

SYSTEMS AND METHODS FOR CONTROLLING PERITONEAL DIALYSIS

Technical Field

- 5 The present disclosure generally relates to systems and methods for controlling peritoneal dialysis, particularly tidal peritoneal dialysis.

Background

- 10 Millions of people worldwide suffer from kidney-related problems, such as chronic kidney disease (CKD) and end-stage renal disease (ESRD), and they may require either dialysis, such as peritoneal dialysis, to maintain life. In peritoneal dialysis, the peritoneum in the patient's abdomen acts as a natural filtration membrane.
- 15 There are a few mathematical models to describe the flow of solutes and water across the peritoneal membrane during a peritoneal dialysis therapy. Some examples of these models are the three-pore model, Pyle-Popovich model, Vonesh's model, and Garred's model. These models have been used to assist physicians to prescribe conventional modes of peritoneal dialysis therapies, such as automated peritoneal
- 20 dialysis (APD), continuous ambulatory peritoneal dialysis (CAPD), or tidal peritoneal dialysis (TPD). Using samples from waste dialysate drained from the patient, these models can be used to determine the mass transfer coefficient (MTAC) of the patient's peritoneal membrane, which is a measure of the solute clearance from the patient. The MTAC can be used by physicians to prescribe suitable peritoneal dialysis therapy
- 25 for the patient to improve the solute clearance.

- In some modes of TPD, a small tidal volume is moved in and out of the patient frequently, and this small tidal volume is cleaned, regenerated, and returned back to the patient. Figure 1 shows an example of this TPD therapy 100 for a patient 110.
- 30 Spent or waste dialysate 120 is discharged from the patient and sent to a filtration device 130 comprising a sorbent material. The filtration device 130 is used to clean the spent dialysate 120 into regenerated dialysate 140. The regenerated dialysate 140 is then returned to the patient 110. Current models to prescribe peritoneal dialysis

therapies are designed to be used for therapies whereby the solutes are removed solely by the peritoneal membrane 150. However, in the TPD therapy 100 as shown in Figure 1, the removal of solutes (such as urea and creatinine) from the patient 110 is done by both the peritoneal membrane 150 and the filtration device 130. As such, 5 current models would not be adequate to determine the MTAC and solute clearance from the TPD therapy 100, and the TPD therapy 100 cannot be reliably controlled to improve the solute clearance for the patient 110.

Therefore, in order to address or alleviate at least one of the aforementioned problems 10 and/or disadvantages, there is a need to provide improved methods for controlling tidal peritoneal dialysis for a patient.

Summary

15 According to a first aspect of the present disclosure, there is a system and method for controlling tidal peritoneal dialysis for a patient. The method comprises:

- measuring solute levels in tidal dialysate discharged from the patient while the patient is undergoing the tidal peritoneal dialysis;

- determining, based on the measured solute levels, a current solute 20 clearance from the tidal peritoneal dialysis;

- comparing the current solute clearance with a target solute clearance for the patient;

- generating, based on the comparison, control instructions for a set of parameters of the tidal peritoneal dialysis; and

- 25 controlling the parameters based on the control instructions while the patient is undergoing the tidal peritoneal dialysis to thereby adjust the current solute clearance towards the target solute clearance.

According to a second aspect of the present disclosure, there is a system and method 30 for controlling tidal peritoneal dialysis for a patient. The method comprises:

- receiving, from a local device communicative with an apparatus for performing the tidal peritoneal dialysis, tidal measurement data comprising

solute levels measured in tidal dialysate discharged from the patient while the patient is undergoing the tidal peritoneal dialysis;

determining, based on the measured solute levels, a current solute clearance from the tidal peritoneal dialysis;

5 comparing the current solute clearance with a target solute clearance for the patient;

generating, based on the comparison, control instructions for a set of parameters of the tidal peritoneal dialysis; and

10 sending, to the local device, the control instructions for controlling the parameters while the patient is undergoing the tidal peritoneal dialysis to thereby adjust the current solute clearance towards the target solute clearance.

According to a third aspect of the present disclosure, there is a system and method for controlling tidal peritoneal dialysis for a patient. The method comprises:

15 measuring solute levels in a set of pre-obtained samples of dialysate from the patient;

determining, based on the measured solute levels, a total solute clearance from the tidal peritoneal dialysis;

20 comparing the total solute clearance with a target solute clearance for the patient;

generating, based on the comparison, control instructions for a set of parameters of a subsequent tidal peritoneal dialysis for the patient; and

25 sending, to a device communicative with an apparatus for performing the tidal peritoneal dialysis, the control instructions for controlling the parameters for the subsequent tidal peritoneal dialysis to thereby adjust the total solute clearance from the subsequent tidal peritoneal dialysis towards the target solute clearance.

