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CLINICAL RESEARCH

A Randomized Controlled Trial Comparing Automated Peritoneal Dialysis and Hemodialysis for Urgent-Start Dialysis in ESRD

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Introduction: Peritoneal dialysis (PD) shows promise for urgent-start dialysis in end-stage renal disease (ESRD), with automated PD (APD) having advantages. However, there is limited multicenter randomized controlled trial (RCT) evidence comparing APD with temporary hemodialysis (HD) for this indication in China.

Methods: This multicenter RCT enrolled 116 patients with ESRD requiring urgent dialysis from 11 hospitals, randomized to APD or HD. Patients underwent a 2-week treatment with APD or HD via a temporary central venous catheter (CVC), followed by a maintenance PD. Outcomes were assessed over 12 months during 8 visits. The primary outcome was dialysis-related complications.

Results: The 1-year incidence of dialysis-related complications was significantly lower in the APD group than in the HD group (25.9% vs. 56.9%, $P = 0.001$). No significant differences were found between the groups in terms of PD catheter survival rates ($P = 0.388$), peritonitis-free survival rates ($P = 0.335$), and patient survival rates ($P = 0.329$). In terms of health economics, the total direct medical cost of the initial hospitalization for patients with ESRD was significantly lower in the APD group (27,008.39 CNY) than in the HD group (42,597.54 CNY) ($P = 0.001$), whereas the duration of the first hospital stay showed no significant difference ($P = 0.424$).

Conclusion: For patients with ESRD needing urgent initiation of dialysis, APD was associated with a lower incidence of dialysis-related complications and lower initial hospitalization costs compared with HD, with no significant differences in PD catheter survival rate, peritonitis-free survival rates, or patient survival rates. These findings can guide clinical decision-making for the optimal dialysis modality for patients requiring urgent dialysis initiation.

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ESRD, characterized by irreversible loss of renal function, is a global health challenge with rising incidence and prevalence.[1] Dialysis serves as a life-saving treatment for ESRD, providing renal replacement therapy when renal function is insufficient. The choice of modality, whether PD or HD, is often

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influenced by a multitude of factors, including patient's clinical condition, personal preferences, and availability of health care resources.[2,3]

In a subset of patients in whom ESRD is detected late or there is a rapid decline in renal function, an "urgent start" to dialysis becomes a necessity.[4] Such situations pose significant clinical challenges due to the heightened risk of complications and a constrained timeframe for adequate preparation.[5] In such contexts, HD via a CVC has traditionally been the go-to approach.[6] Nevertheless, numerous studies have shown a range of complications associated with the placement and utilization of CVC, encompassing issues such as catheter-related infections, thrombosis, and hemodynamic instability, all of which negatively impact patient survival.[7-10]

However, recent advancements in dialysis methods, particularly the advent of APD, have broadened the scope of available treatment options.[11] Urgent-start PD can be defined as initiation of PD in patients with newly diagnosed ESRD who are not yet on dialysis and who require dialysis initiation less than 2 weeks after PD catheter placement, but who do not require emergency dialysis.[12] Specifically, urgent-start PD is primarily designated for patients who have not prechosen a specific dialysis approach, but are considered appropriate candidates for PD.[12-14] APD, a specific form of PD, is gaining traction as a viable modality for renal replacement therapy in urgent-start scenarios.[15-17] The potential advantages of APD extend beyond mere physiological benefits such as fewer hemodynamic fluctuations and a continuous clearance of solutes;[18,19] it also offers enhanced patient comfort, making it a favorable choice for patients and medical practitioners alike.[20-22] Notably, compared to manual PD, APD provides the additional benefit of exerting less intra-abdominal pressure, which is conducive to incision healing and prevents leakage, thus reducing related complications.[19,23,24] Moreover, the dialysis adequacy can be boosted by increasing the frequency of exchanges, offering greater flexibility in managing patients' needs.[17,19,23] Despite these potential advantages, the comparative efficacy and safety of APD and HD in urgent-start scenarios remain under researched, and the current body of evidence is largely rooted in retrospective or observational studies.

