Renal Replacement Therapy

REVIEW

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Historical overview and current practice of peritoneal dialysis in Japan

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Abstract

In the early days of peritoneal dialysis (PD) therapy, its limited duration and peritoneal deterioration were argued to be its disadvantages. Biocompatible solutions and hybrid therapy have been used in Japan to overcome these issues, which resulted in a decrease in encapsulating peritoneal sclerosis (EPS) incidence and an extension of PD continuation; these results have been disseminated worldwide. Peritoneal dialysis outcomes and practice patterns study (PDOPPS), a prospective observational study, has begun to confirm the outcomes of PD therapy, and sufficient evidence has been published, which has influenced the preparation of PD guidelines. Current thinking about PD emphasizes the need to maintain quality of life and life goals as care goals for patients and to provide high-quality care. However, we must conduct basic research on the prevention of peritoneal deterioration.

Keywords: Peritoneal dialysis, PDOPPS, Hybrid therapy, Low GDPs solution

Introduction

In the 1960s, chronic dialysis therapy the world over relied on the Seattle Scribner Group [1]. They laid the foundation for chronic hemodialysis (HD), home HD, peritoneal dialysis (PD), and vascular access. Since then, dialysis therapy has been developed and improved upon by medical professionals from various countries. Figure 1 shows the development of PD therapy, focusing on the name of the primary innovator.

In Japan, dialysis therapy by Scribner-educated doctors began in 1965. Owing to the rapid rise in the number of patients on dialysis, the Japanese central dialysate delivery system has become widespread. As a result, stable and consistent HD is possible in all regions.

From the perspective of PD, this review discusses what we have learned from the world, what has influenced worldwide PD therapy, and the importance of interacting with the international PD healthcare community.

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The issues of peritoneal dialysis and resolution measures

PD therapy was established as home dialysis in 1976 with the development of continuous ambulatory peritoneal dialysis (CAPD) therapy by Popovich and Moncrief [2, 3]. The CAPD system was introduced in Japan in 1985, and various changes and improvements have been seen since the entry of domestic and overseas manufacturers into this field. However, PD using biological membranes is associated with complications such as peritonitis, catheter infection, and peritoneal deterioration.

In 1985, Shaldon ironically stated, "CAPD is a Second-Class Treatment" [4]. He cited (1) a short treatment duration and (2) sclerosing peritonitis secondary to peritoneal deterioration as his reasons for this statement.

These two problems were not addressed and manifested as an encapsulating peritoneal sclerosis (EPS) storm in the 1990s in Japan [5, 6]. Biocompatible neutral bicarbonate dialysis solutions (low-glucose degradation product [GDP] solutions) for preventing peritoneal deterioration have been shown to be effective in Europe since 1996. However, it has not gained popularity due to its high cost in the worlds. Conversely, in Japan, a neutral lactate solution was introduced in 2000, and all PD

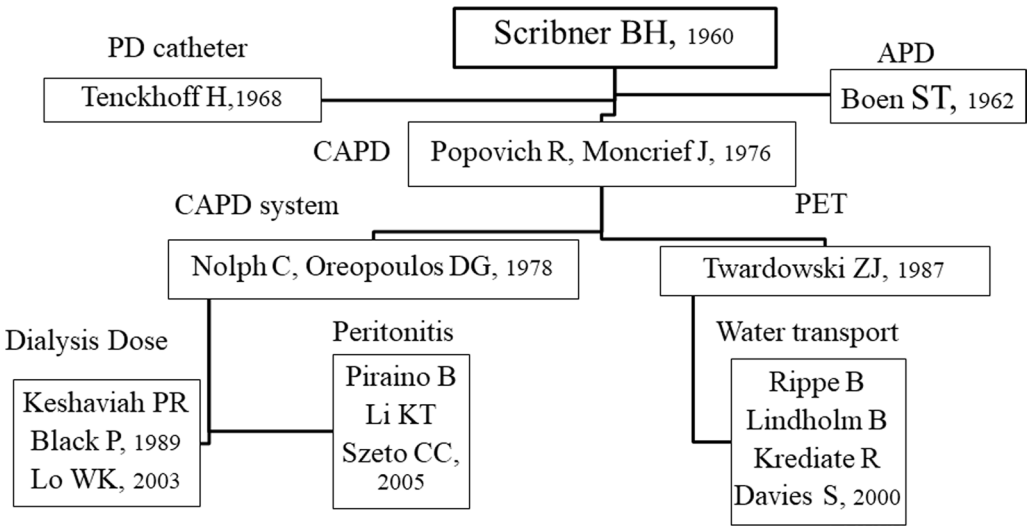

Fig. 1 Historical development of peritoneal dialysis, focusing on the name of the central person

