ORIGINAL ARTICLE

Preventing Peritoneal Dialysis Catheter Exit Site Granuloma and Infection With Fixator Dressing: A Single-center Retrospective Analysis

Lim Xue Meng, Esther Tan Zhao Zhi

Hospital Selayang, Lebuhraya Selayang-Kepong, 68100 Batu Caves, Selangor, Malaysia

ABSTRACT

Introduction: Peritoneal dialysis (PD)-related infection is associated with morbidity and mortality. Exit site care is important to prevent infection and the ensuing tunnel infection and peritonitis. The aim of this study is to compare the use of two different dressings on exit site and tunnel outcomes. **Methods**: A retrospective cohort study was conducted in a tertiary center from January 2023 to July 2024. All patients received either fixator or standard dressing, from immediately after PD catheter insertion up to 21 days. They are then followed up for 30 days. The primary outcomes for this study are exit site granuloma formation and exit site infection. The secondary outcomes are tunnel infection and catheter extrusion. **Results**: A total of 161 patients completed the study, with 111 patients in the fixator group, and 150 patients in the standard group. There were six cases of exit site infections, three in each group. This corresponds to 1 episode per 37 patient-months for fixator dressing, and 1 episode per 50 patient-months for standard dressing. There was no significant difference in exit site infection between the groups. Standard dressing group reported two cases of granuloma infection, and fixator group had none. There is no tunnel infection or catheter extrusion in both groups.**Conclusion**: There is no significant difference between the use of fixator or standard dressing in subsequent granuloma formation, exit site infection, tunnel infection or catheter extrusion. These two types of exit site dressings can be used interchangeably in the early post catheter insertion period.
Malaysian Journal of Medicine and Health Sciences (2026) 22(3): 1-5.doi:10.47836/mjmhs.v22i3.1569

Keywords: Exit Site Dressing, Fixator Dressing, Exit Site Infection, Tunnel Infection, Granuloma Formation

Corresponding Author:
Dr Lim Xue Meng, MD
Email: lim_mich871124@yahoo.com
Tel: +60176271638

INTRODUCTION

Peritoneal dialysis (PD) is a mode of kidney replacement therapy (KRT) used in the management of people with end stage kidney disease (ESKD). According to the 30th report of the Malaysian Dialysis and Transplant Registry 2022, there are a total of 51,256 patients undergoing maintenance KRT, of which 7,940 were on peritoneal dialysis. Dialysis prevalence rate had increased by almost 1.5-fold over the last 10 years. The registry reported an up-trending incidence of new KRT provided, from 9,352 patients in year 2021 to 9,592 patients in year 2022; 18.6% of the new patients are on PD (1). With the increasing number of people on PD, the catheter exit site care becomes a priority for the prevention of complications and prolongation of technique survival. The Standardized Outcomes in Nephrology – PD (SONG-PD) initiative has highlighted the significance of PD-related infection, including exit site and tunnel infection, as a major clinical outcome in PD for patients, caregivers and clinicians (2).

PD catheter-related infections may result in PD peritonitis, transfer to hemodialysis, hospitalization, and death. PD catheter exit site infection is defined as the presence of purulent discharge with or without erythema at the catheter-epidermal interface area (3). After establishing the diagnosis of exit site infections according to the definition above, they can be then classified according to the organism(s) culture results. The ISPD suggested that PD catheter tunnel tract infection is described as the presence of clinical inflammation (erythema, pain, swelling or induration) with or without fluid collection along the tunnel detected via ultrasound imaging (3). The International Society of Peritoneal Dialysis (ISPD) defined PD catheter insertion-related exit site and/or tunnel infection as an incident episode of exit site infection/tunnel infection within 30 days of PD catheter insertion, as these infections are more likely related to the surgical procedure (3,5). Catheter related infection can also be defined by outcome, where refractory catheter-related infection is diagnosed in the event of failure to respond to treatment after two weeks

of effective antibiotic use and intensified exit site care, or after three weeks for Pseudomonas sp. infection (3). Infection-related catheter removal is defined when catheter is removed due to infection not responding to appropriate antibiotic use or salvage procedure (3). The ISPD recommends a target of for exit site infection and PD peritonitis below 0.4 episodes per year at risk, and for catheter insertion-related infection less than 5% of all catheters inserted (4,5). In a tertiary center in Malaysia, exit site infection was reported at 0.05–0.11 episodes per year, lower compared to the international standard target of less than 0.4 episodes per year at risk (6). PD infections constitute 9.5% of drop out from PD program, of which 5% dropped out within three months of treatment in Malaysia in year 2022 (7).

