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Randomized Study of Urgent-Start Peritoneal Dialysis Versus Urgent-Start Temporary Hemodialysis in Patients Transitioning to Kidney Failure

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Introduction: We sought to evaluate the efficacy and complications of urgent-start peritoneal dialysis (PD) compared with urgent-start temporary hemodialysis (HD) followed by subsequent elective transfer to PD.

Methods: In this multicenter open-label prospective randomized controlled trial, adults with kidney failure who required immediate dialysis but did not have access to definitive dialysis were randomized to receive either urgent-start PD or urgent-start temporary HD over 2 weeks to 4 weeks followed by a transition to a chronic PD program according to the country policy. The primary outcome was the composite end point of operation-related, catheter-related, and dialysis-related complications at 6 weeks. Secondary outcomes were 6-week mortality, 6-week technique survival, and 1-week composite complications.

Results: A total of 207 participants requiring urgent-start dialysis were enrolled from 3 tertiary hospitals between November 2018 and February 2020 as follows: 104 were assigned to receive urgent-start PD, and 103 were assigned to urgent-start temporary HD. Compared with urgent-start temporary HD, urgent-start PD had a lower composite complication rate at 6 weeks (19% vs. 37%, risk ratio [RR] 0.52, 95% CI 0.33–0.83), which was primarily accounted for by a reduction in dialysis-related complications (4% vs. 24%, RR 0.16, 95% CI 0.06–0.44). No significant differences were observed between the 2 groups with respect to patient and technique survival rates at 1 week and 6 weeks.

Conclusion: An urgent-start PD strategy during the transition of kidney failure to chronic dialysis is safe and has fewer complications commensurate with their reduced exposure to procedural risk than urgent-start temporary HD up to 6 weeks after dialysis commencement.

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The transition from chronic kidney disease (CKD) to dialysis commencement is both crucial and challenging. Unfortunately, more than half of patients with kidney failure worldwide start dialysis in an unplanned fashion[1–4] despite such unplanned starts being associated with higher risks of morbidity and mortality compared with planned dialysis initiation.[5,6] Usually, these patients are treated with urgent-start HD with a central venous catheter (CVC).[1–3,7,8] Several factors contributing to the apparent preference for urgent-start temporary HD over urgent-start PD include the following: (i) HD catheter placement is a routine procedure, whereas the availability of

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experienced clinicians who are willing and able to place PD catheters at short notice is more limited;[9,10] (ii) nephrology training in PD has been suboptimal compared with HD;[7,10,11] and (iii) financial incentives have historically favored in-center HD.[10]

Urgent-start PD, which is generally defined as an initiation of PD during the break-in period (within 14 days postcatheter insertion),[12,13] has been an important strategy to promote home dialysis. Brazil is an example of a country where this has been successfully applied, demonstrating that urgent-start dialysis resulted in a 256% increase in patients on chronic PD over 3 years.[14] PD is an attractive modality because it is a home-based therapy that reduces center visits and is more conducive to physical distancing during the pandemic era and offers several benefits at the patient level, including initial survival advantage compared with HD, better preservation of residual kidney function, better patient satisfaction, greater flexibility, and improved quality of life. Moreover, PD requires a lower infrastructure setup and offers annual cost savings.[7]

A Cochrane systematic review and meta-analysis of studies involving 991 participants demonstrated that urgent-start PD might reduce the risk of bloodstream infection compared with HD initiated with CVC, but had uncertain effects on the risks of infection-related and catheter-related complications, technique survival, and patient survival.[7] Nevertheless, all of the included studies in the meta-analysis were observational in nature, including 3 prospective cohorts and 4 retrospective designed studies, thereby reducing the certainty of evidence.[7] Recently, a quasi-experimental study involving 93 Brazilian participants with advanced CKD who required immediate dialysis demonstrated comparable outcomes and complications between both modalities.[14] In the present study, we sought to evaluate the efficiency and complications of both modalities in a randomized controlled trial fashion.

METHODS

Study Design

A multicenter open-label randomized controlled trial was conducted in 3 tertiary hospitals in Thailand from November 2018 to February 2020. Computer-generated random numbers using permuted blocks of 4 were placed in sequentially numbered, sealed opaque envelopes to ensure allocation concealment. According to country policy, participants were randomly allocated in a 1:1 ratio to either urgent-start PD or urgent-start temporary HD for 2 weeks to 4 weeks, followed by an elective transition to PD. Both groups were assigned the same general protocol for preprocedural period, immediate postprocedural period, and chronic PD programs. Before randomization, written informed consent was obtained from all the participants or their legal substitute decision-makers. This study was approved by each institutional research ethics committee of all participating facilities (following the World Health Organization International Clinical Trials Registry Platform) and registered on the Thai Clinical Trial Registry (TCTR20181123002). All reporting was performed according to the Consolidated Standards of Reporting Trials guidelines. Data were manually collected using uniform and standardized paper clinical record forms, procedures, and processes implemented across all participating facilities by study coordinators at each participating PD facility and subsequently entered into a data collection system and stored in the data management unit.

Population

Adult patients aged >18 years, with kidney failure (estimated glomerular filtration rate <15 ml/min for >3 months) who accepted long-term dialysis and required immediate dialysis treatment without access to definitive dialysis were enrolled. Indications for immediate dialysis were symptomatic uremia (e.g., nausea, vomiting, or uremic encephalopathy), refractory volume overload, and hyperkalemia that was refractory to conservative medical treatment. Patients who had medical or social contraindications for PD (presence of extensive lower abdominal scar, cutaneous ostomies, large hernia, poor visual acuity, dexterity problems without caregiver availability, history of multiple previous abdominal surgeries, body mass index >35 kg/m^2, and the unsuitable home environment by expedited screening), life-threatening CKD complications requiring emergent dialysis (severe respiratory insufficiency, abdominal infection, severe life-threatening hyperkalemia [characteristic electrocardiogram changes or serum potassium level >6.5 mEq/l], severe acute pulmonary edema, severe uremic encephalopathy, uremic pericarditis), and hemodynamic instability were excluded. In addition, patients who had a severe disability (Karnofsky performance status <40), a terminal illness (advanced-stage cancer or non-kidney end-stage organ failure), or who did not want to receive either HD or PD were excluded.