To address these gaps in knowledge, we conducted a prospective, multicenter, RCT to compare the outcomes of APD and HD for urgent-start dialysis in patients with ESRD. Our study focused on the incidence of dialysis-related complications, PD catheter survival rate, peritonitis-free survival rate, patient survival rate, and health economic indicators. This study aimed to provide evidence-based insights to guide the selection of dialysis modality in urgent-start scenarios, balancing both individual patient factors and health care system resources.

METHODS

Study Design and Participants

We executed a prospective, multicenter, RCT across 11 hospitals involving a total of 116 patients with ESRD requiring urgent-start dialysis from March 2019 to December 2020, and the last follow-up occurred in December 2021. Patients were randomized in a 1:1 ratio into the APD group and the HD group, with each group comprising 58 patients.

Inclusion criteria included patients aged 18 to 80 years and having the necessity for urgent initiation of dialysis due to late presentation or rapid progression of renal disease without a preestablished functional dialysis access. Exclusion criteria included patients with contraindications to PD or HD; those with severe volume overload and pulmonary edema, severe hyperkalemia (serum potassium >6.5 mmol/l), or uremic encephalopathy; those with severe liver failure; those with uncorrectable shock, malignancy or mental disorders; those who were pregnant or lactating, and patients unable or unwilling to provide informed consent for the study. Patients were enrolled in the study if they met the eligibility criteria and none of the exclusion criteria.

This study received ethical approval from the ethics committees of 11 collaborating institutions. It was registered at ClinicalTrials.gov (identifier: NCT02946528) and conducted in accordance with the Declaration of Helsinki, the International Conference on Harmonization's Guidelines for Good Clinical Practice, and applicable local legislation on non-interventional studies and/or observational studies. All patients provided written Informed Consent Forms pre-enrollment. The protocol and all its amendments were approved by the Shanghai Jiao Tong University School of Medicine, Ren Ji Hospital Ethics Committee (2018220) and the ethics committee of each participating center.

Randomization

In this study, we used SAS statistical software (SAS Institute Inc., Cary, NC) to generate a completely randomized sequence and randomly assigned participants in a 1:1 ratio to the APD group or the HD group. We adopted a block randomization method, with every 4 participants as a block, and 2 participants assigned to the APD group and 2 to the HD group in each block, to ensure balance between the treatment groups. The

block randomization sequence was also generated using SAS. Participants who signed informed consent and met the inclusion criteria were assigned a random number according to the order of enrollment, and then allocated to the corresponding treatment group based on the random number. The allocation itself was done using opaque sealed envelopes. Allocation was not accessible to study personnel except to receive a treatment assignment for a specific participant. The entire randomization process was designed and supervised by a third-party statistical agency.

Interventions

In the APD group, patients initially underwent PD catheter insertion and were managed with APD as per an urgent-start PD protocol. In principle, tidal PD was used with a single dwell volume of 1.0 to 1.5 l and a total cyclic treatment time of 8 to 12 hours per day, resulting in a total dialysis dose of 5 to 10 l per day. The dwell volume was incrementally increased over time. After a period of 2 weeks, these patients transitioned to maintenance PD.

In contrast, patients in the HD group initially underwent temporary CVC insertion and initiated HD treatment. These patients underwent 2 to 3 HD sessions per week, employing intermittent HD, hemodiafiltration, or continuous renal replacement therapy, as per their individual clinical needs. Once these patients were stabilized, they underwent PD catheter insertion. Two weeks after PD catheter placement, they were switched to maintenance PD (Supplementary References). The trial protocol (Supplement 1) was approved by the Institutional Review Board at each participating center.

Follow-Up and Outcome Measures

Patients were followed-up with for 12 months, with 8 visits planned. The primary outcome was the incidence of dialysis-related complications. Dialysis-related complications were defined as a composite of noninfectious complications (PD catheter malposition, PD catheter obstruction, leakage, hernia, bleeding around the catheter, or thrombosis) and infectious complications (PD catheter-related infection, peritonitis, or CVC-related infection). Secondary outcomes included PD catheter survival rate (the percentage of PD catheters that remain functional throughout the study period without the need for surgical intervention), peritonitis-free survival rates, patient survival rate, total direct medical cost and duration of initial hospitalization.

