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Validation of PD Adequest 2.0 for pediatric dialysis patients

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Abstract Kinetic modeling has proven to be a valuable tool for peritoneal dialysis (PD) prescription in adult PD patients. The clinical application of this procedure has rarely been studied in children. We therefore evaluated the PD Adequest 2.0 for Windows program (Baxter Healthcare Co., Deerfield, IL) as a prescription aid for the management of pediatric PD patients by comparing the measured and predicted PD clearances, total drain volumes, and net ultrafiltration in 34 children (15 males) (mean age 10.9±6.0 years) receiving long-term PD. In each case, a 4-h peritoneal equilibration test was conducted with a standardized test exchange volume of 1100 ml/m^2 BSA. A total of 43 24-h dialysate (plus urine in 12) collections were analyzed. The levels of agreement between measured and predicted values for weekly peritoneal and total urea Kt/V, weekly peritoneal and total creatinine clearance, daily drain volume, net ultrafiltration and daily peritoneal urea and creatinine mass removal were assessed with correlation coefficients (r_c) and Bland-Altman limits of agreement. The study revealed that there is a basic level of agreement between measured and modeled values for solute removal and total drain volume, with correlation coefficients ranging from 0.75 to 0.98. In contrast, the r_c for net ultrafiltration was only 0.34. The majority (75%) of patients had modeled urea and creatinine clearances that were within 20% of their measured values. These data suggest that the PD Adequest 2.0 for Windows program can predict urea and creatinine clearances with reasonable accuracy in pediatric PD patients, making it a valuable resource in prescription management.

Keywords Pediatric · Peritoneal dialysis · Adequacy · Kinetics · Computer

This is a study of the Pediatric Peritoneal Dialysis Study Consortium

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Introduction

The recently published guidelines of the National Kidney Foundation–Dialysis Outcomes Quality Initiatives (NKF-DOQI) emphasize the importance of achieving dialysis adequacy in terms of solute and fluid removal [1]. In order to accomplish this goal in the setting of an acceptable lifestyle for the patient, great emphasis is now being placed upon the process of dialysis prescription. Historically, prescription management was an empiric process with potential modifications carried out in a trial and error manner. More recently, clinicians can choose from any one of several kinetic modeling software programs to tailor PD prescriptions to the needs of the individual patient. These include the PD Adequest (Baxter Healthcare Co., Deerfield, IL), Pack PD (Fresenius USA, Walnut Creek, CA), and PDC (Gambro AB, Lund, Sweden) programs [2–4]. In particular, the use of PD Adequest version 1.4 has been clinically validated in pediatric and adult patients, whereas the newly released PD Adequest version 2.0 for Windows has until now only been validated in adults [2, 5, 6]. Since PD Adequest 2.0 has incorporated a number of advancements made in the area of membrane-based kinetic modeling, many of which should improve the accuracy and precision with

which solute and fluid removal can be predicted, we conducted a multicenter study for the purposes of clinically validating the use of PD Adequest 2.0 for Windows in pediatric patients by assessing the level of agreement between measured (actual) and modeled (predicted) values of urea and creatinine removal and ultrafiltration. We also compared the results obtained with PD Adequest 2.0 with those obtained with PD Adequest 1.4 in our patients.

Patients and methods

Thirty-four patients [29 automated peritoneal dialysis (APD), 5 continuous ambulatory peritoneal dialysis (CAPD)] from 6 centers in the United States that are participating member institutions of the Pediatric Peritoneal Dialysis Study Consortium (PPDSC) were enrolled in the study. No patient underwent treatment for peritonitis within 6 weeks of entering the study. Institutional Review Board approval and written informed consent was obtained for each study participant.

