

Guidelines

2009 Japanese Society for Dialysis Therapy Guidelines for Peritoneal Dialysis

Working Group Committee for the Preparation of Guidelines for Peritoneal Dialysis,
Japanese Society for Dialysis Therapy

Japanese Society for Dialysis Therapy, Tokyo, Japan

Abstract: The guidelines for peritoneal dialysis (PD) of the Japanese Society for Dialysis Treatment were prepared at 2009. Upon presenting a concrete frame of PD practiced in Japan, it aims to promote PD as a standardized therapy in Japan. Notably, the guidelines recommended combination therapy of PD and hemodialysis as a part of integrated

renal replacement therapy for end-stage renal disease, as well as timely PD withdrawal by peritoneal degeneration in order to prevent progression of encapsulating peritoneal sclerosis. **Key Words:** Dialysis adequacy, Dialysis initiation, Encapsulating peritoneal sclerosis, Nutrition, Peritoneal Dialysis, Peritoneal function.

OBJECTIVE AND ESTABLISHMENT PROCESS OF THE GUIDELINES

In Japan, peritoneal dialysis (PD) was first introduced in 1982. It has since been applied as a self-care and home-based procedure for patients with end-stage renal disease (ESRD) and has contributed to restoring and maintaining patients' social and family lives. Since the opportunities for kidney transplantation are limited in Japan, dialysis therapy is of crucial importance, both from medical and social viewpoints. After the initial rapid adoption of PD in Japan during the 1980s, an increasing number of unpredictable cases of encapsulating peritoneal sclerosis (EPS) after long-term PD resulted in a nationwide decline in PD usage during the last decade. Despite this issue, Japanese nephrologists have embraced PD, as they value the increased patient freedom provided by this modality. With novel PD fluids addressing many of the previous complications of PD, we foresee a rapid adoption of PD in new patients started on renal replacement therapy (RRT).

These guidelines are aimed at defining a modern framework for PD therapy in Japan; specifically, their aim is to establish principles of practice in key areas of PD, as well as to transmit the latest evidence-based methods from around the world to Japanese nephrologists. As such, the guidelines highlight the role of modern PD as an initial treatment in RRT for patients with stage 5 chronic kidney disease (CKD). Especially, these guidelines focus on the importance of informed consent, education of patients, and PD program planning to ensure an optimal outcome. Furthermore, the significance of monitoring residual renal function is noted in the guidelines, while the Committee also recommends the routine evaluation of dialysis doses to ensure the achievement of adequate target levels and adequate nutrition, as well as the absence of overhydration, and the need for regular assessments to detect changes in peritoneal function. The guidelines are presented on the following categories with supplementary comments for pediatric patients:

- Initiation criteria
- Maintenance of adequate dialysis
- Maintenance of adequate nutritional state
- Evaluation of peritoneal function
- Discontinuation criteria to avoid EPS.

Received April 2010.

Address correspondence and reprint requests to Dr Masaaki Nakayama, Fukushima University School of Medicine, Division of Nephrology and Hypertension, 1 Hikarigaoka, Fukushima City, 960-1295, Japan. Email: masanaka@fmu.ac.jp

The Scientific Committee of the Japanese Society for Dialysis Therapy (JSDT) organized a working group in April 2005 to prepare guidelines on PD treatment for Japanese patients. Past scientific meetings of the JSDT, in collaboration with the Japanese Society for Peritoneal Dialysis (JSPD), recognized the necessity of preparing PD guidelines, which resulted in the JSDT Subcommittee for the Preparation of Guidelines inviting a group of PD experts to participate in 2006. A draft of the present guidelines was made open to the public at the Consensus Conference at the 53rd Meeting of the JSDT in 2008, and published in Japanese in April 2009 in the *Journal of the Japanese Society for Dialysis Therapy*.

In preparing the guidelines, relevant publications were collected using Medline. Next, a number of senior clinicians with a wide range of clinical experiences and opinions in Japan were asked to review these publications and synthesize and (while considering their own clinical experiences) summarize relevant medical information in Japanese. This effort was supplemented by original articles, reviews, case reports, and abstracts in Japanese collected exhaustively from domestic publications using the search function of the *Japana Centra Revuo Medicina*. By this procedure, more than 3500 additional documents were collected from domestic publications. The Committee then compiled the guidelines and annotations according to evidence levels from adopted references (evidence levels: I, Systematic review/meta-analysis; II, Randomized controlled study; III, Non-randomized controlled study; IV, Cohort study, case study; V, Case report, case series; VI, Expert opinion, committee recommendations). The final guidelines of the Committee were thus established.

The guidelines were originally published in Japanese in 2009 (1). This English version contains the guideline text, footnotes, addendum, and a part of the appendix.

CHAPTER 1: INITIATION OF PERITONEAL DIALYSIS

1. Before the initiation of peritoneal dialysis, sufficient information concerning hemodialysis, peritoneal dialysis, and kidney transplantation should be provided to the patients, and the decision regarding modality choice must be made with the patient's consent.

(Evidence level VI: Committee opinion)

2. Peritoneal dialysis must be initiated concurrently with patient education to assure patients are adequately trained before starting self-treatment.

(Evidence level III)

3. Initiation of dialysis must be considered in patients with stage 5 CKD (glomerular filtration rate <15.0 mL/min/1.73 m² body surface area (BSA) if they have signs or symptoms of uremia resistant to medical treatment.

(Evidence level VI: Committee opinion)

4. Initiation of dialysis is recommended before glomerular filtration rate reaches 6.0 mL/min/1.73 m² BSA.

(Evidence level VI: Committee opinion)

Footnotes

Signs and symptoms seen in renal failure include: volume overload (edema, pleural effusion, ascites), malnutrition, cardiovascular symptoms (heart failure, hypertension), anemia, electrolyte abnormalities (hypocalcemia, hyperkalemia, hyponatremia, hyperphosphatemia), acid-base imbalance (acidosis), gastrointestinal symptoms, and neurological symptoms.

