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Long-term efficacy of intermittent peritoneal dialysis using various doses

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Abstract. The objective of the present study was to investigate the long-term clinical efficacy of intermittent peritoneal dialysis (IPD) using various doses and to explore the most suitable dialysis dose and practice pattern for patients. A total of 52 inpatients/outpatients who had undergone IPD for more than 5 years were recruited and divided into three groups according to the dialysis dose: 4 liters in Group A, 6 liters in Group B and 8 liters in Group C. The dwell time was 4 h. All patients were fasted overnight. The dialysis adequacy, nutritional status, complication control, blood pressure and intra-abdominal infection were determined and observed among these patients. Barthel index (BI) and Hamilton Depression Scale (HAMD) were employed to measure the activities of daily living (ADL) and degree of depression, respectively. The dialysis adequacy and ultrafiltration volume in Group A were lower than those in Groups B and C, but the residual urine volume was larger than that in the latter two groups. In addition, there was a marked difference in the control of complications between Group A and Groups B and C. When compared to Groups A and B, the nutritional status in Group C was significantly decreased, the mean arterial pressure and intra-abdominal infection rates were dramatically increased, and the HAMD scores were also higher ($P<0.05$). No significant difference was noted in the BI. For patients undergoing long-term IPD, individualized dialysis dose may benefit the dialysis adequacy, nutritional status, control of complications, blood pressure, rate of intra-abdominal infection, ADL and depression.

Introduction

Peritoneal dialysis (PD) is one of the strategies used in the treatment of end-stage renal failure and has been accepted by numerous patients and physicians due to its preservation of residual renal function, stable hemodynamics and ease of operation. The dialysis regimen varies in different regions and countries. In most Western countries and China, a continuous ambulatory peritoneal dialysis (CAPD) program consisting of four 2-liter daily exchanges has been adopted (1). The ideal dose of peritoneal dialysis is important not only for dialysis adequacy, control of multiple complications, increase in long-term survival and improvement of quality of life (QOL), but also for reduced interruption of daily living by dialysis, decline in medical cost and the prolongation of therapeutic dialysis. We modified the traditional CAPD and applied the modified intermittent peritoneal dialysis (IPD) for the maintenance of PD. The dialysis dose was determined according to the specific disease conditions. In the present study, we retrospectively reviewed the clinical data from patients undergoing IPD for the past 5 years and evaluated these patients with the aim to investigate the long-term clinical efficacy of IPD and the advantages and disadvantages of various doses of IPD.

Patients and methods

General information. A total of 52 patients with chronic renal failure were recruited from January 2001 to February 2011 from our department. Patients with mental disorders and physical disabilities were excluded. The patients underwent PD using a double-bag system for >5 years and consisted of 24 males and 28 females, with ages ranging from 26 to 79 years. The duration of IPD was 60-112 months. The primary renal diseases included glomerulonephritis (n=13), diabetic nephropathy (n=24), lupus nephritis (n=1), chronic pyelonephritis (n=2), renal arteriosclerosis (n=11) and interstitial nephritis (n=1).

Dialysis pattern and dose. All patients received IPD. The IPD regimen consisted of four exchanges daily (4-8 liters/day) depending on age, family conditions, types of medical expenses, activities of daily living (ADL) and self-care ability. The patients were divided into three groups according to the dialysis doses. The dialysis dose was 4 liters in Group A (n=17), 6 liters in Group B (n=19) and 8 liters in Group C (n=16). The Baxter double-bag system was used and glucose solution served as penetrant. The concentration of penetrant was 1.5, 2.5 and 4.25% relying on the disease condition. The dwell time was 4 h. It was necessary for the patients to have a dry abdomen (draining of all PD fluid) overnight. In addition, symptomatic treatments were also performed targeting complications of renal failure, and these treatments aimed to

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Table I. Demographics of the patients in the different groups.

Variable	Group A	Group B	Group C	F/c^2	P-value
Gender (male/female)	9/8	11/8	4/12	4.250	0.119
Age (year)	47.2±14.3	47.4±12.1	45.6±11.7	0.100	0.905
Weight (kg)	66.7±12.1	65.3±10.4	62.2±9.5	0.757	0.475
Height (cm)	167.9±6.6	166.3±7.2	167.2±6.2	0.258	0.774

lower blood pressure, increase blood volume and maintain acid-base and electrolyte balance.

