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Is peritoneal dialysis adequate for hypercatabolic acute renal failure in developing countries?

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Is peritoneal dialysis adequate for hypercatabolic acute renal failure in developing countries?

Background. Peritoneal dialysis (PD) is a therapeutic option for acute renal failure (ARF) in developing countries, despite concerns about inadequacy. Shorter and more efficient tidal peritoneal dialysis (TPD) was compared with continuous equilibrating peritoneal dialysis (CEPD) therapy in ARF by using their adequacies as accepted standards and analyzing the solute reduction indices (SRI).

Methods. A prospective, randomized crossover trial was performed in patients with mild to moderate hypercatabolic ARF who were assigned to CEPD and TPD therapy after an adequate washout period. Solute clearances (Kt/V, normalized creatinine clearances) were compared to NKF guidelines. Potassium and phosphate clearances, dextrose absorption, protein losses and costs were compared. Kt/V was compared to $SRI_{dialysate}$, $SRI_{Kt/V.}$

Results. Eighty-seven patients with ARF received 236 sessions of dialysis (118 in each treatment). TPD resulted in higher clearances of solutes than CEPD (creatinine and urea clearances in mL/min of 9.94 ± 2.93, 6.74 ± 1.63 and 19.85 ± 1.95, 10.63 ± 2.62, respectively, $P = 0.001$). TPD and CEPD normalized creatinine clearances (L/week/1.73 m^2 BSA) and Kt/V values were 68.5 ± 4.43, 58.85 ± 2.57 and 2.43 ± 0.87, 1.80 ± 0.32, respectively. CEPD did not meet standards of adequacy. TPD resulted in greater potassium and phosphate clearances, less dextrose absorption and was less expensive. CEPD resulted in less protein loss. Kt/V corresponded to $SRI_{dialysate}$ 0.88 ± 0.12 ($P = 0.076$).

Conclusion. TPD produced higher solute clearances in less time with greater protein loss. CEPD just fell short to meet the dialysis adequacy standard. However, both TPD and CEPD are reasonable options for mild-moderate hypercatabolic ARF. Kt/V appropriately estimates solute removal in PD.

Key words: continuous equilibration peritoneal dialysis, tidal peritoneal dialysis, Kt/V, creatinine clearance, solute reduction index, adequacy of dialysis, end-stage renal disease, India and dialysis.

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Acute renal failure (ARF) remains a common and potentially devastating disorder affecting as many as 5 to 8% of all hospitalized patients, with a higher prevalence in patients in critical care units [1]. ARF in the developed world is more frequently observed in association with multi-organ dysfunction and in elderly patients with complex diseases and surgical trauma (56.9%), where the mortality remains high [1]. In developing countries, ARF is more common secondary to medical causes, namely, ischemic acute tubular necrosis from renal hypoperfusion, infections, insect bites, and pregnancy related causes [2].

Patients with ARF and the dialysis centers that treat them face unique problems in developing countries, such as India. First, dialysis is available only at a few centers in certain metropolitan cities and many of these centers are not equipped to provide all modalities of renal replacement therapy on an emergency basis. In addition, the limited availability of hemodialysis beds, technical and trained nursing staff, and sharing of hemodialysis beds by chronic renal failure (CRF) patients influence the choice of therapy for the patients with ARF. For example, our center at the King Edward Memorial Hospital at the University of Bombay, one of the largest tertiary care multi-specialty hospitals in India, annually treats an average of 1000 to 1100 in-patients in a nephrology service consisting of just 34 beds and 20 hemodialysis machines. Second, dialysis centers experience periodic increase in demands according to seasonal variations in the incidence of ARF. We experience an 18 to 23% increase in admission during the monsoon season (rainfall, between July and September) due to increase in acute gastro-enteritis and other communicable diseases, like malaria and leptospirosis. Third, the cost of treatment is an extremely crucial factor in the selection of therapy in countries that do not posses a government funded health care system. The cost of hemodialysis equipment is approximately rupees (Rs.) 5000 (equiva-

lent to US $120) and that of PD equipment is Rs. 250 to 300 (equivalent of US $5 to 7). To put that into perspective, the cost of hemodialysis equipment is more than one quarter of the average monthly income of an Indian family (per capita GNP = US $390) [3]. Most of the patients are referred approximately one to three days after the onset of ARF. An additional delay of approximately 6 to 12 hours occurs when transferring patients from the medical floors to the dialysis unit due to long waiting lists. Five to eight percent of patients have to be referred to other dialysis centers for lack of beds.

Peritoneal dialysis (PD) for ARF still constitutes the mainstay of therapy in the tropics due to its availability and ease of administration [4]. PD offers several advantages over HD, such as technical simplicity, absence of an extracorporeal circuit, no bleeding risk, excellent cardiovascular tolerance and low risk of hydro-electrolyte disequilibrium. PD also has some limitations, such as risk of peritoneal infection, occurrence of obligatory protein loss, need for an intact peritoneal cavity and overall lower effectiveness. Traditionally, at our center, continuous equilibration peritoneal dialysis (CEPD) is offered to patients with ARF with cardiovascular instability, coagulopathies and without evidence of severe hypercatabolic state for 24 to 48 hours. An overwhelming demand for dialysis beds and hemodialysis machines prompted us to evaluate a more efficient type of PD, tidal peritoneal dialysis (TPD), to facilitate more effective use of scarce medical resources and help make the turnover of beds for dialysis more efficient. TPD used in CRF patients has been shown to increase solute clearances by 13 to 25% over nocturnal intermittent peritoneal dialysis using the same volume of fluid [5].

