

Clinical efficacy of gentamicin cream versus mupirocin ointment for prophylaxis of peritoneal dialysis-related infection; a single-center clinical study

Ittaprach Yimsuk^{1,2}, Pamila Tasanavipas³, Kulthida Chaijumroen³, Piraporn Juntanawiwat⁴,
Wichai Santimaleeworagun⁵, Daraporn Rungprai^{5*}

¹The College of Pharmacotherapy under the Royal College of Pharmacy of Thailand, The Pharmacy Council, Nonthaburi, Thailand

²Department of Pharmaceutical Care, College of Pharmacy, Rangsit University, Pathum Thani, Thailand

³Division of Nephrology, Department of Medicine, Phramongkutklao Hospital, Bangkok, Thailand

⁴Department of Clinical Pathology, Phramongkutklao Hospital, Bangkok, Thailand

⁵Division of Pharmaceutical Care, Faculty of Pharmacy, Silpakorn University, Nakhon Pathom, Thailand

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ABSTRACT

Introduction: Infection is a major complication in patients undergoing peritoneal dialysis (PD). Although daily topical mupirocin effectively prevents peritoneal dialysis-related infections (PDRI) caused by gram-positive bacteria, it does not provide coverage against gram-negative microorganisms. Meanwhile, gram-negative exit-site infections (ESIs) have become increasingly prevalent in Thailand.

Objectives: This study aimed to evaluate the clinical efficacy of 0.1% gentamicin cream as a substitute for 2% mupirocin ointment for PDRI prophylaxis and to examine its adverse reactions.

Patients and Methods: This study was a historically controlled clinical study conducted between December 2020 and June 2023 to compare outcomes for patients treated with gentamicin cream to those treated with mupirocin ointment. The clinical outcomes assessed were the rates of PDRI and catheter removal.

Results: Thirty participants (median age, 62 years) were analyzed, of which 53.3% were males. Daily application of gentamicin to the exit site significantly reduced the incidence of ESI and the composite rate of ESI and infectious peritonitis compared with mupirocin (0.06 vs 0.51 episodes per patient-year for ESI, $P = 0.005$ and 0.42 versus 0.88 episodes per patient-year for composite outcomes, $P = 0.049$, respectively). Although the composite rate of infections was lower in the prospective period, the prophylactic use of topical gentamicin alone did not demonstrate a statistically significant reduction in the incidence of infectious peritonitis specifically ($P = 0.722$). No tunnel or fungal infections were observed. One patient using gentamicin experienced a non-severe allergic reaction.

Conclusion: Daily topical gentamicin application effectively reduced ESI incidence compared with mupirocin. Therefore, gentamicin appears to be an alternative to mupirocin for ESI prophylaxis, particularly in areas with a high incidence of gram-negative bacterial infections.

Trial Registration: The study was retrospectively registered at the ClinicalTrials.gov on February 13, 2022 (ClinicalTrials.gov ID: NCT05251584; <https://clinicaltrials.gov/study/NCT05251584>).

Implication for health policy/practice/research/medical education:

In a clinical study, to evaluate the clinical efficacy of 0.1% gentamicin cream as a substitute for 2% mupirocin ointment for peritoneal dialysis-related infection (PDRI) prophylaxis, we found daily topical gentamicin application effectively reduced exit-site infections (ESIs) incidence compared with mupirocin.

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Introduction

Peritoneal dialysis (PD) is an effective form of kidney replacement therapy. Its overall survival is comparable to that of hemodialysis (1), but according to some studies, PD has a lower mortality rate, especially during the first 2 years (2,3). Compared with hemodialysis, PD has the

advantages of patient autonomy, satisfaction and less hospital visit. However, patient or caregiver burnout, handling of dialysis by themselves and technical failure are the risk factors associated with peritoneal dialysis-related infection (PDRI), especially exit-site infection (ESI) (4).

Previous studies found that, PDRI, i.e., ESI, tunnel

infection and infectious peritonitis, is a major complication in patients receiving PD (5,6). PD catheter loss, which is the most common complication, is associated with catheter-related infections, while mortality is associated with infectious peritonitis (7-9).

Mupirocin is a topical antibiotic that has a high antibacterial activity against gram-positive bacteria, especially staphylococci and streptococci (10). These microorganisms are the most common pathogens of ESI (11,12). Mupirocin reportedly reduces PDRI caused by *Staphylococcus aureus* by 40%–60% (13,14). However, it has less antibacterial activity against gram-negative bacteria, including *Pseudomonas aeruginosa* and *Escherichia coli*. Nowadays, ESI caused by gram-negative bacteria has become more frequent in several countries. Unfortunately, considering the low antibacterial activity against gram-negative bacteria, mupirocin could not reduce the rate of gram-negative ESIs (15). In addition, mupirocin-resistant pathogens were reported in certain studies (16,17).

Gentamicin, an aminoglycoside antibiotic, can eliminate both gram-positive and gram-negative bacteria, including *S. aureus* and *P. aeruginosa* (18). Bernardini et al conducted a randomized controlled study and showed that gentamicin cream has an antibacterial activity against gram-positive bacteria comparable to mupirocin but is more effective in eradicating gram-negative bacteria (15). Moreover, some regions, including Thailand, still have a high rate of PDRI (12,19), particularly those caused by gram-negative bacteria.