The classification of stage 5 CKD (glomerular filtration rate [GFR] <15.0 mL/min/1.73 m² BSA) is made according to the estimated GFR (eGFR) (Addendum 1). At the initiation of dialysis, the GFR should, as often as possible, be determined based on a 24-hour urine sample (Addendum 2).

Commentary

1. Providing information and obtaining consent

At the initiation of dialysis, relevant medical information must be provided to the patients and, if necessary, their families, parents (including surrogates), or caregivers. Consent should be obtained based on information provided by a team consisting of physicians, nurses, medical social workers, and clinical engineers. In providing information and obtaining consent to initiate dialysis, it must be explained that there are three possible renal replacement therapies for ESRD; that is, hemodialysis, peritoneal dialysis, and kidney transplantation, with the advantages and disadvantages of each therapy, aiming to achieve sufficient understanding by the patients and to encourage their selection of dialysis therapy (Addendum 3). Presently, patient information concerning therapy for ESRD provided in Japan is inadequate, and there is a strong tendency for information concerning peritoneal dialysis to be provided only at facilities performing the treatment (2). Information should be provided impartially.

2. Education before initiation of peritoneal dialysis and systematic initiation

Peritoneal dialysis must be initiated concurrently with patient education. Particularly, planned initiation of peritoneal dialysis while the residual renal function

is still present has been confirmed to be important in the avoidance of complications at PD initiation and to improve the prognosis (3). Timely referral to experts and education of patients are critically important, as this will allow for a planned initiation of dialysis at an appropriate time (4,5). Late referrals are associated with longer hospitalization and catheter-related complications. Step-wise initiation of peritoneal dialysis is commonly practiced in Japan. By this approach, a peritoneal dialysis catheter is implanted before the appearance of uremic symptoms, facilitating the initiation of PD at an optimal time (6).

3. Timing of initiation

Although the optimal timing of initiating RRT in patients with ESRD remains uncertain due to a lack of data, the condition of an individual patient, their type of primary kidney disease, age, nutritional status, and comorbidity status have to be taken into account when deciding when to start RRT.

The guidelines prepared by the Research Project on the Treatment for Renal Failure, funded by the Ministry of Health and Welfare in 1991 (7), is widely accepted in Japan today. According to these recommendations, the time for initiation of dialysis should be determined based on a comprehensive evaluation of items such as renal function, signs and symptoms of uremia, severity of impaired activities of daily living (ADL), as well as if the patient is elderly or a child. The validity of these guidelines in hemodialysis patients has been supported by a follow-up study of the survival and complications two years after the initiation of dialysis (7); however, the validity in peritoneal dialysis has not been evaluated.

The renal function of the patient starting dialysis in Japan corresponds in most cases to a GFR <15 mL/min/1.73 m² BSA (stage 5 CKD) (8). Accordingly, stage 5 CKD is regarded as the time when initiation of PD should be considered. Furthermore, the Committee recommends that dialysis needs to be initiated at the appropriate time to maintain and secure a satisfactory nutritional state and high quality of life (QOL) (9–11). To optimize a patient's prognosis, we stress that initiation of dialysis should not be delayed in cases with stage 5 CKD and refractory uremic symptoms.

4. Patients with a GFR <6.0 mL/min/1.73 m² BSA

Preservation of residual renal function (12,13), maintenance of a high QOL, and a high patient satisfaction (14,15) have been reported as medical advantages of PD (Addendum 4); however, in cases without symptoms of uremia, there is no consensus regarding the optimal time to initiate PD (16–18). Considering

the strong relationship between a decrease in the renal function and deterioration of the nutritional status (19,20), and that residual renal function after the initiation of PD exerts a major impact on outcome (21), initiation should not be delayed unduly in patients to be treated with PD. Even in the absence of signs or symptoms of uremia, it is recommended that initiation should be considered before GFR falls below 6.0 mL/min/1.73 m² BSA.

Addendum 1

In adult Japanese patients, the eGFR should be calculated using the formula for eGFR of the Japanese Society of Nephrology (22). This formula is not to be used for the evaluation of renal function in children. (See Supplementary comment to Addendum 4).

$$\text{eGFR (mL/min/1.73 m}^2 \text{ BSA)} = 194 \times \text{Cr}(-1.094) \times \text{age}(-0.287)$$

where Cr (serum creatinine level determined enzymatically) and $\times 0.739$ for females

Addendum 2

Presently, there is no evidence supporting the evaluation of renal function based on the eGFR in regards to determining the timing of initiation of dialysis. Instead, renal function should be determined using 24-hour pooled urine, to the extent possible. In 24-hour pooled urine, the GFR is calculated using the means of creatinine clearance (CrCl) and urea clearance (UN clearance), i.e. $\text{GFR (mL/min/1.73 m}^2) = 0.5 \times (\text{CrCl} + \text{UN clearance})$

Addendum 3

As useful material for explaining renal replacement therapies for ESRD patients, a pamphlet jointly compiled by the Japanese Society of Nephrology, the Japanese Society for Dialysis Therapy, and the Japan Society for Transplantation entitled "Selection of Treatment for Renal Failure. Which would be your choice?" is available via the website of the Japanese Society for Dialysis Therapy (available at: <http://www.jsdt.or.jp/jsdt/19.html>).

Addendum 4

Noting the advantages of PD, a PD First policy, has been proposed (23). Considering the situation in Japan, this Committee defines this concept as "the approach" to consider the initiation of PD first for patients with residual renal function in order to maximize the advantages of this therapy. The underlying reason for this concept is the fact that residual renal function is normally well preserved after the initiation

of PD. In this context, residual renal function is defined as a daily urine volume of 100 mL or higher.

