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COMPARING CONTINUOUS VENOVENOUS HEMODIAFILTRATION AND PERITONEAL DIALYSIS IN CRITICALLY ILL PATIENTS WITH ACUTE KIDNEY INJURY: A PILOT STUDY

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♦ ***Background:*** **There are few reports on the role of peritoneal dialysis in critically ill patients requiring continuous renal replacement therapies.**

♦ ***Methods:*** **Patients with acute kidney injury and multi-organ involvement were randomly allotted to continuous venovenous hemodiafiltration (CVVHDF, group A) or to continuous peritoneal dialysis (CPD, group B). Cause and severity of renal failure were assessed at the time of initiating dialysis. Primary outcome was the composite correction of uremia, acidosis, fluid overload, and hyperkalemia. Secondary outcomes were improvement of sensorium and hemodynamic instability, survival, and cost.**

♦ ***Results:*** **Groups A and B comprised 25 patients each with mean ages of 45.32 ± 17.53 and 48.44 ± 17.64 respectively. They received 21.68 ± 13.46 hours and 66.02 ± 69.77 hours of dialysis respectively ($p = 0.01$). Composite correction was achieved in 12 patients of group A (48%) and in 14 patients of group B (56%). Urea and creatinine clearances were significantly higher in group A (21.72 ± 10.41 mL/min and 9.36 ± 4.93 mL/min respectively vs. 22.13 ± 9.61 mL/min and 10.5 ± 6.07 mL/min, $p < 0.001$). Acidosis was present in 21 patients of group A (84%) and in 16 of group B (64%); correction was better in group B ($p < 0.001$). Correction of fluid overload was faster and the amount of ultrafiltrate was significantly higher in group A (20.31 ± 21.86 L vs. 5.31 ± 5.75 L, $p < 0.001$). No significant differences were seen in correction of hyperkalemia, altered sensorium, or hemodynamic disturbance. Mortality was 84% in group A and 72% in group B. Factors that influenced outcome were the APACHE (Acute Physiology and Chronic Health Evaluation) II score ($p = 0.02$) and need for ventilatory support ($p < 0.01$). Cost of disposables was higher in group A than in group B [INR 7184 ± 1436 vs. INR 3009 ± 1643, $p < 0.001$ (US$1 = INR 47)].**

♦ ***Conclusions:*** **Based on this pilot study, CPD may be a cost-conscious alternative to CVVHDF; differences in metabolic and clinical outcomes are minimal.**

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Conventional hemodialysis is challenging in critically ill patients because of their hemodynamic instability, with multi-organ failure requiring inotropic and ventilatory support. Assuming lesser hemodynamic disturbances, continuous renal replacement therapies—especially continuous venovenous hemodiafiltration (CVVHDF)—have been tried in such patients (1). Continuous peritoneal dialysis (PD) has the advantages of ease of administration, minimal hemodynamic alterations, and safety in individuals with bleeding tendency and heparin allergy. Its use has been declining in developed countries, probably because of concerns about lower efficacy (2,3), although the technique has been shown to be effective even in hypercatabolic states (4–7).

In the resource-poor setting of developing countries, continuous PD remains an important modality of renal replacement therapy because of its lower cost and ease of administration (2,8,9). We attempted an open prospective randomized comparative study of CVVHDF and continuous PD in critically ill patients, aiming for a sample size of 192. Over 3 years, we were able to recruit only 50 patients, which led us to stop the open study and to report our results as a pilot study.

METHODS

An open prospective randomized study of patients with acute kidney injury (AKI) and multi-organ involvement admitted to the intensive care unit and requiring renal replacement therapy (RRT) during a 3-year period starting in June 2005 was performed at Medical College Hospital, Thiruvananthapuram, South India, with prior approval from the institutional human ethical committee. We defined AKI as a rise in serum creatinine of 0.3 mg/dL

or more from baseline or an hourly urine output of less than 0.5 mL/kg. Indications for RRT were any one or a combination of blood urea 150 mg/dL or higher, serum creatinine 3 mg/dL or higher, serum potassium 6 mEq/L or higher, metabolic acidosis with arterial pH 7.2 or lower, together with hourly urine output of less than 0.5 mL/kg for more than 12 hours despite correction of volume depletion.

