

Effect of Exchange Systems and Procedure on Long Term Peritonitis in ESKD Patients Undergoing CAPD: A Retrospective Comparative Cohort Study

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Introduction. Peritoneal dialysis utilizes two distinct double-bag exchange systems (ANDY-Disc from Fresenius Medical Care in Bad Homburg, Germany, and DIANEAL from Baxter in Deerfield, IL). These systems are widely used across the globe. The long-term outcomes of peritonitis with different types of treatment are still questionable. Therefore, we conducted a retrospective comparative cohort study to assess the long-term impact of these two distinct exchange procedures on the true peritonitis rate and the technique durability in real-world settings.

Methods. One hundred and twenty patients, treated with a double-bag exchange system in a Songklanagarind Hospital, located in the south of Thailand from January 2009 to December 2020 were included. The primary outcome was the incidence rate of peritonitis by treatment arm (ANDY-disc and DIANEAL). Secondary outcomes included the pathogenic organism causing peritonitis, time to the first peritonitis, and survival technique between the two systems.

Results. The peritonitis rate for patients using the ANDY-disc in continuous ambulatory peritoneal dialysis (CAPD) was 0.28 episodes per patient-year, while the DIANEAL group had a rate of 0.29 episodes per patient-year. There was no difference in the peritonitis rate between the two groups ($P = .816$). Gram-positive bacterial peritonitis accounted for 33.4% in the ANDY-disc arm and 43.7% in the DIANEAL arm. The 10-year technique survival was 86.1% in the ANDY-Disc group and 73.5% in the DIANEAL group; this did not reach statistical significance.

Conclusion. The ANDY-Disc and DIANEAL exchange systems are comparable in the long-term incidence of peritonitis. Both systems have similar long-term technique survival. However, this should be confirmed by a high-quality trial.

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INTRODUCTION

Peritonitis is a frequent and significant complication of peritoneal dialysis (PD) in the context of continuous ambulatory peritoneal dialysis (CAPD). It is associated with treatment failure, higher healthcare expenses, longer hospital stays,

and a higher risk of death. In fact, the mortality rate in CAPD failure can be as high as 39% within one year.¹⁻⁵

At present, the International Society for Peritoneal Dialysis (ISPD) guidelines recommend only a few strategies to prevent PD-related peritonitis.⁶ These

strategies include administration of antibiotics before catheter insertion, training the patients and their caregivers by skilled nursing staff on aseptic catheter care practices, and using exchange systems with a 'flush before fill technique' for CAPD. However, the evidence lacks in quality, and specifically, the data comparing double-bag systems to Y-set systems for peritonitis events are inconsistent and inconclusive.⁷ A comprehensive analysis of 12 studies evaluated the impact of using transfer sets, such as Y-set or double-bag systems, in CAPD exchanges on the incidence of peritonitis. The findings revealed a much lower risk of peritonitis when using the double-bag system compared to the normal Y systems.⁸ The double-bag system is aseptic, with a combined system consisting of a sterile dialysate-containing bag and an empty bag, both fixed to Y connector tubing. This double-bag system is better accepted by patients and has become more widely used in clinical practice.⁹

There are many centers in Southeast Asia that perform PD using either the ANDY-Disc (Fresenius Medical Care, Bad Homburg, Germany) or DIANEAL (Baxter, Deerfield, IL) bag exchange systems.^{2,4,10} A study conducted by Wong *et al.* compared the efficacy of these two systems in 2003.¹⁰ It was found that individuals who used the ANDY-Disc system were more susceptible to develop peritonitis because the product had some problems, mostly with leaks within the draining and dialysate bags. These investigators concluded that the ANDY-Disc system is not therapeutically equivalent to DIANEAL. Thus, we sought to evaluate the long-term effect of these two different exchange methods on the true peritonitis rate in real-world practice.