Supplementary comment: Initiation criteria for children

In the initiation of dialysis in children, providing information and obtaining consent in a similar manner to adults is necessary. In children, growth and the need for social activities must be taken into consideration. Considering the need for lifetime treatment, including kidney transplantation, an early referral to a pediatric nephrologist is important. Peritoneal dialysis is often selected for children because of its many advantages (24), and it is regarded as the only preferred treatment, particularly for low body-weight children.

The initiation of dialysis in children is also based on renal function, signs, including growth failure, and symptoms of uremia. A GFR of 9–14 mL/min/1.73 m² BSA is recommended by the K/DOQI, and 10–15 mL/min/1.73 m² BSA by the European Paediatric Peritoneal Dialysis Working Group, as indications for the initiation of PD in children (25,26), which is similar to the recommendations in adults. However, the Schwartz formula shown below, which should be used to estimate the GFR in children, is different from the one used in adults.

$$\text{eGFR} = K \times \text{height (cm)} / (\text{serum creatinine level} + 0.2)$$

where the K value = 0.45 for children aged <2 years, 0.55 for those aged 2–12 years, 0.7 for males and 0.55 for females aged 13 years and above. The serum creatinine level is determined enzymatically.

CHAPTER 2: ADEQUACY OF PERITONEAL DIALYSIS

1. The adequacy of peritoneal dialysis must be evaluated regularly according to the removal of accumulated waste products and state of hydration. (*Evidence level VI: Committee opinion*)
2. The efficacy of peritoneal dialysis is evaluated according to the weekly Kt/V_{urea}, which should be maintained at a minimum target of 1.7, using a combined renal and peritoneal clearance of urea. (*Evidence level II*)
3. To avoid fluid overload, an appropriate volume of ultrafiltration must be set, monitored and maintained. (*Evidence level III*)
4. If signs and symptoms of uremia or malnutrition appear, despite the delivery of an adequate dialy-

sis dose, changes in the prescription or therapy should be considered.

(*Evidence level VI: Committee opinion*)

Footnotes

Total Kt/V: Weekly sum of Kt/V_{urea} by peritoneal dialysis and residual renal function

PD Kt/V: Weekly sum of Kt/V_{urea} by peritoneal dialysis

Renal Kt/V: Weekly sum of Kt/V_{urea} by residual renal function

Commentary

1. Definition of adequacy of PD

Adequacy targets for dialysis should include both urea removal and fluid removal; however, many signs and symptoms of uremia cannot be relieved by removal of solutes and fluid alone. Although targets for solute removal by dialysis should include various uremic waste products, most studies have focused especially on the clearance of urea, expressed as Kt/V_{urea}.

The dose of dialysis should be evaluated according to the weekly Kt/V_{urea}, using the sum of Kt/V by peritoneal dialysis and the residual renal function as an index. Management and treatment appropriate for the condition of each patient would be required.

2. Minimum targets of dialysis in peritoneal dialysis therapy

The relationship between the removal of small molecules and the outcome and optimal conditions of PD patients were clearly demonstrated by the results of the CANADA–USA Peritoneal Dialysis Study Group (27). Furthermore, this study confirmed the clinical importance of residual renal function and suggested limitations regarding the impact of peritoneal solute clearance (21). The appropriate peritoneal solute clearance is currently defined by two representative, randomized, prospective, large-scale clinical studies. In the ADMEX Study performed in Mexico, no difference was noted in mortality between a control group (total Kt/V_{urea} = 1.80) and an intervention group in which the volume of PD resulted in a higher peritoneal solute clearance (total Kt/V_{urea} = 2.27), and the difference in peritoneal solute clearance in this range did not contribute to an improvement in the survival rate (28). In a study in Hong Kong, no significant difference was observed in the survival rates between three groups with a total Kt/V_{urea} of <1.7, 1.7–2.0, and >2.0, respectively, but drop out from PD at the physician's discretion was observed more frequently in the <1.7 group, and it was concluded that a total Kt/V_{urea} of ≥1.7 was nec-

essary (29). Moreover, based on a retrospective study in anuric patients, where it was found that the survival rate was highest when the Kt/V_{urea} was 1.67–1.8, it was concluded that the total Kt/V_{urea} should be at least 1.7, and would be adequate at 1.8 (30). On the basis of the above clinical data, a total Kt/V_{urea} of 1.7 is globally recommended as the minimum total clearance to be achieved in PD (31–33).

In Japan, Kumano et al. performed a multicenter survey regarding dialysis dose (34), reporting a total Kt/V of 1.8 and a PD Kt/V of 1.65 (based on the mean value of 239 patients). In this study, 72% of the patients maintained adequate uremic control status, and the nutritional status judged as adequate by physicians reached 71%, supporting the argument that the minimum target of Kt/V of 1.7 may also be appropriate for Japanese PD patients.

Preservation of residual renal function plays a central role for achieving adequacy of dialysis (35). In this respect, it is necessary to avoid dehydration (36), which is a kidney-damaging factor, and to minimize the use of nephrotoxic agents and drugs as much as possible (37). Angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers have been reported to be effective for the preservation of residual renal function in patients undergoing PD (38,39), and they should, therefore, be considered as the first choice for the treatment of hypertension.

3. Avoid overhydration status

The total Na^+ removal and total fluid removal are predictive factors for patient survival, and a high mortality rate has been reported in high transporters of peritoneal membrane, who are likely to have decreased fluid and sodium removal and a higher blood pressure level (40). The cause of drop out from PD due to poor body fluid control has been reported to be high (55%) in Japan (41). Also, the nutritional status of PD patients is reported to improve by correction of hypervolemia (42).

Concerning the relationship between ultrafiltration (UF) volume and outcome, the European Automated Peritoneal dialysis Outcome Study (EAPOS) reported that the prognosis was poor when the daily UF volume was ≤ 750 mL in anuric patients (43); whilst in patients with residual renal function, the body fluid volume is affected by the net balance between water and salt intake and removal, and it is difficult to set a fixed UF volume. Achieving a particular level of UF volume is, however, not the primary target, but maintaining a clinical state without edema, hypertension and cardiac overload is most important (44).