solutions were rapidly replaced by this low-GDP solution, resulting in a reduction in EPS [7].

Another factor affecting PD continuation is fluid overload after residual renal function decline; this has also been overcome by hybrid therapy (PD and HD) that became common in Japan in the 1990s [8].

Due to fewer kidney transplants, long-term dialysis therapy is necessary in Japan. By actively incorporating a low GDP solution and hybrid therapy, more stable PD therapy can be performed than that in other countries. Japan was the first to break away from "Second-Class Treatment." The use of low GDP solutions and hybrid therapy are important innovations presented to the world by Japan as regards PD therapy.

Due to the medical fee system, the medical cost difference between PD and HD is small (although PD is slightly expensive), and there appears to be no economic difference between the two [9].

Unlike HD, PD, which uses biological membranes, uses limited medical consumables. Therefore, prescriptions differ by region or country. Furthermore, with the exception of low GDPs and icodextrin solutions, the development of PD solutions has remained unchanged. PD therapy has not been the focus of additional scientific development. There were many basic studies on peritoneal biocompatibility, deterioration, and regeneration in the early days of PD therapy; however, these studies are now scarce.

Peritoneal dialysis outcomes and practice patterns study

The peritoneal dialysis outcomes and practice pattern study (PDOPPS) was an observational prospective cohort study of subjects and dialysis facilities conducted in several countries [10]. The survey period was three years for each phase; the study was started in mid-2013. The survey styles and methods used in the dialysis outcomes and practice pattern study (DOPPS) were adopted. Unlike DOPPS, it is a joint study with the International Society for Peritoneal Dialysis (ISPD), the Data Integration Center (Arbor Research Collaborative for Health), and the ISPD Committee (workgroup), which manages data under the Steering Committee that controls it and has been established and operated based on these discussions.

Selection of countries and survey facilities: Phase 1 (2014–2017) participants included Canada (Can), Japan (Jpn), the United Kingdom (UK), the United States of America (USA), Australia/New Zealand (A/NZ), and Thailand (Thai); Korea was added in Phase 2. These countries were chosen for their geographically diverse characteristics, differences in practice and prognosis, and relatively large numbers of PD patients.

Facility selection method: The facilities (treating > 15 PD patients) were randomly selected based on characteristics such as geographical conditions and type of public/private according to the basic data of dialysis patients in that country (Japanese Society for Dialysis Therapy (JSDT) in Japan). The Japanese Society for Peritoneal Dialysis (JSPD) is a representative organization in Japan.

A PD-CENSUS (Census Form) list for each facility was created at the start of the survey, and patients were randomly selected from this list. If a patient dropped out of the study, another patient who had been in the facility since the last selection period was chosen to replace that patient.

Objectives and outcomes of the PDOPPS survey: The primary objective of PDOPPS is to clarify the association between PD prescription and patient outcomes, thus improving survival and quality of life. Since the treatment prescriptions differ depending on the facility and the clinical outcomes are adjusted according to the patient characteristics that vary from facility to facility, some relationships are found between the patient treatment prescriptions and the prognosis, even when patient characteristics are considered. The outcomes (goals) were based on these premises (Table 1). Although DOPPS stipulated patient death as the primary outcome, PD often results in death after the transition to HD; therefore, technical failure is the primary outcome of PDOPPS.

Publication of PDOPP: Since 2012, results have been published by the American Society of Nephrology (ASN) and the European Renal Association (ERA), and many papers have been published or planned to date (Table 2).