MATERIALS AND METHODS

Study designs and participants

This study was a retrospective comparative cohort of all end-stage kidney disease (ESKD) patients who underwent peritoneal dialysis with either the ANDY-Disc or DIANEAL exchange systems from January 2009 to December 2020 in Songklanagarind Hospital, affiliated with Prince of Songkla University, is located in southern Thailand. The inclusion criteria were ESKD patients aged 18 years or older treated with CAPD. The exclusion criteria were changing the mode of peritoneal

dialysis to automated peritoneal dialysis, switching to hemodialysis, or being transferred to another center within 6 months after the initiation of CAPD. Tenckhoff (TK) catheters (Medtronic, Dublin, Ireland) had been implanted by open surgery or laparoscopic technique by a surgeon. All patients and caregivers were trained by renal nursing staff and approved of their proficiency before starting on with CAPD at home.

A total of 120 eligible patients were identified from the lists of patients receiving CAPD in the peritoneal dialysis clinic. The prescription of CAPD usually begins with 2 L of fill volume for 3–4 exchanges and a maximum of five exchanges per day. The most common initially used peritoneal dialysis solution was a standard of 1.5% dextrose with lactate buffer (Baxter, Deerfield, Illinois, USA). The nephrologist adjusted the prescription according to the patient's clinical condition. All participants were followed up for at least 6 months. Data from patients after December 31, 2021, was censored. Data were retrieved from the hospital electronic medical records databases. Demographic, clinical characteristics, and laboratory data were collected, which included: age, sex, body weight, body height, body mass index (BMI), cause of ESKD, history of comorbidities, uremic symptoms, medications, blood urea nitrogen (BUN), serum creatinine (SCr), sodium, potassium, chloride, total CO₂ (TCO₂), total calcium, phosphate, albumin, intact parathyroid hormone (iPTH), white blood cell, hemoglobin, and platelet levels, coagulation factors, and other laboratory values from venous blood sampling.

The primary outcome was the incidence rate of PD-related peritonitis between the two exchange systems, reported as episodes per patient-year. According to ISPD guidelines, peritonitis is defined and diagnosed by at least two of the following criteria: abdominal pain and/or cloudy dialysate, a white blood cell count in the effluent of more than 100 cells/mL with at least 50% polymorphonuclear cells, and positive culture results of the dialysate fluid. A stir-bar bottle was used for bacterial culture.⁶ The standard protocol for peritonitis treatment in Songklanagarind hospital was applied, which follows the same approach as outlined in the ISPD guidelines.⁶ Empirical antibiotic therapy was administered by using intraperitoneal cefazolin and ceftazidime, and the medication was adjusted

on the basis of the results of the culture. Secondary outcomes included the pathogenic organism causing peritonitis, time to the first peritonitis, and technique failure, defined as shifting from CAPD to hemodialysis. The decision to shift the mode of dialysis or remove the TK catheter was made by the nephrologist.

The study was approved by the Human Research Ethics Committee of the Faculty of Medicine at Prince of Songkla University with the code number REC 62-426-14-1. The study participants signed the written informed consent from before enrolling in the study.

Statistical analysis

R software Version 3.4.3 was used for statistical analysis. Categorical data are expressed as

frequencies or percentages; the chi-squared or Fisher's exact test was used for intergroup comparisons. Continuous data were recorded as means \pm standard deviation for normally distributed variables and median \pm interquartile range for skew-distributed variables. Statistical differences were compared by using the Student's t-test for normally distributed data and the Mann-Whitney U-test for other variables. The incidence rate of peritonitis was estimated by using a Poisson regression analysis. The first peritonitis-free survival probability curves were analyzed by the Kaplan-Meier method. The comparison of peritonitis-free survival between the two groups was performed by using the peto-peto test. All statistical evaluations were two-sided, and *P*-values $< .05$ were defined as statistically significant.