Objectives

We conducted a single-center, historical controlled study using 0.1% gentamicin cream as a substitute for 2% mupirocin ointment daily applied on the PD exit site to evaluate PDRI rate and to examine its adverse effects.

Patients and Methods

Study participants

This study was a historically controlled clinical study conducted from December 2020 to June 2023 at a PD clinic, Division of Nephrology, Department of Medicine, Phramongkutklao hospital, Bangkok, Thailand. A comparison was made between the historical control period, during which patients were treated with 2% mupirocin ointment from December 2020 to December 2021, and the prospective monitoring period, during which patients were treated with 0.1% gentamicin cream from January 2022 to June 2023. The patient data were accessed for retrospective research purposes in November 2021 and December 2021, then the patient recruitment for prospective period was started from January 2022 to June 2023. The patients who were 18 years of age or older, undergoing PD, attending the PD clinic from 2020 to 2023 and continuously applying 2% mupirocin ointment on the PD exit site for ESI prophylaxis were enrolled to the

study. Conversely, we excluded those who were allergic to gentamicin, were treated with systemic antibiotics within 90 days prior to enrollment, had PDRI within 4 weeks, were using immunosuppressive agents, had less than two months of follow-up and refused to provide written informed consent.

Study protocol

All patients received care from a multidisciplinary team at the PD clinic, including a nephrologist, a PD nurse, and a pharmacist. During the historical control period, patients were trained by the PD nurse on how to prevent ESI through proper wound care. They were instructed to apply 100 mg (approximately 1/4 inch) of 2% mupirocin ointment daily using a cotton bud on the exit site and to cover the wound with gauze dressing secured by microtape. After enrollment, participants entered the prospective monitoring period. They were instructed to switch from the 2% mupirocin ointment to 0.1% gentamicin cream, while continuing the same wound care protocol as before. The cream was dispensed by an investigator.

All patient data were obtained from both paper and electronic medical records. Patient characteristics, as well as the incidence of ESI, tunnel infection, infectious peritonitis, PD catheter removal related to infection and adverse events were monitored for at least 12 months during the prospective monitoring period. The same information in the historical control period was also collected for at least 12 months. During the study, patients were followed up at the clinic every month. At each visit, they received exit-site wound examination by the nephrologist, training on PD care from the PD nurse, and medication use monitoring by the pharmacist. All patients, both in the historical control period and the prospective monitoring period, received the same level of care and were followed up under the same standard. Patient's medications were refilled during clinic visits. Adherence to 0.1% gentamicin cream was assessed through patient interviews and by monitoring the frequency of drug refills. Each tube contains 5 g of 0.1% gentamicin cream, with 100 mg to be applied daily (equivalent to 50 doses per tube). Two tubes were provided, intended to last for approximately 3 months. PDRI was diagnosed by the nephrologist. ESI was defined as an erythematous, purulent discharge and/or identified through exit-site culture and an exit-site scoring system. Tunnel infection was defined as a purulent discharge and confirmed by ultrasonography. Infectious peritonitis was defined by meeting two of the following three International Society for Peritoneal Dialysis (ISPD) criteria: 1) abdominal pain and/or cloudy PD effluent; 2) white blood cells of more than 100 cells/ μ L with more than 50% polymorphonuclear neutrophil from PD effluent that dwells at least 2 hours and 3) positive PD effluent culture (5). Treatment for infection was based on the ISPD guidelines and nephrologist's discretion. The rate of infection was calculated by the number of infection

episodes divided by the total time expressed and reported as an episode per patient-year.

Statistical analysis

The sample size was calculated based on data from a previous unpublished report based on a PD patient registry of Phramongkutklao hospital between 2016 and 2020. The ESI rate was 0.44 episodes per patient-year. Based on these parameters, it was estimated that at least 70 patient-years of follow-up each group or 140 patient-years of total follow-up would be required to detect a 60 percent reduction of ESI rate significant difference with 80% power of analysis (15). However, this study was terminated early after 68.6 patient-years of follow-up because of COVID-19 pandemic. The primary outcomes were the rates of ESI and infectious peritonitis, determined by comparing the effects of 0.1% gentamicin cream and 2% mupirocin ointment applications. The secondary outcomes were the composite rate of ESI and infectious peritonitis. Other outcomes were the number of PDRI episodes classified by microorganisms and the number of PD catheter removals caused by PDRI after 0.1% gentamicin cream application. Patients were followed up from the first day of the study until completed, except for those who were censored due to switching dialysis modality to hemodialysis, kidney transplantation, death or withdrawal from the study.

All data were collected and reported as median with

interquartile range (IQR) for continuous variables and discrete data that were not normally distributed. For continuous variables of demographic characteristics, the Wilcoxon signed-rank test was conducted to compare two related groups. To compare infection rates between groups, we employed generalized estimating equations (GEE) with a negative binomial distribution and a log link function. The model was adjusted for duration of PD and calendar period as a covariate, and the natural logarithm of follow-up person-time was included as an offset variable to estimate incidence rates. A *P* value of less than 0.05 was considered statistically significant. All statistical analyzes were performed using IBM SPSS Statistics for Windows, version 27.0 (IBM Corp., Armonk, NY, USA).

