Effect of Kt/V on survival and clinical outcome in CAPD patients in a randomized prospective study

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Background. There has been a lack of randomized control study on the effect of Kt/V on patient outcome. This interventional study was designed to examine the effect of Kt/V on continuous ambulatory peritoneal dialysis (CAPD) patients' clinical outcome and nutritional status in a randomized prospective manner.

Method. A total of 320 new CAPD patients with baseline renal Kt/V <1.0 were recruited from six centers in Hong Kong and were randomized into three Kt/V targets: group A, 1.5 to 1.7; group B, 1.7 to 2.0; and group C, >2.0. Kt/V and nutritional status were assessed every 6 months and dialysis prescription adjusted accordingly. Nutritional assessment included serum albumin and composite nutritional index (CNI). Patients were allowed to withdraw at the discretion of their physicians or themselves.

Results. Total Kt/V were significantly different between groups (P = 0.000) and the difference was contributed by peritoneal Kt/V only. The overall 2-year patient survival was 84.9%. There was no statistical difference in patient survival among the three groups (2-year survival in group A, 87.3%; group B, 86.1%; and group C, 81.5%). However, there were more patients withdrawn by physicians in group A (group A, 16; group B, 7; and group C, 6; P = 0.023). Total Kt/V or Kt did not significantly affect survival after adjustment to age and diabetes. There was no difference in serum albumin, CNI scores, and hospitalization rate, but there were more patients in group A requiring erythropoietin (EPO) treatment after 1 year.

Conclusion. Patients with total Kt/V maintained below 1.7 had significantly more clinical problems and severe anemia but there was no difference in outcome demonstrated for patients with Kt/V maintained above 2.0 and between 1.7 and 2.0. We recommended that the minimal target of total Kt/V should be above 1.7.

Key words: adequacy, Kt/V, CAPD, survival, nutrition, outcome.

Adequacy of dialysis has long been linked to survival of continuous ambulatory peritoneal dialysis (CAPD) patients. As reflected by Kt/V, it was first used in hemodialysis patients and has a strong association with patient survival [1]. When first adopted in CAPD, the initial Kt/V target representing adequate dialysis was 1.7 [2]. In 1992, Blake et al [3] showed that mortality increased with Kt/V below 1.5. Subsequent studies suggested Kt/V targets ranging from 1.7 to 2.23 [4, 5]. The Canada-United States of America (CANUSA) study published in 1996 examined 680 patients and suggested that the Kt/V target for adequate dialysis should be 2.1 [6]. Based on large amount of literature review, the Dialysis Outcome Quality Initiative (DOOI) of the National Kidney Foundation of the United States recommended Kt/V should be kept above 2.0 in CAPD patients [7]. However, none of the studies were randomized, prospective, or interventional in nature. The Kt/V targets achieved by patients were mainly related to their own body size and residual renal function rather than a difference in dialysis prescription. Therefore, the resultant difference in survival could be related to factors other than the small molecule clearance as reflected by Kt/V.

In Hong Kong, we have reported good CAPD survival on routine three 2 L daily exchange regime and a low mean total Kt/V of 1.76 [8]. Good survival rates had also been reported in American Asian patients and some other Asian countries like Korea and Japan with different dialysis prescriptions [9–11]. These observations suggest that there may exist a difference in effect of Kt/V on mortality in Asians. This study aimed to determine the effect of Kt/V on patient survival and outcome in a randomized prospective interventional manner with the three important historic levels of Kt/V, 1.5, 1.7, and 2.0 chosen as the cutoff levels.