Because the daily clearances of solutes are lower with PD than with daily hemodialysis, there has been concern that PD cannot control the uremia seen in acutely ill ARF patients [6]. Most of the studies that have evaluated PD in hypercatabolic ARF reported PD as having adequate and satisfactory control of fluid and metabolic derangements [7–14]. However, small sample sizes, inadequate measurement of catabolic status, and lack of appropriate measurements of dialysis adequacy were major limitations of these studies [7–14]. Arbitrarily defined optimum levels of post-dialysis blood urea nitrogen (BUN) and creatinine were used as crude indices of dialysis adequacy. Furthermore, it has been increasingly recognized that the delivered dose of dialysis influences patient outcomes in ARF and that the dose delivered to patients with ARF by hemodialysis (HD) is inadequate [15–17]. Given these limitations, there is a pressing need to re-evaluate the adequacy of PD in ARF using accepted standards.

The present prospective study was designed to explore the role of TPD and CEPD in mild-moderate hypercatabolic ARF patients, and to evaluate the adequacy of both types of PD in terms of Kt/V, normalized creatinine clearance and modified solute reduction indices ($SRI_{dialysate}$ and $SRI_{Kt/V}$) [16]. The main objective was to examine the adequacies of both the modalities in ARF rather than to compare high flow dialysis (TPD) with low flow dialysis (CEPD), where the former is expected to yield higher solute clearances. In the absence of accepted standards of adequacy in ARF, clearances were compared to standards derived for CRF patients as proposed by the National Kidney Foundation (NKF), and used in other studies of ARF with HD [16, 18]. SRI is a dialysate-based kinetic method, considered the gold standard in HD, but it has not been studied in PD [19]. We wanted to compare a modified SRI with Kt/V to determine the amount of solute removal in PD. A cost comparison analysis was performed for these two types of PD.

METHODS

Study population

This was a prospective, randomized crossover study, performed with the approval of the hospital ethics committee of King Edward Memorial Hospital, University of Bombay, India. Informed written consent was obtained from all study participants. This tertiary referral center in the city of Greater Bombay (Mumbai) is an 1800 bed hospital, which treats 1.6 to 1.7 million outpatients and 62 to 64,000 inpatients annually; it has a catchment area of approximately 10 million people from the city of Bombay and surrounding areas of western India.

Consecutive patients with hypercatabolic ARF who were referred to the dialysis service during the six-month study period, between 12 to 80 years of age and hemodynamically stable, were considered for the study. Hypercatabolic renal failure was defined as acute renal shut down with an increase of BUN >30 mg/dL/day and creatinine >1 mg/dL/day with one of the following: an increase in serum potassium >1 mEq/L/day, serum uric acid >15 mg/dL, serum phosphate >8 to 10 mg/dL and a decrease of serum bicarbonate > 2 mEq/L/day [20]. Patients were grouped into mild, moderate and severe hypercatabolic ARF according to the severity of catabolism as estimated by the excess urea appearance rate (UNA) (vide infra) [21]. Patients with mild-moderate hypercatabolic ARF (excess UNA, above the dietary nitrogen intake up to 12 g/day) were randomized in the trial. Patients with any of the following conditions were excluded: hemodynamic instability (systolic blood pressure <80 mm Hg), pulmonary edema, severe metabolic acidosis (blood pH <7.2 and plasma bicarbonate <14 mEq/L), and excess UNA of more than 12 g/day (severe hypercatabolic renal failure) [21]. Traumatic PD and malfunctioning dialysis sessions were excluded from the final analysis.

Table 1. Dialysis protocols for tidal peritoneal dialysis (TPD) and continuous equilibrating peritoneal dialysis (CEPD)

Treatment	CEPD	TPD
Initial fill volume (mL) for artificial ascites	2000	2000
Dialysate fluid/cycle *mL*	2000	675 (tidal volume)
Inflow time *min*	10	5
Dwell time *min*	210	10
Outflow time *min*	20	5
Tidal drain *mL*	—	750
Reserve volume *mL*	—	1325
Duration/cycle *min*	240	20
Total exchanges/session	12	36
Total duration of session *hours*	48	12
Total volume (L) of dialysate per session	26	26.3
Flow rate *mL/min*	9	36.5

Anthropometric measurements [height, weight and body surface area (BSA) calculated from DuBois formula] [22] were obtained before initiating dialysis. Prior to initiation of dialysis, a skilled renal dietician supervised dietary intake and a 24-hour urine was collected for urea and creatinine estimation.

Treatment protocols

Patients were randomly allocated as per a standard random number table to either treatment A or B, where treatment A was TPD and B was CEPD. The patients were crossed over to the other treatment protocol after a minimum washout period of 12 hours. The patients were randomized again if the need for dialysis persisted after the initial session. Those patients who completed at least one set of dialysis (CEPD + TPD or TPD + CEPD) were included in the final analysis.

Peritoneal access was established by a stylet catheter (stiff non-cuffed inert catheter equivalent to a Cook catheter) introduced in the midline, infra-umbilically by standard procedure after creating artificial ascites with 2 L of peritoneal dialysis fluid (Dianeal® 2.5%; Baxter Healthcare Corporation, Deerfield, IL, USA). An infusion volume of 2 L was selected, as our patient population would not tolerate higher intra-peritoneal volume secondary to their small average body size. A peritoneal dialysis solution (Dianeal® 2.5%) without heparin or potassium was used for both the protocols (Table 1). TPD and CEPD were performed by PAC-Xtra 2 (Baxter Healthcare Corporation) and manually, respectively. Clinical assessment was performed at six-hour intervals. Patient satisfaction (assessed by pain and comfort during dialysis) was evaluated on a semiquantitative scale, where 0 = no satisfaction and 3 = highest level of satisfaction.

