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Different outcomes between downward and lateral peritoneal dialysis catheter exit-site directions

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Abstract

Background The International Society for Peritoneal Dialysis guidelines suggest lateral or downward exit positions for peritoneal dialysis (PD) catheter. In cases with straight inter-cuff design (used in Thailand), downward exit may lead to more complications due to catheter memory force. We compared lateral (lateral group) and downward (downward group) exits in PD patients.

Methods We retrospectively studied end-stage kidney disease patients with PD catheters from 2011 to 2021 at Chao Phraya Abhaibhubejhr Hospital, Thailand. We analysed catheter malfunction, exit-site infection (ESI) and patient survival.

Results A total of 425 patients, aged 11–87 years (57% female and 59% with diabetes mellitus). 326 had downward exits, and 99 had lateral exits. Both groups had similar 2-years patient survival ($p=0.592$), 1-year survival catheter dysfunction requiring removal ($p=0.146$) and First-year ESI ($p=0.432$). In the lateral exit group, the percent of catheter dysfunction requiring removal was slightly lower (1.01 vs. 3.99, $p=0.204$) while the percent of patient with ESI at first year was slightly higher (8.08 vs. 6.13, $p=0.494$) compared to downward exit group.

Conclusions Lateral exit and downward exit with a straight inter-cuff design have similar outcome of catheter survival/function, exit site infection and patient survival. Lateral exit site is a good option in context of a straight inter-cuff design.

Keywords Lateral exit, Downward exit, Catheter dysfunction, Exit-site infection, Peritoneal dialysis

Introduction

Peritoneal dialysis (PD) serves as an essential kidney replacement therapy, contingent on a secure, functional, and enduring catheter access to the peritoneal cavity, promptly provided. However, catheter-related complications can lead to catheter loss and contribute to discontinuation of PD. As advancements in preventing and treating PD-associated peritonitis have been made, the impact of catheter-related infections and mechanical issues on the duration of PD therapy has gained significance [1].

Irrespective of the approach used for catheter implantation, optimal practices suggested that the skin exit site

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can be directed lateral or downward. A study comparing catheters with a preformed arcuate bend for a downward exit site and catheters with a straight inter-cuff segment for a lateral exit site revealed similar outcomes regarding exit-site infections and mechanical complications [2]. However, in Thailand, we currently have only PD catheter with a straight inter-cuff segment. Concerns arise about the potential disruption of the catheter's shape memory during insertion, which may contribute to tip migration and catheter dysfunction when creating a downward exit site direction as compared to lateral exit direction. Moreover, the downward exit site configuration carries an increased risk of cuff extrusion due to the catheter's shape memory resiliency force, potentially leading to exit-site infections.

Addressing these concerns and optimizing catheter implantation techniques is crucial to enhance the overall success of PD treatment and reduce complications related to catheter placement.

Methods

Study design and subjects

This study includes all PD catheters placed in patients with end-stage kidney disease aged 11 years or older. The catheter implantations were performed using an open surgical dissection technique by the same experienced nephrologist at Chao Phraya Abhaibhubejhr Hospital, Thailand, during the period between August 2011 and November 2021. Only first catheters were included in the analysis. We analysed and compared patient characteristics, incidents of catheter dysfunction necessitating surgical removal and exit-site infections for the first year following catheter insertion between two distinct groups: the downward exit-site configuration group and the lateral exit-site configuration group. The patient survival was followed for minimum of 2 years.

Procedures

Catheter placement by open surgical technique (mini-laparotomy)

Before the catheter placement procedure, patients received a 3-day bowel program to prevent perioperative constipation and were instructed to void before entering the operation room. The procedure was performed under local anaesthesia. The surgical site was prepped using a chlorhexidine-gluconate scrub, and sterile drapes were applied around the surgical field. A 1-inch incision, located 3 cm below the umbilicus, was made through the skin, subcutaneous tissues, and anterior rectus sheath. The underlying muscle fibres were then split to expose the posterior rectus sheath. A small hole was carefully created through the posterior sheath and peritoneum to gain access to the peritoneal cavity.