4. Insufficient dialysis

Clinical signs and symptoms. In patients with symptomatic uremia, changes of PD prescription or dialysis modality should be considered. Inadequate uremic control may be associated with poor compliance to PD prescription, inadequate PD prescription by the physician, or medical reasons making uremic control difficult by PD alone. The minimum target of total solute clearance currently recommended is a total Kt/V_{urea} of 1.7, but it must be noted that this value includes the renal clearance. Whether the peritoneal solute clearance and renal solute clearance by residual renal function are clinically equivalent has been controversial (10). If residual renal function is reduced or lost, there is a risk of accumulating not only small, but also middle-sized, uremic molecules (45). Since the index of peritoneal solute clearance is Kt/V based on urea, which is a small molecule, attention should also be paid to the middle-sized molecules such as β_2 -microglobulin. If uremic control remains unsatisfactory, even after achieving the minimum target of total solute (urea) clearance, a change in therapy must be considered (46–48), especially in patients exhibiting persistent anorexia, deterioration of nutritional status, erythropoietin-resistant anemia, drug-resistant hypertension, hypervolemic state, and restless legs syndrome.

- (1) Blood pressure: Hypertension in hemodialysis patients has been shown to be a risk factor for mortality (49), and control of blood pressure by antihypertensive medication reduces cardiovascular morbidity and mortality rates (50). Although there is no report on the effect of blood pressure control on the prognosis of patients undergoing PD, the importance of controlling hypertension is not considered to differ in PD patients.
- (2) Anemia: The 2008 edition of the Guidelines for Renal Anemia in Chronic Kidney Disease by the Japanese Society for Dialysis Therapy recommends ≥ 11 g/dL as a target hemoglobin level of treatment using an erythropoiesis-stimulating agent in PD patients, but urges withdrawal or dose reduction if it exceeds 13 g/dL (51).
- (3) Nutrition: See section on nutrition.

Change in therapy. In Japan, a combination of PD and hemodialysis is performed as a unique style of RRT treatment (46,52,53). This combination therapy is indicated for patients who cannot maintain the minimum target of total solute clearance by standard PD prescription, or who have symptomatic uremia, despite a total $Kt/V_{\text{urea}} \geq 1.7$, or who have a state of

persistent overhydration. A common treatment mode is to perform PD for 5–6 days and one hemodialysis session (4–5 h, using a high flux dialyzer) per week. Criteria for discontinuation of combination therapy are a “high” peritoneal equilibration test, which is a surrogate marker of encapsulating peritoneal sclerosis (see Chapter 5), and the necessity of two or more hemodialysis sessions per week. This therapy benefits patients in maintaining their QOL (54).

Supplementary comment: Appropriate dialysis in children

Unlike in adults, there has been no large-scale study on the adequacy of dialysis in children. Since the growth of children involves the catabolism of protein, importance should be given to the urea dynamics, as in adults, and the Kt/V_{urea} should be used as an index of the adequacy of dialysis. There have been reports that an increase in Kt/V_{urea} had favorable effects on growth and cardiac function, but they do not serve as sufficient evidence because of the small number of patients in these studies (55,56). Also, the protein requirement per kilo body weight is high in children, and a proportionate solute clearance is, therefore, considered to be necessary; however, there has been no clinical research on this matter, including the potential risk of an increased total solute clearance. The K/DOQI proposes a total Kt/V_{urea} , including renal Kt/V , of 1.8 (25), but a higher total solute clearance may be needed in some patients depending on age, food intake, and urea nitrogen level. Preservation of residual renal function is also important in children, and residual renal function has been reported to be the only factor related to growth (57). Maintenance of euvolemia is important to maintain cardiac function that can withstand the volume overload associated with kidney transplantation. Also, cardiovascular disease is responsible for 44% of deaths in children on PD (58). Milk feeding in infancy contains more water relative to the necessary amounts of nutrients and is likely to induce fluid overload in infants with decreased residual renal function. On the other hand, infants are at reduced risk of dehydration due to a decrease in the milk suckling strength, and the potential for diarrhea and vomiting. Consequently, very careful body fluid management is necessary.

The normal blood pressure in children differs from that in adults, and blood pressure should, therefore, be controlled according to age-adjusted targets. Criteria for hypertension in children have been repeatedly revised since their recommendation in 1987 by an American task force (59); however, no data are available for targets of blood pressure control in chil-

dren undergoing PD. Presently, the goal for antihypertensive treatment in children should be the reduction of blood pressure to less than the 95th percentile unless comorbidities are present, in which case the blood pressure should be lowered to less than the 90th percentile (59).

CHAPTER 3: ADEQUATE NUTRITION IN PERITONEAL DIALYSIS

1. As PD patients have increased risks for the development of malnutrition due to glucose overload and protein loss, individualized nutritional guidance should be provided to all patients. *(Evidence level VI: Committee opinion)*
2. Patients' nutritional status should be assessed routinely using multiple indices. *(Evidence level VI: Committee opinion)*
3. If deterioration of the nutritional status is observed, the prescription of dialysis should be re-evaluated and nutritional intervention performed. *(Evidence level VI: Committee opinion)*

Commentary

1. Malnutrition in PD patients

In chronic dialysis patients, malnutrition is a significant risk factor for patient mortality and low QOL. In PD, it is reported that nutritional status is severely impaired in 5–10%, and mildly or moderately impaired in 30–60% of all patients (60–62). The primary mechanisms of malnutrition in CKD include protein and energy deficiency and systemic inflammation, while the most prolific is a combination of these two factors (63). In PD, overhydration status, which present in one-third of patients (64), is closely connected with the development of malnutrition (65). Furthermore, glucose loading, which suppresses appetite, and loss of protein and amino acids into the dialysate could be additional risk factors for progression of protein energy malnutrition. The nutritional status may be worsened by the loss of residual renal function, or may possibly be due to inadequate dialysis (66,67). For these reasons, monitoring of nutritional status is necessary in all PD patients.

