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Hydrostatic Pressure Gradient Ultrafiltration Device: A Novel Approach for Extracellular Fluids Removal

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Abstract

This study evaluated the outcomes of a novel intra peritoneal absorption chamber for fluids removal through the peritoneal membranes.

An absorption chamber was prepared from a stainless steel coil covered by a collagen membrane and implanted in the peritoneum cavity of four Sprague-Dawley rats.

Two weeks post implantation a venflon needle was inserted to the chamber. Extracellular fluid were drained from the chamber at an average rate of 16 ± 6 cc/kg/day.

Introduction

Diuretics are currently the cornerstone in the treatment of congestive heart failure. However, their effectiveness can be diminished due to a number of factors such as kidney adaptation, kidney failure, and increased central venous pressure.

Ultrafiltration by haemodialysis is associated with myocardial stunning and progression to fixed systolic dysfunction. Peritoneal dialysis offer gentle ultrafiltration. The minimal impact of peritoneal ultrafiltration on hemodynamics would theoretically results in a lower degree of neurohormonal stimulation secondary to ultrafiltration, compared to haemodialysis. However, both procedures are expensive and associated with significant burden and complications.

Our hypotheses is that applying negative hydrostatic pressure in an intra peritoneal absorption chamber can enable ultrafiltration of fluids through the peritoneal membranes, thus resulting in fluids drainage into the urinary system.

In this proof-of-concept study an intra peritoneal absorption chamber that enables ultrafiltration of fluids through the peritoneal membranes was evaluated.

Methods

An absorption chamber (Figure 1) was prepared from a stainless steel coil with a diameter of 0.4 cm and a length of 3-6 cm covered by a collagen membrane (Permacol, Medtronic). Four Sprague-Dawley rats were anaesthetized with isoflurane. The rats underwent mid laparotomy and the absorption chamber was implanted without fixation in the peritoneal cavity. The abdomen was sutured with metal clips. Two weeks post implantation the rats were anaesthetized and a Venflon Peripheral IV Catheter Ported 20g, 25mm Winged was inserted to the chamber (Figure 2). A 1cc syringe was connected to the Venflon and for 3 hours fluids were drained by applying negative hydrostatic pressure. The drained fluids were analyzed in all rats and in one rat a blood sample was taken at the end of the experiment (comparing the chemistry analysis to the fluids drained through the chamber).

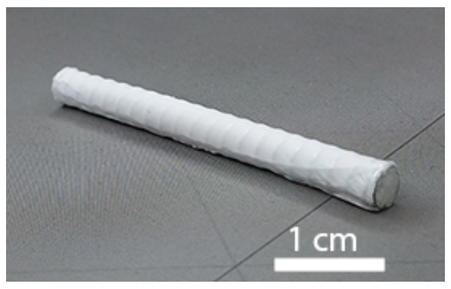

Figure 1: The absorption chamber is made of stainless steel coil with a diameter of 0.4 cm and a length of 3-6 cm covered by a collagen membrane (Permacol, Medtronic).

Figure 2: Fluids drainage through a Venflon cannula inside an absorption chamber implanted in the rat peritoneum.

Conclusions

This proof-of-concept study demonstrates for the first time controlled extracellular fluids removal by producing negative hydrostatic pressure in an absorption chamber implanted in the peritoneum cavity. This concept may potentially have an effect of ultrafiltration, without the cumbersome handling and complications associated with peritoneal dialysis or haemodialysis, and serve as novel treatment for acute as well as chronic advanced heart failure.

Results

Two weeks post implantation the rats were anesthetized and a peritoneal needle was inserted to the chamber. Extracellular fluid were drained from the chamber at an average rate of 16 ± 6 cc/kg/day during 3 hours of negative hydrostatic pressure induction. The fluids electrolytes and proteins were comparable to the serum content.

Table 1. Chemistry analysis of fluids drained from the implanted chamber of four rats and a blood sample from the fourth rat, demonstrating extra cellular properties similar to serum values.