A cost comparison analysis was performed between the two types of PD by including dialysis bed charges (calculated by factoring per unit hour of labor charges for registered nurses, nursing supervisors, technicians, clerical and housekeeping services, and resident doctors; consumables, including needles, syringes, intravenous solutions, intravenous sets, office supplies, minor equipment, vacutainers, and other purchases; dietary supplies; standing expenses like maintenance engineering, power, telecommunications, data processing, hospital security, administrative and quality control expenses). Taxes, depreciation of various items and bed debts were included in calculating the cost of a dialysis bed [23]. Cost of dialysis consumables was also calculated from the cost of a dialysis set, Baxter dialysate fluid and the Cycler PAC-Xtra 2 machine, as well as the expense of machine maintenance. The cost of the machine/person was calculated by dividing the total cost (inclusive of cost of hardware, shipping and handling) by the number of patients likely to use the machine during its lifespan (on average 20 patients use the machine a month for a minimum of 8 to 10 years). Cost was calculated in Indian rupees (Rs.; ~US $1 = 45 Indian Rupees). To make international cost comparison more meaningful, costs in international dollars (I $) also were calculated. The calculation is obtained by adjusting for the purchasing power parity factor, which is defined as the number of units of a country's currency required to buy the same amount of goods or services in the domestic market as the US $1 would buy in the United States [24]. The international dollar represents differences in purchasing power not covered by the official exchange rates. Therefore, Rs. 10.94 spent in India are equal to I $1 (or US $ spent in the United States).

Analysis of samples

Blood samples were collected at baseline for the calculation of catabolism; samples also were collected at baseline and the end of dialysis for the measurement of urea nitrogen, creatinine, total protein, sodium, potassium, calcium, phosphate and glucose. The samples were analyzed using a Hitachi 717 analyser (Boehinger-Mannheim, Rotkreuz, Germany). The dialysate effluent was collected in two large drainage bags (capacity of 15 L/ bag) and the bags were stored at −20°C. An aliquot of 200 mL of dialysate was removed after thorough mixing of the storage bag and was analyzed for the biochemical parameters described below.

Dialysate urea nitrogen was measured by the Diacetyl monoxime method, and creatinine estimations were performed using the modified Jaffe reaction. The coefficients of variation (CV) of dialysate urea nitrogen and creatinine assays were 2.3% to 3.5%, respectively. Measurement of dialysate total protein was performed by turbidimetric analysis using trichloroacetic acid with Ponceau-S dye and that of albumin by the timed endpoint method with Bromocresol Blue. The CV for protein estimation was from 3.2% to 4.0%. Dialysate glucose

was analyzed by the glucose oxidase-peroxidase method and electrolytes by ISE (ion specific electrode). Since glucose interferes with the Jaffe reagent for creatinine estimation, dialysate creatinine was corrected by 0.000531415 for each mg/dL of dialysate glucose [25]. Dialysate phosphate was estimated by the timed endpoint method with ammonium molybdate. Dialysate was cultured for aerobic and anaerobic bacteria using appropriate culture media.

Calculations

Assessment of catabolism

$$\text{Nitrogen balance} = \text{dietary N} - (\text{UN output} + \text{NUN losses}) \quad \text{(Eq. 1)}$$

Dietary protein and calories were calculated from the 24-hour dietary intake of patients closely supervised by a skilled renal dietician. Total protein intake was calculated as per standard charts [26]. Dietary nitrogen (N) was calculated as 16% of the biological protein intake [27]. None of the patients was on enteral or parenteral hyperalimentation and hence the sole nitrogen input was dietary protein intake. Since urea is the major nitrogenous waste product of protein and amino acid degradation, urea nitrogen appearance (UNA) was used to estimate nitrogen output [27]. UNA was calculated as follows: UNA (g/day) = urine urea nitrogen (g/day) + Change in body urea nitrogen (g/day) + Dialysate urea nitrogen (g/day). Change in body urea nitrogen g/day = $(SUN_f - SUN_i$, g/L/day) $\times$ $(BW_i \times 0.60)$ + $(BW_f - BW_i$, kg) $\times$ SUN_f (g/L) $\times$ 1.0 L/kg, where SUN is serum urea nitrogen, BW is the patient's actual body weight, and i and f are the beginning and end of the study period, respectively. Dialysate urea would be = 0, as UNA estimation was performed before beginning dialysis.

Non-urea N (NUN), the nitrogen lost in sweat, respiration, flatus, phlebotomy, and growth of skin, hair and nails, was computed as 0.031g N/kg/day [27]. Excess of urea appearance was then calculated as the difference in the intake of N and UNA + NUN. Based on this calculation patients were categorized as having mild (<6 g/day), moderate (6 to 12 g/day) and severe (>12 g/day) hypercatabolism, as proposed by Druml [21].

Clearance of urea nitrogen and creatinine. Urea nitrogen and creatinine were calculated as follows:

$$\text{Clearance} = \frac{\text{Dialysate volume} \times \text{Concentration of solute}}{(P_1 + P_2)/2} \quad \text{(Eq. 2)}$$

where P_1 is the serum solute concentration before dialysis and P_2 is the serum solute concentration at the end of dialysis. Creatinine clearance was normalized to 1.73 m^2 BSA, and urea clearance was expressed in both mL/min and Kt/V, where K = clearance in mL/min, t = time on dialysis (min) and V = volume of distribution of urea as calculated by the Watson formula [28].

Modified solute reduction indices. The modified solute reduction indices were calculated as follows [16].

$$SRI_{Dialysate} = \frac{\text{Total urea in dialysate (g)} \times 100\%}{(\text{Pre-dialysis BUN g/L}) \times \text{TBW (L)}}$$

$$SRI_{Kt/V} = 1 - e^{-Kt/V} \times 100 \quad \text{(Eq. 3), (Eq. 4)}$$

Statistical analysis

The non-parametric variables, namely, serum urea nitrogen, creatinine, potassium, glucose, protein, albumin and phosphate were expressed as mean ± SD. Since each patient served as his/her own control, pre- and post-dialysis BUN and creatinine values were compared for the two treatment groups using the paired *t* test. Adequacy of the washout period in-between two sessions of dialysis was evaluated by examining the effect of the previous session on the subsequent session. This was performed by the paired *t* test as follows: dialysate urea (DC_{urea}) and creatinine (DC_{Cr}) clearances were compared between T1 and T2, where T1 was the first (T → C sequence) and T2 was the second session (C → T sequence). A similar analysis was performed for the CEPD group [(C1) with (C2)]. Kt/V and SRI between both treatment groups and within the same group (CEPD and TPD) were compared by the paired *t* test. Similarly, $SRI_{dialysate}$, $SRI_{Kt/V}$ within the same treatment group were compared with the paired *t* test. The differences in potassium and phosphate clearances and protein and albumin losses were compared by the paired *t* test. SAS version 7.0 was used for the statistical analysis (SAS Institute Inc., Chicago, IL, USA) [29].