Total energy intake. In the calculation of the total energy intake (dietary energy intake + transperitoneal energy intake), the standard body weight should be based on a body mass index (BMI) of 22; therefore:

$$\text{Standard body weight (kg)} = \text{height (m)}^2 \times 22$$

The recommended total energy intake should be adjusted to 30–35 kcal/kg/day using the standard body weight, which should be set for individual patients according to their age, gender, presence of diabetes, and physical activity level (68). Transperitoneal glucose absorption is influenced by the concentration, total volume, and dwell time of the dialysate and peritoneal function. Nutritional assessment should be performed by subtracting the transperitoneal energy uptake, which is assumed to be approximately 70 kcal in the case of two liters of 1.5% glucose solution over a four-hour dwell, 120 kcal for 2.5% glucose, and 220 kcal for 4.25% glucose solutions (69). PD increases the risk of cardiovascular complications by inducing hypertriglyceridemia, low-HDL cholesterolemia, and the development of obesity by sustained glucose loading (70–72). In diabetic patients, 30–32 kcal/kg/day is considered to be appropriate (73).

Protein intake. In PD, protein losses into the dialysate reach up to 10 g/day; however, this loss is affected by the dialysis prescription, with increased loss occurring with increasing dialysate volumes (74). Therefore, a target protein intake of 1.2 g/kg/day or higher based on the standard body weight has been proposed (75,76), although its theoretical basis is unclear. However, lower protein intake is always accompanied by a lower energy intake, and it is reported that the nutritional status is not worsened when the energy intake is appropriate (66). There is also a report from China concluding that malnutrition is not necessarily induced even when the protein intake is <0.8 g/kg, suggesting that concurrent comorbidities, including hypervolemia, developing during the follow-up to be more clinically important (77). According to the survey by Ishizaki et al. regarding the protein intake in 100 stable Japanese PD patients, the regression line between the normalized protein nitrogen appearance (nPNA) and the percentage creatinine generation rate (%CGR), an index of the muscle component of the body, revealed that a nPNA of 0.9 g/kg/day corresponds to a %CGR of 100% (78). This indicates that the protein intake at which the nutritional state of PD patients is maintained at an adequate level is ≥ 0.9 g/kg/day. We recommend 0.9–1.2 g/kg/day as the target protein intake for Japanese PD patients under the condition of an appropriate energy intake.

Salt intake. Excessive salt intake is closely correlated with inadequate protein intake, which leads to malnutrition and hypertension, and increases the risk of cardiovascular complications (65,77,79). The Japa-

nese Society of Nephrology guidelines recommend a salt intake for PD patients based on the need to balance the intake vs. the amount removed, as shown in the following formula:

$$\text{Salt intake} = \frac{\text{water removal (L)} \times 7.5 \text{ g} + 0.5 \text{ g}}{100 \text{ mL urine volume}} \text{ (68)}$$

Therefore, in PD patients with a declining residual renal function, a salt intake of approximately 7.5 g/day is the maximum limit in patients with an UF volume of 1 L/day. A European study in anuric, automated PD patients found that the outcome was more favorable with UF of ≥ 750 mL, equivalent to a salt removal of ≥ 5.6 g/day (43). As indicated above, guidance on salt intake should be given in consideration of the urine and UF volume of each patient. Indeed, the actual measurement of sodium removal is desirable, especially in cases on automated PD (80).

2. Evaluation of the nutritional status

The nutritional status should be judged by comprehensive evaluations and be performed routinely, at least once every six months. Absence of a progressive decrease in muscle mass is the most important index for assessment of the nutritional status. In this regard, serial body measurements and body composition analysis are extremely important.

Subjective global assessment (SGA). Those physical and clinical features such as gastrointestinal symptoms, body weight changes, and state of dietary intake, are systematically scored as the SGA. The usefulness of SGA scoring in PD patients has been reported (81).

Body measurements. Body measurements are important for the assessment of the patient's nutritional status. In addition to body height, weight, and BMI, mid-upper arm circumference (AC) and triceps skinfold thickness (TSF), arm muscle circumference (AMC), and arm muscle area (AMA) are used as nutritional indices for the estimation of the body muscle and fat masses, but it must be noted that they are affected by the extracellular fluid volume. Recently, muscle strength has also been suggested as an index related to nutritional status and outcome (82).

Methods for body composition analysis. The methods for body composition analysis recognized to be the most reproducible and effective for the assessment of body protein quantity are dual-energy X-ray absorptiometry (83) and bioelectrical impedance

analysis (80,84,85). The latter should be performed after drainage of dialysate.

Blood laboratory tests. For nutritional assessment, serum albumin and prealbumin are commonly used. The serum albumin level is strongly predictive of mortality in patients with ESRD (86); however, in PD patients, many factors affect the serum albumin level, such as inflammation, loss of albumin into the dialysate, and fluid overload (87). Since the serum albumin level has a negative correlation with the level of acute phase protein (88), it is important to explore the presence of malnutrition associated with inflammation, which predicts high mortality in PD patients (89).

3. Nutritional intervention

Malnutrition in PD patients is commonly related to insufficient nutritional intake, loss of nutrients into the dialysis fluid, the presence of chronic inflammation, and uremia due to inadequate dialysis. If a worsening of malnutrition is noted, its cause should be identified and treated, and appropriate nutritional guidance should be provided (90). In cases of severe malnutrition, formulas such as oral high-energy liquid diets are effective. Improvement in the nutritional status by the use of amino-acid-containing peritoneal dialysis fluid has been reported (91), but such a PD solution, at present, is not available in Japan. The effectiveness of nutritional intervention is limited in inflammation-type nutritional disorders, and control of the underlying inflammation is necessary. A change in the PD prescription or a transfer to another modality is needed in patients for whom the targeted dialysis dose cannot be achieved.