30 Systems and methods for controlling tidal peritoneal dialysis according to the present disclosure are thus disclosed herein. Various features, aspects, and advantages of the present disclosure will become more apparent from the following detailed description of the embodiments of the present disclosure, by way of non-limiting examples only, along with the accompanying drawings.

Brief Description of the Drawings

Figure 1 is an illustration of tidal peritoneal dialysis.

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Figures 2A to 2C are illustrations of measurements from tidal peritoneal dialysis.

Figures 3A and 3B are illustrations of a human body undergoing tidal peritoneal dialysis.

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Figures 4A and 4B are illustrative results from animal trials of tidal peritoneal dialysis.

Figures 5A and 5B are illustrations of controlling tidal peritoneal dialysis according to embodiments of the present disclosure.

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Figures 6A to 6C are flowchart illustrations of methods for controlling tidal peritoneal dialysis according to embodiments of the present disclosure.

Detailed Description

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For purposes of brevity and clarity, descriptions of embodiments of the present disclosure are directed to systems and methods for controlling tidal peritoneal dialysis, in accordance with the drawings. While aspects of the present disclosure will be described in conjunction with the embodiments provided herein, it will be understood that they are not intended to limit the present disclosure to these embodiments. On the contrary, the present disclosure is intended to cover alternatives, modifications and equivalents to the embodiments described herein, which are included within the scope of the present disclosure as defined by the appended claims. Furthermore, in the following detailed description, specific details are set forth in order to provide a thorough understanding of the present disclosure. However, it will be recognised by an individual having ordinary skill in the art, i.e. a skilled person, that the present disclosure may be practiced without specific details, and/or with multiple details arising from combinations of aspects of particular embodiments. In a number of instances,

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well-known systems, methods, procedures, and components have not been described in detail so as to not unnecessarily obscure aspects of the embodiments of the present disclosure.

- 5 In embodiments of the present disclosure, depiction of a given element or consideration or use of a particular element number in a particular figure or a reference thereto in corresponding descriptive material can encompass the same, an equivalent, or an analogous element or element number identified in another figure or descriptive material associated therewith.

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References to “an embodiment / example”, “another embodiment / example”, “some embodiments / examples”, “some other embodiments / examples”, and so on, indicate that the embodiment(s) / example(s) so described may include a particular feature, structure, characteristic, property, element, or limitation, but that not every
15 embodiment / example necessarily includes that particular feature, structure, characteristic, property, element or limitation. Furthermore, repeated use of the phrase “in an embodiment / example” or “in another embodiment / example” does not necessarily refer to the same embodiment / example.

- 20 The terms “comprising”, “including”, “having”, and the like do not exclude the presence of other features / elements / steps than those listed in an embodiment. Recitation of certain features / elements / steps in mutually different embodiments does not indicate that a combination of these features / elements / steps cannot be used in an embodiment.

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As used herein, the terms “a” and “an” are defined as one or more than one. The use of “/” in a figure or associated text is understood to mean “and/or” unless otherwise indicated. The term “set” is defined as a non-empty finite organisation of elements that mathematically exhibits a cardinality of at least one (e.g. a set as defined herein can
30 correspond to a unit, singlet, or single-element set, or a multiple-element set), in accordance with known mathematical definitions.

An exemplary tidal peritoneal dialysis (TPD) therapy 100 is described in representative or exemplary embodiments of the present disclosure, with reference to Figure 1. In the TPD therapy 100, a small amount of waste dialysate 120 is discharged from the patient 110 and cleaned by a filtration device 130 comprising a sorbent material. Regenerated dialysate 140 from the cleaned waste dialysate 120 is then returned to the patient 110. The amount of waste dialysate 120 that is cleaned, regenerated, and returned to the patient 110 is known as the tidal volume. As mentioned previously, current models to prescribe peritoneal dialysis therapies are inadequate to determine the solute clearance from the TPD therapy 100.

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One factor for this inadequacy is that the toxins are absorbed by the sorbent material and cannot be sampled in a similar manner as regular APD/CAPD/TPD. In a typical APD/CAPD/TPD therapy, waste dialysate 120 is drained from the patient 110 and collected in a drain bag. A sample taken from this bag is measured for toxin concentration and this concentration is multiplied by the total drained volume of the waste dialysate 120 to determine total toxin clearance from the patient 110. However, the TPD therapy 100 uses a small tidal volume of the waste dialysate 120 and this tidal volume is continuously cleaned by the sorbent material in the filtration device 130. The sorbent material absorbs the toxins that is passed through it and once absorbed, cannot be measured directly. A sample from the drain bag that is taken after the end of the TPD therapy 100, as would be the case in a typical APD/CAPD/TPD therapy, would not provide accurate measurements of the toxin clearance.

