A wearable hemofilter for continuous ambulatory ultrafiltration

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Ultrafiltration is effective for treating fluid overload, but there are no suitable machines for ambulatory treatment. This study summarizes the use of a light-weight wearable continuous ambulatory ultrafiltration device consisting of a hollow fiber hemofilter, a battery operated pulsatile pump, and two micropumps to control heparin administration and ultrafiltration. Six volume-overloaded patients underwent ultrafiltration for 6 h with treatment discontinued in one patient due to a clotted catheter. Blood flow averaged 116 ml min^{-1}, the ultrafiltration rate ranged from 120–288 ml h^{-1} with about 150 mmol of sodium removed. Blood pressure, pulse, and biochemical parameters remained stable with no significant hemolysis or complications. Our data show that the wearable hemofilter appears to be safe, effective, and practical for patients. This device could have a major impact on the quality of life of fluid-overloaded patients with heart failure. Additional studies will be needed to confirm these initial promising results.

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The population affected by congestive heart failure (CHF) continues to expand due to the epidemic growth in the incidence of diabetes, obesity, coronary heart disease, and diastolic dysfunction.[1–3] The improved survival of patients with ischemic heart disease and myocardial infarction fuels further increments in this population. CHF New York Heart Association (NYHA) class III and IV patients are a very significant financial burden to US hospitals and the Medicare program.[4,5] CHF outcomes have improved somewhat with the advent of both pharmacological advances including; angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, natriuretic peptide analogues, diuretics, β-blockers, vasopressin receptor blockers, and also the use of pacemakers and implantable defibrillators.[6–8] However, despite these advances, the treatment of fluid overload and sodium retention, which are the hallmarks of decompensated CHF, remains problematical, and continues to cause morbidity and hospitalization. These two complications are exacerbated by neurohormonal disturbances and systemic inflammation.[9–11] In addition, aggressive diuretic administration may worsen renal function, and thus increasing mortality in these patients.[12,13] Peritoneal and hemodialysis have been advocated as useful treatments in severe cases of CHF refractory to diuretic therapy.[14,15] There is a growing body of scientific literature supporting the notion that the physical removal of fluid, cytokines and/or a myocardial depressant factor by convection[9] (that is, blood ultrafiltration) can significantly improve patient outcomes, and both shorten hospital inpatient stays and intensive care unit utilization.[16–22] However, current ultrafiltration methods require the use of stationary and bulky devices, reliant on mains electricity supply, which do not allow prolonged or continuous ultrafiltration. In addition, such acute hemofiltration treatments performed over 4–6 h, although efficient and capable of removing up to 23 l of ultrafiltrate in a single session[23] are not physiological, and can potentially result in major shifts of fluid from the intravascular compartment, leading to hypotension, and hemodynamic instability. Furthermore, they do not provide for a steady removal of excess fluid and sodium.

A small wearable device that allows ambulatory hemofiltration to be performed in a slow and continuous fashion

could afford patients the possibility of eliminating acute hemodynamic changes and the freedom from spending many hours attached to large stationary ultrafiltration machines currently used for continuous renal replacement therapies. This is not a new concept, as the first attempts to provide such continuous treatments, date back more than 30 years ago, to the pioneering reports by Kolff.[24] We have previously described the feasibility, safety, and efficacy of the wearable artificial kidney (WAK),[25] as well as its use as an ultrafiltration device, in animal studies.[26] This device might not only potentially contribute to improve the quality of life and reduce the mortality of the ever-growing CHF population, but also make these therapies more affordable and reduce the financial burden incurred in treating this condition. This study describes the first human use of a wearable hemofiltration device (Figure 1) to manage fluid overload. As such, this was a preliminary study, designed as proof of concept, and also to assess both patient tolerability and safety.

RESULTS

Six patients with fluid overload successfully underwent hemofiltration using a wearable ultrafiltration device. Patient and treatment parameters are outlined in Tables 1–4. The hourly amount of ultrafiltration fluid removed ranged from 120 to 288 ml h^{-1}. The amount of ultrafiltrate was measured both by volume and weight and corresponded to the rate of removal indicated by the pump. The average ultrafiltration rate was 192 ± 68.3 ml h^{-1}, with a mean total ultrafiltrate volume of 1084.33 ± 335 ml. The average blood flow was 116 ± 11 ml min^{-1}. Patient weights fell from 77.7 to 76.2 kg, despite patients being encouraged to eat and drink.