Within 14 days of enrolling in the study, all patients underwent a peritoneal equilibration test (PET). During the evening prior to the PET, each patient received a 40-ml/kg exchange (range 35–45 ml/kg) of 2.5% Dianeal with a dwell time of 8–12 h. After arrival at the dialysis unit on the day of testing, the overnight dwell was drained. A transfer set change to a Y-type Dianeal PD solution administration set was then conducted to minimize tubing "dead space" or recirculating volume. The test exchange volume of 1100 ml/m^2 body surface area (BSA) was conducted next and was infused over 10 min, with the patient remaining supine during the infusion [7]. Dialysate samples were taken from the overnight exchange bag and at 0, 120, and 240 min of dwell time from the test exchange volume. Blood samples were obtained at 0 and 240 min. All serum and dialysate samples were centrally analyzed (Baxter Healthcare Co., Round Lake, IL) for urea and creatinine on a Kodak Ektachem 700 machine (Eastman Kodak, Rochester, NY). Within 5 days of completing the PET, all patients had one and nine patients had two 24-h dialysate collections that were analyzed for urea and creatinine. Urine was available for 12 of the collections. Finally, PD Adequest 1.4 and 2.0 both use modified pediatric specific formulas for total body water (V_T) and body surface area (BSA) which are given, respectively, as follows [8, 9]:

$V_T = 0.135 \times WT^{0.666} \times HT^{0.535}$ and

$BSA = 0.024265 \times WT^{0.5378} \times HT^{0.3964}$

where WT is patient weight in kilograms and HT is patient height in centimeters.

Statistical analysis

Following completion of the study, data from the long dwell exchange, the PET, and the 24-h collections of urine and dialysate were entered into a batch version of PD Adequest that implemented both the original DOS version 1.4 and the new Windows version 2.0 programs. This program was then used to model values of daily peritoneal urea mass removal (g/day), weekly urea clearance (urea Kt, l/week), weekly urea Kt/V, daily peritoneal creatinine mass removal (g/day), weekly creatinine clearance (CCr, l/week), weekly normalized creatinine clearance (nCCr, l/week/1.73 m^2), total effluent drain volume (l/day) and net daily ultrafiltration (UF, l/day).

The level of agreement between measured (actual) and modeled (predicted) values was assessed using both a correlation analysis and a Bland-Altman analysis [10, 11]. Correlation coefficients (r) between measured and modeled values were computed, as were concordance correlation coefficients (r_c). The r_c measures how close the regression line between modeled and measured values comes to the line of identity, and thereby directly reflects both the level of accuracy and the precision between predicted and measured values.

The level of agreement was also assessed by plotting individual differences between measured and modeled values against the average of the measured values. These differences were then compared against the Bland-Altman limits of agreement, which are defined as the mean of the individual differences ±2SD [11]. These limits estimate the range within which approximately 95% of the differences are expected to fall. A major advantage with a Bland-Altman type of analysis is that, unlike correlation coefficients, limits of agreement are not sensitive to the range of data. However, as Bland and Altman point out, the level of agreement between measured and modeled values is determined, in part, by how reproducible the measured values are themselves. Accordingly, the limits of agreement between modeled and measured values were evaluated against the limits of clinical agreement, which are defined to be 0±2SD of the differences between any two measured values from the same patient. The latter data were generated from the nine patients with repeat 24-h urine and dialysate collections. As with the limits of agreement, the limits of clinical agreement estimate the range within which approximately 95% of the differences between any two measured values obtained on the patient will lie. Thus, the limits of clinical agreement represent the best that can be achieved between measured and modeled values. In other words, if there were perfect agreement between measured and modeled values, then the limits of agreement would coincide exactly with the limits of clinical agreement. A percentage of clinical agreement (P_{CA}) can be determined by calculating the percentage of measured minus modeled differences that fall within the limits of clinical agreement. A coefficient of clinical agreement (C_{CA}) can then be determined as the percentage of clinical agreement divided by its maximum value (i.e., $C_{CA}=P_{CA}/0.95$).