Observation indexes. A routine blood test, clinical biochemistry blood tests, a dialysate routine test and measurements of body weight, ultrafiltration volume, urine volume and blood pressure were performed monthly. In addition, the dialysis adequacy [Kt/V (week), Ccr], nutritional status (SGA and sALB), control of complications (Hb, CO_2CP, K^+, Ca^{2+}, P^- and iPTH), blood pressure control (mean arterial pressure), rate of intra-abdominal infection, ADL and degree of depression were also determined and evaluated. Moreover, the social activities, employment and duration of PD (months) were recorded. The data and clinical information 3 months after PD were used as baseline levels, and those 5 years (60 months) after PD as endpoint levels. The patients who received hemodialysis (HD) or renal transplantation or those who died during the study were excluded from this study.

Evaluation of ADL. Barthel index (BI) was employed to evaluate the ADL of these patients. The total score was 100. The higher the score, the higher the self-care ability (2).

Assessment of depression. The Hamilton Depression Scale (HAMD) was applied to evaluate the degree of depression of the patients (3). This scale was used to observe the symptoms, and the results were relatively objective. In addition, this scale also emphasized somatic symptoms, and the survey was easy to carry out. It is a general scale widely applied in the evaluation of depression in clinical trials and studies in psychiatry. The results of this scale sensitively reflect the changes in the symptoms of depression and this scale has been regarded as one of the best tools in therapy research. The total score of HAMD favorably reflects the degree of depression: the lower the score, the milder the depression. Generally, a score >24 was defined as severe depression, a score between 24 and 17 was defined as intermediate depression and a score <7 was defined as absence of depression. Based on the criteria for depression in combination with the score for HAMD, we applied score 7 as a cut-off value. A score >7 was defined as depression and a score <7 was defined as absence of depression.

Statistical analysis. Statistical analysis was performed with SPSS version 15.0. Quantitative data were expressed as the means ± standard deviation. Comparisons among multiple groups were carried out with analysis of variance and those between two groups with the SNK method. The comparisons of qualitative data were carried with the Chi-square test. P<0.05 was considered statistically significant.

Results

Demographics. There were no marked differences in gender, age, body weight or height among the three patient groups (P>0.05) (Table I).

Parameters 3 months after IPD in the different patient groups (baseline). Three months after IPD, the Kt/V (week) and Ccr were used to evaluate the adequacy of long-term IPD. The nutritional status was objectively assessed according to the incidence of malnutrition (SGA) and the serum levels of albumin (sALB). The hemoglobin (Hb), carbon dioxide-combining power of serum (CO_2CP), serum levels of potassium (K^+), calcium (Ca^{2+}) and phosphorus (P^-), and the free parathyroid hormone levels were also measured to evaluate the control of chronic failure-related complications. The mean blood pressure was measured to evaluate the control of blood pressure. The incidence of intra-abdominal infection was calculated to evaluate the infection following IPD. The BI was determined to assess the ADL, and HAMD was used to evaluate the level of depression. In addition, the long-term self-care and the psychological status were also compared among the three groups. Results are shown in Table II. Statistical analysis showed that the residual urine volume in Group A was significantly larger compared to Group B and that in Group B was higher compared to Group C (P<0.05). The ultrafiltration volume in Group A was markedly less than that in Group B, which was less than that in Group C (P<0.05). No significant differences were observed in the dialysis adequacy, nutritional status, complications, blood pressure control, ADL and degree of depression (P>0.05).

Parameters 5 years after PD in the different patient groups (endpoint). All patients undergoing long-term IPD had good QOL and maintained IPD. Five years after IPD (60 months), the clinical information was again collected from these patients. Results are shown in Table III. Statistical analysis showed that the residual urine volume in Group A was significantly higher than that when compared to Group B, which was higher compared to that in Group C (P<0.05). The ultrafiltation volume in Group A was markedly lower than that in Group B, which was lower than that in Group C (P<0.05). When compared to Groups B and C, the dialysis adequacy was reduced in Group A, but no significant difference was noted in the dialysis adequacy between Groups B and C (P<0.05).

Table II. Clinical information of the patients in the different groups 3 months after IPD.