In order to prevent catheter insertion-related infection, the Kidney Disease Outcome Quality Initiative (KDOQI) recommends keeping the exit site dressing intact for at least seven days after PD catheter insertion to avoid traction injury of the exit site and subsequent granuloma formation and infection (3). The ISPD and the Global Renal Exercise Network practice also recommended fixating the catheter in place to avoid repetitive rubbing of the catheter site during activity to prevent granuloma formation due to the repetitive friction between the PD catheter and the epidermal-dermal interface (8). Granuloma has been associated with exacerbated breakdown of the exit site, therefore, preventing granuloma formation may reduce incidence of exit site and tunnel infection.

The aim of this study is to determine if the use of fixator dressing in early post operative period to prevent friction between the PD catheter and the exit site skin is associated with reduction in exit site granuloma formation, exit site and tunnel infection, as well as catheter extrusion, when compared to standard dressing.

Methods

Study Design and Participants

A retrospective cohort study was conducted among ESKD patients who had undergone PD catheter insertion in Hospital Selayang, Selangor, Malaysia, from January 2023 to July 2024. Medical records of all patients fulfilling the criteria above are included for screening, and patients who have fulfilled inclusion criteria and were followed up for thirty days post catheter insertion. Patients were divided into two groups, namely a group that have used of Loopix wound drainage tube fixing device dressing (Zhejiang HaiChuang Medical Device Co. Ltd., China) for 21 continuous days, and a group that have used standard gauze and non-occlusive dressing. The fixator dressing group included participants from 15th October 2023 up till 31st July 2024, which is then compared to the immediate historical cohort of standard dressing during the period from 1st January 2023 to 15th October 2023. Permission was obtained from the Malaysian Human Research Ethics Committee, and this study was conducted in accordance with the Declaration of Helsinki, the International Conference and Harmonization Guidelines for Good Clinical Practice, and the National Medical Research Registry (NMRR ID-24-03970-FOD).

Patients aged 18 years and above and had PD catheter insertion within the study period and had completed follow up for thirty days were included in the study. Those who had a change in modality (hemodialysis or transplantation), or death, not related to exit site granuloma or infection, are excluded from the study. Sample size estimation for this study was calculated using the two population proportion formulae (Lemeshow and organization, 1990), with sample size for each group amounting to 99 subjects after accounting for twenty percent drop-out each. Patients were assigned into two groups according to their dressing method post catheter insertion, that is, fixator or standard dressing. The treatment allocation was not blinded. All patients had the same dressing for 21 days from the day of PD catheter insertion.

Outcome Measures

The primary outcome was exit site granuloma formation and exit site infection within thirty days of catheter insertion. The secondary outcomes were tunnel infection or catheter extrusion within thirty days of catheter insertion.

Demographic data and clinical records were reviewed. Patients were followed up for thirty days from the day of PD catheter insertion, for evidence of granuloma formation, exit site infection, catheter extrusion, and tunnel infection, which are then tabulated for each of the two groups. Purulent discharge at the catheter-epidermal skin interface, with or without erythema, was used to define exit site infection. Tunnel infection is diagnosed in the presence erythema, edema, induration or tenderness, with or without sonographic evidence of fluid collection along the tunneled segment of the catheter.

Statistical Analysis

Descriptive statistic will be presented as mean and standard of deviation for normally distributed numerical data whereas median and range will be presented for numerical data which is not normally distributed, or frequency and percentage values as appropriate. The independent T-test was used to compare the two dressing groups. The Pearson's Chi Square test for independence was used to compare the differences for categorical data between groups, and the Fisher's exact test was used if the assumption for Chi-square was not met. All analyses will be carried out using SPSS statistical software (version 23, IBM, SPSS, Chicago, IL, USA). A level of significance of less than 0.05 (p value <0.05) will be considered statistically significant.