Supplementary comment: nutrition in children

For sufficient growth and development of pediatric patients, appropriate total energy and protein intakes are critically important, but there is no sufficient evidence concerning the appropriate amount to be recommended. According to recommendations such as the Dietary Recommendations for Children with Chronic Kidney Disease by the Japanese Society of Nephrology (92), and the Dietary Reference Intakes (2005 edition) (93), energy intake from glucose absorption from dialysate should be considered in evaluating energy intake. We recommend an incremental intake of 0.4 g/kg/day in consideration of losses via the dialysate for Japanese patients. Since a high percentage of children are treated with automated PD, glucose absorption from and protein loss to the dialysis fluid should be measured using the total volume of dialysis solution. Insufficient energy intake is a major factor in growth failure in infants

and small children (94), and tube feeding should be considered in those with insufficient oral intake.

In children, body height is useful and convenient for nutritional assessment. Indices related to height used for nutritional assessment are deviation from the standard height (standard deviation score [SDS]), annual growth rate, and use of a growth curve to examine changes in these indices are recommended in Japanese children.

The height SDS decreases gradually in many children undergoing PD (95), and recombinant human growth hormone (rhGH) therapy should be considered if a growth retardation is observed (height SDS $\leq -2SD$, annual growth rate $\leq -1.5SD$) despite sufficient nutritional intake. While the short term rhGH therapy is effective for increasing height, the effect of long-term rhGH therapy on increasing the final height have also been reported (96), but many patients eventually require transplantation and no conclusion has been reached concerning the effects of this therapy.

CHAPTER 4: EVALUATION OF PERITONEAL FUNCTION

1. Peritoneal membrane function changes with time on therapy. Peritoneal function must be evaluated regularly by the peritoneal equilibrium test (PET) using the standard or simplified method ("fast PET").

(Evidence level VI: Committee opinion)

2. Peritoneal function should be assessed once every 6–12 months, as well as early after the initiation of PD and during a recovery period from peritonitis.

(Evidence level V)

Commentary

1. Peritoneal equilibration test

A test of peritoneal function proposed by Twardowski et al (97), and used worldwide is the PET. In the original method for this test, 2.0 L of 2.5% Dianeal (glucose concentration 2.27%) is dwelled for four hours. Two and four hours after infusing the dialysis fluid, the ratios between creatinine in the dialysate (D) and in the plasma (P) (D/P Cr), and between the glucose concentration in the dialysate and its initial concentration (D₀) (D/D₀ Glu) are determined (see Appendix 2). If the evaluation is performed according to the values four hours after infusion alone, the test is called the frequent and short time PET (fast PET). The test results are plotted on the standard curve, and the peritoneal membrane permeability is categorized into "High", "High Average", "Low Average", and "Low". Using

PET, peritoneal permeability can be evaluated without a special device or software, and irrespective of residual renal function.

When the efficiency of urea elimination by standard PD is evaluated, the D/P ratio of urea is nearly 1.0 after a dwell of ≥ 6 h in both patients with “High” and “High Average” transport status. However, as the ultrafiltration volume is lower in “High” than in “High Average” patients, the amount of solute clearance is often smaller in the “High” patients; thus, high permeability (i.e. “High” results in the PET) does not necessarily concur with better dialysis efficacy. Special software is necessary to estimate dialysis efficiency from the results of PET.

2. When to perform PET

It is desirable to test peritoneal function periodically once every six months to one year to check the patient’s condition. In this situation, a simple method is recommended for comparison with past data, rather than strict evaluation of the permeability. If data are accumulated by a standardized method, the test should be performed periodically using the same method. When the test is performed for the first time, for example, in patients beginning dialysis therapy, PET, which is most common throughout the world, is recommended.

PET should be conducted early after the initiation of dialysis, in the recovery period after treatment for peritonitis, and after changing the PD prescription. Baseline data obtained early after initiation are useful for comparing peritoneal function longitudinally; however, as the results of the peritoneal function test performed within one month after starting PD are reported not to accurately reflect the patient’s peritoneal function when receiving PD treatment (98,99), it is recommended to perform the PET ≥ 4 weeks after initiation (99). As the permeability is increased during the course of peritonitis, water removal often becomes difficult when glucose is used as the osmotic agent (100,101). Impairment of the peritoneal function due to peritonitis is often temporary (100,101), and the UF volume recovers in general within three days after the appropriate treatment for peritonitis (102). In consideration of relapsing or recurrent peritonitis, it is recommended to perform PET ≥ 4 weeks after the infection (103). The peritoneal function test should be performed when insufficient UF or symptomatic uremia is observed. Caution is necessary when icodextrin solution is retained over the long dwell before the PET, because it may shift the result to the hyperpermeable side, as compared with the use of glucose solution alone (104).

Supplementary comments: Peritoneal function test for children

The principles and methods of PET in children are the same as those in adults. The results of PET in children have been reported in Western countries, and from 175 children in Japan by the Child PD Study Group, after exclusion of the effect of peritonitis (105). A difference was noted in the volume of dialysate used for PET compared with adults. The results of PET differed depending on the volume of dialysate. Since the body surface area correlates with the peritoneal area regardless of age, the volume of dialysis should be calculated relative to the body surface area. The PD solution infusion volume for PET in children should be 1.100 mL/m² BSA.

CHAPTER 5: DISCONTINUATION OF PERITONEAL DIALYSIS TO AVOID ENCAPSULATING PERITONEAL SCLEROSIS

1. If progression of peritoneal deterioration is confirmed in patients with long-term PD or after peritonitis, discontinuation of PD should be evaluated with a due consideration of the risk of development of encapsulating peritoneal sclerosis (EPS). (*Evidence level IV*)
2. It is recommended to routinely perform the peritoneal equilibrium test (PET) to evaluate peritoneal deterioration. (*Evidence level VI: Committee opinion*)

Footnotes

Peritoneal deterioration is a concept that includes a decrease in peritoneal function resulting from changes in the peritoneal morphology. A decrease in peritoneal function is characterized by insufficient UF and enhancement of peritoneal permeability. Morphological changes refer to findings by laparoscopy, histological examination of the peritoneum, and cytology of mesothelial cells in the drained fluid.