Results

Summarized in Table 1 are the basic demographic characteristics of the 34 patients who enrolled in the study. As a result of the repeat 24-h collections from 9 patients, there were 43 sets of measurements in the 34 patients. Of

Table 1 Summary demographics, anthropometrics and PET values (percentages or means ± standard deviations) of patients (n=34). PET fill volumes are normalized to l/m^2 BSA

Variable	Mean (or %)	SD	Min.	25%	Median	75%	Max.
Sex (males)	15 (44%)	–	–	–	–	–	–
Age	10.9	6.0	0.6	5.0	12.0	15.0	21
Height (cm)	130.9	29.1	60	112	141	149	167
Weight (kg)	34.4	16.4	6.8	18.6	35.4	46.4	62.0
BSA (m^2)	1.11	0.38	0.32	0.76	1.21	1.44	1.61
PET fill volume (ml/m^2)	1086	58.4	812	1076	1100	1104	1165
PET 4 h creatinine D/P	0.70	0.13	0.40	0.61	0.67	0.82	0.90

Table 2 Validation results from all 43 exchanges done in 34 patients across all regimens for PD Adequest versions 1.4 and 2.0 (*pKt* weekly peritoneal urea clearance, *pKt/V* weekly peritoneal urea Kt/V, *pCCr* weekly peritoneal creatinine clearance, *pnCCr* weekly peritoneal normalized creatinine clearance)

Outcome measure	PD Adequest 1.4					PD Adequest 2.0				
	Measured		Predicted			Measured		Predicted		
	Mean	SD	Mean	SD	r_c	Mean	SD	Mean	SD	r_c
Urea removed (g/day)[a]	3.27	1.36	3.06[b]	1.31	0.92	3.27	1.36	3.31	1.45	0.96
Urea pKt (l/week)	42.31	16.20	39.84[b]	15.66	0.90	42.31	16.20	43.14	17.91	0.94
Urea pKt/V	2.26	0.66	2.12[b]	0.59	0.78	2.26	0.66	2.26	0.62	0.80
Urea total Kt/V	2.40	0.60	2.24[b]	0.50	0.70	2.40	0.60	2.37	0.55	0.75
Crt. removed (g/day)	0.44	0.26	0.43	0.29	0.92	0.44	0.26	0.48[b]	0.30	0.94
pCCr (l/week)	26.97	10.72	26.32	11.67	0.86	26.97	10.72	28.95[b]	12.43	0.89
pnCCr (l/week/1.73 m^2)	42.69	11.82	41.77	13.17	0.75	42.69	11.82	45.33[b]	13.38	0.76
Total nCCr (l/week/1.73 m^2)	47.95	13.69	46.53	11.20	0.71	47.95	13.69	50.14	12.74	0.77
Total effluent (l/day)	13.06	6.42	13.14	6.51	0.98	13.06	6.42	13.23	6.57	0.98
UF (l/day)	1.02	0.67	0.77	0.81	0.35	1.02	0.67	0.86	0.89	0.34

[a] The amount removed is based on peritoneal mass transport alone and ignores residual renal clearance
[b] The predicted value is significantly different from the measured value, $P<0.05$