Table 1. Baseline demographics and clinical data of the patients

Characteristics	DIANEAL	ANDY-Disc	<i>P</i>
Total No of patients	64	56	
Age	57.5 (34, 70)	74.5 (64.8, 80)	$< .001$
Sex			
Male	31 (48.4)	28 (50)	1
Female	33 (51.6)	28 (50)	
BMI	22.4 (19.1, 25.1)	23.6 (21.1, 26.2)	.049
Etiologies of renal disease			
Diabetes nephropathy	10 (41.7)	6 (33.4)	
Hypertensive nephropathy	5 (20.8)	4 (22.2)	
Glomerulonephritis	3 (12.5)	3 (16.7)	.982
Obstructive uropathy	1 (4.2)	2 (11.1)	
Unknown	4 (16.7)	3 (16.7)	
Polycystic kidney disease	1 (4.2)	0 (0)	
Comorbidity disease			
Hypertension	58 (90.6)	52 (92.9)	.749
Diabetes	29 (45.3)	36 (64.3)	.058
Ischaemic heart disease	53 (82.8)	31 (55.4)	.002
Cerebrovascular disease	56 (87.5)	48 (85.7)	.986
Peritoneal dialysis exchanger			
Self-performer	8 (12.7)	3 (5.4)	
Caregiver	39 (61.9)	46 (82.1)	.051
Both self-performer and caregiver	16 (25.4)	7 (12.5)	
Laboratory results			
Urea (mg/dL)	69.2 (48, 98)	58 (41.6, 81.4)	.205
Creatinine (mg/dL)	9.4 (6.8, 13.4)	7.3 (5.3, 11.2)	.01
Serum sodium (mmol/L)	137.3 (4.6)	137.3 (4.8)	.945
Serum potassium (mmol/L)	3.8 (0.7)	3.8 (0.6)	.738
Total CO ₂ (mmol/L)	23.4 (20.8, 26.5)	23.4 (21.4, 26.2)	.996
Serum calcium (mmol/L)	8.4 (1)	8.5 (0.8)	.812
Serum albumin (mg/dL)	3.6 (0.6)	3.5 (0.6)	.491
Hemoglobin (g/dL)	8.4 (1.6)	8.8 (1.7)	.201
Intact PTH (pg/mL)	292.9 (187.1)	396.1 (238.4)	.029

Values expressed as median (IQR), number (percent), and mean \pm SD. BMI: body mass index; PTH: parathyroid hormone.

RESULTS

During the study period, 120 patients met the inclusion criteria and were enrolled; 56 patients were in the ANDY-Disc group, and 64 patients were in the DIANEAL group. The percentage of female participants was 50.8%. The median age of the participants was 66.5 years (51.5–76 years). The etiologies of ESKD were diabetic nephropathy (31.4%), hypertensive nephropathy (21.4%), unknown causes (16.7%), chronic glomerulonephritis (14.3%), obstructive uropathy (7.1%), and polycystic kidney disease (2.4%). Among the participants, 9.2% of patients had self-care CAPD, and 90.7% needed a caregiver for exchanges.

Table 1 shows the baseline characteristics of the two groups of patients (Table 1). Participants were older and had a higher BMI in the ANDY-Disc group. CAPD patients in the DIANEAL group had significantly less ischaemic heart disease, a lower SCr level, and a lower iPTH. Other baseline demographic variables were not significantly different between the two groups.

Peritonitis outcome

The total number of episodes of peritonitis was 129 in both groups; 48 episodes were reported in the ANDY-Disc group with 168 patient-years of follow-up, resulting in a peritonitis incidence rate