Commentary

1. Peritoneal deterioration and encapsulating peritoneal sclerosis

In Japanese PD patients, the incidence of EPS is reported to be 0.9–2.4% (106–109), and the negative consequences of this complication are extremely detrimental in regards to a continuation of PD. Deterioration of the peritoneal function is considered to be involved in the development of EPS. Underlying diseases, such as diabetes, aging, uremic toxins, drugs, peritonitis, and various biological stimulants endogenously present in the PD therapeutic system, are thought to contribute to the etiology of EPS, with its

severity generally considered to increase with the time on PD. The effects of peritonitis and the likely biological incompatibility of the PD solution, in particular, are considered to be important. The latter includes acidity, high lactate concentration, high osmotic pressure, high glucose concentration, and glucose degradation products (109,110).

In 1997, the Chronic Renal Failure Study Group of the Long-Term Comprehensive Research Project on Chronic Diseases of the Ministry of Health and Welfare (Study Group on the Assessment and Indications of CAPD Therapy) presented the Guidelines for the Discontinuation of CAPD for the Prevention of Sclerosing Encapsulating Peritonitis (SEP [here, EPS]) in the Guidelines for the Diagnosis and Treatment of Sclerosing Encapsulating Peritonitis (draft) (106,111), which mention a decrease in peritoneal function, peritonitis, and PD duration (≥ 8 years) as factors associated with an increased risk for EPS. Later, a prospective, observational study carried out in Japan confirmed an increasing incidence of EPS with duration of PD therapy, being 0, 0.7, 2.1, 5.9, 5.8, and 17.2% in patients having undergone PD for 3, 5, 8, 10, 15, and ≥ 15 years, respectively (108). Thus, a relationship between the duration of PD therapy and the risk of EPS is evident; however, complete avoidance of EPS is impossible, even by limiting the treatment period. Furthermore, the biocompatibility of PD solutions has improved in Japan, and neutral PD solutions with reduced glucose degradation products are today used as a standard, but the effect of using neutral PD solutions on EPS occurrence has not yet been studied. Under these circumstances in Japan, it is presently difficult to clearly provide guidance relative to a restriction of the duration of PD therapy to avoid EPS. On the other hand, peritonitis has been reported to occur 3.3 times more frequently in those who develop EPS than in those who do not (106), suggesting a close relationship with peritonitis. But the influence of peritonitis is not considered to be the same among all patients; a single episode of peritonitis may have triggered EPS in patients having undergone PD for a long time (112). In addition, a decrease in peritoneal function, time on PD, and the number of peritonitis episodes are likely mutually interrelated, and the independent effect of each factor on the risk of EPS has not been sufficiently evaluated (113). From the above observations, it is important to individually and serially evaluate and estimate the degree of peritoneal deterioration to prevent EPS.

2. Methods to assess peritoneal deterioration

Characteristics of reduced peritoneal function include insufficient UF and increased peritoneal per-

meability. In Japan, the notion of UF failure due to peritoneal deterioration is clinically defined as a 24-hour UF volume < 500 mL when using 2.5% glucose dialysis solution (2 L) four times a day (111). Peritoneal permeability is investigated by examining the D/P creatinine ratio (D/P Cr) as given by PET. Morphological changes of the peritoneum can be identified via laparoscopy (114,115), peritoneal biopsy of the parietal wall (116), and cytological examination of mesothelial cells in drained PD solution (117), commonly displaying specific alterations. Humoral factors in the drained PD solution, such as cancer antigen 125, hyaluronic acid, matrix metalloproteinase-2 (MMP-2), interleukin-6, vascular endothelial cell growth factor, and clotting and fibrinolytic factors, have been reported to be useful as markers of peritoneal deterioration (118–122). Moreover, there have been reports that an increase in the circulating β_2 -microglobulin level (123) and gene polymorphisms (124) are involved in tissue damage. Previous studies have confirmed the interrelations between histological changes, cytological findings of mesothelial cells, D/P Cr, and humoral factors (125–128).

To date, clinical the studies in Japan have shown that D/P Cr (129–131), mesothelial cell area (132), and MMP-2 in the drained PD solution (120) are significantly related to the development of EPS; however, the D/P Cr value from a single test is not sufficiently predictive of EPS, and monitoring the time-course changes are necessary (131). Widening of the mesothelial cell area is correlated with an increased risk of EPS (132), although there are concerns with respects to sensitivity and specificity in using this parameter as a predictive tool. The same issue applies to the use of the MMP-2 level in the drained PD solution. Thus, it is very hard to evaluate peritoneal deterioration by a single test, and, at present, no examination can be an absolutely reliable diagnostic method alone. For this reason, comprehensive judgment based on the results of multiple examinations is needed. Presently, the establishment of a simple and highly reproducible method with high sensitivity and specificity is extremely important.

In the present guidelines, the Committee recommends PET to be performed at least once a year as a basic routine test to identify peritoneal deterioration, as it is an objective, simple, cost effective, and non-invasive test. In patients showing serial increases in the D/P Cr resulting in a “high” D/P Cr sustained over 12 months, one could suspect progression of peritoneal deterioration, and discontinuation of PD should be considered.

Since 70% of the cases of EPS occur after discontinuation of PD (108), monitoring the changes in the peritoneal cavity after discontinuation of PD is also clinically important. In patients having undergone PD over a long period and suspected of having peritoneal deterioration, the retention of the PD catheter for a period after discontinuation of PD to allow for monitoring of changes in the drained PD solution and peritoneal function is considered essential in managing high-risk patients (131,133). This should be performed, however, with the risk of peritonitis in mind.