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METHODS

This is an open-labeled randomized prospective study. From May 1996 until July 1999, new CAPD patients from six participating dialysis centers were recruited into the study. Exclusion criteria included patients with life expectancy less than 6 months, planned living-related kidney transplantation within 6 months, initial renal Kt/V more than 1.0, and amputees. Patients on various forms of automated peritoneal dialysis, day ambulatory, or intermittent peritoneal dialysis were excluded. Patients usually had a period of 4 to 8 weeks of hospital-based intermittent peritoneal dialysis before they started CAPD training. Written consents were obtained during the CAPD training period. The usual initial CAPD prescription was three 2 L exchanges per day. The first adequacy dialysis assessment was conducted at around 4 to 8 weeks after commencement of CAPD. Patients with renal Kt/V more than 1.0 were subsequently excluded. Patients were then randomized in each dialysis center by sequentially opening sealed envelopes containing a randomized group number into three groups with different total Kt/V targets: group A, 1.5 to 1.7; group B, 1.7 to 2.0; and group C, greater than 2.0. Dialysis prescription was adjusted if total Kt/V deviated from the target by more than 0.05. Re-assessment of the adequacy of dialysis indices was done 4 to 6 weeks after adjustment of dialysis prescription. The adequacy of dialysis indices assessed included total, peritoneal, and renal Kt/V, and creatinine clearance. The residual renal function was estimated from averaged urine urea and creatinine clearance normalized to body surface area. The crude body weight was used to calculate V according to Watson [12]. As there is recent report suggesting Kt_{urea} may be a better parameter over Kt/Vurea on predicting outcome, adequacy data were further analyzed with total Kt [13]. Nutritional parameters assessed included normalized protein nitrogen appearance rate (nPNA), according to Randerson, Chapman, and Farrell [14], serum albumin, and composite nutritional index (CNI) according to Harty et al [15] (Appendix 1). CNI scores greater than 10 was regarded as indicative of moderate to severe malnutrition. Skin fold measurements were examined by one single nurse. Reference of standards of the anthropometric measurements were derived from United States National Health and Nutritional Examination Surveys according to the study of Frisancho [16].

Both dialysis adequacy and nutritional assessment were performed on a 6-month basis until October 31, 2000, 15 months from the last patient recruitment, and would be postponed for 4 weeks after an episode of peritonitis or major infection or complication. The physician-in-charge and the patients themselves had the right to withdraw from the study on the grounds of clinical inadequate dialysis or ultrafiltration, or refusal to follow the recommended dialysis prescription, respectively. One peritoneal equilibration test was done at baseline assessment. The study protocol was approved by the Ethical Committee of the Faculty of Medicine, The University of Hong Kong.

Study end point included death, transfer to permanent hemodialysis, and withdrawal from study. Events for "patient survival" included death and for "clinical survival" included death, permanent hemodialysis, and withdrawal from study by physicians. Clinical survival was used to reflect patient survival without adverse outcome that was possibly related to inadequate dialysis. Hospitalization data were retrieved from the Clinical Management System of the Hospital Authority, which recorded all hospitalization of every patient automatically. Other clinical outcome studied included hemoglobin level and the use of erythropoietin (EPO).

According to the CANUSA study, the absolute 2-year survival difference between patients with Kt/V 2.3 and 1.5 was 21%, and between 2.1 and 1.5 was 16%. With an estimated mean 2-year survival of 85% at a mean Kt/V level of 1.85 and 2-year dropout rate of 28% in Hong Kong, a minimal sample size required to a showed a 21% absolute survival difference with a power of 0.8 was 240, and for 16% difference was 370. It was determined that the minimal sample size should be 300 in order to show a magnitude of survival difference similar to that of the CANUSA study.

Analysis of variance and Kruskal-Wallis test were used to compare parametric and nonparametric data between groups, respectively. Chi-square test was used to compare proportions between groups, whereas test of linear trend was used when a trend was found among the groups. Log rank test was used to compare survival distribution. Time-dependent Cox proportional hazard model was used to determine the adjusted risk of each factor on mortality. A P value of 0.05 was taken as the level of statistical significance. SPSS 10.0 was the computer software employed for statistic calculation.

RESULTS

Over a period of 3.3 years, 320 patients, including 103 diabetics (32.3%), gave consent and were recruited into the study. There were 104 patients in both group A and group B, and 112 patients in group C. Peritoneal equilibration test data were missing in 12 patients (six in groups A, four in group B, and two in group C). The baseline demographic, clinical, dialysis adequacy, and nutritional data were shown in Table 1. Body weight and baseline peritoneal dialysate (PDF) volume prescription were higher in group A, probably a result of a slightly more, but not statistically significant different, male patients in group A (P = 0.059).