A General Protocol for Preprocedural and Immediate Postprocedural Periods

Standard protocols were employed uniformly. The preoperative protocol included blood transfusion to a target hematocrit level of >25%, cryoprecipitate factor

administration (10 units statin) if blood urea nitrogen exceeded 80 mg/dl, and prophylactic antibiotic administration (cefazolin 1 g 1 hour before catheter insertion). The postoperative protocol that was applied routinely included dietary counseling, laxative agents (senna) to prevent constipation, a cough suppressant (as needed), erythropoietin, and a diuretic. According to the reimbursement policy, erythropoietin was provided but capped at 4000 units twice weekly. A high-dose diuretic to aid with volume management was used when appropriate in patients with significant residual kidney volumes (>100 ml/day). Heparin (500 U/l) was added to each dialysis exchange for as long as the dialysate effluents were bloody or contained fibrin.

Urgent-Start PD Protocol

After urgent-start PD was allocated to a patient, PD catheter implantation was executed using the Seldinger percutaneous technique under local anesthesia. All implants were performed by experienced nephrologists (defined as having performed >30 procedures per year for >3 years) using a double-cuffed, coiled PD catheter, length 57 cm (Argyle PD catheter kit, Covidien, Minneapolis, MN) and midline or paramedian approach. A deep cuff was inserted onto the anterior rectus sheath without a purse-string suture. A needle was used to puncture the abdominal wall through the peritoneal cavity under ultrasound guidance, followed by the insertion of a guidewire and the PD catheter. Rapid PD exchanges started immediately after catheter insertion and continued until the drained PD fluid was clear. Then, the patients were treated with manual acute PD exchanges with a commercially available PD solution (Dianeal or Andy disc solution containing sodium 132–134 mEq/l, potassium 0 mEq/l, chloride 96–98 mEq/l, calcium 3.5 mEq/l, lactate 35–40 mEq/l). Exchanges were started with a dwell volume of 800 ml to 1000 ml depending on the patient's weight in a supine position, then gradually increased to 1.5 liters to 2 liters within 2 weeks. The number of exchanges and the dextrose concentrations of the PD solutions were determined by the extent of uremic symptoms and volume status, respectively. Depending on clinical judgment, 3 to 5 exchanges were performed over 4 hours to 8 hours a day, 5 times a week. With this protocol, the average ultrafiltration was about 100 ml to 200 ml with 1.5% dextrose solutions and increased up to 500 ml with 4.25% dextrose solutions for 2 hours to 3 hours dwell time.

Urgent-Start HD Protocol

An 11.5F nontunneled CVC (13.5, 16, or 20 cm) was inserted under routine ultrasound guidance by an experienced nephrologist, preferably in the right internal jugular vein (or alternatively in the femoral vein if required) before the beginning of HD treatment. HD sessions were performed with an HD machine (4008H Fresenius Medical Care, Sankt Wendel, Germany) and polysulfone low flux dialyzer 1.5 m^2 (Elisio150, Nipro, Osaka, Japan). The HD prescriptions involved a blood flow rate of 150 ml/min to 250 ml/min, a dialysate flow rate of 300 ml/min to 500 ml/min, for 2 hours to 4 hours, and 2 to 3 times per week according to the patient's metabolic needs (daily if required) and continued until the end of the break-in period of the chronic PD program. To prevent dialysis disequilibrium syndrome, the blood flow rate, dialysate flow rate, and dialysis duration were limited at 150 ml/min to 200 ml/min, 300 ml/min to 400 ml/min, and 2.0 hours to 2.5 hours for the first few HD sessions, respectively. The concentration of sodium (135–145 mEq/l), potassium (2–3 mEq/l), bicarbonate (26–28 mEq/l), and calcium (2.5 or 3.5 mEq/l) in the dialysis solution were adjusted according to the patient's condition and blood chemistry results. As appropriate, heparin or 0.9% normal saline flush was used to prevent circuit clots. Net ultrafiltration was adjusted according to patients' fluid status with a maximum rate of 0.8 liters per hour during the dialysis session.

Chronic PD Program

The patients of both groups were transferred to the chronic PD program because of the country's "PD First" policy. The patients could decline chronic PD and choose chronic HD, but they had to fully self-fund their dialysis-related costs. The chronic PD program started when the metabolic and fluid volume statuses were controlled and after the patient or caregiver received PD training. Nevertheless, the timing was affected by the randomization group. For the urgent-start temporary HD group, chronic PD started 2 weeks after PD catheter insertion in line with 2019 International Society for Peritoneal Guidelines recommendations.[15] Typically, the PD catheter was placed after HD had been started at least 3 sessions (12, interquartile range 8–15 days). For the urgent-start PD group, chronic PD started after starting 2-liter dialysis fluid exchanges. The PD training process was initiated after a gap of 1 week to 2 weeks after PD catheter insertion, depending on the uremic state of the patients and the nephrologist's judgment in the urgent-start PD group. The typical PD training duration was 4 days to 5 days but was longer if required. PD patients and family members or caregivers assisting in inpatient care received educational and hands-on training. All patients and caregivers had to pass a performance test to ensure that they were ready to perform chronic PD exchange by themselves at home. If possible, an in-

person home visit was conducted in all cases within 4 weeks after hospital discharge.

Outcomes

The primary outcome was a composite of operation-related, catheter-related, and dialysis-related complications at 6 weeks. The definitions of each predefined complication are demonstrated in Supplementary Table S1. The secondary outcomes included composite complications at 1 week, intraoperative and postoperative complications, catheter patency rate, technique, and patients' survivals at 1 and 6 weeks after randomization. In addition, the total number of operations in both groups was reported; and safety outcomes and causes of death were monitored and collected.