Variable	Group A	Group B	Group C	F/c^2	P-value
Urine volume (ml/day)	1,046±414	745±332[a]	578±256[a,b]	8.030	0.001
Ultrafiltration volume (ml/day)	324±265	463±221[a]	626±294[a,b]	5.587	0.007
Dialysis adequacy					
Kt/V (week)	1.14±0.62	1.67±0.86	1.32±0.75	2.310	0.110
Ccr[c]	51.54±14.17	59.06±11.61	56.23±10.44	1.728	0.188
Nutrition status					
Incidence of malnutrition (SGA)	11.80%	15.80%	37.50%	3.790	0.150
sALB (g/l)	37.4±8.2	35.7±7.9	32.5±7.3	1.662	0.200
Control of complications					
Hb (g/l)	91.7±14.1	99.4±12.3	89.3±16.4	2.452	0.097
CO_2CP (mmol/l)	21.4±5.20	23.1±4.7	23.7±3.5	1.153	0.324
K^+ (mmol/l)	4.33±0.54	4.37±0.56	4.04±0.72	1.472	0.239
Ca^{2+} (mmol/l)	1.94±0.31	2.04±0.32	2.01±0.25	0.528	0.593
P (mmol/l)	1.42±0.44	1.56±0.61	1.64±0.86	0.484	0.620
iPTH (pg/ml)	92.5±15.8	89.4±22.1	81.6±16.7	1.497	0.234
Control of blood pressure					
Mean arterial pressure (mmHg)	90±13	94±17	98±12	1.284	0.286
BI	91±12	86±8	83±10	2.683	0.078
HAMD	6±3	7±4	9±5	2.328	0.108

[a]P<0.05 vs. Group A; [b]P<0.05 vs. Group B; [c]liters/week/(1.73 m^2); Ccr, total creatinine clearance, including residual renal creatinine clearance (Crcr) and peritoneal creatinine clearance (Cpcr).

Table III. Clinical information of patients in different groups 5 years after IPD.

Variable	Group A	Group B	Group C	F/c^2	P-value
Urine volume (ml/day)	977±434	659±372[a]	516±224[a,b]	7.280	0.002
Ultrafiltration volume (ml/day)	436±248	642±383[a]	855±331[a,b]	6.730	0.003
Dialysis adequacy					
Kt/V (week)	1.04±0.57	1.67±0.64[a]	1.56±0.74[a]	4.657	0.014
Ccr[c]	44.23±14.38	57.62±12.34[a]	55.41±11.26[a]	5.534	0.007
Nutrition status					
Incidence of malnutrition (SGA)	17.60%	21.10%	56.3%[a,b]	7.093	0.029
sALB (g/l)	36.2±7.8	36.6±4.3	26.4±4.8[a,b]	16.487	<0.001
Control of complications					
Hb (g/l)	90.4±13.3	96.6±11.5	87.30±13.7	2.426	0.099
CO_2CP (mmol/l)	22.5±4.6	24.5±3.2	23.10±3.4	1.343	0.270
K^+ (mmol/l)	4.57±0.74	4.61±0.47	4.22±0.56	2.163	0.126
Ca^{2+} (mmol/l)	1.88±0.37	2.15±0.46	2.03±0.37	1.992	0.147
P (mmol/l)	2.04±0.46	1.81±0.33	1.77±0.57	1.724	0.189
iPTH (pg/ml)	116.7±31.6	99.1±17.6	102.5±19.4	2.565	0.087
Control of blood pressure					
Mean arterial pressure (mmHg)	91±11	93±12	96±14	0.683	0.510
Incidence of intra-abdominal infection (/month/patient)	0.032±0.008	0.037±0.023	0.093±0.035	32.151	<0.001
BI	88±10	84±9	82±8	1.897	0.161
HAMD	7±3	10±4[a]	13±4[a,b]	10.822	<0.001

[a]P<0.05 vs. Group A; [b]P<0.05 vs. Group B; [c]liters/week/(1.73 m^2). BI, Barthel index; HAMD, Hamilton Depression Scale.

The nutritional status in Groups A and B was superior to that in Group C (P<0.05), but there was no significant difference between Groups A and B. The incidence of complications was comparable among the three groups (P>0.05) and no dramatic difference was observed in the control of blood pressure (P>0.05). The incidence of intra-abdominal infection in Groups A and B was different from that in Group C (P<0.05) but was similar between Groups A and B (P>0.05). There was no significant difference in the BI among the three groups (P>0.05). The HAMD score in Group C was markedly higher compared to that in Group B, which was higher than that in Group A (P<0.05).

Discussion

The solute and excessive water are cleared during PD through the peritoneum exerting a therapeutic effect. CAPD and IPD are the most common types of dialysis. The classic IPD is the initial type of PD and is mainly applied in acute renal failure patients who are temporarily unsuitable for HD. Generally, a 2-liter exchange is performed during 2 h (draining time: 20 min, dwell time: 90 min, refilling time: 10 min) and a total of 25 liters of fluid are used for dialysis. The exchange during a short time period achieves extremely high ultrafiltration. However, this method cannot assure the complete removal of solute. Therefore, IPD is only applied temporarily (in the presence of acute renal failure, during the training of CAPD, in the presence of leakage, after abdominal surgery and in patients with excessive body fluid who require heavy dehydration). In addition, IPD is also used in elderly patients without vascular pathways and in patients with unstable efficacy of HD who cannot self-manage CAPD. In CAPD, the dialysate is filled into and dwells in the abdominal cavity for a certain duration followed by draining. These procedures are carried out four times daily or depending on the disease condition. Therefore, dialysate dwells in the abdomen through 24 h. However, the dialysis adequacy of CAPD is superior to IPD, and CAPD has been the most common method for PD (4-6).