The mean total Kt/V of each group were well main-

	Group A	Group B	Group C	P value
Number	104	104	112	
Age mean \pm SD	56.9 ± 14.0	58.5 ± 12.7	60.9 ± 12.3	0.080
Male:female ratio	60:44	47:57	47:65	0.053
Diabetes mellitus number	28 (26.9%)	33 (31.7%)	42 (37.5%)	0.249
CVS disease number	14 (13.5%)	17 (16.4%)	22 (19.6%)	0.473
Kt/V, total	1.98 ± 0.38	2.06 ± 0.40	2.11 ± 0.38	0.044
Kt/V, peritoneal	1.53 ± 0.31	1.59 ± 0.33	1.62 ± 0.31	0.105
Kt/V, renal	0.44 ± 0.29	0.46 ± 0.27	0.49 ± 0.28	0.494
Creatinine clearance, total	76.0 ± 19.4	76.8 ± 22.0	80.1 ± 21.3	0.308
Creatinine clearance, peritoneal	41.5 ± 12.6	39.8 ± 13.3	42.3 ± 11.6	0.309
Residual GFR mL/min	2.38 ± 1.38	2.48 ± 1.52	2.64 ± 1.45	0.396
D/P creatinine	0.70 ± 0.15	0.67 ± 0.13	0.70 ± 0.13	0.119
Dialysate volume L/day	6.35 ± 0.76	6.12 ± 0.47	6.19 ± 0.58	0.022
Serum albumin g/L	33.5 ± 4.3	33.8 ± 4.1	33.6 ± 4.8	0.874
Body weight kg	58.6 ± 10.6	55.8 ± 10.6	55.0 ± 9.0	0.026
Total body water L	32.3 ± 5.2	30.4 ± 4.9	30.0 ± 4.4	0.001
BMI kg/m^2	22.1 ± 3.3	22.0 ± 3.8	21.8 ± 3.1	0.847
CNI	6.61 ± 5.07	6.54 ± 5.50	6.69 ± 5.33	0.988
Malnourished number	23 (22.1%)	24 (23.1%)	26 (23.4%)	0.979
nPCR g/kg/day	1.01 ± 0.26	1.05 ± 0.26	1.04 ± 0.24	0.477
Hemoglobin g/dL	8.44 ± 1.44	8.57 ± 1.43	8.56 ± 1.59	0.774

Table 1. Baseline demographic, clinical, adequacy of dialysis, and nutritional data of the three study groups

Abbreviations are: BMI, body mass index; CNI, composite nutritional index; nPCR, normalized protein catabolic rate; GFR, glomerular filtration rate.

tained within the target range from 1 month onward (Fig. 1). The mean peritoneal and renal Kt/V of each group were shown in Figure 1 B and C. The difference in total Kt/V between groups were mainly due to difference in peritoneal Kt/V (P = 0.000) but not renal Kt/V (P = NS) except at 7 and 19 months (P = 0.029 and 0.017, respectively, higher in group C). The total Kt was also significantly different between groups from 1 month to 25 months (P = 0.000) (Fig. 2). The volume of PDF prescribed was significantly different from 1 month to 25 months (Fig. 3).

Study end point data

Over a mean follow-up period of 24.3 ± 13.2 months (range, 1.3 to 56.7 months), 70 patients died. Of the 70 deaths, 17 were related to cardiovascular complications, including four sudden deaths, 12 related to peritonitis, 11 related to other infections, 7 from malignancy, 6 from withdrawal from dialysis for social reasons, and 3 from cerebrovascular accidents. There were five deaths from unknown causes and nine from miscellaneous causes. Thirteen patients were transferred to hemodialysis, mostly related to peritonitis, 19 patients were transplanted, 16 patients were withdrawn from study because of partial recovery of renal Kt/V exceeding 1.0, and four patients were lost to follow-up. Of the 44 patients who refused to continue the study, 38 patients refused to increase the number of exchange further. Physicians elected to withdraw 29 patients from the study based on clinical evidence of inadequate ultrafiltration in 13 patients, inadequate dialysis in six patients, and excessive ultrafiltration in 10 patients. There was no difference among the groups in the number of patients who died or withdrew from study by themselves, but there were significantly more patients who were withdrawn by physicians in group A compared to group B and C (P = 0.023) (Table 2). By completion of the study, 127 patients were still alive and remained in the study.