Statistical Analysis

All data were analyzed on an intention-to-treat basis (a comparison analysis of the urgent-start dialysis groups according to their original allocation after randomization). Continuous variables were presented as mean ± SD, whereas categorical variables were presented as counts and percentages. Comparison of baseline characteristics between both groups was performed using unpaired t test for continuous data whereas χ^2 test and Fisher exact test were performed for categorical data. The primary and secondary outcomes were analyzed using unconditional maximum likelihood estimation as a cumulative RR with a 95% CI. A composite complication end point was considered to have occurred if one or more of the prespecified complications (Supplementary Table S1) occurred in a participant. Thus, a participant with more than one of the listed complications was counted as experiencing one composite end point. A forest plot was conducted for the primary outcome. Kaplan–Meier curves and log-rank tests were performed for outcomes with time-to-event data. Survival analysis for all patients was considered from the time of treatment allocation until the occurrence of the outcome of interest, discontinuation of the study, death, or end of study at 6 weeks of follow-up, whichever came first. Several sensitivity analyses were conducted, including considering all bacteremia episodes as infection-related outcomes, excluding intradialytic hypotension from the dialysis-related complications outcome, and adjustment of analysis of the primary outcome for chance imbalances in baseline characteristics after randomization using multiple logistic regression analysis with and without propensity score. Assuming a non-inferiority margin of 10%, a composite complication rate after urgent-start HD of 24%,[16] a 1:1 sampling ratio, a drop-out rate of 30%, and a 2-sided alpha of 0.05, a sample size of 101 participants per group was predicted to have 80% power of detecting a reduction in composite complications of at least 50% in the urgent-start PD group. All statistical calculations were performed using R 4.0.5 (R Core Team, Vienna), except the forest plot, which was performed using Revman 5.3 (Cochrane Collaboration, Oxford, United Kingdom). A 2-tailed $P < 0.05$ was considered statistically significant.

RESULTS

Participant Characteristics and Follow-up

There were 320 patients with kidney failure who required urgent-start dialysis during the study period, of whom 207 participants were included in this study (Figure 1). The participants were randomly assigned to either urgent-start PD ($n = 104$) or urgent-start temporary HD ($n = 103$). Nine patients (5 in the urgent-start PD group and 4 in the urgent-start temporary HD group) were withdrawn from the study early before entering chronic dialysis because of failed dialysis access function ($n = 1$), serious complications ($n = 5$), dialysis withdrawal ($n = 2$), or refusal to further participate in the study ($n = 1$). No loss to follow-up occurred, but 4 participants died during the chronic dialysis period (2 in each group). The median time to death was 28 days. Therefore, 97 participants in each group completed the follow-up. Most of the baseline characteristics were comparable between groups, including age, sex, body mass index, comorbidity, cause of kidney failure, late referral to a nephrologist, and preceding admission with CKD complication (Table 1). Nevertheless, the urgent-start temporary HD group had higher levels of blood urea nitrogen, creatinine, and phosphate; and lower levels of hemoglobin, albumin, and estimated glomerular filtration rate than the urgent-start PD group. Additionally, uremia and volume overload were more prevalent as an indication of dialysis in the urgent-start temporary HD group (Table 1).

Primary Outcomes

Compared with urgent-start temporary HD, the urgent-start PD group had a lower 6-week overall composite complication rate (19% vs. 37%, RR 0.52, 95% CI 0.33–0.83) and dialysis-related complications (4% vs. 24%, RR 0.16, 95% CI 0.06–0.44), but no differences in operation-related, catheter-related, and infection-related complications (Table 2 and Figure 2).

In the urgent-start temporary HD group, 6% of the patients had hemothorax, pneumothorax or hematoma from CVC insertion, 3% of the patients required catheter reinsertion from malfunction, and 6 participants had bacteremia (3 Coagulase-negative staphylococci, 2 *Staphylococcus aureus*, and 1