The total amount of sodium removed was 150.7 ± 46.5 mmol. The pretreatment serum sodium was 137.3 ± 3.1 mmol l^{-1}, and did not significantly change during treatment, being 138 ± 4.0 mmol l^{-1} after 3 h and 139 ± 3.6 mmol l^{-1} after 6 h of treatment. Similarly, the pretreatment serum potassium was 5.1 ± 1.0 mmol l^{-1} and did not change, being 5.1 ± 0.9 mmol l^{-1} at the end of the study. The sieving coefficients for creatinine and urea were 0.98 ± 0.02 and 0.96 ± 0.05, respectively. The mean urea and creatinine clearances were 3.1 ± 0.9 and 3.2 ± 1.0 ml min^{-1}, respectively.

There were no significant changes in heart rate, respiratory rate, and/or temperature during the 6 h of ultrafiltration treatment. There was a marginal, but significant decrease in mean arterial pressure from 109.4 ± 18.5 to 101.8 ± 17.3 mm Hg ($P < 0.03$) (Table 3).

There were no changes in ECG pre- and posttreatment with the hemofiltration device, and no observed arrhythmias or changes in oxygen saturation. As fluid was successfully removed, the hematocrit did increase after both 3 and 6 h of treatment (Table 4). There was a modest but significant fall in the peripheral platelet count. As with the hematocrit, there was a marginal increase in serum lactate dehydrogenase. This was probably due to a plasma volume effect rather than significant hemolysis.

Initially, all patients were treated when lying down on a bed, but during the study, all patients that so desired got out of bed and walked around (Figure 2). There were no technical complications or untoward effects, in terms of blood pump malfunction, disconnections, and/or ultrafiltration/heparin pump errors. However, in one patient treatment had to be terminated after 4 h due to a clotted catheter. All patients were favorably impressed with the treatment, and no patient made any complaints. During the study, patients were encouraged to be ambulatory, eat and drink, so as to try and simulate ordinary daily activity, while being connected to the wearable hemofiltration device.

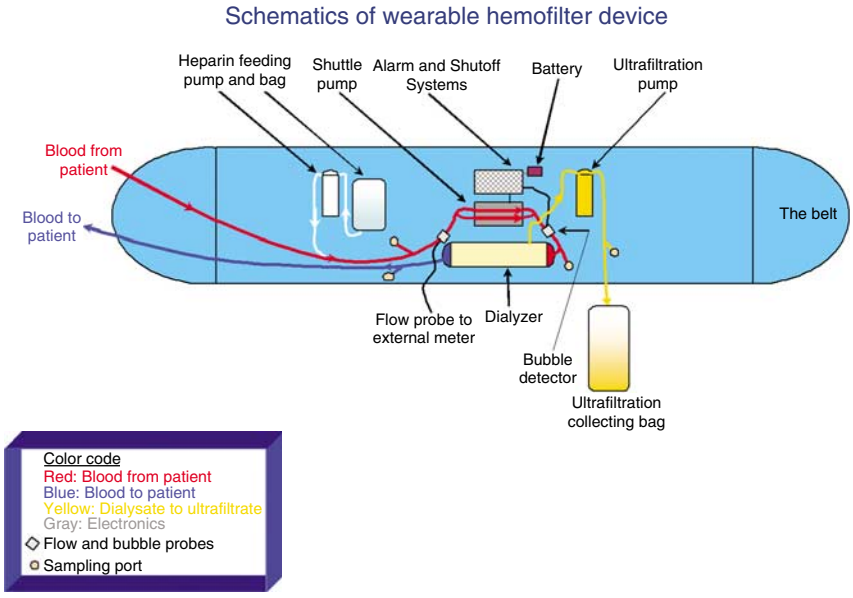

Figure 1 | Diagram of the wearable hemofilter.