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Another factor for this inadequacy is that regular regeneration of the regenerated dialysate 140 from the sorbent material does not allow the toxin concentration to reach the same levels as that in the patient's blood. More specifically, as the filtration device 130 constantly cleans, regenerates, and returns the regenerated dialysate 140 back to the patient 110, the constant removal of toxins from the dialysate within the patient 110 results in the waste dialysate 120 having a toxin concentration relative to blood that is lower than that of typical APD/CAPD. The toxin concentration of the waste dialysate 140 will increase until it reaches a steady state whereby the rate of toxin absorption/removal by the sorbent material is equal to the rate of toxin flow from blood

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to dialysate via the peritoneal membrane 150. As shown in Figure 2A, this steady state is then maintained relatively consistent throughout the rest of the TPD therapy 100.

Another factor is that the TPD therapy 100 has two phases – the sorbent phase and the non-sorbent phase – as shown in Figure 2B. During the sorbent phase, waste dialysate 120 is constantly cleaned, regenerated, and returned as regenerated dialysate 140 to the patient 110. This constant removal of toxins from the tidal volume of waste dialysate 120 prevents waste dialysate 120 from equilibrating with blood. The non-sorbent phase begins at the end of the sorbent phase. During the non-sorbent phase, the waste dialysate 120 is no longer cleaned and regenerated and the dialysate is left to dwell within the patient's peritoneum. Due to the toxin concentration gradient between the dialysate and blood, the non-sorbent phase will continue to remove toxins from the blood, hence allowing toxins in the dialysate within the peritoneum to reach similar levels as the blood. Upon completion of the non-sorbent phase, the waste dialysate 120 is drained completely from the patient 110. However, the toxin concentration in the drained waste dialysate 120 will be different from the toxin concentration in the tidal volume of waste dialysate 120. Existing models that are based on samples of the drained waste dialysate 120 cannot accurately measure the toxin clearance from the TPD therapy 100.

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Another factor is that the regenerated dialysate 140 that returns to the patient 110 is not homogenously mixed with the dialysate within the peritoneal cavity, because of other organs 160 within the peritoneal cavity and the location of the peritoneal dialysis catheter 170. As shown in Figure 3A, the catheter 170 is permanently installed within the peritoneal cavity and is connected to an external connector through which fresh dialysate can be introduced. The tip of the catheter 170 is typically installed towards the bottom of the peritoneal cavity to facilitate complete draining of waste dialysate 120 from the peritoneal cavity. The peritoneal cavity is an abdominal cavity that contains multiple internal organs 160, such as stomach, spleen, liver, intestines, etc. Because of the various organs 160 within the peritoneal cavity and the relatively small tidal volume of waste dialysate 120 relative to the dialysate volume in the peritoneal cavity, the regenerated dialysate 140 that returns to the peritoneal cavity would not be homogenously mixed with the dialysate volume throughout the entire peritoneal cavity.

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The portion of the dialysate volume that is closest to the catheter tip has lower toxin concentration (since the regenerated dialysate 140 is most concentrated there), and the portion of dialysate volume that is furthest from the catheter tip has higher toxin concentration. This concentration gradient allows toxins to communicate along the
5 arrows as shown in Figure 3B and then removed via the catheter tip as the waste dialysate 120. However, because of this concentration gradient, the toxin concentration of the tidal volume of the waste dialysate 140 in the area around the catheter tip is lower than the average toxin concentration of the entire dialysate volume. The average toxin concentration that is measured based on samples of the drained
10 dialysate volume cannot accurately measure the toxin clearance from the TPD therapy 100.

Another factor is that during the draining of the waste dialysate 120 at the end of the TPD therapy 100, toxins continue to transfer to the waste dialysate 120 despite the
15 decreasing volume of the waste dialysate 120 being drained. This drain phase is will typically take around 15-20 minutes and during this period, there is additional toxin clearance happening that is similar to the non-sorbent phase. As shown in Figure 2C, the additional clearance from the drain phase can result in a difference in measured toxin concentration of the drained waste dialysate 120, and subsequently lead to
20 inaccurate measurement of toxin clearance from the TPD therapy 100.

Various parameters can be used to measure the toxin clearance based on samples of the final volume of drained waste dialysate 120 at the end of therapy, including standard Kt/V urea clearance, creatinine clearance, and beta-2 microglobulin
25 clearance. The standard Kt/V urea clearance can be determined by calculating X_{urea} based on Equation 1. The creatinine clearance can be determined by calculating X_{crea} based on Equation 2 and can be normalized later by the body surface area ($BSA = 1.73 \text{ m}^2$). The beta-2 microglobulin clearance can be determined by calculating X_{b2m} based on Equation 3 and can be normalized later by the BSA. Clearance calculations
30 are typically performed based on dialysate samples from a single therapy and the clearance values are then multiplied by the number of therapies per week to determine the weekly toxin clearance.