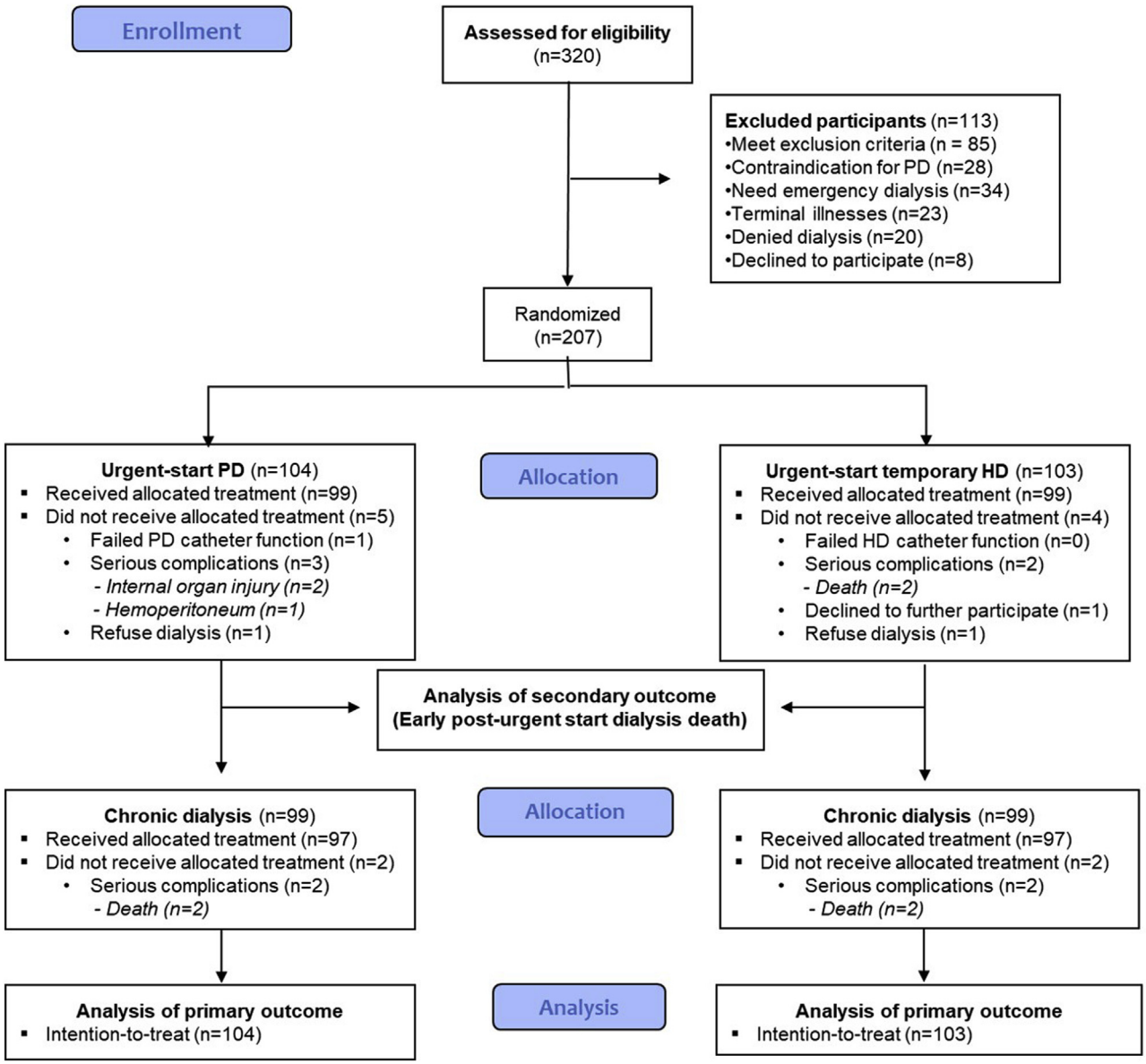

Figure 1. Patient flow diagram. HD, hemodialysis; PD, peritoneal dialysis.

Escherichia coli). Two of the 6 patients with bacteremia met the Infectious Diseases Society of America diagnostic criteria for definitive catheter-related bloodstream infection (Supplementary Table S1),[17] whereas the remaining 4 patients did not meet that criteria (i.e., had a positive culture at only 1 site or a potential alternative source for bacteremia or positive cultures with different organisms at both sites). Sensitivity analysis of the risk of infection-related complications according to treatment group, accounting for all episodes of bacteremia or peritonitis is depicted in Supplementary Table S2. The median number of HD sessions was 5 sessions per participant. A total of 24 and 2 participants developed intradialytic hypotension and dialysis disequilibrium syndrome, respectively. Of note, all episodes of intradialytic hypotension and dialysis disequilibrium syndrome occurred in the first week of HD initiation, whereas the catheter-related bloodstream infections presented >7 days post-CVC insertion.

The overall operation-related complication rate of PD catheter insertion was 15 of 201 (7%) and was comparable between the urgent PD and urgent-start temporary HD (and subsequent PD) groups. There were 12 (6%) catheter-related complications (particularly peri-catheter leakage), which were more common in the urgent-start PD group (8 vs. 4 episodes) (Table 2). All peri-catheter leakage resolved after decreasing dwell volumes and interrupting PD for a short period (3, IQR 3–5 days).

Table 1. Clinical characteristics at baseline

Characteristics	Total (N = 207)	Urgent HD (n = 103)	Urgent PD (n = 104)
Age, yr	56 ± 13	55 ± 14	57 ± 10
Male gender	104 (50)	53 (51)	51 (49)
BMI, kg/m^2	23 ± 4	23 ± 4	24 ± 4
Nephrologist follow-up <3 mo	165 (80)	82 (80)	83 (80)
eGFR, ml/min per 1.73 m^2	4 ± 2	3 ± 2	4 ± 2
Serum creatinine, mg/dl	14 ± 6	15 ± 7	12 ± 5
Serum urea, mg/dl	103 ± 33	109 ± 32	97 ± 33
Serum albumin, gm/dl	3.2 ± 0.6	3.0 ± 0.6	3.2 ± 0.6
Hemoglobin, gm/dl	7.6 ± 1.6	7.4 ± 1.5	7.9 ± 1.6
Serum sodium, mmol/l	133 ± 6	133 ± 6	134 ± 6
Serum potassium, mmol/l	4.5 ± 0.7	4.5 ± 0.7	4.4 ± 0.7
Serum chloride, mmol/l	97 ± 8	96 ± 8	97 ± 8
Serum bicarbonate, mmol/l	19 ± 5	18 ± 5	19 ± 4
Serum calcium, mg/dl	7.8 ± 1.2	7.6 ± 1.2	8.0 ± 1.2
Serum phosphate, mg/dl	6.7 ± 2.5	7.4 ± 2.5	6.1 ± 2.2
Comorbidity			
Diabetes mellitus	117 (57)	54 (52)	63 (61)
Hypertension	184 (89)	93 (90)	91 (88)
Stroke	3 (1)	2 (2)	1 (1)
Coronary artery disease	8 (4)	3 (3)	5 (5)
Chronic heart failure	8 (4)	3 (3)	5 (5)
Chronic obstructive pulmonary disease	2 (1)	2 (2)	0 (0)
Liver disease	2 (1)	1 (1)	1 (1)
Primary kidney disease			
Diabetic nephropathy	115 (56)	53 (51)	62 (60)
Glomerulonephritis	12 (6)	10 (10)	2 (2)
Lupus nephritis	1 (0.5)	1 (1)	0 (0)
Urate nephropathy	9 (4)	3 (3)	6 (6)
Unknown	70 (34)	36 (35)	34 (33)
Previous admission from CKD			
None	136 (66)	68 (66)	68 (65)
1	50 (24)	24 (23)	26 (25)
More than 1	21 (10)	11 (11)	10 (10)
Abdominal surgical scar	6 (3)	2 (2)	4 (4)
Reason for urgent dialysis			
CKD unawareness	58 (28)	37 (36)	21 (20)
Defer dialysis decision	6 (3)	2 (2)	4 (4)
Delay referral	115 (56)	49 (48)	66 (63)
Unpredicted worsening kidney function	27 (13)	15 (15)	12 (12)
Non-adherence to treatment	1 (0.5)	0 (0)	1 (1)
Indication for dialysis			
Uremia	177 (86)	96 (93)	81 (78)
Volume overload	108 (52)	63 (61)	45 (43)
Hyperkalemia	20 (10)	13 (13)	7 (7)

BMI, body mass index; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; HD, hemodialysis; PD, peritoneal dialysis.
Data are presented as mean ± SD or counts (%).