RESULTS

A total of 113 patients with ARF were referred to the Division of Nephrology for dialysis support over the six-month period. Twenty patients with severe hypercatabolic ARF (excess UNA above nitrogen intake >12 g/day) secondary to burns ($N = 5$), septicemia ($N = 7$), traumatic rhabdomyolysis ($N = 3$), hemolytic uremic syndrome (HUS) and thrombotic thrombocytopenic purpura (TTP; $N = 5$) were excluded from the study. Three patients were excluded due to traumatic and/or malfunctioning dialysis, and three patients improved without further need of dialysis after a single session of PD. These 26 excluded patients received hemodialysis for two to seven weeks. Three out of five patients with burns and four out of seven patients with septicemia succumbed due to the causes unrelated to hemodialysis. Two patients with the TTP/HUS progressed to chronic dialysis.

Baseline demographic and clinical characteristics of

Table 2. Baseline demographic and clinical characteristics of cohort ($N = 87$)

Characteristics	Values[a]	Characteristics	Values
Urine output *mL*	325 ± 28 (50–1386)	Serum sodium *mEq/L*	132 ± 8.7 (120–156)
Systolic blood pressure *mm Hg*	110 ± 20 (85–148)	Serum potassium *mEq/L*	6.9 ± 3.2 (4.7–7.1)
Diastolic blood pressure *mm Hg*	96 ± 16 (72–110)	Total protein *g/dL*	4.8 ± 1.76 (3.9–6.1)
Total protein intake *g/day*	30.2 ± 11.7 (13.57–48.9)	Serum albumin *g/dL*	3.1 ± 1.8 (2.6–4.1)
Urea nitrogen appearance rate *g/day*	38.97 ± 11.38 (22.23–51.95)	Serum calcium *mg/dL*	8.9 ± 1.7 (7.1–10)
Excess of UNA *g/day*	7.42 ± 3.65 (3.65–11.72)	Serum phosphorous *mg/dL*	7.5 ± 2.6 (5.1–10.6)
Pre-dialysis BUN *mg/dL*	78.19 ± 12.8 (60–145)	Serum uric acid *mg/dL*	6.8 ± 2.7 (3–12.8)
Pre-dialysis creatinine *mg/dL*	8.19 ± 1.56 (5.8–10.3)		

[a] Values are presented as mean ± SD (range)

Table 3. Causes of acute renal failure ($N = 87$)

Diagnosis	*N* patients	Contributory factors
Renal hypoperfusion and ischemic ATN	20	Acute gastroenteritis (19) Complete heart block (1)
Leptospirosis	15	Jaundice, dehydration, DIC
Glucose-6: phosphate deficiency with hemolysis	12	Following ingestion of drugs like Primaquine, Quinidine and Dapsone
Liver diseases	2	Cirrhosis with hematemesis and shock leading to acute tubular necrosis (ATN)
Snake bite	11	Elapidae (5) leading to disseminated intravascular coagulation (DIC) Vipiridae (6) leading to cellulitis and *S. aureus* septicemia
Malaria	10	Malignant *Falciparum* malaria with DIC, dehydration
Drug-induced ATN	3	Rifampicin-induced interstitial nephritis (1) Gentamicin-induced ATN with dehydration and contrast nephropathy (2)
Glomerular diseases	2	Rapidly progressive glomerulonephritis (1) Acute nephritic syndrome (post-streptococcal glomerulonephritis) (1)
Acute pyelonephritis	2	*Klebsiella* pneumonia in solitary kidney
Surgical	8	Post-cardiac and aortic surgeries
Obstetrics	2	Toxemia of pregnancy with DIC

the 87 patients included in the analysis are shown in Table 2. The mean ± SD of age was 34.7 ± 10.6 years and the male:female ratio was 1.6:1. The mean ± SD of weight and the BSA were 62.3 ± 8.6 kg, 1.56 ± 0.8 m^2, respectively. Medical causes of the ARF predominated (88%), while surgical (9%) and obstetric causes (2%) accounted for the remainder (Table 3). A total of 236 treatment sessions on 87 patients were analyzed (CEPD = 118 and TPD = 118).

Pre-dialysis BUN and creatinine values were not significantly different between the two groups (Table 4). The mean ± SD of the washout period was 15 ± 2.5 hours (range 12.8 to 20.4 h). Pre-dialysis BUN values in the group where TPD was received first (T1) versus the group receiving it second (T2) were 73 ± 21.5 and 79 ± 13.6 mg/dL, respectively ($P = 0.087$, NS). Serum creatinine values in the T1 and T2 groups were 8.3 ± 1.9 and 7.6 ± 1.7 mg/dL, respectively ($P = 0.075$, NS). Similar observations were obtained for CEPD (pre-dialysis BUN in C1 of 74 ± 15.3 mg/dL and C2 of 73 ± 10.4 mg/dL, and creatinine of 7.6 ± 1.2 mg/dL in C1 and 7.4 ± 1.6 mg/dL in C2; both P = NS). Thus, the washout period was adequate, as the sequence of dialysis had no bearing on urea and creatinine clearances.