Characteristics of Japanese PD in PDOPPS

Patient characteristics: The patient characteristics are almost the same in developed countries, with the exception of Thailand and Japan. In Japan, the patients are slightly older and have been undergoing PD for a longer duration. No hindrances were observed in the treatment comparisons for any country. Patients in Thailand were young and had a high rate of diabetes, which is characteristic of Southeast Asia [11].

Interestingly, caregiver involvement in PD bag exchange is exceptionally high in Thailand [11]. In Thailand, the PD-first policy forms the basis of dialysis therapy, and caregivers are required to assist in its

Table 1 Purpose of PDOPPS

Main outcomes
The risk of withdrawal from PD in prescriptions
Second outcomes
Evaluate the impact of PD prescriptions on
Mortality
Withdrawal from PD (transfer to HD)
Reasons of withdrawal
PD-related Complications
The following six workgroups were established as ISPD committees to consider these investigations
Clinical Application of PD Therapy
PD Catheter Access and Function
Patient Training and Education
Dialysis Prescription and Fluid Management
Infection Prevention and Management
Patient Support

Table 2 Publication of PDOPPS

Methodology	
PDOPPS: Unifying Efforts to Inform Practice and Improve Global Outcomes	Perit Dial Int 2016 [10]
Infection-peritonitis	
Regional variation in the treatment	Nephrol Dial Transplant 2019 [13]
Peritoneal Dialysis-Related Infection Rates and Outcomes	Am J Kidney Dis 2020 [17]
Variation in Peritoneal Dialysis-Related Peritonitis Outcome	Am J Kidney Dis 2022 [18]
Low Serum Potassium Levels	Kidney Int Rep 2020 [16]
International peritoneal dialysis training practices	Nephrol Dial Transplant 2022 [14]
QOL/patient's condition (not quoted in the text)	
Patient-reported advantages and disadvantages	BMC Nephrol 2019
Burden of Kidney Disease, Health-Related Quality of Life	Am J Kidney Dis 2021
The Association of Functional Status	Perit Dial Int 2019
PD prescription	
International comparison of peritoneal dialysis prescriptions	Perit Dial Int 2020 [11]
International Icodextrin Use	Kidney360 2022 [12]
Anemia	
International Anemia	Perit Dial Int 2019 [19]
Outcomes	
Mortality, hospitalization, and transfer to hemodialysis and hybrid therapy	Perit Dial Int 2022 [24]
Variation in Peritoneal Dialysis Time on Therapy	Clin J Am Soc Nephrol 2022 [22]
MBD	
Association of Single and Serial Measures of Serum Phosphorus	Nephrol Dial Transplant 2022 [20]

Displaying part of title, publication, reference number

maintenance. This indicates that caregiver involvement is necessary. It should also be devised for older patients with PD in Japan.

PD prescriptions: The primary distinguishing feature of PD in Japan is that the percentage of PD patients on automated PD (APD) is 37%, which is lower than that on CAPD; however, the reverse is seen in other countries. The total Kt/V indicated that the dialysis dose for APD was 1.83; it was 1.91 for CAPD, and 46% of the patients had a total Kt/V of ≤ 1.7, which is lower than that in other countries in terms of dialysis dose and dialysate usage (average 6.56 L) [11].

PD solutions: The usage rate of icodextrin solutions was 43% or more in Japan, almost the same as that in developed countries other than the USA. In the USA, the 3.86% glucose solution concentration was high. In Japan, 3.86% glucose is not used; low-glucose concentration dialysate is the norm [11]. However, the total water removal, mortality rate, and transition to HD did not differ with or without icodextrin in PDOPPS countries. [12]. Furthermore, biocompatible low-GDP solutions have been used in almost 100% of cases in Japan [11].

PD-related infections: The treatment for infections in Japan differs from that in other countries. Intraperitoneal administration of antibacterial agents and agents to prevent exit-site infection is uncommon [13, 14]. Some of these results also influenced the development of the JSDT-PD guidelines in 2019 [15]. A relationship between the incidence of peritonitis and hypokalemia has also been reported [16].

Although the incidence of peritonitis in Japan is low (0.26-year incidence) [17, 18], there is a significant disparity in the quality of care between facilities in all regions and countries, including Japan. If this disparity is corrected, the incidence is expected to decrease further.