$$X_{urea} = \frac{FD_{urea}}{B_{urea}} \times \frac{V_{FD}}{V_{TBW}} \quad \text{Equation 1}$$

$$X_{crea} = \frac{FD_{crea}}{B_{crea}} \times V_{FD} \quad \text{Equation 2}$$

$$X_{b2m} = \frac{FD_{b2m}}{B_{b2m}} \times V_{FD} \quad \text{Equation 3}$$

5 FD_{urea} = Urea concentration (mmol/L) in the final volume

FD_{crea} = Creatinine concentration (mmol/L) in the final volume

FD_{b2m} = Beta-2 microglobulin concentration (mmol/L) in the final volume

B_{urea} = Urea concentration (mmol/L) in blood

B_{crea} = Creatinine concentration (mmol/L) in blood

10 B_{b2m} = Beta-2 microglobulin concentration (mmol/L) in blood

V_{FD} = Final volume (L)

V_{TBW} = Volume of total body water (L)

The parameters B_{urea} , B_{crea} , B_{b2m} , and V_{TBW} are predetermined.

15 As explained above, the toxin concentrations in the final volume of the drained waste dialysate 120 cannot accurately determine the toxin clearance from the TPD therapy 100. Embodiments of the present disclosure measure the toxin concentrations in the tidal volumes of the waste dialysate 120 during the TPD therapy 100. Various animal (pig) trials have been conducted using the TPD therapy 100, specifically with the
20 filtration device 130 and sorbent material for regenerating dialysate. As shown in Figures 4A and 4B, data taken from these trials shows that the toxin concentrations (urea and creatinine) in the final volume at the end of the TPD therapy 100 are consistently higher than in the tidal volumes sampled at various cycles during the TPD therapy 100.

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Because of the difference in toxin concentrations, the Equations 1-3 for the final volume above cannot be used to measure the toxin concentrations in the tidal volumes. Samples of the tidal volume should be taken during therapy to better represent the toxins that are absorbed by the sorbent material. Additional parameters are used to
30 measure the toxin clearance based on samples of the tidal volumes of the waste dialysate 120 during therapy. The standard Kt/V urea clearance can be determined by

calculating Y_{urea} based on Equation 4. The creatinine clearance can be determined by calculating Y_{crea} based on Equation 5 and can be normalized later by the BSA. The beta-2 microglobulin clearance can be determined by calculating Y_{b2m} based on Equation 6 and can be normalized later by the BSA.

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$$Y_{urea} = \frac{TD_{urea}}{B_{urea}} \times \frac{V_{TD}}{V_{TBW}} \times N \quad \text{Equation 4}$$

$$Y_{crea} = \frac{TD_{crea}}{B_{crea}} \times V_{TD} \times N \quad \text{Equation 5}$$

$$Y_{b2m} = \frac{TD_{b2m}}{B_{b2m}} \times V_{TD} \times N \quad \text{Equation 6}$$

- 10 TD_{urea} = Urea concentration (mmol/L) in the tidal volume
 TD_{crea} = Creatinine concentration (mmol/L) in the tidal volume
 TD_{b2m} = Beta-2 microglobulin concentration (mmol/L) in the tidal volume
 V_{TD} = Tidal volume (L)
 N = Device efficiency factor (%)
- 15 The parameters V_{TD} and N are predetermined.

The value for TD_{urea} , TD_{crea} , or TD_{b2m} can be a single outflow timepoint data to represent an average toxin clearance by the sorbent material, or an average of multiple timepoints or continuous measurements to more accurately determine the toxin clearance by the sorbent material. If multiple timepoints or continuous measurements are used, the parameters Y_{urea} , Y_{crea} , Y_{b2m} can be split up into multiple segments with various concentrations and tidal volumes. For example, if there are continuous measurements, then V_{TD} may be 250 ml for each cycle and there may be 56 discrete outflow concentrations to calculate total clearance from the tidal volumes.

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Further, the device efficiency factor N is included to account for any potential efficiency losses due to dead volume and/or sorbent clearance efficiency. This is especially so for small tidal volumes because any dead volume would have a higher impact on efficiency compared to normal peritoneal dialysis. For example, a 25 ml dead volume for a 250 ml tidal volume represents a 10% reduction in efficiency, whereas a 25 ml dead volume for a 2500 ml final volume represents a 1% reduction in efficiency).

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The parameters Y, which are derived from samples taken during the TPD therapy 100, can be combined with the parameters X, which are derived from samples taken at the end of the TPD therapy 100, to more accurately determine the total toxin clearance.

5 The clearance values are then multiplied by the number of therapies per week to determine the weekly toxin clearance. Depending on the clearance values and the target clearance for the patient 110, suitable peritoneal dialysis therapy may be prescribed for the patient 110 to improve the toxin clearance.

