\partial C}{\partial x}$$

where J is the mass flux; C and D denote the concentration and permeability constant respectively; and the parameter x is the distance perpendicular to the membrane from the higher to the lower concentration side [6]. Once the dialysate fills the abdominal cavity, the permeability of the peritoneal membrane permits movement of certain molecules like urea, creatinine and potassium from the blood into the dialysate. Therefore, to have an efficient PD, enough time should be spent for adequate mass transfer. This time is of course different for various molecules since the concentration gradients as well as the peritoneal permeability to these molecules are different. Having elapsed adequate time for transport of the wastes, the dialysate liquid which is now rich in metabolites should be drained back from the abdominal cavity. Repetition of this procedure ensures that sufficient amount of the waste metabolites is removed from the blood [7, 8].

Figure 2: The flowmeter: The three pins are for power supply, ground and output signal

In general, PD can be done using two major types—continuous ambulatory PD (CAPD) and automated PD (APD). In CAPD technique, the dialysate is injected into the peritoneal cavity under its weight. After a long time, the retained fluid, which is now rich in waste metabolites, is drained by gravity again. Since in CAPD neither injection nor drainage of the liquid is done automatically, the procedure is roughly out-of-control and the results are not saved. On the other hand, once a device controls the operations of the dialysis, all values for volumes, times and flows can be registered for each cycle of the dialysis. The machine may also detect problems and inform the patient of them. If the device is well-programmed, even some physiological alarms can be phenomenologically checked and recorded.

APD is superior to CAPD in terms of functionality and survival rates [9-11]. APD, on the other hand, requires few hours of the patient's daily time. The operations of the dialysis, although may be done at home, wastes the patient's time since they are forced to stay and connect to the device. The devices are often heavy and their power is supplied by electrical lines leading to restrain the patients and limit their daily activities.

Because using a device in APD considerably improves the survival rate of patients, designing a novel ambulatory APD device would significantly improve the life quality of patients as it solves some of the restrictions of the APD devices. In this report we describe a new design for a novel ambulatory APD device.

Design

Circulating the dialysate

In the new design, for miniaturizing of the device the gravitational force was omitted; instead, a tiny pump was used for circulating the dialysate. It is convenient for the pump to either inject or drain the dialysate into or from the patient's peritoneal cavity. Additionally, mechanical parts of the pump should not be in direct contact with the dialysate because of sterility. Therefore, a peristaltic (roller) pump was used (Fig. 1).

Measurement of flow

To determine the amount of the dialysate that was injected or drained into or from the body, the device required using two flowmeters located in the paths of injection and drainage. These flowmeters linearly report the amounts of liquids passed through them. The flowmeters used were appropriate for medical use in terms of their working temperature and the flow range (Fig. 2).

Triway valve

The injected and also drained dialysate should conduct through the same catheter inserted in abdominal cavity. Therefore, the channels should be appropriately switched between injection and drainage tubes. Within the device, a precise angle-driven servomotor provides the right way during the injection and drainage phases (Fig. 3).

Figure 3: Triway valve with attached servomotor

Power supply

One of the advantages of this new design is that it does not depend on electrical line. The mechanical and electrical equipment is so designed that a portable 12–14 V battery can provide the working energy. This battery can be attached to the device during the dialysis operation and detached after the required cycles have been completed. The battery is rechargeable. If the energy of the battery is not sufficient for all cycles of the complete dialysis, the device can intelligently detect it and raise an alarm.

Electrical equipment

The controlling system of the device is programmed on a micro-controller chip (ATMEGA 32). The program commands the peristaltic pump to inject or drain the dialysate by specifying appropriate voltage. Also, the pulses received from the flowmeters are interpreted by the microprocessor. The proper angular position of the servomotor is additionally controlled by the implemented program. The microprocessor unit also is capable to manage