Results

Patient Characteristics

There are a total of 275 patients who had undergone laparoscopic peritoneal dialysis catheter insertion in a tertiary center from 1st January 2023 to 31st July 2024. Among the 261 patients who fulfilled the inclusion and exclusion criteria, 150 patients had standard dressing upon insertion of the peritoneal dialysis catheter whereas 111 patients are identified to have received the fixator dressing post catheter insertion up to 21 days. All the patients were followed up for thirty days from the date of catheter insertion and completed this study. The baseline characteristics of the patients according to their dressing types are summarized in Table 1. The average age of the patients in fixator dressing group was 54.9 years and 53.8 years in the standard dressing group. More than 90% of the patients have hypertension at baseline, and more than half of both groups had diabetes mellitus. Standard dressing group had more patients with obesity.

Table I: Baseline characteristics of subjects categorized according to two groups of dressings.

Characteristics	Fixator dressing (n = 111)	Standard dressing (n = 150)	p value
Mean age, year ± SD	54.9 ± 15.61 years	53.8 ± 13.46 years	0.26
Gender, n (%)			0.94
Male	72 (64.9%)	98 (65.3%)	
Female	39 (35.1%)	52 (34.7%)	
Hypertension, n (%)	103 (92.8%)	136 (90.7%)	0.54
Diabetes mellitus, n (%)	71 (64.0%)	93 (62.0%)	0.75
Obesity, n (%)	7 (6.3%)	20 (13.3%)	0.07

In this study, there were two cases of exit site granuloma formation in the standard dressing group, whereas there is none found in the fixator dressing group. Exit site infection was likewise, similar between both groups, with three cases each (p=0.70). The rate of exit site infection was not significantly different between the two groups: 1 episode per 50 patient-months for standard dressing, and 1 episode per 37 patient-months for fixator dressing. Among the exit site infection cases, two cases were caused by staphylococcus aureus, two were caused by pseudomonas aeruginosa, and one reported mixed organism of more than three kinds, and one was a culture negative case. All granuloma and exit site infections responded to treatment well and remained on PD.

From this study, we found that we have no documented case of tunnel infection or PD catheter extrusion within thirty days of catheter insertion. There was no reported adverse event associated with both the dressing types.

Discussion

Peritoneal dialysis (PD) is a modality for maintenance kidney replacement therapy for end stage kidney disease patients. It can be done at the comfort from home and is associated with better preservation of residual kidney function, which is associated with superior survival (9,10). PD-related infection and peritonitis are the major cause of PD drop out, morbidity and mortality (3, 11). An analysis of ANZDATA which included incident PD patients with technique failure recorded 62% mortality, and infections were significantly associated with mortality compared to other causes of technique failure (P<0.0001) (12). Exit site granuloma formation and subsequent exit site infection is significantly associated with the resultant peritonitis (13). In Malaysia, PD-related infections are the second cause (9.5%) of drop-out from PD program, and five percent of the incident PD patients drop-out within the first three months (7).

This is a retrospective observational cohort study conducted among 161 end stage kidney disease patients who had undergone peritoneal dialysis catheter insertion in a tertiary center from January 2023 to July 2024. All of the patients had undergone laparoscopic peritoneal dialysis catheter insertion with pre peritoneal tunneling technique, performed by three consultant nephrologists in the operating theater, using double-cuffed, coiled tip, straight tunnel segment PD catheter. Fixator dressing functions as an anchor for the PD catheter to be fixed at a constant point at the epidermal surface, eliminating the abrasion between the PD catheter and exit site skin. Standard dressing involves fixating the PD catheter with gauze and non occlusive dressing at the exit site, a practice similar worldwide among centers with a PD program.

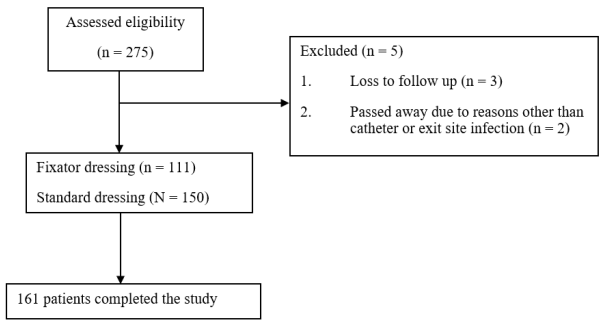

Figure 1: Patient selection flowchart.