Post-dialysis BUN and creatinine levels were significantly lower than pre-dialysis levels in both the groups (BUN lowered by 35.4% in TPD and 17% in CEPD, while creatinine lowered by 38% in TPD and 15% in CEPD; Table 4). Post-dialysis BUN and creatinine values were significantly lower in TPD compared to CEPD (P values were 0.04 and 0.02, respectively). Clearances of urea and creatinine in mL/min were significantly different between TPD and CEPD (with TPD > CEPD). Normalized creatinine clearance and Kt/V were significantly higher in TPD, as were SRI (Table 4). The estimated weekly Kt/V for CEPD of 1.80 and normalized creatinine clearance of 58.85 L/week/1.73 m^2 BSA fell short of matching the standards of adequacy as proposed by the NKF (weekly Kt/V of ≥2.0 and normalized creatinine clearance of ≥60 L/week/1.73 m^2 BSA for CAPD) [18]. The estimated weekly Kt/V and normalized creatinine clearance in TPD were 2.43 and 68.5 L/week/1.73 m^2, respectively (Table 4). Hence, the TPD exceeded the standards of adequacy as per the NKF guidelines (weekly Kt/V of ≥2.2 and normalized creatinine clearance ≥66 L/week/1.73 m^2 BSA for APD) [18].

Overall, Kt/V corresponded to SRI of 0.88 ± 0.12 ($P = 0.093$). In the TPD group no significant differences were noted in Kt/V, $SRI_{dialysate}$ or $SRI_{Kt/V}$; Kt/V corresponded to 0.86 ± 0.06 of $SRI_{dialysate}$ and 0.92 ± 0.04 of $SRI_{Kt/V}$

Table 4. Pre- and post-dialysis BUN and creatinine, solute clearances (Kt/V, normalized creatinine clearances and solute removal indices) and ultrafiltrate in TPD and CEPD

	TPD		CEPD		
Variables	Mean ± SD	Range	Mean ± SD	Range	*P* value
Pre-dialysis BUN *mg/dL*	78.80 ± 8.30	68–125	77.96 ± 22.10	63–118	0.67
Post-dialysis BUN *mg/dL*	50.84 ± 11.30	42–68	64.71 ± 12.4	59–82	0.04
Pre-dialysis creatinine *mg/dL*	8.16 ± 2.73	4.9–10.30	7.79 ± 2.49	4–9.70	0.62
Post-dialysis creatinine *mg/dL*	5.01 ± 1.9	4.2–7.90	6.52 ± 1.61	4.60–8	0.02
C_{cl} *mL/min*	9.94 ± 2.93	7.14–20.92	6.74 ± 1.63	3.94–9.34	0.01
L/session/1.73 m²	9.79 ± 1.13	6.94–11.34	7.40 ± 1.21[a]	5.53–9.79	0.031
L/week/1.73 m²	68.5 ± 4.43	49.60–73.36	58.85 ± 2.57	43.73–68.49	0.035
C_{ur} *mL/min*	19.85 ± 1.95	15.67–23.01	10.63 ± 2.62	8.38–12.52	0.001
Kt/V (session)	0.34 ± 0.14	0.18–0.50	0.26 ± 0.07[a]	0.12–0.39	0.001
Kt/V (week)	2.43 ± 0.87	1.11–3.49	1.80 ± 0.32	1.47–2.75	0.001
$SRI_{Dialysate}$	28.46 ± 4.6%	41–57.9%	20.64 ± 5.93%	14–36.45%	0.02
$SRI_{Kt/V}$	21.06 ± 4.03%	15.62–30.48%	15.53 ± 5.45%	9.5–21.47%	0.02
UF *ml/min*	4.28 ± 0.70	3.01–5.8	1.82 ± 0.13	0.80–2	0.04
L/session	2.88 ± 0.71	1.89–4.14	2.01 ± 0.28[a]	0.38–2.44	0.03

The difference was considered statistically significant by paired *t* test for $P < 0.05$ for $N = 87$. C_{ur} is dialysate urea.
[a] Values of CEPD tabulated for 24 hours for comparison

Table 5. Comparison of total protein, albumin losses, dextrose absorption, potassium and phosphate clearances in TPD and CEPD

	TPD		CEPD		
Variables	Mean ± SD	Range	Mean ± SD	Range	*P* value
Total protein loss *g/session*	10.49 ± 1.55	5.16–16.25	6.63 ± 1.25	4.92–10.38	0.001
Albumin loss *g/session*	6.32 ± 1.03	3.18–12.23	3.48 ± 2.10	1.65–9.30	0.02
Potassium clearance *mL/min*	24.56 ± 5.8	19–34.26	16.81 ± 4.6	10.23–25	0.01
Phosphate clearance *mL/min*	14.23 ± 5.4	8.21–30	9.60 ± 3.90	5–15.23	0.042
Dextrose absorption *g/session*	98.63 ± 21.43	56–158.14	168.27 ± 23.80	118–282	0.0001

The difference considered statistically significant by paired *t* test for $P < 0.05$ for $N = 87$.

($P = 0.09$). Similarly, in the CEPD group Kt/V corresponded to 0.90 ± 0.04 and 0.87 ± 0.03 with $SRI_{dialysate}$, $SRI_{Kt/V}$, respectively ($P = 0.08$). Within the same treatment group, $SRI_{dialysate}$ and $SRI_{Kt/V}$ were not significantly different (TPD and CEPD *P* values were 0.082 and 0.097, respectively).

Statistically significant higher losses of protein and albumin and clearances of potassium and phosphorous were observed with TPD (Table 5). Ultrafiltrate was greater in TPD, while glucose absorption was more in CEPD (Tables 4 and 5). The cost of TPD was less than CEPD (difference was Indian Rs. 688; Table 6).

In the TPD group, 9 (7%), 9 (7%), 17 (15%), 83 (70%) sessions were graded from 0 to 3, respectively, while in the CEPD group, 38 (32%), 39 (33%), 15 (13%), 26 (22%) sessions were graded from 0 to 3, respectively. Hence, 70% of sessions in TPD and only 22% in CEPD were graded with the highest level of satisfaction. None of the patients experienced abdominal pain during rapid exchanges of TPD.