Next, a purse-string suture was placed around the opening at the level of the peritoneum and posterior rectus sheath. A 62 cm-length, silicone rubber, two-cuff, coiled tip PD catheter with a straight intersegment (Argyle TM peritoneal catheter) was prepared by rinsing and flushing it with saline, with any air squeezed out of the Dacron cuffs by gently rolling the submerged cuffs between fingers. The catheter, which was straightened over an internal stylet, was then advanced through the peritoneal incision toward the pelvis. The advancement of the catheter into the peritoneal cavity was mainly guided by a sense of touch. In case the catheter tip could not be inserted deep enough or encountered any resistance, the operator had the option to reinsert it by changing the direction until a satisfactory position was achieved.

Once the catheter was satisfactorily placed, the stylet was completely withdrawn, and the purse-string suture was tied to secure the catheter in position. Before closing the sheath, catheter patency and flow function testing was performed. For successful testing, the infusion of 300 ml of saline should result in unimpeded inflow and outflow, with more than 70 ml of outflow drained. If the catheter patency testing was not passed, the pure-string suture was untied, and the catheter was reinserted by the same procedure.

To ensure the catheter tip remained oriented toward the pelvis, a simple interrupted suture of the rectus sheath was performed in a caudocranial direction. Additionally, the internal stylet was bent to create subcutaneous tunneling in a manner that allow for customized skin exit-site direction for each patient. All exit sites were positioned above the belt line. After the closure of the skin and subcutaneous tissues, the catheter adapter, transfer set, and mini cap were assembled with the external catheter during the procedure.

Primary and secondary outcomes

The primary outcome of this study was to assess and compare the incidence of catheter dysfunction necessitating surgical removal between the two groups (downward exit-site configuration and lateral exit-site configuration). As for the secondary outcome, we aimed to evaluate and compare the incidence rates of exit-site infections and patient survival between the two groups.

Catheter dysfunction necessitating surgical removal was defined by mechanical failure in dialysate inflow or outflow in which reversible causes of dysfunction, e.g., constipation, urinary retention, ileus, intraluminal clot or fibrin etc. were find out and correct by non-operative treatment (activity, laxative, drainage, manual reduction and rtPA). Exit-site infection was defined as the presence

of purulent discharge, with or without erythema of the skin at the catheter epidermal interface.

Statistical analysis

Descriptive statistics were used to present the results, with categorical variables expressed as frequencies and percentages, continuous normally distributed variables presented as mean and standard deviation (SD), and continuous non-normally distributed variables displayed as median values with the interquartile range (IQR). Demographic data between groups were compared using Chi-squared and Wilcoxon Mann–Whitney U tests for categorical and continuous variables.

To evaluate the 1-year survival of catheter removal due to a mechanical problem, the first exit-site infection, and to examine the 2-year survival of patients in both downward and lateral exit-site directions, we employed Kaplan–Meier survival analysis and Log–rank test. Incidence rates were reported per 100 person-months.

A p value of less than 0.05 was considered statistically significant. All statistical analyses were conducted using STATA software release 14 (StataCorp LP, College Station, Texas, USA).

Results

A total of 425 patients were enrolled in the study. Patient ages were ranging of 11–87 years. 57% were female, and 59% had diabetes. Of the total, 326 patients were directed downward, while 99 patients had a lateral PD catheter exit. Notably, all cases of lateral exit-site direction were initiated after December 2019. Comparison between the downward and lateral exit-site directions showed no significant difference in the 2-year death rate ($p=0.612$) (Table 1) and 2-year patient survival ($p=0.592$) (Fig. 1-3rd).

During the 1-year follow up after catheter placement, the survival analysis for catheter dysfunction requiring surgical removal and first time of ESI were comparable in both groups. However, it has trend of catheter dysfunction requiring surgical removal in downward group and shorter time to first ESI in lateral group. The percent of catheter dysfunction requiring surgical removal were slightly higher in the downward exit-site group compared to the lateral group (3.99 vs. 1.01, $p=0.204$) (Table 1) and also with the incidence rate (0.4 vs 0.1 per 100 person-months, $p=0.146$) (Table 2, Fig. 1-1st). The percent of patient with ESI at first year were slightly lower in the downward exit-site group compared to the lateral group (6.13 vs. 8.08, $p=0.494$) (Table 1) and also with the incidence rate (0.61 vs 0.86 per 100 person-months, $p=0.432$) (Table 2, Fig. 1-2nd). Importantly, there were no occurrences of catheter leakage or cuff protrusion observed in either of the groups at first year (data not shown).