In mainland China, only 10% of patients receiving dialysis undergo PD (7). It is generally accepted that the efficacy of PD and HD is comparable in the first 3-5 years of dialysis. Thereafter, the efficacy of PD is inferior to that of HD over time. We should acknowledge that PD has several shortcomings, which are the main reasons why PD cannot be applied widely and for a long duration. For example, the water and small solutes during PD cannot be sufficiently removed when compared to HD, and PD may induce abdominal distention, decrease the appetite, increase the incidence of malnutrition and enhance the risk for intra-abdominal infection. In addition, peritoneal ultrafiltration failure may occur after 2-3 years of PD.

In addition, peritoneal angiogenesis and fibrosis, dysfunction of aquaporins and tight junction protein and aggregation of intra-abdominal mast cells may occur and interact with each other following PD. This results in damage to the peritoneum and alters the peritoneal structure and transportation function. Finally, peritoneal ultrafiltration failure occurs resulting in failure of PD (8). Peritoneal fibrosis is also one of the main causes of PD failure. PD may induce peritoneal fibrosis resulting in PD failure, in which numerous other factors are involved, including recurrent peritonitis (9) and influence of the dialysate on the peritoneum and cytokines (10).

Peritonitis is one of the key causes resulting in withdraw from PD (11). The peritoneum has the potent ability of self-repair. However, recurrent peritonitis may cause transient or even permanent alteration of the peritoneal function. The transient change includes intra-abdominal infiltration of inflammatory cells, increased loss of proteins, enhanced transportation of vasogenic solute and decrease in ultrafiltration. The permanent changes consist of a series of alterations of the peritoneal structure and function, which lead to damage to mesothelial cells, collagen deposition, peritoneal thickening and finally peritoneal fibrosis.

When a large amount of non-physiological dialysate is filled into the abdomen, the peritoneum is immersed in a dialysate with low pH value, high glucose, lactate and a glucose degradation product. Therefore, the original physiological environment of the abdomen is altered and the defense function of the abdomen is compromised (12). In addition, the mesothelial cells of the peritoneum are also damaged resulting in peritoneal fibrosis. The dialysate is rich in glucose, the metabolism of which is one of the main causes of side effects in dialysis, including hyperinsulinism, hyperglycemia and hyperlipidemia. During PD, the glucose concentration of the dialysate is 14-40 folds higher than that in body fluid. The mesothelial cells are directly exposed to this high glucose environment. Research showed that a high glucose environment damages and inhibits the proliferation of mesothelial cells, interferes with the metabolism of extracellular matrix, and alters the structure and morphology resulting in transformation of these cells into fibroblasts (13). Moreover, a low pH value and lactate not only affect mesothelial cells, but inhibit and damage leukocytes in the peripheral blood and abdomen.

It is generally accepted that PD adequacy refers to i) dialysis with sufficient dose or favorable efficacy of dialysis; ii) the mortality rate will not increase when the dialysis dose is higher than the cut-off value; iii) the patients have no discomfort, have good appetite and increased body weight and physical recovery, the chronic complications are reduced or absent and the toxins in uremia are completely removed (14). However, increasing studies reveal that the dialysis adequacy cannot be evaluated with the rate of urea and creatinine clearance alone, and the water balance as well as homeostasis are two more important factors for the evaluation. Thus, sufficient PD may refer to dialysis with an approximate amount of dialysate to maintain long-term survival and relatively high QOL. In Western countries, the dialysis dose is calculated according to the DPI of 1-2 g/kg/day at which the nitrogen balance is maintained (15). However, in China, the protein intake is usually lower than 1-2 g/kg/day. In addition, there is individual variation in the dialysis adequacy as height, body weight, metabolism rate, diet composition, food intake and residual renal function influence the dialysis adequacy. Thereby, the dialysis dose and type of dialysis may vary among patients.