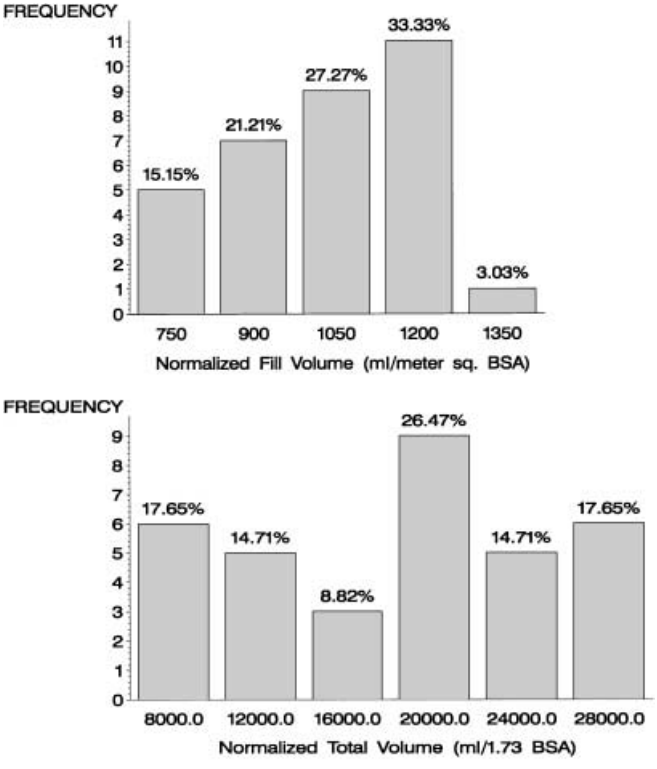

Fig. 1 Distribution of fill volumes and total prescription volumes for patients undergoing CAPD or APD

the 43 daily collections, 5 were from patients receiving CAPD and the remaining 38 were from patients receiving APD. Baseline CAPD prescriptions consisted of three exchanges per 24 h (median number of exchanges = 3) with daytime fill volumes per exchange ranging between 365 and 1387 ml (mean ± 1SD: 917±416 ml). Among the APD patients, the number of exchanges over a 24-h period ranged between 6 and 29 exchanges at night (median number of nightly exchanges = 12) and between 0 and 2 exchanges during the day (median number of daytime exchanges = 1). Nighttime fill volumes among APD patients ranged between 731 and 1315 ml (mean ± 1SD: 1066±178 ml). Figure 1 summarizes the distribution of fill volumes and total prescription volumes for CAPD and APD patients combined.

Overall means, standard deviations and concordance correlations between measured and predicted values for PD Adequest versions 1.4 and 2.0 are presented in Table 2. The results indicate that both versions provide acceptable levels of agreement between measured and modeled values, although PD Adequest 2.0 does offer better overall agreement. There were no statistically significant differences, on average, between measured versus predicted values except for marginal differences in urea clearances under PD Adequest 1.4 and marginal differences in peritoneal creatinine clearances under PD Adequest 2.0 ($0.01<P<0.05$). If the *P* values are adjusted for simultaneous inference across all ten outcome measures listed in Table 2, there were no resultant significant differences, on average, between measured and predicted values regardless of which version of PD Adequest was used.

Presented in Figs. 2–4 are the concordance correlations which compare individually measured values against predicted values using PD Adequest 2.0. The predicted values of peritoneal urea removal, volume of urea cleared (daily and weekly) and weekly urea Kt/V (Fig. 2) are in good agreement with measured values for CAPD and APD patients combined ($0.80\leq r_c\leq 0.96$). Interestingly, the concordance correlation for total urea Kt/V (peritoneal plus residual renal) was lower than for peritoneal urea Kt/V. This may be due to the range of values for the observed peritoneal Kt/V (range: 1.24–4.44) being greater than that for total Kt/V (range: 1.34–4.44), a manifestation of patients with little or no residual renal function being prescribed greater doses of peritoneal dialysis than patients with substantially higher