There were 4 episodes of peritonitis, 2 in each group. Peritonitis rates were not significantly different between the urgent-start PD and urgent-start temporary HD groups (0.18 vs. 0.29 episodes per patient-year at risk, respectively, incidence rate ratio 0.6, 95% CI 0.04–8.34).

Because patients in the urgent-start temporary HD group required both HD and PD catheter insertions and were exposed to 2 different dialysis modalities compared with the urgent-start PD group, which only had PD catheter insertion and was only exposed to PD, an additional analysis was performed at 1 week when each group had only had 1 type of catheter inserted and only 1 type of dialysis modality exposure. The overall 1-week composite complication rates were lower in the urgent-start PD group compared with the urgent-start temporary HD group (13% vs. 27%, respectively, RR 0.50, 95% CI 0.28–0.89). No significant differences were observed in 1-week operation-related, catheter-related, infection-related, and dialysis-related complications. Nevertheless, dialysis-related complications only occurred in the urgent-start temporary HD group (24% vs. 0%), whereas catheter-related complications only occurred in the urgent-start PD group (5% vs. 0%).

In a sensitivity analysis in which logistic regression analysis was performed to adjust for differences in baseline characteristics because of play of chance, no differences were observed in the direction, magnitude, and statistical significance of the 1-week and 6-week composite outcomes (Supplementary Table S3). Nevertheless, when dialysis-related complications were excluded from the analysis of the composite outcome, both modalities were comparable with respect to 1-week (RR 1.98, 95% CI 0.83–4.71) and 6-week (RR 0.94, 95% CI 0.53–1.66) composite complications (Supplementary Table S4).

Secondary Outcomes

There were 9 deaths as follows: 4 in the urgent-start PD group and 5 in the urgent-start temporary HD group. Five participants died before receiving chronic dialysis therapy (2 in the urgent-start PD group and 3 in the urgent-start temporary HD group). Mortality rates in both groups were comparable at 1 week (2% vs. 3%, RR 0.66, 95% CI 0.11–3.87) and at 6 weeks (4% vs. 5%, RR 0.79, 95% CI 0.22–0.87). The causes of death are shown in Table 3. A total of 5 patients had permanent HD transfer (3 pleuroperitoneal leakages and 2 catheter malfunctions). Both groups had 1-week and 6-week technique survival rates that were >90% and similar as follows: at 1-week (95% vs. 95%, RR 1.00, 95% CI 0.94–1.06) and at 6-week (93% vs. 91%, RR 0.98, 95% CI 0.91–1.06) (Table 2). Kaplan–Meier survival curves comparing patient survival and technique survival in both groups at 6-week follow-up are displayed in Figures 3 and 4, respectively.

DISCUSSION

In this study, both 1-week and 6-week composite complications rates of urgent-start PD were significantly lower than those of urgent-start temporary HD, mainly with respect to dialysis-related complications.

Table 2. Risk ratio of outcomes according to treatment group

	1 Week follow-up				6 Weeks follow-up			
Outcomes	**Urgent-start HD (n = 103)**	**Urgent-start PD (n = 104)**	**Risk ratio (95% CI)**	***P*-value**	**Urgent-start HD (n = 103)**	**Urgent-start PD (n = 104)**	**Risk ratio (95% CI)**	***P*-value**
Operation-related[a]	6 (6)	9 (9)	1.49 (0.55– 4.02)	0.43	11 (11)	9 (9)	0.81 (0.35–1.87)	0.62
	2 Pneumothorax/ Hemothorax (HD)	2 Organ injury (PD)			1 Organ injury (PD)	2 Organ injury (PD)		
	4 Hematoma (HD)	5 Hemoperitoneum (PD)			3 Hemoperitoneum (PD)	5 Hemoperitoneum (PD)		
		2 Surgical site bleeding (PD)			3 Surgical site bleeding (PD)	2 Surgical site bleeding (PD)		
					2 Pneumothorax/ Hemothorax (HD)	0 Pneumothorax/ Hemothorax (HD)		
					4 Hematoma (HD)	0 Hematoma (HD)		
Catheter-related	0 (0)	5 (5)	NA	NA	7 (7)	8 (8)	1.13 (0.43–3.01)	0.80
	0 DLC malfunction (HD)	0 Flow restriction (PD)			2 Flow restriction (PD)	1 Flow restriction (PD)		
		5 Peri-catheter leakage (PD)			2 Peri-catheter leakage (PD)	7 Peri-catheter leakage (PD)		
					3 DLC malfunction (HD)	0 DLC malfunction (HD)		
Infection-related	0 (0)	0 (0)	NA	NA	4 (4)	2 (2)	0.50 (0.09–2.64)	0.40
	0 Bacteremia (HD)	0 PD peritonitis (PD)			2 PD peritonitis (PD)	2 PD peritonitis (PD)		
		0 ESI/Tunnel infection (PD)			0 ESI/Tunnel infection (PD)	0 ESI/Tunnel infection (PD)		
		0 Sepsis/Bacteremia (PD)			2 Sepsis/Bacteremia (PD/HD)	0 Sepsis/Bacteremia (PD/HD)		
Dialysis-related[b]	25 (24)	0 (0)	NA	NA	25 (24)	4 (4)	0.16 (0.06 –0.44)	< 0.001
	24 IDH (HD)	0 Pleuroperitoneal leakage (PD)			2 Pleuroperitoneal leakage (PD)	2 Pleuroperitoneal leakage (PD)		
	2 DDS (HD)				24 IDH (HD)	2 IDH (HD)		
					2 DDS (HD)	0 DDS (HD)		
Composite complications	28 (27)	14 (13)	0.50 (0.28 to 0.89)	0.01	38 (37)	20 (19)	0.52 (0.33–0.83)	0.005
Mortality	3 (3)	2 (2)	0.66 (0.11 to 3.87)	0.64	5 (5)	4 (4)	0.79 (0.22 –2.87)	0.72
Technique survival	98 (95)	99 (95)	1.00 (0.94 to 1.06)	0.99	96 (93)	95 (91)	0.98 (0.91 –1.06)	0.62