Survival data

The overall patient survival rate at 1 year was 94.8% (255 patients) and at 2 years was 84.9% (154 patients). The 2-year patient survival was 87.3%, 86.1%, and 81.5% for study groups A, B, and C, respectively (Fig. 4). The difference was not statistically significant (P = 0.9924) However, there was a trend for better 2 years' clinical survival in group B over group A (0.054) (Fig. 5). The difference between groups B and C were not significant. When patient survival was examined according to intention-to-treat analysis, including death after withdrawn from study, there was also no statistical difference (P = 0.8186).

After adjusting for age and diabetes mellitus, using the multivariate Cox proportional hazard model and treating total Kt/V as a time-dependent covariate, the relative risk for mortality for every 0.1 unit increase in total Kt/V was 0.942 (95% CI, 0.875 to 1.015; P = 0.119). The relative risk for every 1 L of Kt per week was 0.997 (95% CI, 0.976 to 1.019; P = 0.803). Adding cardiovascular disease into the model did not affect the relative risk of Kt/V or Kt significantly.

Nutritional data

There was no difference in serum albumin or CNI scores at any time point of the three study groups (Figs. 6 and 7). There was also no difference in the change of



final CNI scores (at the end of study or the last score before death or removal from study) from baseline among the three study groups (the mean change of group A was -1.56; group B, -1.32; and group C, -1.77). nPNA was lower in group A but was not different between groups B and C (Fig. 8).

Hemoglobin level and hospitalization rate

There was no significant difference in the hemoglobin levels among the three groups. However, there were significantly more patients in group A receiving EPO after 1 year (Table 3), indicating higher incidence of severe anemia requiring EPO in group A. The hospitalization rates were similar for all groups (group A, 9.4 \pm 16.9; group B, 9.8 \pm 16.1; and group C, 7.1 \pm 10.1 days/ patient/year, P = 0.334).

DISCUSSION

Apart from the recently published ADEMEX study [17], this study is the only large-scale randomized prospective interventional study on the effect of small solute clearance on peritoneal dialysis patient survival. It was designed to maintain patients' Kt/V at a predetermined level by adjusting peritoneal dialysis prescription for falling residual renal function. The effect of residual renal function was minimized by excluding patients with renal Kt/V above 1.0, and as a result, around 50% of new patients were excluded from the study. The resultant difference in total Kt/V was mainly due to difference in peritoneal instead of renal Kt/V. Similar to the AD-EMEX study, but contrary to most published observational studies, our study did not show a major impact of total Kt/V or Kt on patient survival, even after adjust-



Fig. 2. The mean total Kt of the groups at different time points of study. The error bar depicts 95% CI of the mean. The difference between groups was significant from 1 month to 25 months (P = 0.000). Symbols are: (\Box) group A; (\blacksquare) group B; (\bigcirc) group C.



Fig. 3. The daily peritoneal dialysis fluid prescription of the groups at different time points of study. The error bar depicts 95% CI of the mean. The difference between groups was significant from 1 month to 25 months (P = 0.000 for months 1 to 19, and P = 0.002 for month 25). Symbols are: (\Box) group A; (\blacksquare) group B; (\bigcirc) group C.

Table	2.	Clinical	outcomes	of	patients	of	the	three	study	groups
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Study groups	А	В	С	P value
Total number of patients	104	104	112	
Follow-up months ^a	22.7 ± 13.5	24.7 ± 13.1	25.3 ± 13.1	0.306
Deaths	20	24	26	0.729
Transfer to permanent hemodialysis	6	1	6	0.148
Transplantation	5	8	4	0.387
Withdraw from study	30	19	24	0.176
By physicians	16	7	6	0.012 ^b
Inadequate dialysis	6	0	0	0.002 ^b
Inadequate ultrafiltration	8	4	1	0.012 ^b
Excessive ultrafiltration	2	3	5	0.283 ^b
By patients	14	12	18	0.624
Refusal to increase peritoneal dialysis fluid	12	9	16	0.423
Patient request increase peritoneal dialysis fluid	2	0	0	0.124
Other reasons	0	3	2	0.238

 a Mean \pm SD

^bBy test of linear trend

ment for the slight, but not statistical, difference in age, gender, and diabetic distribution between groups. No reasons for this slight baseline difference could be identified, and the difference likely happened by chance.