Discussion

Before the year 2000, the conventional practice was to insert double-cuff peritoneal catheters with an arcuate tunnel, convex upwards, aiming to position the catheter tip in the true pelvic inlet to prevent tube migration and create a downward exit-site configuration to reduce the risk of exit-site infection. However, bending a catheter with a straight inter-cuff segment into an arcuate configuration can introduce tubing stress, potentially increasing

Table 1 Demographic characteristics of ESKD patients in the study

Variable	Total ($n=425$)	Downward ($n=326$)	Lateral ($n=99$)	p value
Female	242 (56.94)	180 (55.21)	62 (62.63)	0.192[a]
Age (years)	56.27 ± 14.21	55.77 ± 14.38	57.89 ± 13.58	0.207[b]
Diabetes mellitus	251 (59.06)	187 (57.36)	64 (64.65)	0.197[a]
Height (cm)	159.3 ± 8.53	159.25 ± 8.92	159.59 ± 7.14	0.700[c]
eGFR (ml/min/1.73 m^2)	4.62 ± 2.90	4.80 ± 3.09	4.01 ± 2.06	0.052[b]
BUN (mg/dL)	105.0 ± 40.20	105.58 ± 43.09	103.31 ± 29.65	0.840[b]
Albumin (g/dL)	3.4 ± 0.61	3.35 ± 0.62	3.47 ± 0.59	0.170[c]
Hemoglobin (g/dL)	8.2 ± 1.57	8.22 ± 1.59	8.25 ± 1.51	0.854[c]
Within 1 year follow-up after catheter placement				
Catheter dysfunction requiring surgical remover	14 (3.29)	13 (3.99)	1 (1.01)	0.204[d]
Exit-site infection	28 (28.00)	20 (21.50)	8 (6.50)	0.494[a]
Within 2 years follow-up after catheter placement				
Death	171 (40.24)	129 (39.57)	42 (42.42)	0.612[a]

ESKD end-stage kidney disease, *SD* standard deviation, *IQR* interquartile range

Statistical analyses: [a]Chi-square test, [b]Wilcoxon Mann–Whitney U test, [c]Independent Sample *t* test, and [d]Fisher's Exact test