DDS, dialysis disequilibrium syndrome; DLC, double lumen catheter; ESI, exit-site infection; HD, hemodialysis, IDH, intradialytic hypotension; NA, not available; PD, peritoneal dialysis.
[a]In the urgent-start temporary HD group, 1 patient developed organ injury and surgical site bleeding, and 1 patient developed surgical site bleeding and pneumothorax at 6 weeks follow-up.
[b]In the urgent-start temporary HD group, one patient developed both IDH and DDS at 7 days follow-up; 1 patient developed all 3 outcomes, and 1 patient developed IDH and pleuroperitoneal leakage at 6 weeks follow-up.
Risk is presented as counts (%). All data were analyzed on an intention-to-treat basis.

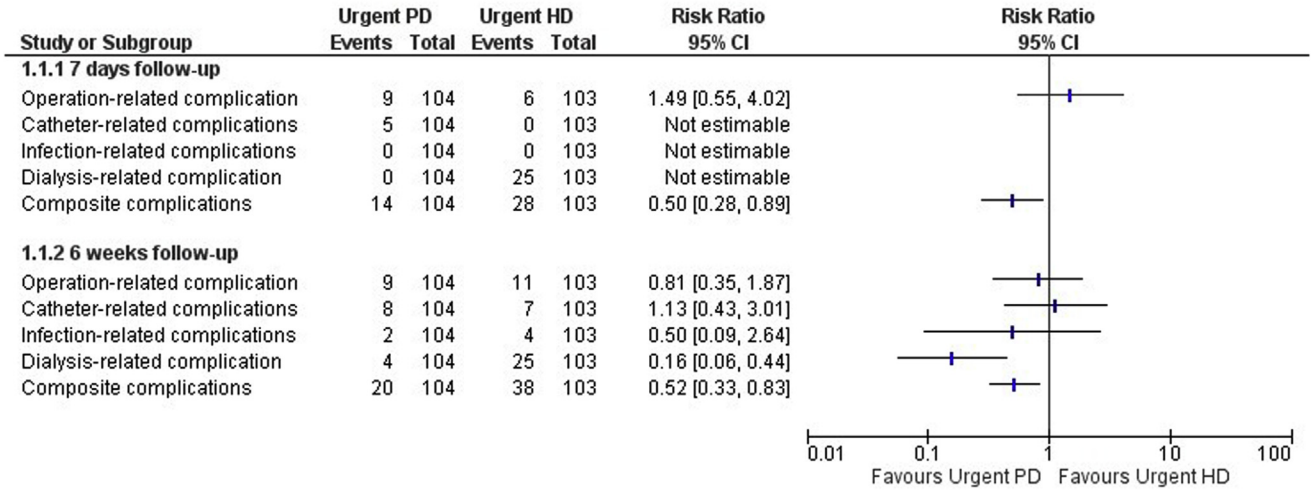

Figure 2. Risk ratio of complication outcomes. Number is presented as counts for patients with relevant complications. HD, hemodialysis; PD, peritoneal dialysis.

Table 3. Cause of death of the enrolled participants in the study

Cause of death	Urgent-start PD (n = 4)	Urgent-start HD (n = 5)
Infection (e.g., pneumonia, herpes zoster)	0	2
Internal organ injury (bowel perforation)	1	0
NSTEMI	1	1
Uremic encephalopathy	1	0
Unknown (death at home)	0	1
Withdraw dialysis	1	1

HD, hemodialysis; NSTEMI, non-ST segment elevation myocardial infarction; PD, peritoneal dialysis.

Nevertheless, both modalities were comparable between 1-week and 6-week patient and technique survivals. In addition, urgent-start temporary HD tended to have a higher peritonitis rate, whereas 1-week catheter-related complications and intradialytic hypotension or dialysis disequilibrium syndrome only occurred in participants receiving urgent-start PD and temporary HD, respectively. Catheter-related bloodstream infections occurred late after 7 days of CVC insertion.

Our study confirms the previous observational findings that urgent-start PD had fewer short-term and intermediate-term complications compared with urgent-start temporary HD.[16,18] Nevertheless, this is the first study to demonstrate this finding with high-certainty evidence. Higher incidences of catheter-related complications in urgent-start temporary HD compared with planned HD via a fistula or a graft have been well documented.[18] The meta-analysis conducted by Htay *et al.*[7] also found that HD initiated with CVC may increase the risk of catheter-related bacteremia. Infectious complications represent a major cause of morbidity and mortality in dialysis patients.[19,20] The early risk of bacteremia in HD patients is related to CVC as the initial access.[20–22] Our study demonstrates that the longer a CVC was left in-situ, the higher the rate of catheter-related bloodstream infection. Furthermore, the duration of HD catheter use was directly associated with the risk of bacteremia, leading to increased mortality during the first 12 months of starting dialysis.[5,23]

Commencement of urgent-start temporary HD increased the risk of HD access-related complications and the risk of dialysis-related complications, especially in the first week of HD. Rapid blood urea nitrogen and fluid removals in the first few HD sessions, particularly in patients with unusually high blood urea nitrogen levels and fluid overload, could lead to intradialytic hypotension and dialysis disequilibrium syndrome because of the sudden change in serum osmolarity and intravascular volume.[24,25] In advanced-stage CKD, considerable fluid accumulation often occurs, and determining how much fluid to remove by ultrafiltration on HD to achieve dry weight can be challenging. In contrast, starting unplanned dialysis in kidney failure with PD is generally gentler.