Three episodes of post-dialysis peritonitis due to *S. aureus* were observed after CEPD. Peritoneal leaks were noted in five sessions (4 with CEPD, 1 with TPD) and one catheter required exchange due to partial blockage.

Sixty patients became dialysis free after a single set of PD (CEPD and TPD), while 23 underwent two and just four patients required three sets of dialysis. One patient had sudden death in the polyuric phase of acute tubular necrosis (ATN) due to pacemaker failure. Out of 87 patients, four required implementation of HD when PD was judged inadequate to control uremia (one patient with RPGN and 3 with superimposed septicemia following viperine snakebite). The adequacy parameters in these four patients were as follows: Normalized creatinine clearance (L/session/1.73 m^2 BSA) of 6.94 ± 1.72 in TPD, 5.53 ± 0.18 in CEPD and Kt/V (per session) 0.18 ± 0.05 in TPD, 0.12 ± 0.02 in CEPD.

DISCUSSION

This was a prospective randomized crossover study involving 87 patients with mild-to-moderate hypercatabolic ARF who were subjected to 236 treatment sessions of PD (CEPD = 118, TPD = 118). Patients with mild-to-moderate hypercatabolic ARF (excess UNA <12 g/day) were included in the study. The washout period was adequate in between the two sessions of dialysis. There was a significant difference between pre- and post-dialysis BUN and creatinine for both the groups. Mean urea clearances (mL/min) for TPD was 19.85 ± 1.95 and that

Table 6. Cost comparison between the treatment protocols (CEPD for 48 hours and TPD for 12 hours)

Type of expenses	Cost per day	CEPD	TPD
Labor and consumable items	Rs. 375/day	Rs. 750	Rs. 100
Labor charges (nursing, paramedical, clerical, administrative and resident doctors, etc.).	(US $ 8.30)[a] (I $ 34.28)[b]	(US $ 16.60) (I $ 68.56)	(US $ 2.22) (I $ 9.14)
Consumables			
Dietary supplies			
Nonconsumable items	Rs. 75/day	Rs. 150	Rs. 37.5
(maintenance, power, telecommunications, data process)	(US $ 1.66) (I $ 6.86)	(US $ 3.32) (I $ 13.71)	(US $ 0.83) (I $ 3.43)
Others	Rs. 50/day	Rs. 100	Rs. 25
(taxes, depreciation, interest rates, etc.)	(US $ 1.11) (I $ 4.57)	(US $ 2.22) (I $ 9.14)	(US $ 0.55) (I $ 2.29)
Cost of dialysis			
Expense of machine (Total cost of machine = Rs. 360,000, US $ 8000)	Rs. 150/session (US $ 3.33) (I $ 13.71)	0	Rs. 150 (US $ 3.33) (I $ 13.71)
Expense of consumables			
Baxter Bags	Rs. 250/L (US $ 5.55) (I $ 22.85)	Rs. 6500 (US $ 144.45) (I $ 594.15)	Rs. 6500 (US $ 144.45) (I $ 594.15)
Dialysis set		Rs. 350 (US $ 7.78) (I $ 31.99)	Rs. 350 (US $ 7.78) (I $ 31.99)
Total		Rs. 7850 (US $ 174.44) (I $ 717.55)	Rs. 7162.5 (US $ 159.14) (I $ 654.71)

[a] US dollars (approximately 1 US $ = 45 Indian Rupees)
[b] International dollars (Rupees 10.94 spent in India are equal to I $ 1)

for CEPD was 10.63 ± 2.62, while the creatinine clearances in TPD was 9.94 ± 2.93 and in CEPD was 6.74 ± 1.63 ($P = 0.001$). Similarly, in TPD and CEPD the normalized creatinine clearances (L/week/1.73 m^2 BSA) were 68.5 ± 4.43 and 58.85 ± 2.57, and estimated weekly Kt/V values were 2.43 ± 0.87 and 1.80 ± 0.32, respectively. TPD achieved the standards of adequacy as per the NKF guidelines, while CEPD fell short of the standards [18]. Kt/V appropriately measured the solute losses in PD. Tidal peritoneal dialysis was superior to CEPD in the removal of potassium, phosphates and in generating ultrafiltrate. TPD was better tolerated, consumed less time and was less expensive. Excess protein loss was the only limitation of TPD in ARF.

In the present study, the young age of patients with ARF, and the predominance of medical causes of ARF (due to acute diarrheal illnesses, infections like malaria and leptospirosis, hemolysis secondary to glucose 6-phophate deficiency, insect and snake bites) are consistent with the experiences reported from other centers in India [2]. In recent years, the pattern of acute renal failure in India has shown a change similar to that noted in the West, albeit at a less impressive pace [4].

Patients with ARF represent a heterogeneous cohort with a wide variety of causes and contributing factors leading to renal shut down, presenting with varying severity and at different stages. A crossover study design was utilized to eliminate confounding variables. In other studies with a crossover design in stable CRF patients, washout periods of two to three days have been used [30]. In hypercatabolic ARF with rapid accumulation of uremic toxins, a minimum washout period of 12 hours was considered adequate. Tenckhoff catheters have proven to be superior to stiff stylet or Cook catheters [31], however, the latter are still used for intermittent peritoneal dialysis at most of the centers in India due to its low cost and ease of introduction [4].

There are a number of factors contributing to net protein breakdown in patients with ARF. These are inadequate supply of nutritional substrates, loss of nutritional substrates during dialysis, increased circulating concentration of catabolic hormones, systemic inflammatory response syndrome and exposure to bio-incompatible membrane during hemodialysis. [32]. Inadequate protein intake in Indian renal failure patients is common, which may compound negative nitrogen balance [33, 34]. The methods of assessing catabolism and definitions of catabolism vary from biochemical indices (rate of rise of BUN, serum creatinine, uric acid, potassium, phosphorous) to the net production of urea of more than 25 g/day [7–10, 20]. In renal insufficiency, UNA provides a better method for the assessment of protein catabolism [21].