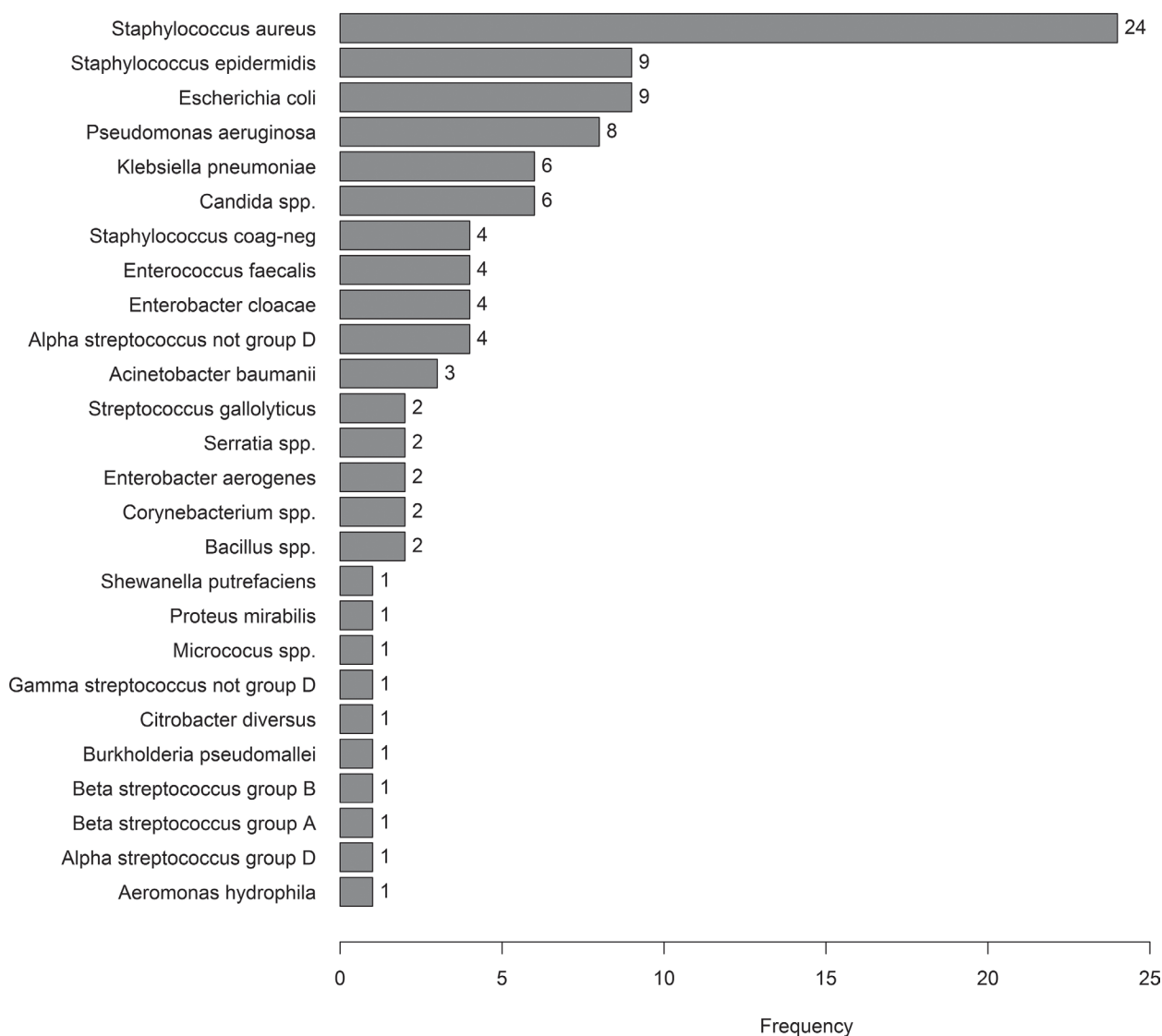


Figure 1. Total causative microorganisms in CAPD-related peritonitis

of 0.28 episodes per patient-year. There were 81 episodes in 272 patient-years of follow-up, defining 0.29 episodes per patient-year in the DIANEAL group. There were no differences in the peritonitis rate between the two groups (incidence density ratio [IDR] 1.04; 95% CI, 0.73-1.49; $P = .816$). In the group of 85 patients who survived during the study period (the survival group), the incidence of peritonitis for ANDY-Disc was 0.24 episodes per patient-year, and for DIANEAL, it was 0.29 episodes per patient-year. No statistically significant difference was observed in peritonitis rates between the two exchange methods among the survival groups (IDR 1.2; 95% CI, 0.78-1.86; $P = .403$). Regarding the 35 patients who died during the study period (the death group), there were 0.37 and 0.31 episodes per patient-year for ANDY-Disc and DIANEAL, respectively (IDR 0.86; 95% CI, 0.41-1.79; $P = .678$).