Patients were randomized to receive either pump-assisted CVVHDF (group A) or continuous PD (group B). Signed informed consent was obtained from the patient (or from the closest relative when patients had altered sensorium or were on ventilatory support). Patients with life-threatening acute pulmonary edema and recent abdominal surgery were excluded. Patients who died within 6 hours of dialysis initiation were excluded from the final analysis.

Vascular access for CVVHDF was a double-lumen hemodialysis catheter introduced into the femoral vein. Speed of the blood pump (2008-B: Fresenius Medical Care, Bad Homburg, Germany) was adjusted between 100 mL and 150 mL per minute, and a polysulfone hemofilter (Nipro 0.5 – 0.7 m^2: Fresenius Medical Care) was used. The dialysate was locally available sterile PD fluid with a composition of 0.556 g sodium chloride, 0.478 g sodium acetate, 0.15 g sodium metabisulphite, 0.152 g magnesium chloride, 0.22 g calcium chloride, and 1.7 g dextrose per 100 mL. This solution was run in at a rate of 1 L/h. Heparin was given pre-pump, and the dose was adjusted to keep clotting time at 2.5 times normal. In patients with a bleeding tendency, the circuit was rinsed with heparinized saline, and saline flushes 150 mL were given pre-filter every 15 minutes. Replacement fluid given pre-filter was mainly lactated Ringer's solution, except in patients with liver dysfunction, in whom normal saline with varying added amounts of calcium chloride, sodium bicarbonate, potassium, and magnesium was administered, depending on biochemical results. Replacement fluid amounts were based on degree of fluid overload and central venous pressure.

In patients randomized to continuous PD, a rigid PD catheter (Medionics International, Markham, ON, Canada) was introduced percutaneously. Each exchange consisted of 2 L of locally available PD fluid manually instilled using a flush-before-fill technique, with closed drainage, that was repeated after a dwell time of 30 minutes. Exchanges of 1 L were used for those with hypoxia and respiratory distress. When fluid removal was inadequate, 100 mL sterile 25% dextrose was added to each cycle.

Both groups were assessed for blood urea, serum creatinine, serum electrolytes, and arterial blood gases every 6 hours and on termination of dialysis. The volume of spent dialysate was noted for every cycle, and aliquots of 5 mL were collected for dialysate urea and creatinine estimation every 24 hours, or sooner if dialysis had to be terminated. Urea and creatinine clearances were calculated using the formula UV/P, in which U is the urea or creatinine level in the spent dialysate, V is the mean volume of dialysate in milliliters per minute, and P is the mean of blood urea and serum creatinine estimated during the procedure.

In each group, causes of renal failure and severity were assessed using the APACHE (Acute Physiology and Chronic Health Evaluation) II score (10), serum creatinine, and number of organs involved at the time of dialysis initiation. Time taken to initiate dialysis after the initial consultation, duration of dialysis, and total and net ultrafiltration were analyzed.

The primary outcome was originally intended to be successful correction of uremia. After the study was completed, we decided to use a composite index based on correction of uremia, acidosis, hyperkalemia, and fluid overload to measure primary outcome. Uremia was considered to be corrected when blood urea declined to less than 40 mg/dL or to less than 50% of its initial value. Acidosis was considered to be corrected when pH reached or exceeded 7.25, or when serum bicarbonate reached or exceeded 15 mEq/L, or both. Hyperkalemia was defined as a serum potassium of 6 mEq/L or more; it was considered to be corrected once the level was 5.5 mEq/L or less. Fluid overload was considered in the presence of any combination of pitting edema, fine basal crepitations, raised jugular venous pulsation, and a central venous pressure of 12 cmH_20 or more. Disappearance of those criteria was considered to indicate correction.

Secondary outcomes were improvement of sensorium and hemodynamic instability, cessation of dialysis, mortality result, and costs. Patients who were not fully conscious or oriented in time and place were considered to have altered sensorium. All patients requiring inotropic support for blood pressure maintenance were considered to have hemodynamic disturbance; correction was defined as the withdrawal of inotropic supports. A decision to stop dialysis was generally taken when adequate correction of uremia, fluid overload, hyperkalemia, and acidosis were deemed to have been achieved, or when urine output had improved, or both. Once a patient became hemodynamically stable, conventional hemodialysis was started if warranted. Endpoints included cessation of dialysis after improvement, transfer to conventional dialysis, cessation of dialysis because of complications, and death.