Table II: Comparison between the use of fixator dressing and standard dressing in association with outcomes such as granuloma formation, exit site infection, tunnel infection and catheter extrusion.

	Fixator dressing (n = 111)	Standard dressing (n = 150)
Granuloma formation	0	2 (1.3%)
Exit site infection	3 (2.7%)	3 (2%)
Tunnel infection	0	0
Catheter extrusion	0	0

In our study, all patients had received either the fixator dressing or standard dressing using gauze and non-occlusive dressing, post catheter insertion up to 21 days. According to the ISPD 2023 guidelines, it is recommended to keep the exit site dressing intact for a minimum of seven days after PD catheter insertion to immobilize the catheter and reduce the likelihood of infection (3). Continuous friction at the point of contact between the PD catheter and the skin surface leads to granuloma formation with subsequent exit site and by extension, tunnel infection. Complete healing time for exit site post PD catheter insertion takes up to four to six weeks to occur (14). In our study, we have found no significant difference between the use of fixator dressing compared to standard dressing, in various outcomes such as granuloma formation, exit site infection, tunnel infection, and catheter extrusion within four weeks post PD catheter insertion. When we extend the duration of the study to six weeks, there is one additional case of exit site infection in each of the groups (staphylococcus aureus in standard dressing, pseudomonas aeruginosa in fixator dressing), which remains insignificant (p = 0.66). There are no additional cases recorded for granuloma formation, tunnel infection or catheter extrusion. The lack of catheter extrusion can be explained by the technique of catheter insertion practiced in our center.

Figure 2: Fixator dressing

Table III: Organisms found in exit site infection according to the dressing types.

Exit site infection organism	Fixator dressing (n = 3)	Standard dressing (n = 3)
Staphylococcus aureus	1	1
Pseudomonas aeruginosa	2	0
Mixed organism (>3)	0	1
Culture negative	0	1

The findings of our study are supported by a previous study which involved 2460 incident PD patients followed up for a median of 14.8 months, that it did not find any significant difference between different types of dressing used during the exit-site healing phase following PD catheter insertion, in its association with exit site infection (15). The lack of difference between the two groups in our study is partly contributed by the very low incidence of granuloma formation and exit site infection among the patients in our center, compared to that set by the international guidelines. No tunnel infections or catheter extrusions were observed in either group for up to six weeks post PD catheter insertion.

Both fixator and standard dressings are safe to be used with no recorded adverse event during the period of study. Therefore, based on the data of our study, both types of dressing can be used interchangeable in the early post catheter insertion period, with no significant difference in infection or extrusion outcome.

Strength and Limitations

This is a novel pilot study comparing the use of fixator and standard exit site dressing, focusing on the early post catheter insertion period to prevent exit site granuloma, infections and catheter extrusion. This study involves a large cohort of patients with newly inserted PD catheter and compared the two dressings within thirty days in a tertiary center.

In view of the significantly low incidence of exit site and tunnel complications in our center, more participants are required to demonstrate any significant difference between types of dressing and exit site outcomes. The low rate of exit site and tunnel complications also complicates any prospective studies that may be conducted in our center in future. In the future, a similar study can be conducted with an extended period to evaluate the long-term outcomes with the use of different types of dressings, as exit site healing period post PD catheter insertion may vary and longer in some participants.

Conclusion

Exit-site dressing post PD catheter insertion is important to fix the catheter and to prevent exit site infection and subsequent extension to peritonitis. Our study showed that there is no difference between the use of fixator or standard dressing in outcomes such as granuloma

formation, exit site infection, tunnel infection or catheter extrusion, and both dressings are safe to be used. These two types of exit site dressings can be used interchangeably in the early post catheter insertion period.