Statistical Analysis

All statistical analyses were performed using SPSS 22.0 statistics software (SPSS Inc., Chicago, IL). Data were analyzed using appropriate statistical tests. Categorical variables were analyzed using chi-square or Fisher exact tests, and continuous variables were analyzed using Student's t test or Mann-Whitney U test, as appropriate. Survival analyses were performed using the Kaplan-Meier method and compared using the log-rank test. Assuming 1-year composite complication rate after urgent-start PD and HD of 25% and 55%, respectively, according to our previous clinical experience, a 1:1 sampling ratio, a drop-out rate of 10%, and a 2-sided alpha of 0.05, a sample size of participants 58 per group was predicted to have 90% power of detecting a reduction in composite complications. A 2-tailed P-value < 0.05 was considered statistically significant. All analyses were performed using statistical software. The full analysis set, which was used for all analyses, included all enrolled patients. Missing data were not imputed unless otherwise specified.

RESULTS

Study Population

The study initially screened 140 patients. Among these, 24 participants were excluded due to various reasons. A total of 116 patients were included in the study, 58 in each of the APD and HD groups (Figure 1). Seven patients (4 in the APD group and 3 in the HD group) were withdrawn from the study early because of kidney transplantation ($n = 3$), transfer to maintenance HD ($n = 1$), or refusal to further participate in the study ($n = 3$). No loss to follow-up occurred; however, 4 participants died during the maintenance dialysis period (1 in the APD group and 3 in the HD group). Therefore, 53 participants in the APD group and 52 participants in the HD group completed the follow-up. The mean age of the participants was 52.2 $\pm$ 14.2 years, with 66.4% being male. The median time from catheter insertion to the initiation of dialysis was 4 days in the APD group, as the protocol specified a transition to maintenance PD 14 days after catheter insertion. Baseline patient characteristics are reported in Table 1.

Dialysis-Related Complications

The incidence of dialysis-related complications at 1-year follow-up was considerably lower in the APD group in comparison to the HD group (15 [25.9%] vs. 33 [56.9%], $P = 0.001$). Specifically, there are statistically significant differences in noninfectious complications (9 [15.5%] vs. 20 [34.5%], $P = 0.032$). Moreover, the incidence of infection-related complications was higher in the HD group, although this difference was not statistically significant (6 [10.3%] vs. 13 [22.4%], $P = 0.132$). Notably, the APD group faced complications such as PD-catheter malposition (3.4%), PD-catheter obstruction (6.9%), leakage (3.4%), hernia (1.7%), PD catheter-related infection (5.2%), and