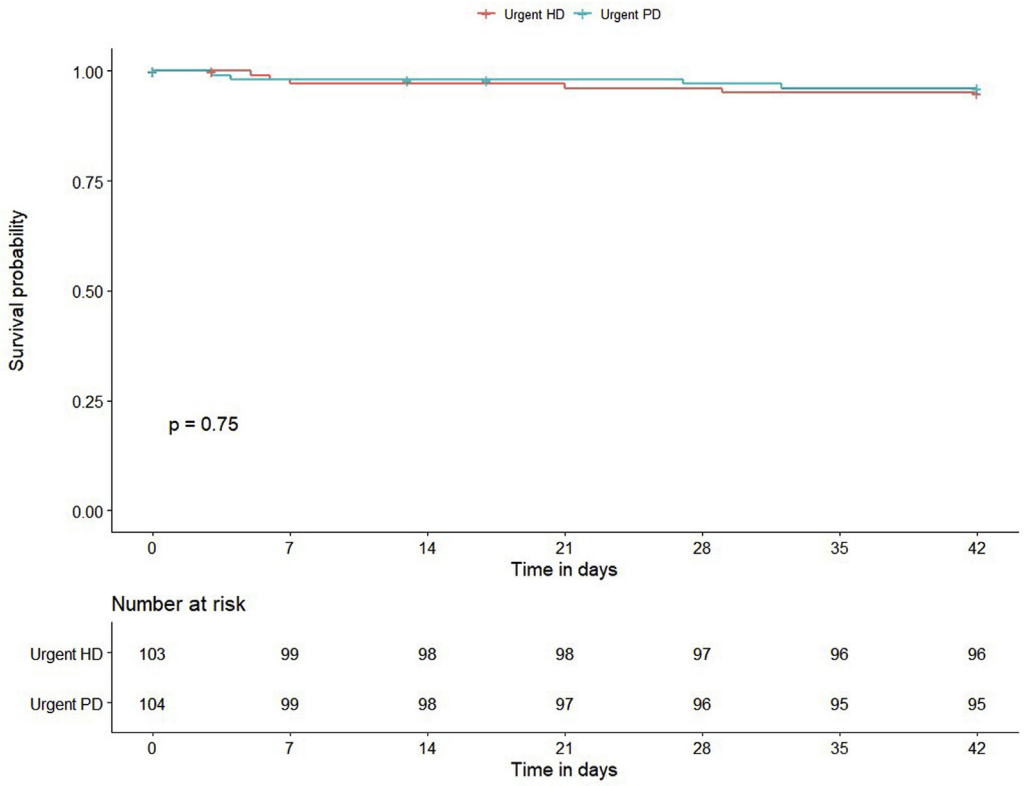

Figure 3. Kaplan–Meier curves comparing patient survival. HD, hemodialysis; PD, peritoneal dialysis.

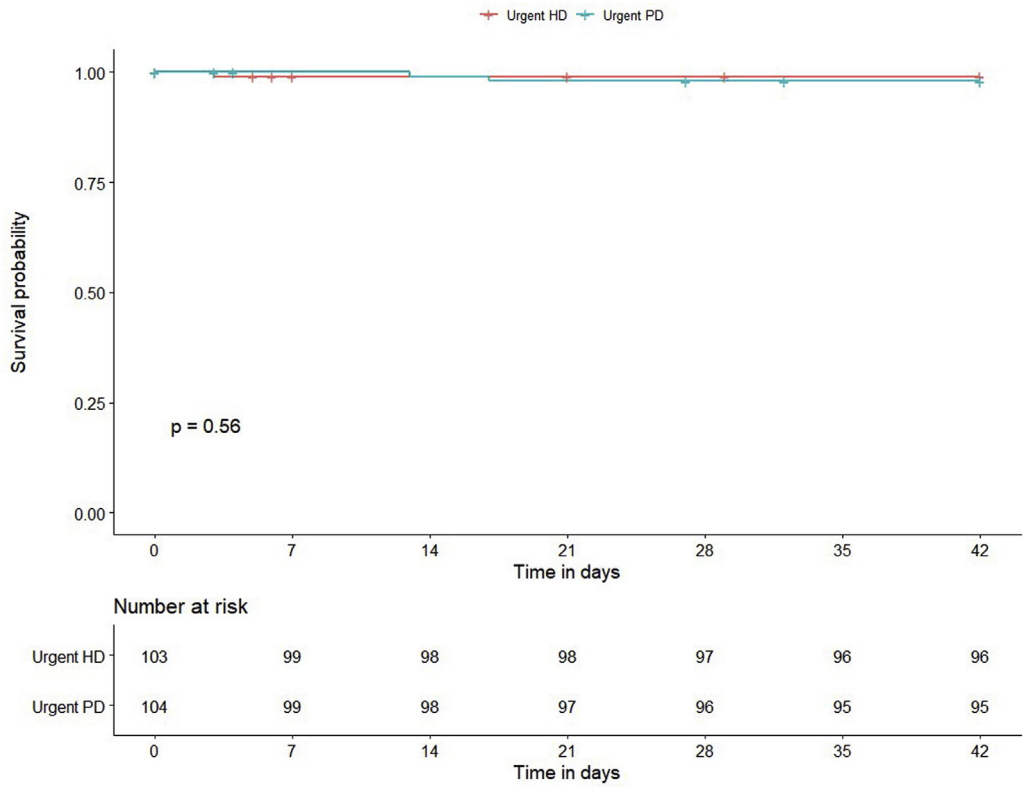

Figure 4. Kaplan–Meier curves comparing technique survival. HD, hemodialysis; PD, peritoneal dialysis.

PD removes fluid and urea continuously, leading to a reduced risk of dialysis disequilibrium syndrome and hemodynamic disturbance. In our study, all intradialytic hypotension and dialysis disequilibrium syndrome episodes occurred in the first week of urgent-start temporary HD. Nevertheless, they did not occur at all in the urgent-start PD group, thereby contributing to higher 6-week dialysis-related complications and overall, 6-week composite complications in the urgent-start temporary HD group. If dialysis-related complications were excluded from the analysis, both modalities were comparable with respect to the composite outcome at 1-week and 6-week.