The pathogenic organism causing the first peritonitis is shown in Figure 1. Overall, gram-positive bacterial infection had the highest incidence, accounting for 36.9% of all cases. Gram-negative organisms accounted for 31.8% of cases, negative culture accounted for 24.1%, and fungal peritonitis had the lowest incidence at 4.5%. Gram-positive bacteria made up 33.4% of the ANDY-Disc group (*Streptococcus* species 10.5%; *Staphylococcus epidermidis* 8.3%; *Staphylococcus aureus* 6.2%; coagulase-negative *Staphylococcus* other than 2.1% or another Gram-positive organism 6.3%), while gram-negative bacteria made up 33.3%. The DIANEAL arm had a substantial number of patients (43.7%) with a gram-positive pathogen, primarily *Staphylococcus aureus* (24.7%). Gram-negative organisms were present in 30.4% of cases. Fungal peritonitis had a low incidence in both arms; 6.2%

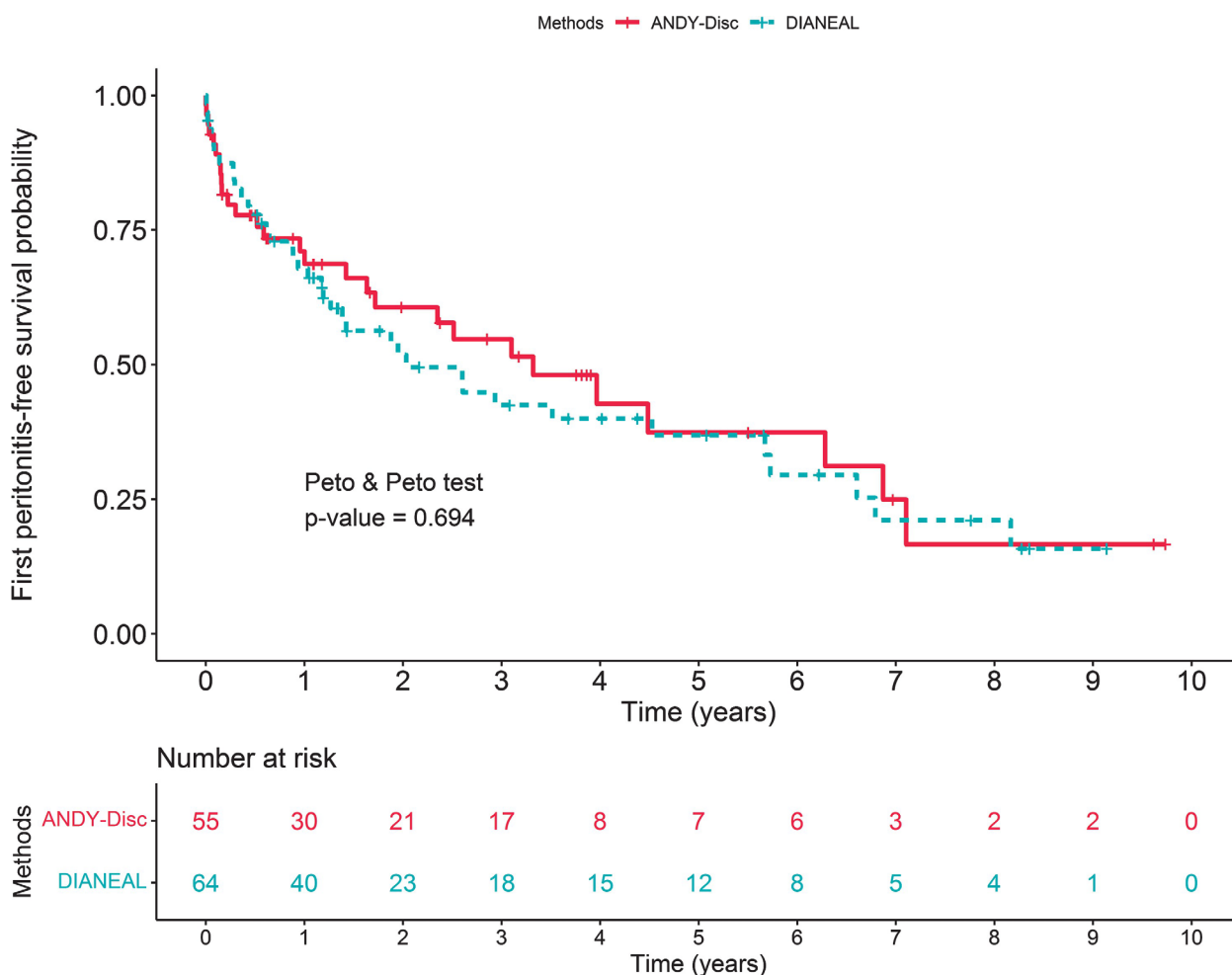


Figure 2. Time to first peritonitis-free survival probability by treatment arms

in ANDY-Disc and 8.6% in DIANEAL. However, there were no statistically significant differences in organisms between the two exchange methods ($P = .288$).

The median time to develop first peritonitis in the ANDY-Disc group was 3.3 years (range 1.7–7.1 years) and 2.0 years (range 1.2–5.7 years) in the DIANEAL group. Figure 2 shows the Kaplan-Meier curve of the first peritonitis-free survival probability. There were no significant differences between the two exchange methods in these events.

Technique survival outcome

The overall technique failure rate was 10.8% in the two systems. For the ANDY-Disc system, the rate of technique failure was 9%, and 12.6% for the DIANEAL system. The median time to technique failure was 2.3 years in both groups (range: 1

month to 10 years). At 1 year and 10 years, the technique survival in the ANDY-Disc group was 95.8% and 86.1%, respectively, and in DIANEAL, it was 96.5% and 73.5%. Beyond two years, there appeared to be a difference in technique survival, with the ANDY-Disc system having a higher survival rate, although it was not statistically significant, as shown in Figure 3.

DISCUSSION

The aim of this study was to compare the long-term outcomes of peritonitis between ANDY-Disc and DIANEAL over a period of 10 years. Additionally, the study attempted to analyze the incidence of peritonitis episodes in both groups, which did not reach statistical significance.

Peritonitis in CAPD patients has become one of the most common problems among patients