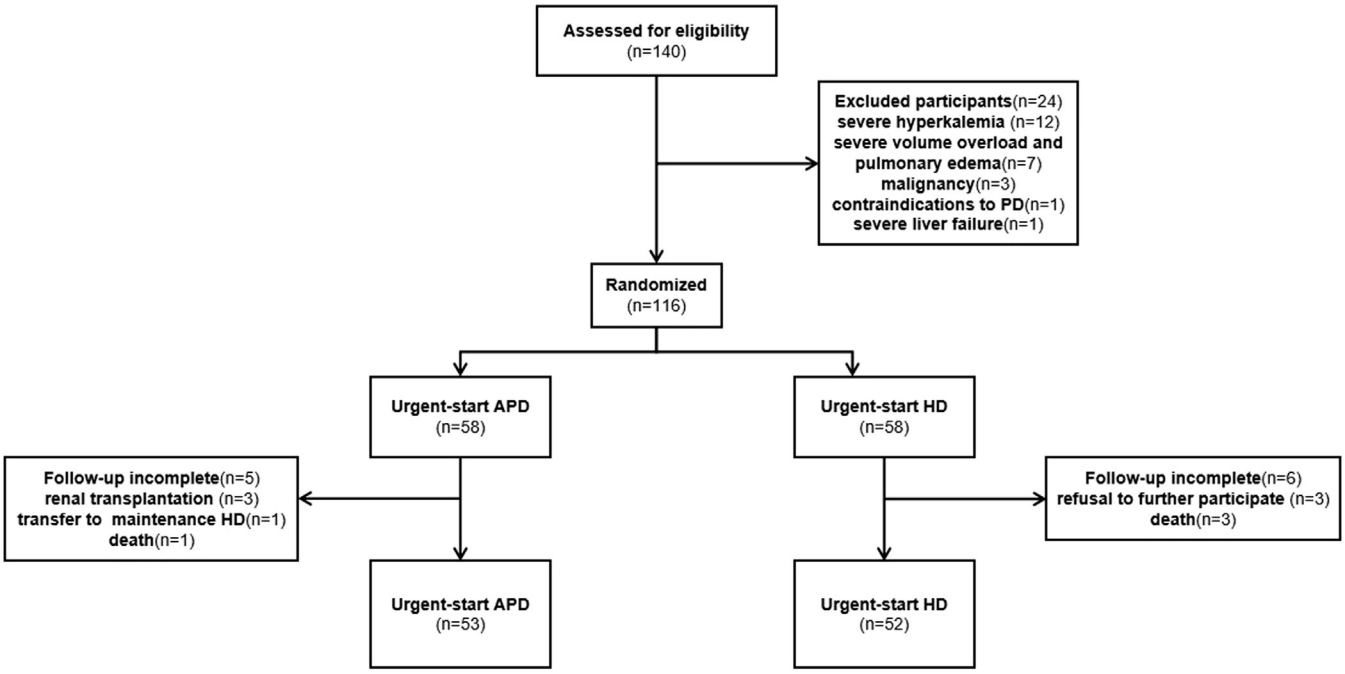

Figure 1. Patient flowchart. APD, automated peritoneal dialysis; HD, hemodialysis.

peritonitis (5.2%). Conversely, in the HD group, CVC-related or anticoagulation-related complications accounted for 24.1% of cases, with bleeding around the catheter (15.5%), CVC-related infection (5.2%), and thrombosis (3.4%). Meanwhile, complications were more frequent and varied, with a remarkable 32.7% of patients experiencing PD-related complications. These included PD-catheter malposition (5.2%), PD-catheter obstruction (3.4%), leakage (3.4%), hernia (3.4%), PD catheter-related infection (5.2%), and peritonitis (12.1%) (Table 2).

A significant difference in the complication rates within 6 weeks was observed, with 15.5% (9/58) in the APD group and 36.2% (21/58) in the HD group ($P = 0.020$). Specifically, the HD group showed significantly higher instances of bleeding around the catheter ($P = 0.006$). In addition, the HD group had a higher prevalence of CVC-related infections (5.2%) and thrombosis (3.4%); whereas the APD group exhibited a marginally higher incidence of PD catheter obstruction (5.2%) and leakage (3.4%), although these differences were not statistically significant. PD-related infectious complications were comparably distributed between the 2 groups (Supplementary Table S1).

PD Catheter Survival Rate and Peritonitis-Free Survival Rate

There was no significant difference in the PD catheter survival rate between the 2 groups (log-rank = 0.744, $P = 0.388$) (Figure 2).

During the follow-up period, 3 cases of peritonitis occurred in the APD group, and 7 in the HD group. No significant difference in peritonitis-free survival was observed between the 2 groups (log-rank = 0.931, $P = 0.335$) (Figure 3).

Patient Survival Rate

The 1-year patient survival rate was 97.9% in the APD group and 94.3% in the HD group. There was no significant difference between the 2 groups (log-rank = 0.953, $P = 0.329$) (Figure 4).

Health Economic Indicators

The total direct medical cost of the first hospitalization for patients with ESRD in the APD group was significantly lower than that in the HD group (27,008.39 [17,676.54– 37748.30] vs. 42,597.54 [17,764.57–56,312.28] CNY, $P = 0.001$). The duration of the initial hospitalization was comparable between the 2 groups, with the APD group averaging 23 days and the HD group averaging 22.5 days, resulting in a statistically insignificant difference ($P = 0.424$).