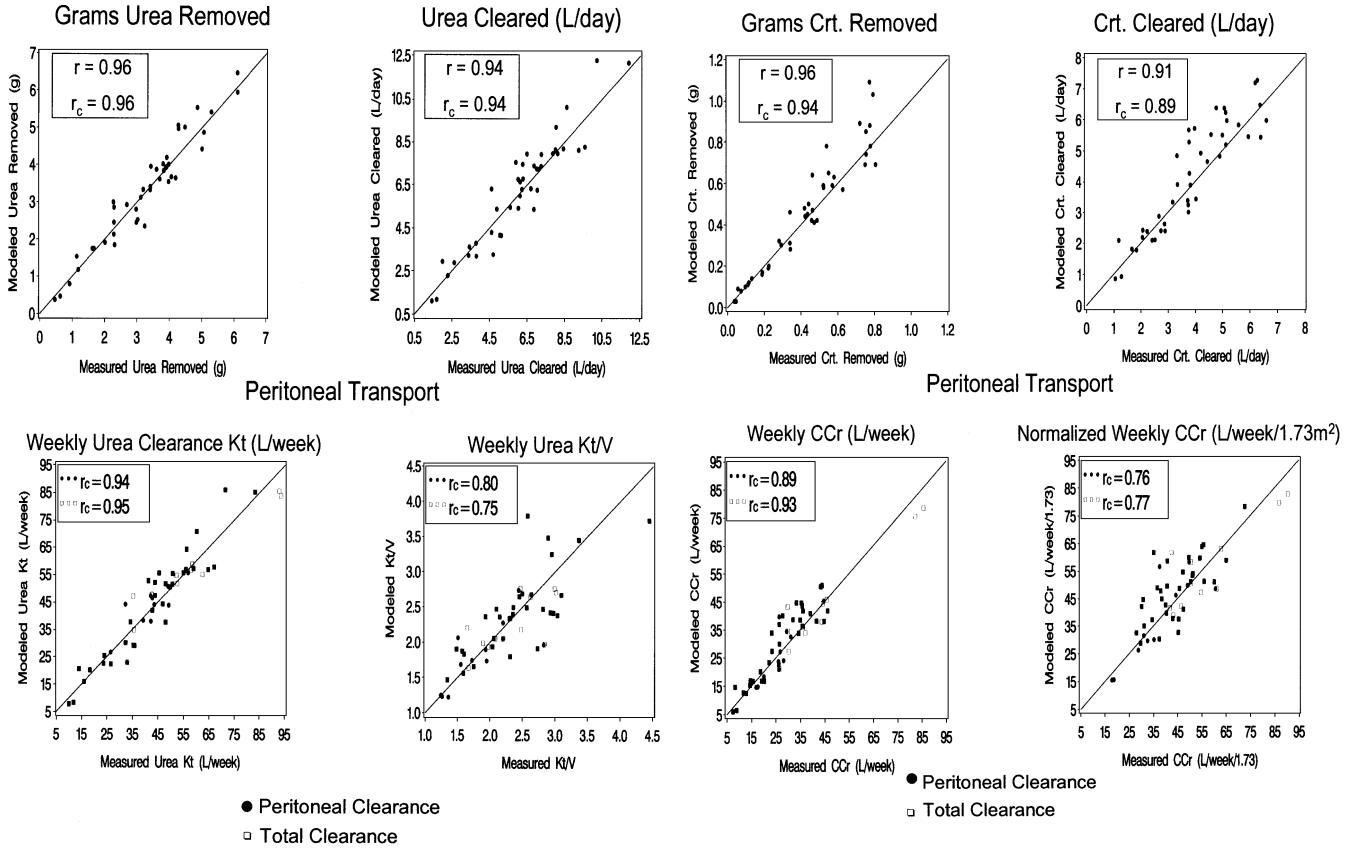

Fig. 2 Measured (actual) versus modeled (predicted) peritoneal urea mass transport (amount of urea removed in g/day, and volume of urea cleared in l/day) and weekly urea clearance (weekly clearance, Kt, in l/week and weekly urea, Kt/V). Total weekly urea clearance (Kt and Kt/V) is based on both peritoneal and residual renal urea clearance while urea mass transport (the amount of urea removed and the volume of urea cleared) is restricted to peritoneal urea mass transport. Individual patient points are the individual values from each 24-h collection done per patient