10 Various embodiments of the present disclosure describe devices and methods for controlling tidal peritoneal dialysis for a patient 110, particularly to improve the solute or toxin clearance. The tidal peritoneal dialysis may be the TPD therapy 100 using the sorbent material to clean and regenerate dialysate for the patient 110. More specifically, the TPD therapy 100 may be performed using a TPD apparatus 200
15 having the filtration device 130 with the sorbent material. As shown in Figure 5A, a patient tubing 210 is connected between the apparatus 200 and the catheter 170 in the patient 110 for performing the TPD. Waste dialysate 120 flows from the patient 110 through the patient tubing 210 to the apparatus 200 to be cleaned (outflow phase), and regenerated dialysate 140 flows from the apparatus 200 through the patient tubing
20 210 to the patient 110 (inflow phase). Further, a device 220 is connected to or integrated with the apparatus 200 for controlling the TPD to improve the solute clearance.

In some embodiments as shown in Figure 6A, there is a method 300 for controlling
25 TPD for the patient 110, wherein the method 300 may be performed by the device 220. The method 300 includes a step 310 of measuring solute levels in tidal dialysate discharged from the patient 110, i.e. waste dialysate 120 during the outflow phase, while the patient 110 is undergoing the TPD. For example, the device 220 includes suitable probes / sensors for measuring the concentrations of toxins or solutes, such
30 as urea and creatinine, in the tidal dialysate.

In some embodiments as shown in Figure 5A, the device 220 includes a sampling component that is coupled to a sampling port 230 in the patient tubing 210. The

sampling component is configured for extracting a set of samples from the tidal dialysate flowing along the patient tubing 210. In one embodiment, the device 220 measures the solute levels in the samples and the samples continue to flow along the patient tubing 210. Since the samples come into contact with the sampling component and are returned to the patient 110, the sampling component should be sterile and biocompatible to prevent contamination. In another embodiment, the samples are sacrificial samples and the device 220 measures the solute levels in the sacrificial samples. The sacrificial samples are not returned to the patient 110 and it would not be necessary for the sampling component to be sterile.

Further, the solute levels are measured from samples of the tidal dialysate discharged from the patient 110 during the outflow phase. In the preceding inflow phase, regenerated dialysate 140 flows from the apparatus 200 to the patient 110 through the patient tubing 210. At the end of the inflow phase, a dead volume of dialysate remains inside the patient tubing 210, which can be about 25 ml. As explained above, a 25 ml dead volume for a 250 ml tidal volume represents a 10% reduction in efficiency. When the outflow phase begins, samples should not be taken from the patient tubing 210 because the dead volume, which comes from the regenerated dialysate 140, still in the patient tubing 210. After the outflow phase begins, tidal dialysate flow from the patient 110 starts to push the dead volume back to the apparatus 200. During this outflow phase, samples can be taken from the patient tubing 210 so that the measured solute levels more accurately indicate the toxin clearance from the patient 110.

Preferably, the sampling component is configured to extract the samples from the tidal dialysate flowing along the patient tubing 210 after a predefined duration after outflow of the tidal dialysate from the patient 110 begins, i.e. the tidal dialysate begins discharging from the patient 110. For example, if it takes 1 minute for the outflowing tidal dialysate to push the dead volume back to the apparatus 200, the sampling component may extract the samples after 2 minutes from when the outflow phase begins. Optionally, the device 220 may further incorporate the device efficiency factor to account for any potential efficiency losses due to the dead volume.

In some embodiments as shown in Figure 5B, the device 220 is integrated with the apparatus 200 and the sampling component is configured for extracting a set of samples from the tidal dialysate flowing within the apparatus 200. In one embodiment, the device 220 measures the solute levels in the samples and the samples continue
5 to flow within the apparatus 200. Since the samples come into contact with the sampling component and are returned to the patient 110, the sampling component should be sterile and biocompatible to prevent contamination. In another embodiment, the samples are sacrificial samples and the device 220 measures the solute levels in the sacrificial samples. The sacrificial samples are not returned to the patient 110 and
10 it would not be necessary for the sampling component to be sterile.

Further, the solute levels are measured from the samples of the tidal dialysate discharged from the patient 110 during the outflow phase to account for the dead volume as explained above. Preferably, the sampling component is configured to
15 extract the samples from the tidal dialysate after a predefined duration after outflow of the tidal dialysate from the patient 110 begins. Optionally, the device 220 may further incorporate the device efficiency factor to account for any potential efficiency losses due to the dead volume.

20 The method 300 further includes a step 320 of determining, based on the measured solute levels, a current solute clearance from the TPD. More specifically, the device 220 is configured for determining the current solute clearance using the Equations 4-6 since the solute levels were measured from samples of the tidal dialysate. The method 300 further includes a step 330 of comparing the current solute clearance with
25 a target solute clearance for the patient 110. The target solute clearance is predetermined by physicians for the patient 110 based on the unique biological, health, and medical conditions of the patient 110.