DISCUSSION

To our knowledge, our research stands as the first multicenter RCT in our country, rigorously comparing the outcomes and complications of APD and HD as primary dialysis methods for patients with ESRD in need of urgent-start dialysis with long-term follow-up. This study marks a significant advancement in the field because it not only introduces a novel approach to utilizing APD as the urgent initiation PD method but also follows a standardized APD prescription. The

Table 1. Baseline characteristics of study patients

Characteristics	APD (n = 58)	HD (n = 58)	P-value
Gender (n [%] men)	40 (69.0)	37 (63.8)	0.555
Age (yr)	52.4 ± 14.6	51.9 ± 13.8	0.862
Weight (kg)	68 (59, 80)	65 (58, 75)	0.413
BMI (kg/m^2)	24.95 ± 4.52	23.77 ± 3.82	0.149
Primary disease (n [%] men)			
Primary glomerulonephritis	25 (43.1)	19 (32.8)	0.251
Diabetic kidney disease	10 (17.2)	15 (25.9)	0.259
Hypertensive nephrosclerosis	5 (8.6)	2 (3.4)	0.242
Polycystic kidney disease	1 (1.7)	1 (1.7)	1.000
Lupus nephritis	1 (1.7)	0 (0.0)	0.315
Comorbidities (n [%])			
Hypertension	56 (96.6)	52 (89.7)	0.143
Diabetes	28 (48.3)	25 (43.1)	0.576
Infection	11 (19.0)	9 (15.5)	0.623
Cerebrovascular disease	5 (8.6)	7 (12.1)	0.542
Coronary atherosclerotic heart disease	6 (10.3)	4 (6.9)	0.508
Heart failure	2 (3.4)	7 (12.1)	0.083
Abdominal surgical history	2 (3.4)	5 (8.6)	0.242
Scr (umol/l)	875.7 ± 254.0	880.3 ± 271.2	0.928
BUN (mmol/l)	30.4 (24.3, 35.9)	27.3 (22.7, 32.9)	0.135
eGFR (ml/min per 1.73 m^2)	5.6 (4.0, 7.0)	5.8 (4.0, 7.5)	0.535
K (mmol/l)	4.47 ± 0.60	4.41 ± 0.67	0.600
Na (mmol/l)	141.0 ± 3.6	140.6 ± 3.1	0.541
Cl (mmol/l)	102.7 ± 4.8	102.9 ± 4.6	0.793
pH	7.34 ± 0.06	7.35 ± 0.06	0.773
HCO3	21.6±3.6	21.2±3.9	0.608
Hb (g/l)	85.4 ± 20.2	83.7 ± 18.6	0.635
Alb (g/l)	34.5 ± 4.7	33.6 ± 6.4	0.369
Pre-albumin (g/l)	302.6 ± 74.6	289.3 ± 86.8	0.402
Ca (mmol/l)	1.96 ± 0.24	1.94 ± 0.26	0.668
Corrected Ca (mmol/l)	2.09 (1.92, 2.25)	2.14 (1.92, 2.25)	0.855
P (mmol/l)	2.09 (1.78, 2.57)	2.00 (1.72, 2.45)	0.475
PTH (ng/l)	313.0 (218.6, 413.1)	424.3 (248.0, 610.0)	0.094
TC (mmol/l)	4.40 ± 1.03	4.37 ± 1.22	0.864
LDL (mmol/l)	2.82 (1.98, 3.46)	2.26 (1.82, 3.24)	0.285

Alb, serum albumin; APD, automated peritoneal dialysis; BNP, brain natriuretic peptide; BUN, blood urea nitrogen; Ca, serum calcium; Corrected Ca, serum corrected calcium; eGFR, estimated glomerular filtration rate; Hb, hemoglobin; HCO3, serum bicarbonate; HD, hemodialysis; K, serum potassium; LDL, low-density lipoprotein; Na, serum sodium; P, serum phosphate; PTH, parathyroid hormone; Scr, serum creatinine; TC, total cholesterol.
Baseline characteristics are expressed as mean ± SD for normally distributed data, median (25th percentile, 75th percentile) for nonnormally distributed data, and frequencies and percentages for categorical data.