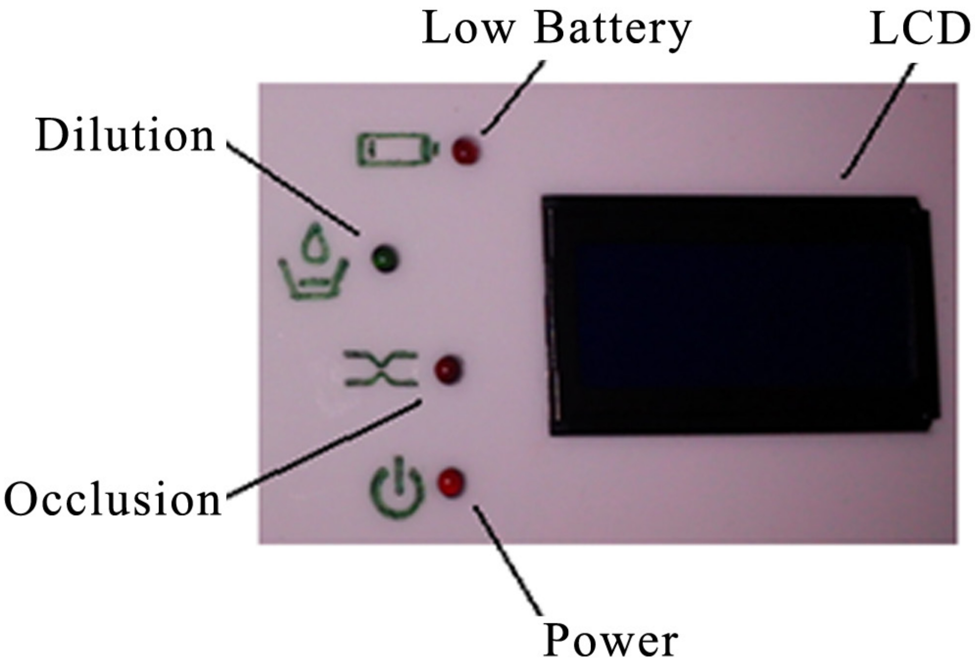

Figure 4: Alarms' LEDs of the device

the alarms. For instance, once the tubes are occluded by an object or by collapsing the walls, the systems identifies it and raises an alarm.

By measuring the volumes of the drained and injected dialysate in each cycle, the device may raise a "physiological alarm." If the amount of drained volume at the end of the cycle is considerably lesser than the injected volume, it means that there is a problem with absorption of the extra-water. In other words, the concentration of the electrolytes in the dialysate is so high that extra-drainage will occur by osmosis. To correct this problem, a dialysate with lower concentration of the electrolytes should be used. Once the device detects this physiological fact at the end of the cycle, it would notice the patient by writing on the LCD panel, turning on an LED and raising an alarm that he or she must use a diluter dialysate in the next cycle. Figure 4 shows the LED set of alarms on top of the box.

Timing of the sub-operations during a cycle is adjusted by the microprocessor. This unit calculates and determines when the pump should be ceased the injection of the dialysate into the body, when the time of the dwelling

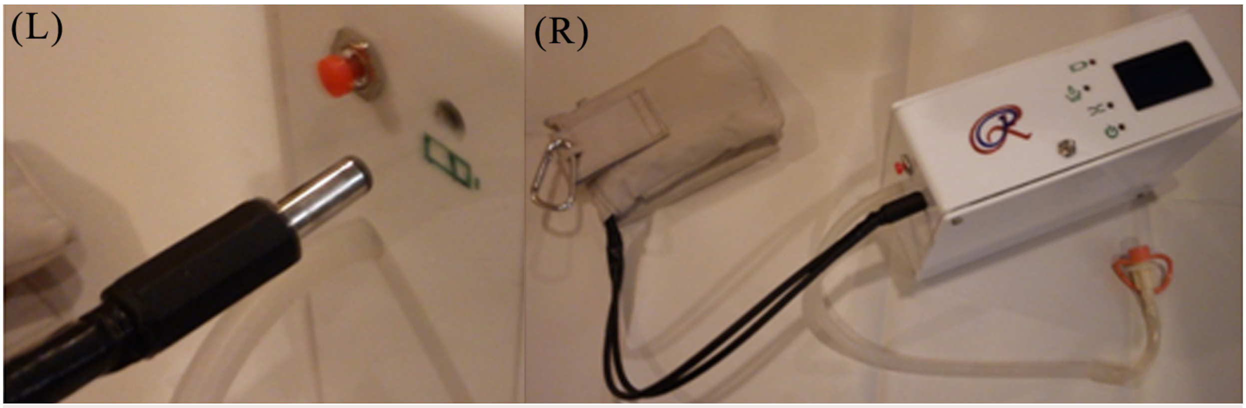

Figure 5: View of the device (R) and its battery connection (L)

phase is elapsed, and when the liquid in the peritoneal cavity are completely sucked out.

In each cycle, the volumes of dialysate injected into and drained from the peritoneal cavity and also the times are stored in an SD card.

Results

The new PD device is shown in Figure 5. The overall size of the box is 16×12.5×6 cm^3. The relatively small size of the device helps the patient to wear it while the dialysis operations are going on which might improve the patient's quality of life.

The accuracy of the flowmeters used was 4% for the injection and 7.6% for the drainage phases.

To prevent any infectious problems, as one of the main obstacles with PD, the device renders a sterility mode after each daily use.

After the last cycle, an external steam sterilizer pushes 80 °C steam through the circuit for 15 minutes to disinfect the tubes [12]. No bacterial gowth was observed after 24 hours.

Discussion

We developed a novel generation of wearable PD device. The small size of the device is the main advantage of the system. Previous PD systems mainly work based on the concept of changes in weights of the dialysate containers while the dialysate is either injected or drained back. The weight is then converted to volume to estimate the amount of excess water removed. One of the problems in these systems however is their frequent need for calibration. The new design can directly measure the amount of flow and volume; no calibration is required. Using a peristaltic pump in the new design removes the need for gravity flow of dialysate that was necessary for previous types of PD machines. This also made the size of the device small. The maximum voltage necessary for the device is 14 V, which can be provided by a rechargeable battery. All these made the device portable. The patient can wear it and move while dialysis is going on.

Since the liquids drained from the peritoneal cavity at the final stages are mixed with air, the accuracy of the values reported by the drain flowmeter is notably lower than that of the injection flowmeter, although the relative error is still under 10%.

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