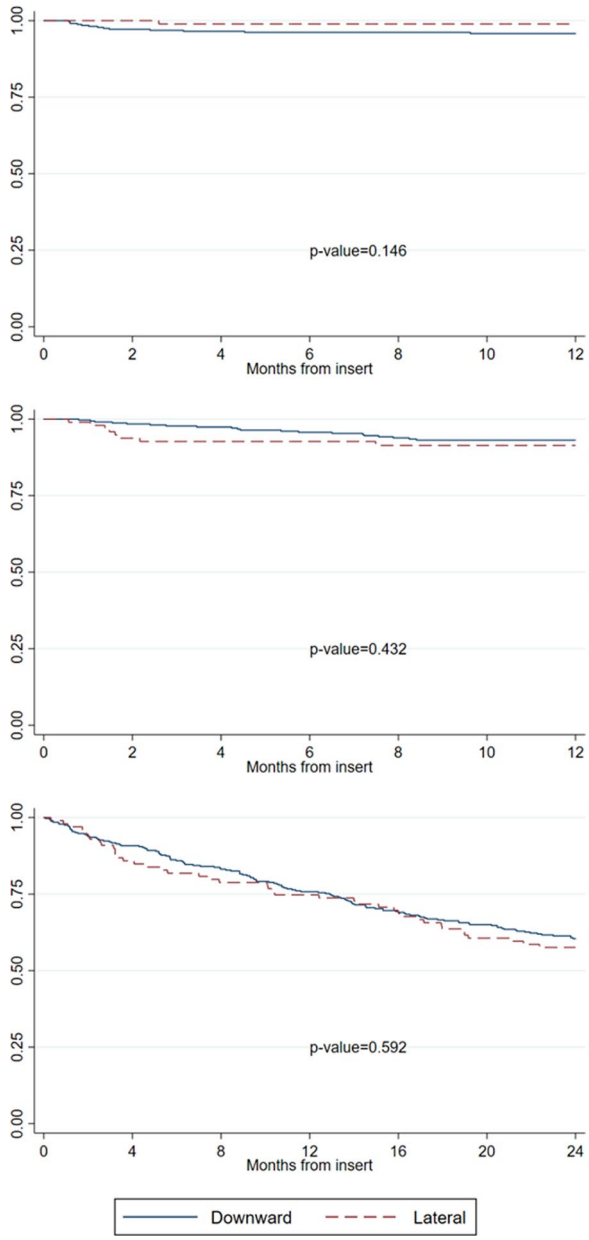

Fig. 1 Peritoneal catheter survival comparison between downward and lateral exit-site direction in PD catheters with straight inter-cuff segment placement. 1st figure 1 year survival catheter dysfunction requiring surgical removal. 2nd figure 1 year survival first exit-site infection after catheter placement. 3rd figure 2 years patient survival (death)

the risk of internal catheter tip migration and exit-site infection due to cuff extrusion. In response to these concerns, a preformed arc bend design, commonly referred to as the "swan neck" design, was developed and utilized since 1991 [3, 4]. Numerous studies have demonstrated that both the swan neck and a straight inter-cuff segment design did not influence the number of technique failures, the long-term catheter and patient survival and the infectious outcomes [5–9].

In settings where only the straight inter-cuff segment design is available, the latest International Society for Peritoneal Dialysis (ISPD) guidelines now recommend laterally directed exit-site to mitigate complications arising from the catheter's shape memory resiliency force [1]. Supporting this recommendation, Crabtree JH and Burchette RJ conducted a prospective analysis comparing infectious and mechanical complications between 85 catheters with a preformed arcuate bend producing a downward exit site and 93 catheters with a straight inter-cuff segment configured to create a lateral exit site. Their findings showed that both catheter types, employing downward and lateral tunnel-tract and exit-site configurations, yield equivalent outcomes for infectious and mechanical complications [2].

In Thailand, the swan neck design was unavailable, and only the straight inter-cuff segment design was employed. Surgeons and nephrologists were accustomed to inserting a catheter with an arcuate tunnel, convex upwards, and downward exit site as the ideal approach. Out study aimed to explore the potential benefits of the lateral exit-site direction in a large sample size, which might challenge our traditional practices. The results indicated that laterally directed exit of the PD catheter with a straight inter-cuff segment has the nonsignificant lower incidence of catheter dysfunction requiring surgical removal but carried a nonsignificant higher risk of exit-site infection compared to the downward exit. These findings reaffirmed the conventional understanding that minimizing the incidence of catheter tip migration requires proper consideration of tubing resiliency forces, and a downwardly directed exit site would seemingly be less prone to contamination due to gravity flow away from the skin sinus tract orifice.

Based on the results of this study, a laterally directed exit-site of the PD catheter with a straight inter-cuff segment may be preferable to the downward exit site, as catheter malfunction is a major reason for PD discontinuation, while exit-site infections can be readily treated and prevented. In general, our hospital doesn't use routine tropical exit site antibiotic prophylaxis in all cases which is consistent with PDOPP data [10]. If we start using antibiotic ointment in clinical practice, the incidence of infection is likely to decrease. Our study found that no cases of exit-site infection resulted in serious complications requiring catheter removal. In Thailand, we have only one size length of the straight inter-cuff segment catheter, which is long compared to the size of the patient's abdomen. This results in the exit site of the catheter being located high, above the belt line, near the umbilicus. Patients are therefore taught to wear