The method 300 further includes a step 340 of generating, based on the comparison,
30 control instructions for a set of parameters of the TPD. The method 300 further includes a step 350 of controlling the parameters based on the control instructions while the patient 110 is undergoing the TPD to thereby adjust the current solute clearance towards the target solute clearance. For example, the device 220 is

communicatively connected to the apparatus 200, such as via wired or wireless connections, to control various components of the apparatus 200 and the TPD parameters. Preferably, the method 300 is performed iteratively whereby the solute levels of the tidal dialysate are regularly measured and the TPD parameters are regularly controlled to enable the patient 110 to achieve the target solute clearance. The TPD parameters may include, but are not limited to, glucose dosing, flow rate, and tidal volume. For example, one or more of the glucose dosing, flow rate, and tidal volume can be increased or decreased, as appropriate, based on the difference between the current solute clearance and target solute clearance.

At the end of the TPD therapy 100, the final volume of waste dialysate 120 is drained and collected in a drain bag. The device 220 can be used to measure the solute levels in the waste dialysate 120 during the final drain phase. Alternatively, the device 220 can be coupled to the drain bag to measure the solute levels in the waste dialysate 120 collected in the drain bag. Accordingly, in some embodiments, the method 300 may include measuring the solute levels in the drained dialysate from the patient 110 after the TPD has ended.

The method 300 may further include determining a total solute clearance from the TPD based on the measured solute levels in the tidal dialysate and drained dialysate. More specifically, the device 220 is configured for determining the total solute clearance using the Equations 1-6 since the solute levels were measured from samples of the tidal dialysate and drained dialysate. The method 300 may further include comparing the total solute clearance with the target solute clearance. The method 300 may further include generating, based on the comparison, control instructions for the parameters of a subsequent TPD for the patient 110, and controlling the parameters based on the control instructions for the subsequent TPD. More specifically, when the patient 110 undergoes the next TPD therapy 100, the device 220 controls the TPD parameters based on the difference between the total solute clearance and target solute clearance so as to enable the patient 110 to achieve the target solute clearance.

Various steps of the method 300, including the comparison of the solute clearances and generation of the control instructions, are performed by the device 220 that is

connected to or integrated with the apparatus 200. For example, the apparatus 200 is configured for performing various functions of the device 220 to improve the solute clearance.

- 5 In many embodiments, there is a system for controlling the TPD and the system includes the device 220. Further, the system may include a remote server or remote computer that is communicatively connected to the device 220 across a communication network. The device 220 may be referred to as a local device that is communicative with the apparatus 200 for performing the TPD.

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In some embodiments as shown in Figure 6B, there is a method 400 for controlling TPD for the patient 110, wherein the method 400 may be performed by the remote server.

- 15 The remote server may be based on a centralized model, decentralized model, or hybrid model. As used herein, a server is a physical or cloud data processing system on which a server program runs. The server may be implemented in hardware or software, or a combination thereof. Some non-limiting examples of the server include computers, laptops, mini-computers, mainframe computers, any non-transient and
20 tangible machines that can execute a machine-readable code, cloud-based servers, distributed server networks, and a network of computers.

The communication network is a medium or environment through which content, notifications, and/or messages are communicated among various components.

- 25 Suitable security protocols, such as encryption protocols, may be implemented in the communication network for secure communications among the components. Some non-limiting examples of the communication network include a virtual private network (VPN), wireless fidelity (Wi-Fi) network, light fidelity (Li-Fi) network, local area network (LAN), wide area network (WAN), metropolitan area network (MAN), satellite network,
30 Internet, fibre optic network, coaxial cable network, infrared (IR) network, radio frequency (RF) network, and any combination thereof. Various components in the communication network may connect to the communication network in accordance with various wired and wireless communication protocols, such as Transmission

Control Protocol / Internet Protocol (TCP/IP), User Datagram Protocol (UDP), 2nd to 5th Generation (2G to 5G) communication protocols, Long Term Evolution (LTE) communication protocols, and any combination thereof. Each component to the communication network includes a data communication or transceiver module to communicate and transmit / receive data over the communication network. Some non-limiting examples of a transceiver module include an antenna module, a radio frequency transceiver module, a wireless transceiver module, a Bluetooth transceiver module, an Ethernet port, a Universal Serial Bus (USB) port, or any other module / component / device configured for transmitting and receiving data.

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The method 400 includes a step 410 of receiving, from the device 220, tidal measurement data comprising solute levels measured in tidal dialysate discharged from the patient 110 while the patient is undergoing the TPD. More specifically, the solute levels are measured by the device 220 that is connected to the apparatus 200, such as described above with reference to Figures 5A and 5B, and the tidal measurement data is sent from the device 220 to the remote server.

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The method 400 further includes a step 420 of determining, based on the measured solute levels, the current solute clearance from the TPD. The method 400 further includes a step 430 of comparing the current solute clearance with the target solute clearance for the patient 110. The method 400 further includes a step 440 of generating, based on the comparison, control instructions for a set of parameters of the TPD. It will be appreciated that the steps 420,430,440 are similar or analogous to the steps 320,330,340 and are not further described for purpose of brevity.