Two major challenges of using urgent-start PD as a default mode for unplanned dialysis were catheter flow restriction and peri-catheter leakage. Our study reveals that the flow restriction rate was comparable between the 2 groups and consistent with 2 systematic reviews.[12,13] Retention of uremic toxins in advanced-stage CKD may alter gut microbiota, leading to decreased bowel movement,[26,27] and potentially causing PD catheter flow restriction because of tip migration. In our study, a laxative medication protocol for mitigating constipation before and after PD catheter insertion might explain the equivalent results of catheter-related complications between the groups. Intraluminal PD catheter blood clots, which may occur from uremic hemoperitoneum or catheter trauma, could additionally cause PD catheter flow restriction. Rapid PD exchanges starting immediately after catheter insertion and continuing until drained PD fluid was clear in the urgent-start PD protocol might have prevented catheter malfunction from intraluminal blood and fibrin clots. Nevertheless, in our study, urgent-start PD seemed to have a higher incidence of peri-catheter leakage than planned PD following a break-in period of at least 14 days in the urgent-start temporary HD group. It is well documented that the incidence of PD leakage is higher with shorter break-in periods.[28,29] Nonetheless, a 7% peri-catheter leakage rate is well within the range of peri-catheter leakage rates reported following urgent-start PD in the literature.[29–34] The PD prescription protocol with small and incremental PD volumes might be critical in minimizing postoperative peri-catheter leakage. Moreover, as demonstrated by previous studies, all of the peri-catheter leakages in our study resolved within short time frames and did not require HD transfer.[28,35,36]

Our study demonstrates similarities in 1-week and 6-week patient and technique survivals between both modalities, which is in concordance with the previous findings from observational and quasi-experimental designed studies,[14,37,38] which demonstrated no significant difference in patient survival at 3, 6, and 12 months between unplanned PD and HD patients. Nevertheless, these findings should be interpreted with

caution because all of the studies examined survival as a secondary outcome, and sample sizes were small, such that the possibility of type II statistical error cannot be excluded. One patient in our study developed uremic encephalopathy after initiation of urgent-start PD. Therefore, careful selection of patients who do not have emergency indications for dialysis and the availability of prompt HD backup if serious CKD complications occur were critical for safely using urgent-start PD.

The unplanned start of dialysis is a challenging global problem. Home dialysis, including PD, has gained much attention during the pandemic because of the lower risk of acquiring COVID-19 than in-center HD.[10,39] Urgent-start PD is an attractive strategy to overcome this challenge. Our findings confirm that unplanned dialysis patients could be treated safely with urgent-start PD without jeopardizing patient outcomes, at least in patients who are suitable for long-term PD. Nevertheless, the modality for long-term dialysis should depend on the patient's preference and shared decision-making. The availability of an urgent-start PD program enables patients with kidney failure to have a dialysis option other than HD. Furthermore, setting up the hospital infrastructure for urgent-start PD programs was beneficial to the patients and the healthcare system because of the lower cost.[40] Lastly, urgent-start PD is one of the essential keys to increasing home dialysis utilization and promoting patient-centered healthcare in the next decade.

Our study shows the high success rate of PD catheter insertion in advanced-stage CKD and the safety from an acceptable complication rate.[41,42] Two critical factors of success of PD catheter insertion in our study were as follows: (i) the experienced nephrologists who performed PD catheter insertion and (ii) the availability of standardized preoperative and postoperative protocols.

The strengths of this study include the following: (i) it was the first randomized controlled trial comparing the outcome of urgent-start PD and temporary HD with CVC in patients undergoing crash-start dialysis; (ii) the study was conducted in non-university-based hospitals, reflecting real-life practices; (iii) compliance with the intervention was excellent (93%); and (iv) results were analyzed on an intention-to-treat basis. Nevertheless, there were some limitations of this study. Of all participants, 5% deviated from the protocol because of uncontrolled factors. Although we had followed the inclusion criteria, some unpredictable conditions (e.g., accidental internal organ injury, failed dialysis catheter, and refusal of allocated dialysis) occurred. Although site investigators were not informed of the randomization block size, which was fixed at 4, they may have been able to predict the assignment of sequential participants. In addition, the open-label design may have introduced observer and performance biases. Some imbalances in baseline characteristics were observed between the 2 groups because of play of chance. However, multivariable adjustment for these characteristics did not appreciably alter the magnitude, direction, or statistical significance of the composite complication rates at 1 week and 6 weeks. Furthermore, we did not measure residual kidney function or record the amount of blood transfused in the study, so we could not determine whether urgent-start PD preserved residual kidney function better or caused fewer bleeding complications than urgent-start temporary HD. Moreover, because the outcomes assessors were not blinded and no adjudication committee was available in our study, the possibility of detection bias cannot be excluded. Finally, the study findings might not be generalizable to other countries, particularly in the setting of higher body mass index populations or where PD catheter placement is not performed by nephrologists.

In conclusion, urgent-start PD strategy is a viable option for patients transitioning from kidney failure to dialysis. In the setting where PD is the final modality of choice, urgent-start PD is safe, requiring only a single operation and avoiding temporary CVC, leading to fewer overall complications than urgent-start temporary HD during the transition period. In addition, using an urgent-start PD strategy provided comparable patient and technique survivals to urgent-start temporary HD strategy up to 6 weeks after dialysis commencement.

DISCLOSURE

DJ has previously received consultancy fees, research grants, speaker's honoraria, and travel sponsorships from Baxter Healthcare and Fresenius Medical Care, consultancy fees from AstraZeneca and AWAK, and travel sponsorships from Amgen. He is also is supported by an Australian National Health and Medical Research Council Practitioner Fellowship. TK has received consultancy fees from VISTERRA as a country investigator and speaking honoraria from Astra Zeneca and Baxter Healthcare. All the other authors declared no competing interests.

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SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Table S1. Definitions and diagnosis details of complications.

Table S2. Sensitivity analysis of risk ratio of outcomes according to treatment group accounting for all bacteremia episodes.

Table S3. Sensitivity analysis of odds ratio of primary outcome according to treatment group using logistic regression.

Table S4. Sensitivity analysis of risk ratio of outcomes according to treatment group excluding intradialytic hypotension.

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