Table 2 Outcome of different exit-site directions

Variable	Total ($n=425$)	Downward ($n=326$)	Lateral ($n=99$)	p value
1 year survival of catheter dysfunction requiring surgical removal				0.146
Time at risk	4270.16	3267.93	1002.23	–
Incidence rates (per 100 person-months)	0.33 (0.19, 0.55)	0.40 (0.23, 0.69)	0.10 (0.01, 0.71)	–
1-year survival (%)	96.50 (94.15, 97.91)	95.76 (92.81, 97.52)	98.90 (92.46, 99.84)	–
Mean survival time (months)	11.66 (11.48, 11.84)	11.59 (11.37, 11.81)	11.90 (11.70, 12.10)	–
At 25 percentiles (months)	Not reached	Not reached	Not reached	–
At 50 percentiles (months)	Not reached	Not reached	Not reached	–
1 year survival of first exit-site infection after catheter placement				0.432
Time at risk	4199.89	3264.23	935.66	–
Incidence rates (per 100 person-months)	0.67 (0.46, 0.97)	0.61 (0.40, 0.95)	0.86 (0.43, 1.71)	–
1-year survival (%)	92.69 (89.57, 94.90)	93.12 (89.53, 95.51)	91.42 (83.53, 95.63)	–
Mean survival time (months)	11.42 (11.21, 11.64)	11.50 (11.28, 11.72)	11.17 (10.61, 11.73)	–
At 25 percentiles (months)	Not reached	Not reached	Not reached	–
At 50 percentiles (months)	Not reached	Not reached	Not reached	–
2 years patient survival				0.592
Time at risk	7803.38	6025.54	1777.82	–
Incidence rates (per 100 person-months)	2.19 (1.89, 2.55)	2.14 (1.80, 2.54)	2.36 (1.76, 3.20)	–
1-year survival (%)	75.53 (71.15, 79.34)	75.77 (70.74, 80.06)	74.75 (64.96, 82.17)	–
2-year survival (%)	59.76 (54.94, 64.25)	60.43 (54.90, 65.50)	57.58 (47.24, 66.60)	–
Mean survival time (months)	18.36 (17.59, 19.13)	18.48 (17.61, 19.36)	17.96 (16.31, 19.61)	–
At 25 percentiles (months)	12.72 (9.59, 14.55)	12.91 (9.50, 14.95)	10.42 (4.53, 17.15)	–
At 50 percentiles (months)	Not reached	Not reached	Not reached	–

Statistical analyses: Kaplan–Meier survival analysis and Log-rank test

low-waist pants to reduce friction between the edge of the pants and the catheter. A higher position of exit site (lateral exit) may avoid exit site and catheter trauma. Also, in patients with a flabby abdomen, a high exit site location makes it easier to clean and secure the catheter with the rubber band. Moreover, to create subcutaneous tunneling for customized downward skin exit-site direction has a bit difficult than lateral exit-site direction for new surgical trainees. Based on the advantages of both exit site directions, if they are combined and applied in clinical practice, the placement of a straight inter-cuff segment catheter with a semi-oblique downward exit site without any tension during insertion may be the best method, providing benefits in terms of both catheter dislodgement and exit site infection.

The strengths of this study lie in its large sample size, uniform surgical technique and catheter design performed by the same physician, consistent follow-up care provided by the PD nurse team, and all cases having good or acceptable flow during intraoperative catheter patency testing, indicating that the initial catheter function in both groups were similar. However, a potential criticism is that the catheter assignment was not randomized, and all cases of lateral exit-site direction were initiated during the last 2 years of the study, the selection bias is introduced. Future studies with randomized allocation could further validate the findings of this research.

Abbreviations

ISPD	The International Society for Peritoneal Dialysis
PD	Peritoneal dialysis
ESKD	End-stage kidney disease
ESI	Exit-site infection
rtPA	Recombinant tissue plasminogen activator
SD	Standard deviation
IQR	Interquartile range

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Author contributions
The research work was conducted collaboratively by the authors. WT conducted a comprehensive review of the literature, conceptualized the study, and played a key role in protocol development, obtaining ethical approval, patient recruitment, and writing the initial draft of the manuscript. PP was actively involved in the data analysis process. KP provided supervision throughout the study and contributed to the interpretation of the results. All authors participated in the critical review and approval of the final version of the manuscript.

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

Declarations

Ethics approval and consent to participate
This study protocol was reviewed and approved by the Ethic Committee of Chao Phraya Abhaibhubejhr Hospital. IRB-BHUBEJHR-246.

Consent for publication
Not applicable.

Competing interests
The authors declare that there is no conflict of interest.

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