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The method 400 further includes a step 450 of sending, to the device 220, the control instructions for controlling the parameters while the patient 110 is undergoing the TPD to thereby adjust the current solute clearance towards the target solute clearance. When the device 220 receives the control instructions, the device 220 controls various components of the apparatus 200 and the TPD parameters. Preferably, the method 400 is performed iteratively by the device 220 and remote server, whereby the solute levels of the tidal dialysate are regularly measured and the TPD parameters are regularly controlled to enable the patient 110 to achieve the target solute clearance.

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It will be appreciated that various aspects of the method 300 apply equally to the method 400 and are not further described for purpose for brevity. For example, the device 220 may measure the solute levels in the drained dialysate from the patient 110 after the TPD has ended, and send to the remote server the drained measurement data comprising the solute levels measured in the drained dialysate. The remote server may then determine the total solute clearance based on the measured solute levels in the tidal dialysate and drained dialysate, compare the total solute clearance with the target solute clearance, and generating, based on the comparison, control instructions for the parameters of a subsequent TPD for the patient 110.

In some embodiments as shown in Figure 6C, there is a method 500 for controlling TPD for the patient 110. Firstly, a set of samples of dialysate discharged from the patient 110 is obtained. More specifically, the samples are taken from the tidal dialysate during the TPD and from the drain dialysate at the end of the TPD. For example, the samples may be extracted from the sampling port 230 in the patient tubing 210. For example, the device 220 may be configured such that the sampling component automatically extracts the samples at predetermined cycles of the TPD. Alternatively, the sample extraction may be manually triggered by the patient 110. The samples are then delivered to a laboratory where the method 500 is performed, such as using a suitable remote computer in the laboratory.

The method 500 includes a step 510 of measuring the solute levels in the set of pre-obtained samples from the patient 110. The method 500 further includes a step 520 of determining, based on the measured solute levels, a total solute clearance from the TPD. The method 500 further includes a step 530 of comparing the total solute clearance with a target solute clearance for the patient 110. The method 500 further includes a step 540 of generating, based on the comparison, control instructions for a set of parameters of a subsequent TPD for the patient 110.

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The method 500 further includes a step 550 of sending, to the device 220, the control instructions for controlling the parameters for the subsequent TPD to thereby adjust the total solute clearance from the subsequent TPD towards the target solute

clearance. It will be appreciated that various aspects of the methods 300 and 400 apply equally to the method 500 and are not further described for purpose for brevity.

5 In the method 300, the measurement data of the solute levels is processed by the device 220 to determine the current solute clearance and compare against the target clearance solute for the patient 110. The device 220 automatically controls the TPD parameters in real-time to adjust the current solute clearance towards the target clearance solute. In the method 400, the measurement data of the solute levels is processed by the remote server and the remote server sends instructions to the device
10 220 to control the TPD parameters. For example, the remote server may send instructions to automatically control the TPD parameters in real-time. Alternatively, a physician may review the measurement data and manually trigger sending of the instructions to the device 220. In the method 500, the solute levels are measured in a laboratory and the control instructions are generated in the laboratory. The instructions
15 may be automatically sent to the device 220 to control the TPD parameters for the next TPD therapy 100. Alternatively, a physician may review the measurement data and manually trigger sending of the instructions to the device 220. Further alternatively, the control instructions may be manually programmed into the device 220.

20 The methods 300,400,500 can be used by various stakeholders, including physicians and product designs, to improve the dialysis apparatus 200 and optimize its use for patients 110 who need to undergo peritoneal dialysis. For example, a TPD apparatus 200 for a particular patient 110 should be optimized for the optimal combination of dialysate flow rate and tidal volume that enables the patient 110 to achieve the target
25 solute clearance.

In the foregoing detailed description, embodiments of the present disclosure in relation to systems and methods for controlling tidal peritoneal dialysis are described with reference to the provided figures. The description of the various embodiments herein
30 is not intended to call out or be limited only to specific or particular representations of the present disclosure, but merely to illustrate non-limiting examples of the present disclosure. The present disclosure serves to address at least one of the mentioned problems and issues associated with the prior art. Although only some embodiments

of the present disclosure are disclosed herein, it will be apparent to a person having ordinary skill in the art in view of this disclosure that a variety of changes and/or modifications can be made to the disclosed embodiments without departing from the scope of the present disclosure. Therefore, the scope of the disclosure as well as the
5 scope of the following claims is not limited to embodiments described herein.