Additionally, the traditional HD and PD only focus on the removal of small solutes and neglect the importance of exchange volume. However, the increased removal of small solutes fails to improve the high mortality following dialysis (16). Volume load is closely related to hypertension, left ventricular hypertrophy, inflammation and malnutrition, and

has been an important indicator predicting the mortality of PD patients (17,18). These findings demonstrate the importance of management of exchange volume and blood pressure control. Assuring the dialysis adequacy and preventing peritoneal fibrosis are the keys to delay peritoneal ultrafiltration failure and prolong the duration of PD.

To solve these problems encountered in PD, we did not employ the traditional CAPD in the present study; the modified IPD was applied for the treatment. Two to four exchanges were performed and patients were assured to have a dry abdomen. This is different from that in traditional CAPD, in which the abdominal cavity is exposed to dialysate throughout 24 h. In this treatment, the abdominal cavity is dry for a relatively long duration which is the physiological environment. Therefore, the peritoneal mesothelial cells have enough time to repair and the functions of intra-abdominal organs recover. In addition, sleep and appetite as well as nutritional status are significantly improved, while infections due to repeated operations are reduced. In the long-term observation, results demonstrate that this method favorably prevents and delays peritoneal fibrosis and peritoneal ultrafiltration failure, which maintain the long-term efficacy of PD and the QOL of PD patients, and prolong the duration of PD.

In the present study, these patients underwent PD smoothly for more than 2-3 years, which is the upper limit of duration for traditional CAPD. In addition, the dialysis adequacy, nutritional status, degree of anemia, acid-base balance, ion metabolism levels, function of parathyroid gland, blood pressure control, incidence of intra-abdominal infection, ADL, degree of depression and residual renal function all demonstrate the favorable clinical efficacy of IPD. Moreover, we also found that a dry abdomen at night improved sleep, maintained cardiovascular function and reduced fluid retention, which are beneficial for the recovery of gastrointestinal function. The exchange of 2-3 times daily is also acceptable for patients. Therefore, this method is not only economical, but increases the compliance of patients to treatment.

In the present study, although the ultrafiltration, dialysis adequacy and complication control in Group A were inferior to those in Groups B and C, the regimen in Group A required only 2-liter daily exchanges, the number of operation was relatively low and the dwell time was short. Therefore, the gastrointestinal response to PD was mild and patients had a good appetite. Moreover, the ADL was not markedly limited by PD, the incidence of infection was relatively low and the nutrition status and QOL were favorable (19). Malnutrition is very common in patients receiving PD and can be used to predict the incidence of complications and mortality (20,21). In addition, one study also revealed that improvement in nutrition status is beneficial for the control of complications (22).

In Group B, the improvement was superior to that in Groups A and C. In terms of the number of operations, the dwell time and the influence on the gastrointestinal function and ADL, the treatment in Group B was acceptable. In Hong Kong, the main dialysis regimen consists of three 2-liter exchanges (23). In Group C, four exchanges were carried out. The number of operations was relatively higher and the dwell time longer, which significantly affected the gastrointestinal function. Therefore, ADL in Group C was less than that in Groups A and B, and the nutritional status and blood pressure control were inferior to those in Groups B and A. Moreover, the incidence of intra-abdominal infection and the degree of depression in Group C were markedly increased when compared to Groups A and B.

To date, numerous studies have demonstrated that anxiety and depression are the most common comorbidities in patients with uremia (24-26). Both PD and HD affect the ADL. The ADL is related to the self-reported QOL and mood status as well as social function (27). Patients with depression usually participate in less social activities. Long-term lack of activities is harmful for the health of these patients and acts as an independent risk factor of increased mortality (28). In addition, there is evidence showing that social activities are also related to prognosis (27). Through affecting social activities and influencing QOL, depression predicts a poor prognosis. Therefore, increasing social activities appropriately improves depression and enhances the QOL. When compared to traditional CAPD, IPD used in the present study was a type of dialysis using individualized dose. It significantly increased ADL, which subsequently relieved the burden conferred by PD on patients and improved depression. Thus, the QOL of these patients was improved and the duration of dialysis was prolonged. Since we used this method for dialysis, several patients underwent PD for more than 10 years and this treatment was ongoing. The majority of patients underwent PD for more than 5 years and the clinical efficacy was satisfactory.

Taken together, in the present study we investigated the clinical efficacy of long-term IPD. Our results showed that a dry abdomen for a certain duration in patients undergoing PD was beneficial for the repair of peritoneal mesothelial cells, delay of peritoneal failure, improvement in functions of internal organs, decrease in fluid retention, preservation of residual renal function, increase in ADL, improvement of depression, elevation of QOL and relief of economic burden exerting excellent clinical efficacy. In addition, the dialysis dose of 6 liters was more applicable for Chinese patients receiving PD.

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