Parameters	Rat 1	Rat 2	Rat 3	Rat 4	Average	Blood test Rat 4
Weight [kg]	0.42	0.32	0.35	0.376	0.37±0.04	
Drained volume [cc/3Hrs]	0.4	0.6	1.0	0.8	0.7±0.3	
Extrapolation [L/Day/Kg]	0.008	0.015	0.023	0.017	0.016±0.006	
Extrapolation [L/Day/70Kg]	0.533	1.05	1.6	1.191	1.1±0.4	
Diameter [cm]	0.4	0.4	0.4	0.4		
Length [cm]	6	5	5	3		
Sodium [mmol/L]	136	145	142	139	140±4	138
Potassium [mmol/L]	12.7	5.3	5.8	7.0	8±3	6.5
Phosphor [mg/dL]	9.7	6.8	8.7	9.8	9±1	9.0
Urea [mg/dL]	37.6	37.4	34.9	44.9	39±4	50.9
Creatinine [mg/dL]	0.3	0.36	0.35	0.41	0.36±0.05	0.46
Albumin [g/dL]	2.6	3.1	3.5	3.1	3.1±0.3	3.9

Future Design

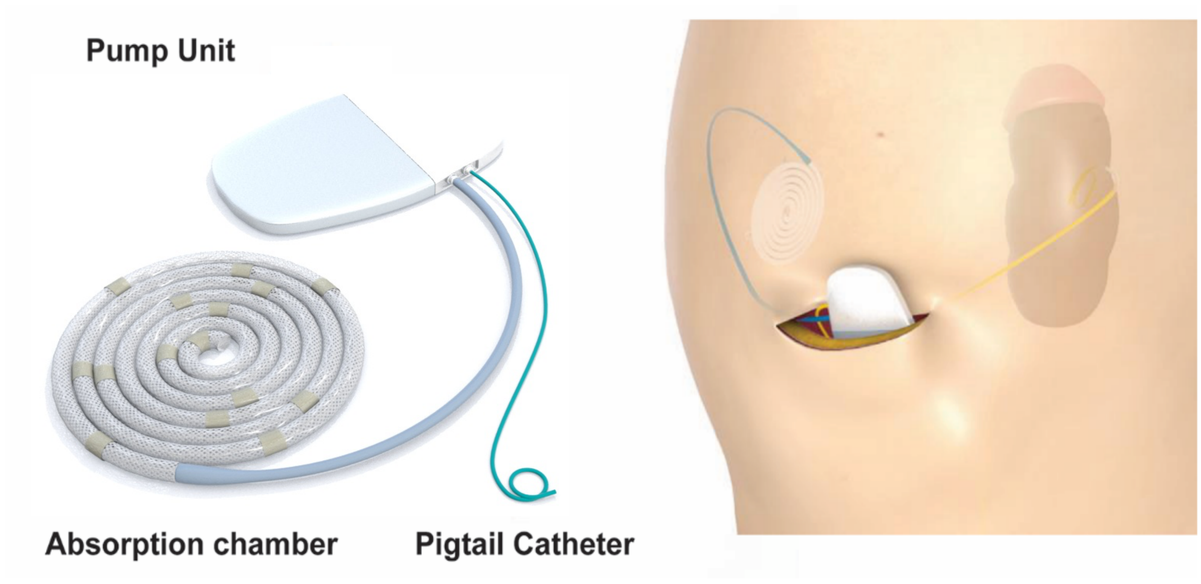

Figure 3: Left: The device is constructed from a spiral absorption chamber (membrane wrapped tube frame), pump unit (controller, telemetry rechargeable battery, pump motor) and an extended pigtail catheter; Right: An illustration of the device in its implanted configuration.

Clinical Perspective

Heart failure affects nearly 23 million people worldwide. About half of the patients with stable heart failure have some degree of renal failure. Renal failure in this group is associated with 50% increase in mortality compared to patients with normal renal function. Advanced heart failure patients with chronic fluids overload poses a major challenge to the clinician. Once diuretic resistance and/or cardiorenal syndrome develops the options for chronic fluid removal is limited to the need for chronic intravenous diuretics followed by dialysis ultrafiltration. The novel device described here will enable for the first time controlled extracellular fluids removal based on the patient clinical need in adjustable to both acute and chronic state, with an implantable device.

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