Anemia management: The achievement rate of the target hemoglobin was the same in developed countries, but Japan was the only country using long-acting erythropoiesis-stimulating agent (ESA) preparations in almost 100% of the PD patients [19]. This indicates a lack of self-ESA injection at home. In iron condition, ferritin levels ≤ 300 ng/mL are as high as 83%, and iron prescription is limited, as in HD patients.

Mineral bone disorder (MBD) management: The association of serum phosphorus and parathyroid hormone (PTH) levels with outcomes was investigated, and it was revealed that hyperphosphatemia (especially persistent hyperphosphatemia [high ACU]) correlated with mortality[20], similar to HD [21]. The risks of both high and low PTH levels were assessed, and the risks differed from those of HD (manuscript in preparation). Continuous treatment may have an effect on this and will be a topic for future research.

Outcomes: The primary outcome was the transition from PD (death or HD). However, the situation differs from country to country, making it difficult to make a general comparison.

In particular, the rate of kidney transplantation was low in Japan and Thailand (2%), and there was an inverse correlation between transplantation rate and PD duration (average PD duration in Jpn was 3.2 years; Thai, 2. 8 years; the USA, 2.3 years; Can, 2. 2 years; A/NZ, 2.1 years; and the UK, 1.7 years). In Japan, 11% of patients switched to hybrid therapy for three years on PD [22]. A higher risk of HD transfer was observed in patients with psychiatric disorders or an elevated body mass index. Issues related to solute clearance are common, particularly in Canada (13%) and Japan (16%). Water removal problems were common in Japan (29%) but not elsewhere (4%–10%). The proportion of patients with a total weekly Kt/V ≥ 1.7 at a facility was not associated with death or HD transfer.

The PDOPPS showed that basic care for kidney failure differs from country to country, affecting PD continuation. Importantly, infection (peritonitis) was confirmed as the greatest risk factor to PD continuation. Furthermore, the dialysis dose did not significantly contribute to the outcomes. This was also noted in the ISPD recommendations described later [23].

Although data collection is still ongoing and it is necessary to obtain precise results, Table 3 shows the characteristics of PD that have been identified in Japan.

In Japan, the dialysis dose is lower, the rates of peritonitis and withdrawal are lower, and it is assumed that better PD therapy is being performed than that in other countries. One factor for this is that hybrid therapy is standardized, unlike in other countries.

Similar to previous reports from Japan, PDOPPS also cited the fluid removal problem as a reason for transfer to hybrid therapy [24]. However, the rate of direct HD transfer is less common than that in other regions

Table 3 Characteristics of Japanese PD revealed from PDOPPS

PD prescriptions
CAPD > APD
Lower dialysis dose: lower PD volume and Lower Kt/V
Relatively low-glucose solutions
Biocompatible solution; low GDPs solution
Relative higher Ca solution: Ca $\geq$ 3.5 mEq/L
PD catheter
Surgical insertion
Peritonitis
Low incident rate
Disparity between facilities
Higher % of culture-negative
Outcomes
Lower mortality and transfer HD
Higher hybrid therapy
Disparity between facilities

as hybrid therapy has the possibility to overcome fluid management.

The greatest effect of hybrid therapy is that body fluid control becomes easier with fluid removal by HD once or twice a week. The Japanese Renal Data Registry analyses show decreased all-cause mortality, cardiovascular mortality, and congestive heart failure-related mortality compared to those with PD alone [25]. Furthermore, a reduction in acute cardiovascular events and improvement in left ventricular ejection fraction (LVEF) and left ventricular mass index (LVMI) have been reported after switching from PD alone to hybrid therapy [26].

The disparity between facilities (personal thoughts dominate prescription)

As indicated by the differences in peritonitis rates and PD prescriptions, one of the PDOPPS findings suggests that regional and country differences, as well as facility differences in the same region, are widespread.

In the DOPPS study on HD, the disparity between facilities was minimal. HD largely depends on the equipment and medical systems in an area. Although there are regional differences, it is unlikely that there are disparities between facilities in the same area.