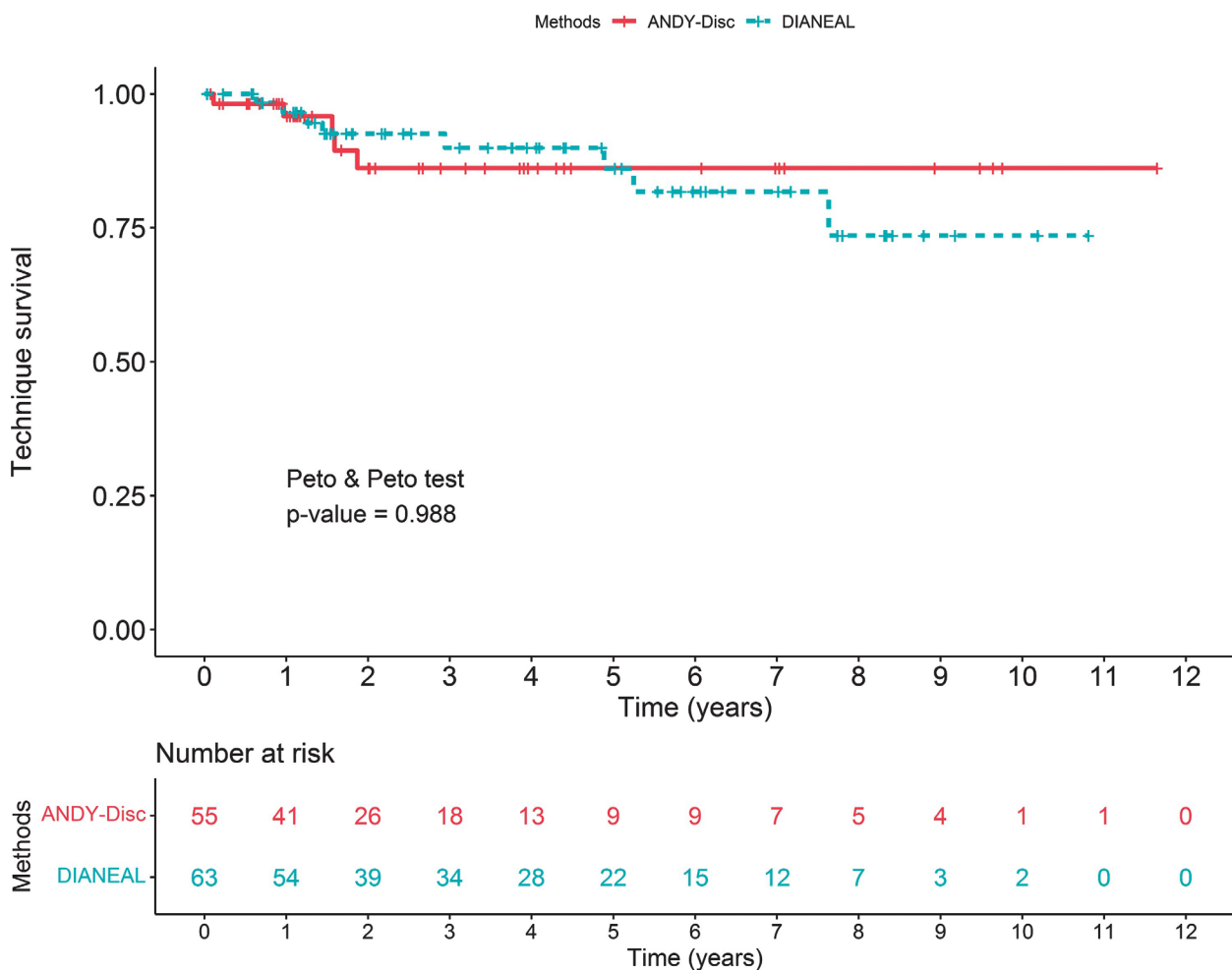


Figure 3. Technique survival probability by treatment arms

in common practice.^{1,3} The two main causes of this infection are peritoneal dialysis-related and secondary peritonitis.^{2,4} Peritoneal dialysis-related peritonitis can happen when an infection spreads from the outlet or exit site, or when organisms are touched during exchanges.^{8,10} The latest ISPD guideline focused on PD training for patients and caregivers to achieve good performance in terms of avoiding peritonitis events.⁶ The literature shows that not wearing a face mask and cap during exchanges was an independent risk factor for first peritonitis.¹¹ This emphasizes the importance of a proper bag exchange step and touch contamination in determining peritonitis outcomes. However, the exchange method systems and peritonitis outcomes had to be evaluated, as there are no specific recommendations in the guidelines due to limited studies.

Our study was conducted to identify the peritonitis outcomes with two exchange methods employing double-bag systems, i.e., the Fresenius Medical Care ANDY-Disc system and the Baxter DIANEAL system. This revealed that the incidence rate of PD-related peritonitis with ANDY-Disc was 0.28 episodes per patient-year and 0.29 episodes per patient-year for the DIANEAL system, which was not statistically significant. These findings correlate with the results of the Peritoneal Dialysis Outcomes and Practice Patterns Study (PDOPPS), which identified 2,272 peritonitis episodes in 7,051 patients in 209 facilities across seven countries (crude rate, 0.28 episodes/patient-year).¹²

In 1995, Kiernan *et al.* found that the Ultra Twin bag system had a significantly lower peritonitis rate than the Ultra Y-set (one episode per 33.9 patient month and one episode per 11.7 patient months, respectively).¹³ These results reflect the lack of touch contamination that occurs in the Ultra Y-set system due to the necessary spiking procedure. Additionally, previous studies confirmed the superiority of the Freeline Solo twin-bag exchange system in reducing the peritonitis rate compared with the Basic Y single-bag exchange method.¹⁴ Later, several innovative double-bag exchange systems became available on the market and many clinical trials demonstrated therapeutic equivalence. Li *et al.* were the first to report a similar incidence of peritonitis and exit site infection with two double-bag exchange systems with a follow up period of 12 months, i.e., Stay-Safe from Fresenius Medical Care