Approximate cost of disposables in Indian rupees (US$1 = INR 47) included those for a double-lumen

hemodialysis catheter (INR 2000), hemofilter (INR 3000), blood tubing set (INR 400), heparin (INR 100), collecting bag (INR 40), replacement fluid (INR 40 per liter), PD fluid (INR 40 per liter), PD catheter (INR 250), and Y-connection set (INR 100). Charges for nursing and medical personnel services were not considered, because these charges were not levied in our center. Time taken to correct various abnormalities and complications occurring during dialysis were also noted for each group.

STATISTICAL ANALYSIS

Assuming a 20% difference in primary outcome between the two groups, for 80% power and 95% confidence, it was calculated that a sample size of 192 patients would be required to observe a statistically significant difference. Because we were able to include only 50 patients in a 3-year period at a single center, a significant difference in outcome was not anticipated.

Analyses were performed using the SPSS software application (version 11.0 for Microsoft Windows: SPSS, Chicago, IL, USA). Comparisons between variables having a Gaussian distribution used means ± standard deviation, and significance was assessed using the Student t-test. Skewed distributions used medians and interquartile ranges, with the Mann–Whitney U-test for comparisons. For qualitative variables, the chi-square or Fisher exact test was used. Significance was set at $p < 0.01$.

RESULTS

Figure 1 shows details of recruitment and flow in the study. More patients in group A died within 6 hours of starting dialysis, mainly after hemodynamic disturbances, but the difference was nonsignificant ($p = 0.20$). The causes of AKI were predominantly sepsis and acute tubular necrosis, followed by pre-renal factors.

The groups were not significantly different in baseline characteristics (Table 1).

Table 2 shows the effects of the dialytic modes. The groups had similar composite outcomes. Group A received significantly more replacement fluid than did group B (13.12 ± 12.2 L vs. 2.8 ± 2.1 L, $p < 0.001$). Hypotension occurred in 10 group A patients and in 1 group B patient during the procedure ($p < 0.001$), requiring transient or permanent discontinuation of dialysis in 8 group A patients (80%). Early clotting of the hemofilter occurred in 6 patients. In group B, catheter block occurred in 3