Claims

1. A system for controlling tidal peritoneal dialysis for a patient, the system comprising:
- 5 a device communicative with an apparatus for performing the tidal peritoneal dialysis, the device configured for:
- measuring solute levels in a set of samples of tidal dialysate discharged from the patient while the patient is undergoing the tidal peritoneal dialysis;
- 10 determining a current solute clearance from the tidal peritoneal dialysis based on:
- (i) the measured solute levels in the samples of tidal dialysate;
- (ii) tidal volumes of the samples of tidal dialysate; and
- 15 (iii) a device efficiency factor that accounts for dead volumes associated with the tidal peritoneal dialysis;
- comparing the current solute clearance with a target solute clearance for the patient;
- generating, based on the comparison, control instructions for a set of parameters of the tidal peritoneal dialysis; and
- 20 controlling the parameters based on the control instructions while the patient is undergoing the tidal peritoneal dialysis to thereby adjust the current solute clearance towards the target solute clearance.
- 25 2. The system according to claim 1, the device further configured for:
- extracting the samples of tidal dialysate as a set of sacrificial samples;
- and
- measuring the solute levels in the sacrificial samples.
- 30 3. The system according to claim 1 or 2, wherein the device is configured for measuring the solute levels in the samples of tidal dialysate after a predefined duration after the tidal dialysate begins discharging from the patient.

4. The system according to any one of claims 1 to 3, the device further configured for measuring solute levels in a set of samples of drained dialysate that is drained from the patient after the tidal peritoneal dialysis has ended.
- 5 5. The system according to claim 4, the device further configured for determining a total solute clearance from the tidal peritoneal dialysis based on the measured solute levels in the samples of tidal dialysate, the tidal volumes of the samples of tidal dialysate, and the measured solute levels in the samples of drained dialysate.
- 10 6. The system according to claim 5, the device further configured for:
comparing the total solute clearance with the target solute clearance;
generating, based on the comparison, control instructions for the
parameters of a subsequent tidal peritoneal dialysis for the patient; and
controlling the parameters based on the control instructions for the
15 subsequent tidal peritoneal dialysis.
7. A system for controlling tidal peritoneal dialysis for a patient, the system comprising:
a local device communicative with an apparatus for performing the tidal
20 peritoneal dialysis,
a remote server communicative with the local device, the remote server
configured for:
receiving, from the local device, tidal measurement data
comprising solute levels measured in a set of samples of tidal dialysate
25 discharged from the patient while the patient is undergoing the tidal
peritoneal dialysis;
determining a current solute clearance from the tidal peritoneal
dialysis based on:
(i) the measured solute levels in the samples of tidal
30 dialysate;
(ii) tidal volumes of the samples of tidal dialysate; and
(iii) a device efficiency factor that accounts for dead
volumes associated with the tidal peritoneal dialysis;

comparing the current solute clearance with a target solute clearance for the patient;

generating, based on the comparison, control instructions for a set of parameters of the tidal peritoneal dialysis; and

5 sending, to the local device, the control instructions for controlling the parameters while the patient is undergoing the tidal peritoneal dialysis to thereby adjust the current solute clearance towards the target solute clearance.

10 8. The system according to claim 7, the remote server further configured for:

 receiving, from the local device, drained measurement data comprising solute levels measured in a set of samples of drained dialysate that is drained from the patient after the tidal peritoneal dialysis has ended; and

 determining a total solute clearance from the tidal peritoneal dialysis
15 based on the measured solute levels in the samples of tidal dialysate, the tidal volumes of the samples of tidal dialysate, and the measured solute levels in the samples of drained dialysate.

 9. The system according to claim 8, the remote server further configured for:

20 comparing the total solute clearance with the target solute clearance;
 generating, based on the comparison, control instructions for the parameters of a subsequent tidal peritoneal dialysis for the patient; and
 sending, to the local device, the control instructions for controlling the parameters of the subsequent tidal peritoneal dialysis.

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10. A system for controlling tidal peritoneal dialysis for a patient, the system comprising:

 a local device communicative with an apparatus for performing the tidal peritoneal dialysis,

30 a remote computer communicative with the local device, the remote computer configured for:

measuring solute levels in a set of pre-obtained samples of tidal dialysate discharged from the patient while the patient is undergoing the tidal peritoneal dialysis;

5 measuring solute levels in a set of pre-obtained samples of drained dialysate that is drained from the patient after the tidal peritoneal dialysis has ended;

determining a total solute clearance from the tidal peritoneal dialysis based on:

10 (i) measured solute levels in the samples of tidal dialysate,
 (ii) tidal volumes of the samples of tidal dialysate;
 (iii) the measured solute levels in the samples of drained dialysate; and

 (iv) a device efficiency factor that accounts for dead volumes associated with the tidal peritoneal dialysis;

15 comparing the total solute clearance with a target solute clearance for the patient;

 generating, based on the comparison, control instructions for a set of parameters of a subsequent tidal peritoneal dialysis for the patient; and

20 sending, to the local device, the control instructions for controlling the parameters for the subsequent tidal peritoneal dialysis to thereby adjust the total solute clearance from the subsequent tidal peritoneal dialysis towards the target solute clearance.