and Ultra Bag from Baxter Healthcare.¹⁵ Similar to our findings, they reported no significant difference in the peritonitis rate between the two exchange systems. Although Stay-Safe and ANDY-Disc are composed of different materials, they have similar fluid transfer system designs. After that, the new Fresenius Medical Care ANDY-Disc system was introduced. A previous study by Wong *et al.* did not demonstrate the therapeutic equivalence of ANDY-Disc and Ultra Bag.¹⁰ However, they showed a trend toward a higher peritonitis rate in the ANDY-Disc arm. The explanation for this finding was associated with product defects on ANDY-Disc and a less familiar exchange procedure.¹⁰ This seems to differ from our results showing that the risk of peritonitis using ANDY-Disc was comparable with DIANEAL. Although we did not collect data on product defects in this study, our center (Songklanagarind hospital) reported no leakage from dialysis bags and drainage systems.

In our study, the microorganisms causing peritonitis were predominantly gram-positive bacteria (33.4% in ANDY-Disc arm, 43.7% in DIANEAL arm). Gram-negative peritonitis accounted for 33.3% in the ANDY-Disc group and 30.4% in the DIANEAL group. This was consistent with previous studies.^{16,17} In a study by Fan *et al.*,¹⁶ the organisms that were detected in first peritonitis were gram-positive bacteria at 32% and 22.7% gram-negative bacteria; however, they did not mention the exchange system used in the study. Gadola *et al.* reported gram-positive bacteria as the most common causative organisms in peritonitis using a double-bag exchange system (Fresenius or Baxter).¹⁷ Our result found a comparable rate of gram-negative bacteria as in the Thai population in PDOPPS.¹²

The different exchange double-bag systems may not influence peritonitis events, but they might be impacted by knowledge and the exchange technique; the concept was supported by Dong and Chen.¹¹ They found that failure to wear a face mask and cap during PD exchanges was significantly associated with first peritonitis in patients using a double-bag connection system. Furthermore, patients who scored in the highest quartile in terms of their knowledge about the required measures to perform peritoneal dialysis (PD) had a decreased incidence of peritonitis compared to those in the middle and lower quartiles, as reported by Sayed *et al.*¹⁸

This shows that patient attitude and behavior are important domains in the prevention of peritonitis.

There were no differences between the two groups in technique failure in this study (10-year technique survival was 86.1% in the ANDY-Disc group and 73.5% in the DIANEAL group). This was probably because of the non-significant difference in the peritonitis rates in both arms. This result is different from a previous study that reported a higher technique failure rate in the ANDY-Disc group due to a higher peritonitis rate in this group.¹⁰

Based on our results, we suggest that the type of double-bag exchange system might not be related to bacterial access in CAPD procedures, especially with intensive nurse training. These findings could be generalized to other countries, since double-bag systems are commercially available and similar in terms of the exchange method.

The strength of our cohort study is the long follow-up period. However, there are some limitations to our study. Firstly, the study was conducted in a single center with a small number of patients. Thus, different baseline characteristics of patients and different CAPD training and practices may affect different peritonitis outcomes. Secondly, our study was a retrospective cohort, so the CAPD training program and prescription depended on the nursing practice and decision of the nephrologist, respectively. This bias may affect different peritonitis incidences and patterns. Hence, a randomized controlled trial should be performed to confirm these results.

CONCLUSION

In terms of peritonitis performance, the ANDY-Disc and DIANEAL exchange methods produce comparable results. The two exchange systems have a similar time to first peritonitis and technique survival. Our study also confirmed the effect of a low incidence of peritonitis in the double-bag system era. However, this needs to be confirmed with a higher-quality trial.

AUTHORS CONTRIBUTION

PD: conception and design of the study. PD: collection of data. PD and AP: data analysis and interpretation. AP: drafting of the first manuscript. All authors reviewed and edited the different versions of the manuscript and approved the final version of the manuscript.

DATA AVAILABILITY

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

FUNDING

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ETHICAL CONSIDERATIONS

The study received approval from the Human Research Ethics Committee of the Faculty of Medicine at Prince of Songkla University with the code number REC 62-426-14-1. All participating patients had comprehensive clinical data. Written informed consent was obtained from the patients and/or their guardians.

PATIENT CONSENT FOR PUBLICATION

Not applicable

CONFLICT OF INTERESTS

The authors declare no conflict of interests

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