Fig. 3 Measured (actual) versus modeled (predicted) peritoneal creatinine mass transport (amount of creatinine removed in g/day, and volume of creatinine cleared in l/day) and weekly creatinine clearance (weekly clearance, CCr, in l/week and normalized weekly clearance, nCCr, in l/week/1.73 m^2). Total weekly creatinine clearance (CCr and nCCr) is based on both peritoneal and residual renal creatinine clearance while creatinine mass transport (the amount of creatinine removed and the volume of creatinine cleared) is restricted to peritoneal creatinine mass transport. Individual patient points are the individual values from each 24-h collection done per patient

levels of residual function. In terms of peritoneal creatinine removal, volume of creatinine cleared (daily and weekly) and weekly normalized creatinine clearance, the results shown in Fig. 3 indicate that a reasonable level of agreement exists between measured and predicted values among pediatric patients ($0.76 \leq r_c \leq 0.94$). The concordance correlation between measured and modeled ultrafiltration was considerably lower (Fig. 4, r_c=0.34). However, there was excellent overall agreement between measured and modeled drain volumes (Fig. 4, r_c=0.98). Because of the high concordance between measured and modeled drain volumes, the relatively poor level of agreement between measured and modeled ultrafiltration had little impact on the accuracy and precision with which urea and creatinine clearances were predicted.

The preceding results suggest that there is a basic overall level of agreement between measured and modeled values for solute removal for both CAPD and APD patients. To confirm this and to summarize the level of agreement based on individual differences between mea-

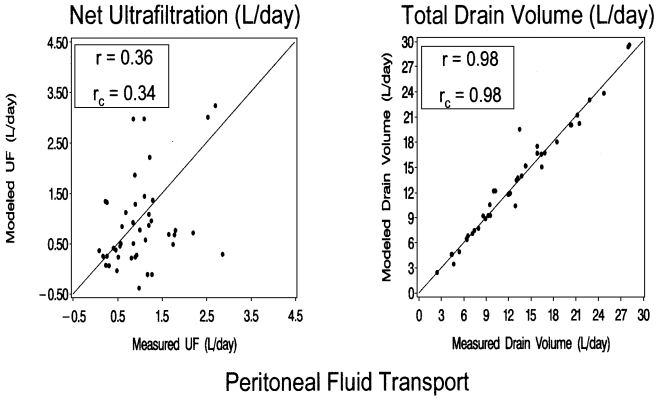

Fig. 4 Measured (actual) versus modeled (predicted) net ultrafiltration (l/day) and total drain volume (l/day). Individual patient points are the individual values from each of the 24-h collections done per patient

Table 3 Comparison of absolute differences between measured versus modeled as well as measured versus measured peritoneal clearances

Cumulative % patients	5%	10%	25%	Median (50%)	75%	90%	95%
Absolute difference in modeled pKt/V | Measured-modeled |	0.02	0.03	0.07	0.19	0.43	0.66	0.82
Absolute difference in measured pKt/V | Measured 1-measured 2 |	0.04	0.04	0.10	0.23	0.42	0.80	0.80
% Absolute difference in modeled pKt/V | Measured-modeled |/measured	1.1%	1.6%	2.5%	9.7%	18.9%	28.1%	30.6%
Absolute difference in modeled pCCr | Measured-modeled | in l/week/1.73 m^2	0.6	1.0	2.6	5.4	9.2	12.7	17.7
Absolute difference in measured pCCr | Measured 1-Measured 2 | in l/week/1.73 m^2	0.7	0.7	2.4	3.9	4.5	14.6	14.6
% Absolute difference in modeled pCCr | Measured-modeled |/measured	1.5%	3.4%	7.4%	14.8%	20.0%	39.5%	44.8%