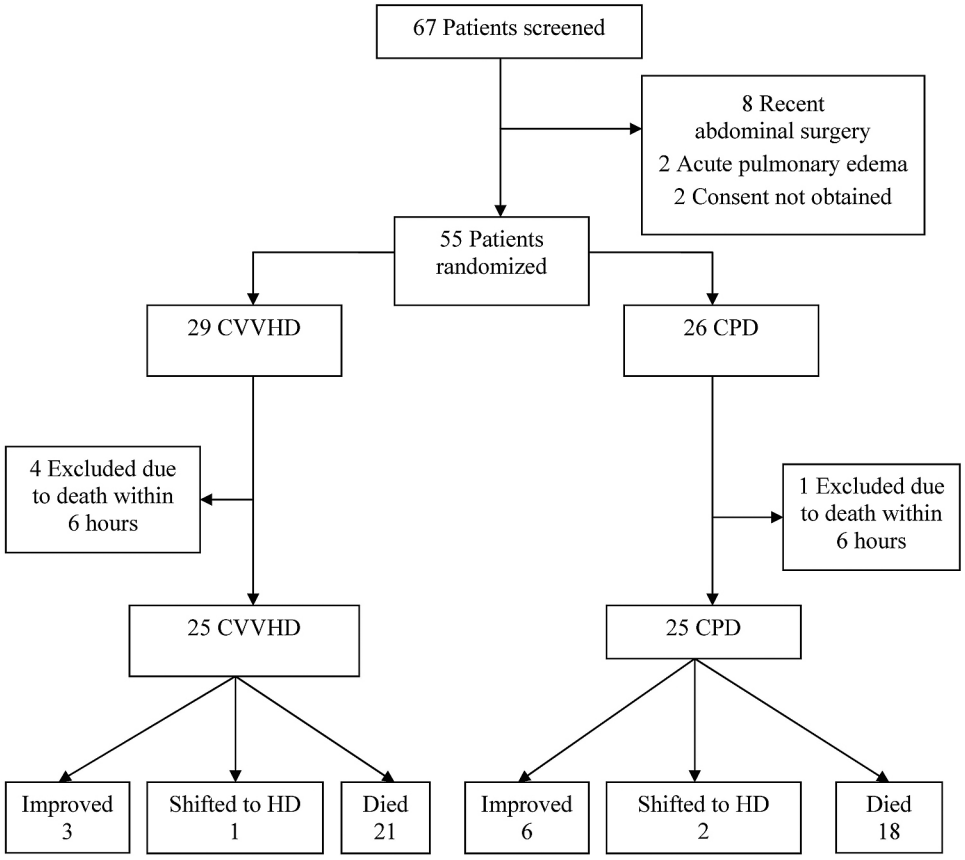

Figure 1 — Patient flow diagram. CVVHD = continuous venovenous hemodiafiltration; CPD = continuous peritoneal dialysis; HD = hemodialysis.

patients; pericatheter leak in 2; and poor outflow, cloudy dialysate, hypotension, hypoxia, and cardiac arrest in 1 each. Mortality was 84% (n = 21) in group A and 72% (n = 18) in group B (p = 0.49). Cost of disposables was higher in group A than in group B (INR 7184 ± 1436 vs. INR 3009 ± 1643, $p < 0.001$). Factors influencing outcome were APACHE II score ($p = 0.02$) and need for ventilatory support ($p < 0.01$).

DISCUSSION

The dialytic mode used in critically ill patients with AKI varies greatly depending on center and location. Although no definite superiority of continuous renal replacement therapies (CRRTs) over conventional hemodialysis (11,12) has been determined, CRRT is preferred in patients on inotropic supports in some centers, because those patients may have greater hemodynamic disturbance (13). Variants such as slow, low-efficiency dialysis (14) and daily hemodialysis may also be effective (15). In hypercatabolic and hemodynamically unstable patients, CVVHDF may have advantages because of better urea clearance (16). In developed countries, PD is rarely used because of fears about its efficacy (3), but it is often used in resource-strapped countries because of easy availability, low cost, and ease of administration (2,8,9). Peritoneal dialysis has been shown to be effective in hypercatabolic patients (4–7), and we have found it effective in correcting acidosis (17). It has several advantages, such as relative safety in patients with hemodynamic disturbance, thrombocytopenia, and bleeding tendencies. It can also be easily administered to

TABLE 1
Baseline Patient Characteristics

Variable	Group HDF	Group CPD	p Value
Patients	25	25	
Mean age (years)[a]	45.32±17.53	48.44±17.64	NS
Sex (male:female)[b]	15:10	16:9	NS
Time to initiate dialysis after initial consultation (hours)[c]			
Mean	9.94±6.378	17.29±15.90	NS
Median	8.00	8.00	
Interquartile range	5	23.62	
Cause of renal failure (n)[b]			
Sepsis	12	7	NS
Pre-renal/ATN	10	7	
Leptospirosis	1	4	
Snakebite	0	3	
Postoperative	2	4	
Organ involvement[b]			
Three	7	11	NS
Four	10	8	
Five	8	6	
APACHE II score[c]			
Mean	18.44±5.96	17.76±6.79	NS
Median	18	19	
Interquartile range	7	13	
Serum creatinine at onset (mg/dL)[a,d]	4.96±1.49	4.69±1.7	NS
Inotropic support (n)[b]	22	22	NS
Ventilatory support (n)[b]	22	15	NS
Mean Glasgow coma scale score[a]	5.08±2.7	5.04±3.1	NS

HDF = hemodiafiltration; CPD = continuous peritoneal dialysis; NS = nonsignificant; ATN = acute tubular necrosis; APACHE II = Acute Physiology and Chronic Health Evaluation II.

[a] Student t-test.

[b] Chi-square test.

[c] Mann–Whitney U-test.

[d] To convert serum creatinine in milligrams per deciliter to moles per liter, multiply by 88.4.