Katirtzoglou et al used CEPD for five hypercatabolic patients and seven with non-hypercatabolic ARF or acute exacerbation of CRF, and observed an adequate decrease in BUN and serum creatinine [8]. Cameron and colleagues treated 15 patients with ARF due to burns, cardiac and aortic surgery, with the rate of urea produc-

tion of more than 0.88 g/kg/day with PD and 1 to 3 L/h exchanges [10]. With urea dialysance of 13 to 20 mL/min, all except for 2 of the 15 patients were able to maintain a BUN value <200 mg/dL, which the authors considered satisfactory control (13.4 g of peritoneal urea nitrogen clearance vs. 28.7 g of urea nitrogen production). This led them to conclude that hypercatabolism alone is not a contraindication to PD use. Indraprasit et al treated 10 patients with continuous dialysis using Tenckhoff catheters with 1 to 1.5 L exchanges, and dwell adjusted to maintain adequate waste products, fluid and electrolyte balance for 2 to 30 days [9]. They noted urea clearance of 12.1 ± 1.2 mL/min equivalent to 120 mL/min of hemodialysis clearance over four hours. Each of these studies and others suffer from limited sample size and inappropriate or lack of measurements for catabolic state [7–14]. Furthermore, success of PD was based on control of fluid, electrolyte and solute balance, as these studies were completed before the concept of "adequacy" evolved.

Adequacy of dialysis dose in ARF is a subject of controversy for many reasons [15–17]. Recent studies have shown that dialysis dose is one of the major contributing factors to patient survival (abstract; Schiff et al, *J Am Soc Nephrol* 8:290A, 1997). There is no satisfactory marker of dialysis adequacy in ARF [17]. There are a number of reasons preventing extrapolation of the clearance-based dialysis dosage (Kt/V and normalized creatinine clearance) from the chronic dialysis population to acute dialysis [16, 17]. These include the hypercatabolic state in ARF as compared to "eubolism" in ESRD patients. In ARF, water content of the body is increased due to excessive production of endogenous water. Urea kinetic modeling is not validated in ARF. Urea generation can vary from hour to hour requiring a dynamic urea kinetic model. Finally, there is currently no consensus on what levels of urea solute removal are adequate or optimal. It has been suggested that in the absence of a consensus, it seems reasonable to at least attempt to deliver dialysis doses similar to those received by patients with CRF [17]. Hence, we have compared doses of PD received by ARF patients with the present standard for CRF patients on maintenance dialysis as per the NKF guidelines [18].

The solute reduction index (SRI) used in HD (a dialysate-based index) measures the total amount of urea removed during a dialysis treatment, while the blood-based method, namely, Kt/V, measures the fractional change in blood urea concentration [16]. SRI is not influenced by urea redistribution or the type of kinetics employed [19]. Therefore, in HD SRI is considered by many to be the gold standard for measuring the dose of dialysis. Evanson et al noted Kt/V to overestimate the dose of dialysis in HD in patients with ARF as compared to a dialysate-based index [16]. There are scant data on the significance of SRI in PD. Kt/V in PD quantifies directly the amount of solute removed in the effluent for the amount of dialysis time and factored for urea distribution. Hence, Kt/V in PD is a dialysate-based method rather than a blood-based method as in HD. In contrast to HD, PD allows the steady equilibration between the blood and dialysate compartment and urea redistribution, and the kinetics (single and double pool) do not pose an issue in PD. A marginal difference obtained between $SRI_{dialysate}$ and Kt/V supports the fact that the latter does not overestimate solute removal in PD.

Clearances of small molecules on peritoneal dialysis depend on the permeability of the peritoneal membrane, volume of effluent drained and total time on dialysis. TPD is claimed to increase solute clearances by increasing peritoneal membrane contact at the end of drainage and the beginning of infusion and by preventing the formation of a stagnant fluid film by maintaining high dialysate flow rate. However, Flanigan et al observed that the amount of dialysate necessary to achieve these clearances exceeded that needed in CCPD (continuous cyclic peritoneal dialysis) by 68% and CAPD by 150% [35, 36]. Increase in solute clearances in PD is found to be in proportion to dialysate flow rate [30, 35–37]. In the present study, TPD with high flow rate (37 mL/min) yielded greater solute clearances and ultra filtrate volume as compared to CEPD (9 mL/min), though the total volume of fluid used was the same.

In the present study, differences of 51% and 37% were observed between BUN and creatinine in the TPD and CEPD groups, respectively. The higher differences observed in TPD are due to the short dwell time, which increases discrepancies between urea and creatinine kinetics [36]. Urea and creatinine clearances obtained in the present study were higher for the total dialysate fluid and the flow rate as compared to other studies (Table 7) [9, 11, 30, 37–40]. Comparison among these studies ideally cannot be done due to the differences in the study populations (animal model in Ash et al vs. humans), causes of renal failure (ARF vs. CRF) and treatment protocols [9, 11, 30, 37–40]. Nevertheless, higher clearances could be explained by the racial differences in peritoneal permeability characteristics, higher reserve volume, utilization of a larger effective surface area of peritoneum and possibly by changes in the permeability of peritoneal membrane in ARF [41–48]. It has been shown that the peritoneal surface correlates well with the body surface area [42]. The average BSA of Asians is less than that of Africans and Caucasians and therefore, the Asians would have a proportionately lower peritoneal surface area (average BSA of Asian, Africans and Americans is 1.65, 2.06, 1.89 m^2, respectively) [44–46]. Hence, with the same volume of infused fluid a proportionately larger effective peritoneal surface area would be utilized. Increased levels of circulating in-

Table 7. Comparison of total dialysate, flow rate, solute, potassium, phosphate clearances, protein and albumin losses in various studies