prescription has been honed through rigorous clinical practice at our center.[15,16,25-28] Furthermore, our research sets itself apart from previous work by offering a longer follow-up period, because past studies have predominantly focused on short-term complications.[29-32] Importantly, our study also factors in economic considerations, expanding the scope beyond clinical outcomes alone. This comprehensive approach

Table 2. One-year dialysis-related complications distribution (APD and HD Groups)

Complications distribution	APD (n = 58)	HD (n = 58)	P-value
Total	15 (25.9)	33 (56.9)	0.001
Noninfectious complications	9 (15.5)	20 (34.5)	0.032
PD-catheter malposition	2 (3.4)	3 (5.2)	1.000
PD-catheter obstruction	4 (6.9)	2 (3.4)	0.675
Leakage	2 (3.4)	2 (3.4)	1.000
Hernia	1 (1.7)	2 (3.4)	1.000
Bleeding around the catheter	0 (0.0)	9 (15.5)	0.006
Thrombosis	0 (0.0)	2 (3.4)	0.476
Infectious complications	6 (10.3)	13 (22.4)	0.132
PD-catheter-related infection	3 (5.2)	3 (5.2)	1.000
Peritonitis	3 (5.2)	7 (12.1)	0.321
CVC-related infection	0 (0.0)	3 (5.2)	0.242

APD, automated peritoneal dialysis; CVC, central venous catheter; HD, hemodialysis; PD, peritoneal dialysis.
Complication distributions for APD and HD are expressed as n (%).

sheds new light on the utility of PD as a first-line treatment for patients with ESRD requiring urgent-start dialysis, especially in settings where HD resources may be limited.

Significantly, this study's findings align with previous research, demonstrating a notably lower incidence of dialysis-related complications in the APD group compared to the HD group at 1-year follow-up. The lower incidence can be attributed to several factors. The APD group avoided the use of temporary CVC for HD, thereby minimizing the risk of complications such as thrombosis, CVC-related infections, and HD-associated risks such as increased bleeding due to anticoagulation. In addition, early initiation of APD did not significantly elevate the risk of short-term PD-related complications such as peritonitis, hernia, and leakage. Consequently, the incidence of dialysis-related complications was lower in the APD group. Our results echo previous shorter-term studies,[25-27,29-43] while providing a more comprehensive picture due to our multicenter RCT study design and extended follow-up period. This emphasizes that, even in the context of an

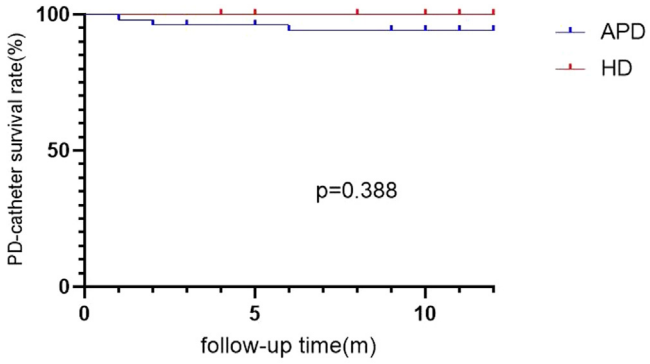

Figure 2. PD-catheter survival rate between APD and HD group. APD, automated peritoneal dialysis; HD, hemodialysis; PD, peritoneal dialysis.