TABLE 2
Outcomes of Dialysis

Variable	Group HDF	Group CPD	*p* Value
Patients	25	25	
Duration of dialysis (hours)[a]			
Mean	21.68±13.46	66.02±69.77	0.01
Median	20	48	
Interquartile range	19	74.5	
Ultrafiltration volume (L)[a]			
Mean	20.31±21.86	5.31±5.75	<0.001
Median	17.1	2.8	
Interquartile range	22.25	1.04	
Net ultrafiltration (L)[a]			
Mean	2.9±2.4	2.8±4.1	NS
Median	2.3	1.6	
Interquartile range	3.43	4.13	
Composite correction of metabolic parameters and fluid overload (*n*)[b]	12	14	NS
Urea clearance (mL/min)[a]			
Mean	21.72±10.41	9.36±4.93	<0.001
Median	19.62	9.58	
Interquartile range	10.67	8.43	
Creatinine clearance (mL/min)[a]			
Mean	22.13±9.61	10.5±6.07	<0.001
Median	20.79	9.97	
Interquartile range	10.4	10.04	
Correction of			
Uremia (*n*)[b]	16	12	NS
Acidosis (*n/N*)[b]	5/21	14/16	<0.001
Fluid overload (*n/N*)[c]	16/17	12/14	NS
Hemodynamic disturbances (*n/N*)[b]	5/25	9/16	NS
Altered sensorium (*n/N*)[c]	2/16	5/13	NS
Hyperkalemia (*n/N*)[c]	2/4	2/5	NS
Time to correct			
Uremia, complete or partial (hours)[a]			
Mean	18.56±13.74	28.83±31.29	NS
Median	14.5	14.0	
Interquartile range	9.5	38	
Acidosis, complete or partial (hours)[a]			
Mean	6.0±0	12.71±6.91	NS
Median	6	12	
Interquartile range	0	12	
Fluid overload (hours)[a]			
Mean	3.35±1.64	10.58±7.04	<0.001
Median	3.0	9.0	
Interquartile range	2	85	

HDF = hemodiafiltration; CPD = continuous peritoneal dialysis; NS = nonsignificant.
[a] Mann–Whitney U-test.
[b] Chi-square test.
[c] Fisher exact test.

patients on inotropic and ventilatory supports, although diaphragmatic movement may possibly be compromised in patients on ventilators, and vasoconstriction of the peritoneal capillary bed may limit solute transport in hypotensive patients (18).

Few studies have compared CRRT and PD in patients with AKI, and reports about efficacy and cost are conflicting (2,6). When falciparum malaria was the major cause of AKI, PD with a stiff catheter, an open drainage system, and manual exchanges of 2 L with 30-minute dwell times was found to be inferior to CVVHDF with regard to resolution of acidosis and renal failure, and mortality was high (2). In patients with severe ischemic or nephrotoxic acute tubular necrosis, PD with a flexible (Tenckhoff) catheter and an automated cycler delivering 2-L exchanges with 30- to 50-minute dwells resulted in metabolic control, patient outcomes, and renal recovery that were similar to those observed with daily hemodialysis (6).

In our patients, sepsis and acute tubular necrosis predominated. Although we observed no difference in composite correction of metabolic parameters and fluid overload, urea and creatinine clearances both seemed better with CVVHDF, and acidotic correction appeared better with continuous PD. However, firm conclusions cannot be drawn because of the limited number of patients. As noted by others, the better uremic correction with PD could be a result of the wider-bore flexible catheter used with a cycler (5,6) and the tidal exchanges (5). Because most of our patients were on inotropic supports, and because CVVHDF was more frequently associated with hypotensive episodes, it is possible that lactic acidosis may have contributed to the poorer correction of acidosis in the CVVHDF group. It has been reported that the use of lactate-based replacement fluid in CVVHDF and lactate-based fluid in continuous PD may be deleterious in patients having compromised liver function; bicarbonate-based fluids may be preferable (19) in those cases. We avoided use of lactate-based replacement fluid in liver dysfunction. Because of the lack of availability of bicarbonate-based PD fluid in our center during the study, acetate-based PD fluid was used. Use of bicarbonate-based PD fluid may have resulted in better correction of acidosis.

Ultrafiltration was higher and fluid correction was faster with CVVHDF. The 30-minute dwell time that we used to maximize urea clearance may account for the poorer fluid removal, because a longer dwell may be preferable (20). Use of PD solutions containing icodextrin could improve ultrafiltration rates, though at a higher cost (21). Although reports that hourly high-dose ultrafiltration rates of approximately 35 mL/kg may be beneficial in sepsis-associated renal failure because of the removal of inflammatory cytokines (22), that hypothesis has not been substantiated; standard hourly ultrafiltration rates of 20 mL/kg appear to be equally effective (23). We were able to achieve average standard ultrafiltration rates with CVVHDF, but rates were substantially lower in the continuous PD group—a circumstance that did not appear to affect outcomes. Despite smaller ultrafiltration rates, removal of inflammatory cytokines is also possible in continuous PD, albeit to a lesser extent (24). Others have also observed that low ultrafiltration rates do not influence outcome (25).