	TPD						CEPD			
				Vychytil et al [38]						
Variables	Steinhauer et al [40]	Pirano et al [30]	Ash et al [39]	Low flow	High flow	Chitalia et al	Indraprasit et al [9]	Gateldi et al [11]	Ash et al [39]	Chitalia et al
Total fluid *L*	23	30	14.4	15	30	26.3	N/A	10	2	26
Flow rate *mL/min*	51	62.5	63	28	50	37	N/A	6.9	8.3	9
Reserve vol *mL*	0.75–1	1	1	1.25	0.75	1.325	0	0	0	0
C_{ur} *mL/min*	19.5 ± 3.2	20 ± 3	22.1	13.19 ± 1.74	17.25 ± 2.36	19.85 ± 1.95	12.1 ± 1.2	7.62 ± 1.28	10.4	10.63 ± 2.62
C_{cl} *mL/min*	15.2 ± 1.7	10 ± 3		8.9 ± 1.48	11.3 ± 1.89	9.94 ± 2.93		5.4 ± 1.02		6.74 ± 1.63
UF *mL/min*	4.73 ± 0.92	3.3 ± 1.6		1.06 ± 0.21	1.16 ± 0.34	4.28 ± 0.7				1.82 ± 0.13
Phosphate clearance *mL/min*	10.5 ± 1.29	11 ± 3		7.62 ± 1.24	9.35 ± 1.72	14.23 ± 5.4				9.6 ± 3.9
Potassium clearance *mL/min*	18.5 ± 3	24 ± 4			24.56 ± 2.58					16.81 ± 4.6
Protein loss *g/session*	17.48 ± 2.72			5.13 ± 0.51	4.54 ± 0.49	10.49 ± 1.55				6.63 ± 1.25
Albumin loss *g/session*	6.6 ± 0.6			3.47 ± 0.3	3.40 ± 0.31	6.32 ± 1.03				3.48 ± 1.14
Dextrose absorption *g/session*				57.3 ± 3.78	69.76 ± 10.06	98.63 ± 21.43	165 ± 12.67			168.27 ± 23.8

[a] Observations in live normal dog. Urea clearance is derived from glucose clearance, urea clearance twice of glucose clearance) [9, 11, 30, 37-40].

flammatory mediators and cytokines have been observed in ARF [47]. Local prostaglandins have been shown to increase peritoneal membrane permeability [48]. It is plausible that the cytokines and prostaglandins in ARF could alter the permeability of the peritoneal membrane.

Obligatory protein and albumin losses can compound the negative nitrogen balance in ARF, especially if the dialysis is continued for a longer period of time. Most of the patients in this study became dialysis free after four treatments of PD. Protein losses as high as 48 grams per session [49] have been reported in intermittent peritoneal dialysis. Higher potassium and phosphorous clearances were noted in the present study as compared to the CRF population (Table 7). Also, it has been shown that in TPD potassium kinetics closely follow the creatinine kinetics [36]. A wide difference between these two kinetics was observed in the present study. This may be explained by the presence of hyperkalemia and hyperphosphatemia in hypercatabolic ARF. The greater potassium and phosphorous clearances observed with TPD compared to CEPD may be due to the higher flow rate (Table 5). Dextrose absorption of more than 500 g/day has been observed in patients receiving PD with a 4.5% solution [50], and this can lead to hepatic steatosis, increased CO_2 production and worsening respiratory failure. On the other hand, dextrose absorption can contribute 500 to 2000 calories per day to substantially contribute to caloric supplementation in the hypercatabolic state and facilitate cellular uptake of potassium to control hyperkalemia [50]. The higher dextrose absorption observed in CEPD is due to a longer dwell time, allowing prolonged contact of dialysate for dextrose absorption. Obviously, TPD being shorter was perceived as more comfortable than CEPD. Disturbances of blood gas exchange from abdominal dialysate distension may cause serious sequela in ARF patients with compromised respiratory function [51]. The use of a lower volume of fluid for a shorter period of time in TPD would minimize this problem.

A hospital bed in the developing world is cheaper that in the United States (average cost of a dialysis bed in USA = US $500–1000, while in India would be US $11–12), especially in a government run hospital. The Baxter dialysate used for the study was imported, thereby increasing the cost of dialysate. The cost could be substantially reduced if the fluid could be manufactured locally. In CRF patients on home cycler dialysis, higher costs due to the requirement for more dialysate to achieve the same clearances seen in TPD is a major concern [36]. However, for in-patient dialysis, the occupation of a dialysis bed for a shorter time and a reduced need for the trained nursing staff decreased the cost of TPD. The cost of a dialysis bed is greater for manually performed CEPD, which requires trained nursing staff for longer time periods. The estimated cost presented here is for a government run university hospital and would be higher in a private hospital.

Our study presents evidence of adequate solute removal by PD for mild-to-moderate hypercatabolic ARF in the developing countries according to the existing standards of adequacy. One of the limitations of this study is that the patient base differs from the most of the studies dealing with the hypercatabolic ARF. The patients in the present series predominantly were mild-to-moderate hypercatabolic rather than the severe hypercatabolic patients (rhabdomyolysis, multi-organ failure, and sepsis syndrome) found in other series. Therefore, these findings may not apply to the patient population in the developed countries due to differences in etiologies, co-morbid conditions and level of hypercatabolism. Many of the infectious conditions leading to ARF in developing countries are self-limiting and renal

function improves with the definitive treatment of the etiology of ARF [4].

Both TPD and CEPD are reasonable options for mild-moderate hypercatabolic ARF, even though CEPD just fell short to meet the adequacy standard. Tidal peritoneal dialysis provides better clearances at the same volume and results in lesser in-patient costs for the patients with ARF. Its use should be encouraged at the centers with availability of the cycler to enable more rapid dialysis bed turnover. Higher protein loss in TPD was the only limitation to its use in ARF.

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