Acknowledgement

We would like to express our sincere appreciation to the Department of Nephrology, Hospital Selayang in Malaysia for their assistance and support during the data collection process. We would like to thank the Director General of the Ministry of Health Malaysia for the opportunity to conduct this study.

REFERENCES

1. Ong LM, Bavanadan S, Hooi LS & Choo CL. 30th Report of the Malaysian Dialysis and Transplant Registry 2022: Chapter 1: All kidney replacement therapy in Malaysia. 15th July 2024. No. e-ISSN: 3009-0679.
2. Manera KE, Johnson DW, Craig JC, et al. Establishing a core outcome set for peritoneal dialysis: report of the SONG-PD (Standardized Outcomes in Nephrology-Peritoneal Dialysis) consensus workshop. Am J Kidney Dis 2020; 75(3): 404–412. doi: 10.1053/j.ajkd.2019.09.017.
3. Chow KM, Li PK, Cho Y, et al. ISPD Catheter-related Infection Recommendations: 2023 Update. Perit Dial Int. 2023;43(3):201-219. doi: 10.1177/08968608231172740.
4. Li PK, Chow KM, Cho Y, et al. ISPD peritonitis guideline recommendations: 2022 update on prevention and treatment. Perit Dial Int 2022; 42(2): 110–153. doi: 10.1177/08968608221080586.
5. Crabtree JH, Shrestha BM, Chow KM, et al. Creating and maintaining optimal peritoneal dialysis access in the adult patient: 2019 update. Perit Dial Int 2019; 39(5): 414–436. doi: 10.3747/pdi.2018.00232.
6. Mushahar L, Mei LW, Yusuf WS, et al. Exit-site dressing and infection in peritoneal dialysis: a randomized controlled pilot trial. Perit Dial Int 2016; 36(2): 135–139. doi: 10.3747/pdi.2014.00195.
7. Mushahar L, Bavanadan S, Manocha AB, et al. 30th Report of the Malaysian Dialysis and Transplant Registry 2022: Chapter 10:Peritoneal dialysis. 15th July 2024. No. e-ISSN: 3009-0679.
8. Bennett PN, Bohm C, Harasemiw O, et al. Physical activity and exercise in peritoneal dialysis: International Society for Peritoneal Dialysis and the global renal exercise network practice recommendations. Perit Dial Int 2022; 42(1): 8–24. doi: 10.1177/08968608211055290.
9. Bargman J.M., Thorpe KE & Churchill DN. Relative contribution of residual renal function and peritoneal clearance to adequacy of dialysis: a reanalysis of the CANUSA study. J. Am. Soc. Nephrol. 12, 2158–2162 (2001). doi: 10.1681/ASN.V12102158
10. Vonesh EF, Snyder JJ, Foley RN & Collins AJ. Mortality studies comparing peritoneal dialysis and hemodialysis: what do they tell us? Kidney Int. 70 (Suppl. 103), S3–S11 (2006). doi: 10.1038/sj.ki.5001910.
11. Lan PG, Clayton PA, Saunders J, et al. Predictors and outcomes of transfers from peritoneal dialysis to hemodialysis. Perit. Dial. Int. 35, 306–315 (2015). doi: 10.3747/pdi.2013.00030.
12. Chen JHC, Johnson DW, Hawley C, et al. Association between causes of peritoneal dialysis technique failure and all-cause mortality. Sci. Rep. 8, 3980 (2018). doi: 10.1038/s41598-018-22335-4.
13. Lin J, Ye H, Li J, et al. Prevalence and risk factors of exit-site infection in incident peritoneal dialysis patients. Perit Dial Int. 2020 Mar;40(2):164-170. doi: 10.1177/0896860819886965.
14. Twardowski ZJ, Prowant BF. Exit-site healing post catheter implantation. Perit Dial Int. 1996;16 Suppl 3:S51-S70. PMID: 8860150. doi:10.1177/089686089601603S03.
15. Figueiredo AE, de Mattos C, Saraiva C, et al (BRAZPD II Investigators). Comparison between types of dressing following catheter insertion and early exit-site infection in peritoneal dialysis. J Clin Nurs. 2017 Nov;26(21-22):3658-3663. doi: 10.1111/jocn.13738. Epub 2017 Mar 22. PMID: 28122398.