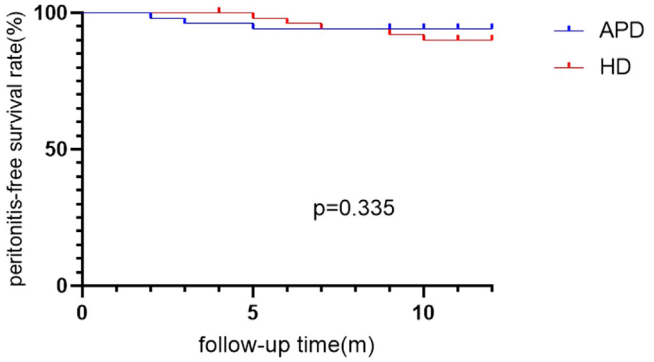

Figure 3. Peritonitis-free survival rate between APD and HD group. APD, automated peritoneal dialysis; HD, hemodialysis.

urgent need for dialysis, PD may present a safer therapeutic choice for managing patients with ESRD. Moreover, the diminished complication rate underscores that APD might be better tolerated by patients over the long-term, potentially enhancing treatment adherence and improving overall outcomes. This study further extends the understanding of ESRD management, highlighting the enduring benefits of PD and APD treatment in the context of longer-term patient care.

Moreover, our results showed no significant difference between the APD and HD groups in terms of PD catheter survival rate, peritonitis-free survival rate, and patient survival rate. These findings further underscore the feasibility and safety of APD as an acceptable treatment modality alternative to HD in terms of an urgent need for dialysis. Importantly, despite the high prevalence of comorbid conditions such as diabetes and hypertension in our study population, the survival rates in both groups were encouraging, indicating that both methods can be effectively implemented for ESRD treatment.

In terms of health economics, we found that the total direct medical cost of the first hospitalization for patients with ESRD in the APD group was significantly lower than that in the HD group. This suggests that

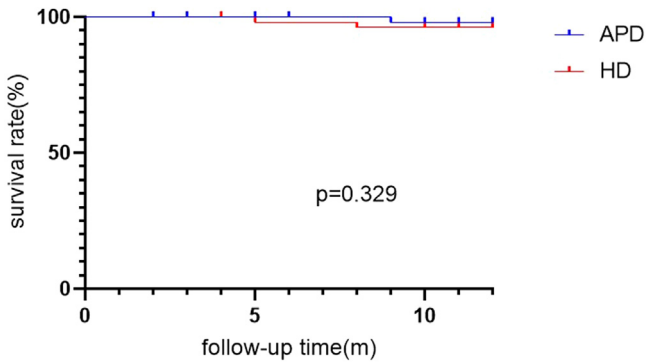

Figure 4. Patient survival rate between APD and HD group. APD, automated peritoneal dialysis; HD, hemodialysis.

APD could potentially offer a cost-effective alternative to HD, particularly in resource-limited settings. However, the length of the first hospital stay did not differ significantly between the 2 groups, indicating that the overall burden on health care facilities might be similar with both dialysis methods.

Despite these promising findings, several limitations must be acknowledged and necessitate careful interpretation. The open-label design could introduce observer and performance biases, and the lack of blinding among outcome assessors and absence of an adjudication committee may permit detection bias. In addition, our findings may not extend to different ethnicities or regions, given the potential for more acceptance of small volume PD in Asian populations with generally smaller body sizes. This may limit the generalizability to populations with higher body mass indexes or where PD catheter placement is not typically performed by nephrologists. Lastly, the lack of patient-reported outcomes such as quality of life in this study underscores the need for their inclusion in future investigations. As such, though our findings are promising, future research should account for these limitations for a more comprehensive understanding of PD.

In conclusion, our study suggests that APD is a viable, safe, and potentially cost-effective option for the management of urgent-start dialysis in ESRD, with a lower incidence of dialysis-related complications and comparable survival rates to HD.

DISCLOSURE

All the authors declared no competing interests.

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DATA AVAILABILITY STATEMENT

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

AUTHOR CONTRIBUTIONS

HJ wrote the original manuscript. WF and LW performed data curation and supervision. XZ, YD, GW, YL, XC, NW, GJ, ZG, XW, and YQ were subprincipal investigators. SL conducted the statistical analysis. ZN conceived and designed the study, revised the manuscript and was the principal investigator. All the authors critically reviewed the manuscript and approved the final version for submission.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Supplement 1. Research Protocol.

Supplementary References.

Table S1. Six-week-dialysis-related complications distribution (automated peritoneal dialysis and hemodialysis groups).

CONSORT 2010 checklist.

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