In the ADEMEX study [17], 965 prevalent CAPD patients with peritoneal creatinine clearance below 60 L/week were randomized into control group and intervention group to increase the peritoneal creatinine clearance to above 60 L/week [17]. The range of clearance studied was quite similar to ours, but there were differences in study design. One studied Kt/V and the other creatinine clearance and one recruited only incident patients and the other also prevalent patients. Lack of improvement in patient survival when dialysate prescription was increased just for increasing clearance was shared in both interventional studies.

Compared to the CANUSA study, which recruited 680

patients with only 109 patients (16%) and the ADEMEX study with only 33% patients remaining on study at 24 months, we have recruited many fewer patients but have many more patients remaining on study at 24 months (154 patients, 48%). The 2-year survival rate was also much higher. With the current sample size, survival, and dropout rate, the statistical power allows it to detect a 19% difference in 2-year survival. This magnitude of difference in survival was clearly absent in our patients. In this study, the maximal difference in 2-year survival between groups was 5.8%. To demonstrate a 5% 2-year survival difference requires a sample size of around 2800 patients, around the total number of new CAPD patients in all of Hong Kong in 4 years. Such benefit is probably not clinically important.

Although poorer patient survival was not found in group A, significantly more patients were withdrawn from







Fig. 5. Cumulative clinical survival of the three groups. The difference was not statistically significant (P = 0.1580). The difference in 2-year survival between groups A and B was marginally insignificant (P = 0.054).

study by the physicians to deal with the clinical problems, which mainly included inadequate ultrafiltration and clinical inadequate dialysis (Table 2). As a result, clinical survival was lower in group A, particularly when compared to group B (P = 0.054). Apart from the lower clinical survival, more group A patients required EPO. This suggests that they were more uremic comparing to other groups [18, 19]. The apparently similar hemoglobin level between groups was a result of using more EPO in group A.

There is a concern of the lack of better outcome in the higher target group as a result of lower compliance in this group. Though there was slightly more patient refusal to increase dialysis as a cause of withdrawal from study in group C, the difference was not statistically significant. Patient's refusal was at least partly related to them feeling well and not seeing the necessity to increase volumes, in an environment where 3×2 L has been the standard practice. This in no way presupposes that the compliance in this group was particularly poor as there were equal numbers who withdrew in the three groups



Fig. 6. The mean serum albumin level of the three groups at different time points of study. The error bar depicts 95% CI of the mean. The difference was not significant at other time points. Symbols are: (\Box) group A; (\blacksquare) group B; (\bigcirc) group C.



Fig. 7. The mean composite nutritional index (CNI) scores of the three groups at different time points of study. The error bar depicts 95% CI of the mean. The difference was not significant at other time points. Symbols are: (\Box) group A; (\blacksquare) group B; (\bigcirc) group C.

from patient preference at a time when there had been a significant increase in the dialysate volumes in groups B and C after the first month (clearly shown in Fig. 3). While this raises the possibility of reduced compliance in patients with higher PDF prescription, it is unlikely to explain entirely the findings of this study as there was likely to be noncompliance in all the treatment groups. It is recognized that there is great difficulty in accurately monitoring compliance in a large study at home and we concede that this may have had an influence on the outcomes; however, this point could not be verified as compliance was not formerly assessed in this study.

Groups	А	В	С	P value
Hemoglobin level g/dL				
Baseline	8.4 ± 1.4	8.6 ± 1.4	8.6 ± 1.6	0.771
Months				
7	9.0 ± 1.7	9.2 ± 2.0	9.2 ± 1.9	0.551
13	9.0 ± 1.7	9.2 ± 2.0	9.2 ± 1.9	0.754
19	9.0 ± 2.2	9.0 ± 2.0	9.1 ± 1.6	0.890
25	9.3 ± 2.4	8.8 ± 2.0	9.0 ± 1.4	0.591
31	10.0 ± 2.2	8.8 ± 2.1	8.9 ± 1.5	0.096
Percentage of patients on EPO				
Baseline	10.6%	5%	5.7%	0.311
Months				
7	16.7%	9.9%	5%	0.009ª
13	19.4%	10.1%	8.6%	0.030ª
19	32%	14.8%	13%	0.007^{a}
25	37.1%	19.5%	14%	0.014 ^a
^a B ³¹ _v test of linear trend	50%	18.2%	28%	0.067