We observed no difference in the correction of hemodynamic disturbance between the groups, although hypotensive episodes and early deaths were more frequent with CVVHDF, which may have been a result of hemodynamic fluctuations. The small number of patients may limit the validity of those observations, however.

Cloudy dialysate rates as high as 42% have been reported with manual exchanges (2), but we had only 1 episode. Use of closed drainage, with the flush-before-fill technique may have contributed to this result.

Composite correction of metabolic parameters was achieved in about 50% of patients, but the mortality rate was high in both groups, suggesting death because of other organ involvement. Our mortality rate appeared higher than that in other centers in India, with a mortality of 60% observed in septic patients (26). Similar observations of 80% mortality have been reported in critically ill AKI patients requiring dialysis (27). We noted that the main factors influencing outcome were the severity of the underlying disease and the need for ventilatory support, but not the modality of dialysis. Similar observations were made when CRRT was compared with conventional hemodialysis by others who reported that outcome was influenced by associated liver disease, sepsis, and trauma, but not the type of dialysis (28). In a similar setting, no differences in the rates of death or renal recovery have been reported with various dialytic modes (29–32). Reports from Vietnam of poor outcome with PD (2) may have been because most patients had falciparum malaria, and fulminant falciparum malaria may possibly block the small arterioles, resulting in decreased peritoneal blood flow and limited efficacy (33).

Dialysis duration was longer in the PD group, suggesting that more time was needed for correction, but that finding may be confounded by the high mortality rate, which resulted in premature termination of dialysis.

Cost was greater in our CVVHDF group, which differs from the observation in Vietnam, where PD was costlier (2). The lower cost of PD fluid in India (approximately $1 per liter) could be a reason. Higher cost with CVVHDF has also been reported by others (34). A comparison of costs

when dialysis is delivered by cycler has not been made (5,6), but use of plasticizer-free continuous ambulatory PD bags and tubing would have more than tripled the costs. The main justification cited for the use of such bags (as opposed to conventional PD bags made from polyvinylchloride by local hospital pharmacies) has been the fear that plasticizers such as diethylhexylphthalate can damage the peritoneal membrane in the long run (35). However in AKI, this concern is minimal, because the dialysis requirement is short-term only. Use of locally-made sterile PD fluid in bags, together with a flexible catheter and a cycler, may achieve better uremic correction at a lower cost in developing countries. Tidal and continuous equilibration PD, which use lesser amounts of PD fluid, could also reduce costs without compromising efficacy (5,7). Because we did not account for staff costs, our observations may not be applicable to other centers, especially those in developed countries.

A major limitation in our single-center study is a sample size inadequate for observing a statistically significant difference in the correction of individual parameters and in outcome. Given that our criteria for starting dialysis might appear aggressive, it is possible that some parameters might have been corrected even without dialysis. It is also possible that presence of edema might not have been a true representation of fluid overload in patients with multi-organ failure.

CONCLUSIONS

Continuous PD appears to be a form of CRRT that can be used in critically ill patient because it requires only minimally trained staff and little infrastructure. Because of lesser fluid shifts with continuous PD, monitoring can be less intensive than it is in CVVHDF. Continuous PD is probably effective in the early stages of AKI, when gross fluid overload and hypercatabolic renal failure are rare. It may be life-saving for patients who develop AKI in the rural setting, where delays in transferring patients to referral hospitals can be anticipated (8,9). A shift to other modalities such as CVVHDF or conventional hemodialysis—or even subsequent transfer to better equipped hospitals—could be considered later in selected patients who do not reach acceptable correction of metabolic parameters or who develop fluid overload.

Our pilot study highlights two important points that should be considered in designing bigger and better studies of renal replacement therapies in intensive care units in the future. First, the equal outcomes that we observed suggest that there are no ethical issues in allowing patients to be randomized to CVVHDF or to continuous PD. Second, recruitment at a single center is difficult; to recruit a bigger sample, future attempts must be conducted in multiple centers.

Overall, our pilot study suggests that continuous PD may be as effective a modality as CVVHDF for the treatment of AKI in critically ill patients. It may also be cost effective, and it deserves further study.

DISCLOSURES

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