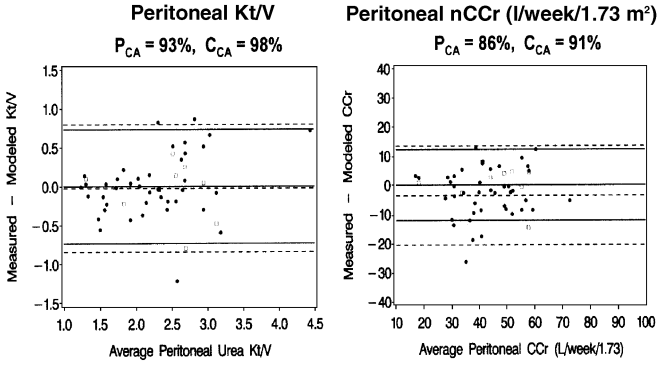

Fig. 5 Individual differences (measured–modeled) plotted against average measured weekly peritoneal urea Kt/V and weekly normalized CCr (l/week/1.73 m^2). *The solid lines* represent the expected mean difference ± the limits of clinical agreement (i.e., 0±2SD) between any two measured values and *the dashed lines* represent the mean difference ± the limits of agreement between individually modeled and measured values. *Solid black circles* are the measured–modeled differences corresponding to each 24-h collection. *Open squares* are measured–measured differences corresponding to the two 24-h collections (i.e., measured day 1–measured day 2) done in nine evaluable patients. Among the CAPD/APD patients, 93% of the modeled Kt/V values fell within the limits of clinical agreement (P_{CA}=93%), yielding a coefficient of clinical agreement of 98% (C_{CA}=98%), while 86% of the modeled nCCr values fell within the limits of clinical agreement (P_{CA}=86%), yielding a coefficient of clinical agreement of 91% (C_{CA}=91%)

sured and modeled values as well as between two measured values on the same patients, a Bland-Altman analysis was performed on weekly peritoneal urea Kt/V, weekly peritoneal creatinine clearances and daily net ultrafiltration. Table 3 and Fig. 5 summarize the results for weekly peritoneal urea Kt/V and weekly peritoneal normalized creatinine clearance (pnCCr). The results show there is a reasonable level of agreement between measured and modeled values of weekly pKt/V (C_{CA}=98%), and weekly pnCCr (C_{CA}=91%) among CAPD and APD patients. Overall, 75% of patients had modeled clearances that were within 20% of their measured values. Although there was no significant difference, on average, in the net ultrafiltration between measured versus modeled values (Table 2, mean measured UF=1.02 l, mean modeled UF=0.86 l, *P*=0.2506), a Bland-Altman analysis did show a lower level of agreement (C_{CA}= 39%) between measured and modeled values.

Discussion

The PD prescription process for children with end-stage renal disease (ESRD) ideally results in an individualized PD regimen that takes the following factors into consideration: patient size, peritoneal membrane transport capacity, cost and patient lifestyle [12, 13]. Recognizing that the absence of data correlating dialysis dose to clinical outcome in pediatrics has prevented the determination of definitive adequacy guidelines, recommended goals for solute and water removal should also be considered [12–16]. An empiric prescription is often determined at the institution of PD whereas adjustments to the prescription may be necessary if the initial or subsequent clearance assessments reveal solute removal to be suboptimal [15, 17]. While the institution of various prescriptions can take place in a trial-and-error manner, this approach is laborious, time consuming and may be associated with a prolonged period under dialysis. In contrast, the kinetic modeling software programs have been developed as a powerful means of rapidly (within minutes) and accurately estimating levels of clearance that may be obtained with a variety of prescription alternatives [2–4].

In PD Adequest, data derived from a carefully performed PET and overnight exchange can, in combination with a validated kinetic model, be used to describe the rate of solute mass transport (e.g., grams of urea and creatinine removed) and fluid transport between the blood and peritoneal cavity. Therefore, the primary output from PD Adequest is the predicted amount of solute and fluid

removed from or absorbed into the body over time. These data are then used to calculate solute clearance (l/day), which is then normalized to patient size using either total body water (TBW) for urea (i.e., weekly Kt/V) or BSA for creatinine (i.e., CCr, l/week/1.73 m^2). The initial version of PD Adequest (version 1.1) was based on the Pyle-Popovich model in which solute mass transport is described using a two-pool compartment model [18, 19]. Subsequently, versions 1.2–1.4 were modified to reflect key aspects of the three-pore membrane model as described by Rippe and colleagues. The kinetic model used was validated both scientifically and clinically in a number of studies [2, 5, 20, 21]. In the only prior pediatric study, Verrina et al. clinically validated the use of version 1.4 in 29 patients ranging in age from 4 to 12 years [5]. These authors demonstrated good agreement between measured and modeled CCr (r_c=0.937) and Kt/V (r_c=0.768) and less favorable results for ultrafiltration, the latter finding presumably as a result of individual day-to-day and perhaps exchange-to-exchange variability in this parameter.