In the case of PD, a biological membrane is used, and the difference in prescription is smaller because the PD solution has almost the same composition and continuous therapy. On the contrary, most prescription of PD therapies and guidance for patients depend on the individual medical staff and seem to be based on their thoughts and preferences.

This disparity between facilities is a problem, and whether it should be unified or take advantage of the high degrees of freedom of patients with PD is a major concern.

Future directions in PD

Will Japan's PD affect the world in the future? An EPS storm is one of the factors affecting the changes in PD prescriptions in Japan. As a result, biocompatible solutions, high-glucose solution restriction, and hybrid therapy have been developed and presented as evidence from Japan.

Evidence from the PDOPPS is expected to influence the development of future guidelines. In particular, the extension of the PD continuation rate by using hybrid therapy is expected to influence treatment selection in other countries (although medical reimbursement restrictions have become a hurdle).

PDOPPS is analyzed only for patients undergoing PD; the data have not been compared with those for HD. Therefore, the significance of PD for HD remains unclear. However, comparing the superiority and inferiority of therapies is impossible, and it is important to consider the select the appropriate therapy on an individualized basis. Therefore, a shared decision-making process for selecting the appropriate type of renal replacement therapy is imperative.

The efficiency of PD depends on ultrafiltration, which removes excess water to restore normal body fluid status. Aquaporin-1(AQP1) is a transcellular protein located in the microvascular endothelium. A variant of AQP1 has been associated with decreased ultrafiltration and an increased risk of death or technique failure among patients treated with PD [27]. An icodextrin solution is effective in patients with AQP1 variants. However, there are cases where stable body fluid management cannot be achieved even with icodextrin use. The use of low-Na PD solutions has also been attempted in such cases, but its use is still limited [28]. Therefore, countermeasures are limited to restricting salt intake through patient education. Salt restriction (< 2 g sodium or 5 g sodium chloride per day) for all PD patients is recommended in the ISPD-GL [29].

Can the Japanese clinical practice of peritoneal dialysis change the world?

Recent ISPD recommendations aim to establish realistic care goals that maintain the quality of life for patients undergoing PD as much as possible by enabling them to meet their life goals and minimizing symptoms and treatment burden while ensuring high-quality care [23]. Management of (1) patient-reported outcome measures, (2) fluid status, and (3) nutrition status is emphasized. There is insufficient evidence regarding the previously recommended dialysis doses (Kt/V and Ccr). The aim is that the patient should feel well, and it is critical to assist the medical staff in this regard.

The root of this recommendation seems to involve the essential form of treatment for PD therapy as continuous treatment with little rapid change (peak concentration hypothesis [30]). However, there is concern that overemphasizing this ISPD recommendation may undermine the scientific perspective.

DOPPS has demonstrated a good survival rate in Japanese HD patients [31]. This was also observed in PD based on the results of PDOPPS. One reason is that HD and PD are considered almost equivalent in terms of medical fees in Japan, and treatment can be selected without considering the medical system's limitations.

Can these results have an impact on PD therapy and its guidelines worldwide? For example, in Taiwan and South Korea, hybrid therapy can be adopted as the medical fee systems are similar; however, the generalizability is limited.

Japan is expected to develop medical devices in the future such as (1) infection-resistant PD catheters and (2) fully automatic PD exchange systems. Furthermore, it is also essential to consider the preliminary results of basic research regarding the prevention of peritoneal deterioration, an area still under study.

Abbreviations

HD: Hemodialysis; PD: Peritoneal dialysis; CAPD: Continuous ambulatory peritoneal dialysis; EPS: Encapsulating peritoneal sclerosis; GDPs: Low-glucose degradation products; PDOPPS: Peritoneal Dialysis Outcomes and Practice Patterns Study; DOPPS: Dialysis Outcomes and Practice Patterns Stud; ISPD: International Society for Peritoneal Dialysis; JSDT: Japanese Society for Dialysis Therapy; JSPD: Japanese Society for Peritoneal Dialysis; ASN: American Society of Nephrology; ERA: European Renal Association; APD: Automated peritoneal dialysis; MBD: Mineral bone disorder; ACU: Area under the curve; PTH: Parathyroid hormone.

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