Supplementary comment: EPS in children

In PD patients in whom PD is initiated in childhood, attention to the risk of EPS is also necessary. In Japanese patients in whom PD was initiated at an age of 15 years or younger, EPS has been reported to have occurred in 2% of all patients, in 6.6% of those who had undergone PD for 5 years or longer, and in 22% of those who had undergone PD for 10 years or longer (134). However, as the number of pediatric patients is insufficient for valid analysis, the criteria for adults should be used to evaluate the risk of EPS and peritoneal deterioration in this patient category.

APPENDICES

Appendix 1

Committee members

Masaaki Nakayama (Chairperson)
 Hideki Kawanishi (Chairperson of the Scientific Subcommittee)
 Tadashi Tomo (Chairperson of the Guidelines Subcommittee)
 Hideki Hirakata (Supervisor)
 Takashi Akiba (Supervisor)
 Makoto Hiramatsu
 Noritomo Itami
 Kenji Kasai
 Yoshie Kanazawa
 Ikuto Masakane
 Hidetomo Nakamoto
 Nakahiro Wada
 Akihiro Yamashita

Appendix 2

Methods to evaluate the dose of dialysis

These guidelines recommend the Kt/V_{urea} as an evaluation index, but the creatinine clearance may also be used. In the combination therapy of hemodi-

alysis and PD, the adequacy of dialysis should be determined using the concept of the body fluid clear space (135). These indices are calculated as follows.

A. Urea Kt/V (Kt/V_{urea})

1. The usual dialysis fluid is injected.
2. After t (min), the fluid is drained as usual, the drainage volume ($V_D(t)$) is recorded and a sample of drained dialysis fluid ($C_D(t)$) is collected.
3. [1] and [2] above are repeated for the day.
4. On the same day, blood is sampled, and the blood urea nitrogen concentration (C_B) is determined.
5. The amount of eliminated urea nitrogen ($V_D(t) \times C_D(t)$) for the day (four times) is summed and the total is divided by C_B .
6. The Kt/V for the day is calculated by dividing the result of [5] by the body fluid volume (V_B). V_B (mL) is calculated from the correlations with the height (HT [cm]) and body weight (BW [kg]). The following are typical correlation equations.

Hume and Weyers equation (136):

$$V_B = 194.786 \times HT + 296.785 \times BW - 14012.934 \quad (\text{male})$$

$$V_B = 344.547 \times HT + 183.809 \times BW - 35270.121 \quad (\text{female})$$

Watson and Watson equation (137):

$$V_B = 107.4 \times HT + 336.2 \times BW + 2447 - 95.16 \times \text{age} \quad (\text{male})$$

$$V_B = 106.9 \times HT + 246.6 \times BW - 209.7 \quad (\text{female})$$

7. The Kt/V for the week is calculated by multiplying the result of [6] by 7.

Note: Instead of [1]–[3] above, the total volume of drained fluid (8–10 L) for the day may be collected in a vessel, and the total amount of elimination for the day may be calculated from the urea nitrogen concentration and volume of this solution.

B. Creatinine clearance ($CrCl$)

1. The usual dialysis fluid is injected.
2. After t (min), the fluid is drained as usual, the drainage volume ($V_D(t)$) is recorded and a sample of drained dialysis fluid ($C_D(t)$) is collected.
3. [1] and [2] above are repeated for the day.
4. On the same day, blood is sampled, and the creatinine concentration (C_B) is determined.
5. The amount of eliminated creatinine ($V_D(t) \times C_D(t)$) for the day (four times) is summed, and the $CrCl$ of for the day is calculated by dividing the sum by C_B .

6. The body surface area (BSA [m^2]) is calculated, and the Ccr per $1.73 m^2$ is calculated by multiplying the Ccr for the day determined in [5] by $1.73/BSA$. The BSA is calculated using the Du Bois equation (138).

$$BSA = 0.007184 \times HT(0.725) \times BW(0.425)$$

where height (HT [cm]) and body weight (BW [kg]).

7. The Ccr for the week is calculated by multiplying the result of [6] by 7.

Note: Instead of [1]–[3] above, the total volume of drained fluid (8–10 L) for the day may be collected in a vessel, and the total amount of elimination for the day may be calculated from the urea nitrogen concentration and volume of this solution.

C. Dialysis dose in combination therapy of PD and hemodialysis The procedure using the body fluid clear space is described below. The target solute is urea nitrogen, in principle, but the evaluation of other solutes is possible by the same method.

1. The usual dialysis fluid is injected.
2. After t (min), the fluid is drained as usual, the drainage volume ($V_D(t)$) is recorded, and a sample of dialysis fluid ($C_D(t)$) is collected.
3. [1] and [2] above are repeated for the day (see Note 1).
4. On the days of PD, [1]–[3] above are repeated.
5. The amount of eliminated urea nitrogen ($V_D(t) \times C_D(t)$) is summed for the day, and the daily amounts of eliminated urea nitrogen on the days of PD are totaled (see Note 2).
6. On the days of hemodialysis, the blood is sampled before treatment, and the $C_B(0)$ of urea nitrogen is determined.
7. During hemodialysis, the total volume (or part) of the dialysis fluid is pooled, and the total amount of eliminated urea nitrogen is calculated (139).
8. The total amount of eliminated urea nitrogen determined in [7] is divided by $C_B(0)$.
9. The clear space for the week is calculated by summing up the results of [5] and [8].

Note: 1. Instead of [1]–[2] above, the total volume of drained fluid (8–10 L) for the day may be collected in a vessel, and the total amount of elimination for the day may be calculated from the urea nitrogen concentration and volume of this solution.

2. Step [4] above must not be substituted for the amount of eliminated urea nitrogen on a day multiplied by the number of days of PD, because the blood urea nitrogen concentration changes markedly, and the eliminated amount varies widely from day to day, even on the same regimen.

Acknowledgment: The Committee expresses their special thanks to Dr Anders Tranaeus for comprehensively reviewing the English language version of the guidelines.

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