A number of advancements in the area of membrane-based kinetic modeling were incorporated into PD Adequest 2.0 for Windows. These enhancements include modifying the solute mass transport equations to better reflect the role of solute absorption and updating solute mass transfer area coefficients (MTACs) to reflect their dependence on both fill volumes and dwell times [22–25]. The clinical application of PD Adequest 2.0 was subsequently validated in a multinational study of 104 adult patients conducted by Vonesh et al. [6]. In that study, excellent agreement between measured and modeled urea Kt/V (r_c=0.89), CCr (r_c=0.93) and total drain volumes (r_c=0.98) was noted.

Although the level of precision is somewhat lower than that observed for adults, our results also indicate that both PD Adequest 1.4 and PD Adequest 2.0 can accurately and precisely predict weekly urea Kt/V and weekly normalized creatinine clearance for the pediatric patient undergoing either CAPD or APD. It must be emphasized that the predictions are solely intended to expedite the establishment of individualized dialysis prescriptions and do not substitute for the need to accurately quantitate solute clearance after a particular PD regimen is instituted [26].

Although the correlation for net ultrafiltration is lower than expected, this is due, in part, to a narrow range of values, excessive variation within patients and the limited input of data required for estimating key kinetic parameters. It is expected that improvement in modeled ultrafiltration values can be achieved by increasing the amount of input used to estimate the ultrafiltration parameters, ultrafiltration coefficient (L_{PA}) and fluid absorption rate (Q_L). Specifically, by obtaining the fill volume, drain volume, dwell time and percentage dextrose for additional exchanges other than the long dwell and the PET exchange currently used, estimates of L_{PA} and Q_L would improve, particularly if 1- and 2-h exchanges were included. Since PD Adequest currently uses only two drain volumes to estimate L_{PA} and Q_L, the estimates obtained are sensitive to measurement errors in the two drain volumes. Part of the variation in the measured ultrafiltration volumes is likely due to phenomena such as pocketing of fluid, incomplete drains and patient body position at the time of dwell and/or drain. These are all factors that go beyond the predictive capabilities of any kinetic model and hence these factors all contribute directly to the lack of precision between measured and modeled ultrafiltration. However, most important is the fact that the lack of precision in modeled ultrafiltration values has little impact on the kinetic model's ability to accurately and precisely predict urea and creatinine mass transport or clearance. Net ultrafiltration is but a small fraction of the overall effluent volume, and it is the latter volume that is accurately estimated by PD Adequest 2.0 and that is used to calculate solute removal and clearance.

Finally, we anticipate that some additional improvement to PD Adequest 2.0 in its ability to predict clearances is possible by improving how the program takes into account the time-dependent nature of the mass transfer area coefficients (MTACs). For example, better estimates of peritoneal clearance and ultrafiltration may be possible by modeling several intermediate time points during an exchange and subsequently updating the body and dialysate concentrations at each intermediate time point.

In summary, both PD Adequest 1.4 and PD Adequest 2.0 can predict urea and creatinine clearances with a reasonable level of accuracy and precision in pediatric patients, although the results are slightly better with version 2.0. The lower than desired correlation between measured and modeled UF is due in part to a narrow range of UF values, the inability to predict changes in residual dialysate volume per exchange and a limited input of data used to estimate key UF parameters. The use of this kinetic model can now be reliably used in the clinical forum to provide initial estimates of solute clearances and thereby streamline the dialysis prescription process for the pediatric patient receiving peritoneal dialysis [27, 28].

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