 Table 3. Hemoglobin levels and percentage of patients on EPO of the study groups at different time point

Malnutrition is highly predictive of patient mortality. We used nPNA, serum albumin, and CNI to reflect patient's nutritional status. nPNA is not an ideal dietary protein intake parameter as there may exist a mathematical coupling with Kt/V [20]. Serum albumin, although highly predictive of mortality in many studies [21, 22], is not a pure nutritional marker. CNI was derived using more anthropometric measurements to reflect the nutritional status [15]. Our earlier cross-sectional study on 937 prevalent CAPD patients in Hong Kong showed that serum albumin and CNI were both more powerful predictors of mortality than Kt/V [23]. In this study, there were no significant differences in albumin and CNI between the study groups. The nPNA was lower in group A but was similar between groups B and C. This finding may suggest that the negative impact of low Kt/V on protein intake was more prominent with Kt/V level below 1.7 in our patients. This is in line with a recent report from Hong Kong showing that improvement in nPNA with increased dialysis prescription in Chinese anuric peritoneal dialysis patients was not seen in patients with Kt/V above 1.9 [24].

Hospitalization rate can be viewed as a composite of all complications and morbidity. There were studies showing both the presence and absence of beneficial effect of Kt/V on hospitalization rate [19, 25]. In this study, there was a slightly, but not statistically significant, reduced hospitalization rate in the highest Kt/V group.

CONCLUSION

Patients with Kt/V maintained below 1.7 clearly had more clinical problems suggesting inadequate dialysis. The clinical advantage of pushing Kt/V above 2.0 was, however, not observed. While an improved patient survival advantage in patients maintaining their Kt/V above 2.0 may be obscured by a higher dropout rate, the fact



Fig. 8. The mean normalized protein catabolic rate (nPCR) of the three groups at different time points of study. The error bar depicts 95% CI of the mean. At 7 months, the difference was significant between groups A and B (P = 0.014) but not between groups B and C. The difference was not significant at other time points. Symbols are: (\Box) group A; (\blacksquare) group B; (\bigcirc) group C.

remains that clinical survival was not different between those maintaining their Kt/V between 1.7 and 2.0 and those above 2.0. It was at least partly related to slightly more withdrawal in the latter group from the study for excessive ultrafiltration or patient nonacceptance. Based on these findings, we therefore recommended that for all practical purposes, the minimal Kt/V target should be 1.7 and patients should be kept at Kt/V between 1.7 and 2.0. While one should not refrain from increasing the dialysis prescription to higher Kt/V levels in order to achieve good control of other clinical parameters, deliberate maintenance of Kt/V above 2.0 without these indications may not be necessary. Because our study was conducted among a relatively homogeneous racial population with low comorbidity and mortality and was limited to patients with low residual renal function, extrapolation of our recommendation to other populations with a different racial mix, comorbidity and morbidity and to patients with higher baseline residual renal function must be done with caution.

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APPENDIX 1 THE COMPOSITE NUTRITIONAL INDEX [15]

Scores	0	1	2	3
Subjective global assessment category	Α	В	С	_
% reference weight	>90	80-89	70–79	$<\!70$
Body mass index				
Male	>21	20-20.9	19–19.9	<19
Female	>20	19–19.9	18-18.9	$<\!\!18$
Albumin, g/L	>35	30-34.9	25-29.9	<25
Percentile				
Dry weight	>15	10-15	5 - 10	<5
Triceps skin fold	>15	10-15	5 - 10	<5
Subscapular skin fold	>15	10-15	5-10	<5
Arm muscle area	>15	10-15	5-10	<5

Reference body weight is the patients' dry weight expressed as a percentage of individual comparative reference weight at 50th percentile. Total score above 10 was regarded as moderate to severe malnutrition.

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