Results

Out of 45 PD patients assessed for eligibility for the study, 13 had used other topical antibiotics apart from mupirocin, and two denied to provide written informed consent. Thirty patients were enrolled in the study. Although two patients discontinued the intervention (one withdrew consent, one due to an adverse drug reaction), all 30 patients were included in the intention-to-treat analysis, accounting for 823.2 patient-months (68.6 patient-years). The CONSORT flow diagram of the study is presented in Figure 1.

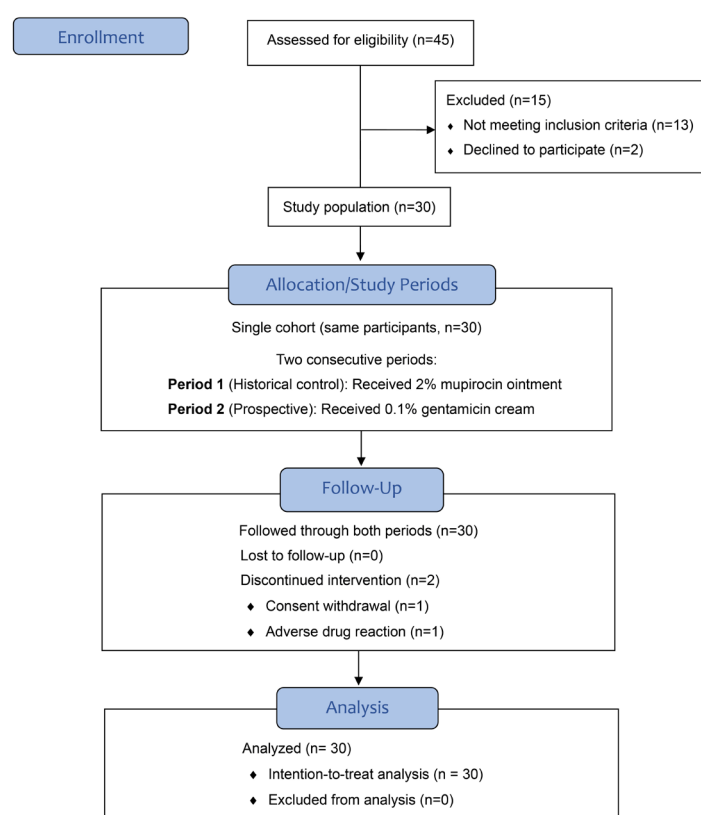


Figure 1. CONSORT Flow diagram of the study. All 30 participants completed follow-up during both study periods. Data from Period 1 were analyzed as the historical control and compared with data from Period 2, which represented the prospective intervention period.

Table 1 summarises the patient's characteristics. The participant's median age was 62 years. Additionally, 53.3% of them were males, and 13.3% received automated PD. Hypertension was the most common underlying disease (96.7%), followed by diabetes mellitus (40.0%). The median serum levels of albumin and potassium were 3.56 g/dL (IQR 3.29, 3.87) and 3.79 mEq/L (IQR 3.63, 4.27) for the historical control period and 3.54 g/dL (IQR 3.22, 3.81) and 3.78 mEq/L (IQR 3.49, 3.81) for the prospective period, respectively. The median duration of PD was significantly longer in the prospective period (25.5 months; IQR, 16.50–44.25) compared to the historical control period (18.5 months; IQR, 6.00–40.75; $P < 0.001$). No other significant differences were observed in baseline characteristics between the two groups.

Between the two periods, the prospective period with 0.1% gentamicin cream application had a significantly lower ESI rate compared to the historical control period with 2% mupirocin ointment, at 0.06 vs. 0.51 episodes per patient-year (adjusted incidence rate ratio, aIRR = 0.16, 95% CI 0.04–0.58, $P = 0.005$). In contrast, the rate of infectious peritonitis did not differ significantly between the historical control and prospective periods, at 0.34 vs. 0.36 episodes per patient-year (aIRR = 1.13, 95% CI 0.58–2.19, $P = 0.722$). The composite rate of ESI and infectious peritonitis was significantly lower in the prospective period compared to the historical control period (0.42 versus 0.88 episodes per patient-year; aIRR = 0.58, 95% CI: 0.33–0.99, $P = 0.049$). No tunnel or fungal infection was found during the treatment in both periods. The PDRI rates during the study periods and causative pathogens of PDRI in this study were showed in **Table 2** and **Table 3**, respectively.

Each period had one case of PD catheter removal caused by PDRI. During the historical control period, the catheter was removed after recurrent ESI and was then replaced after the infection was successfully treated. During the prospective period, the catheter was removed following the diagnosis of refractory infectious peritonitis, and the dialysis modality was eventually switched to hemodialysis. Furthermore, allergic reactions to gentamicin or its excipients were also reported. One patient who used 0.1% gentamicin cream experienced adverse reactions, including local redness and itchiness around the exit site, which developed two days after application. However, the symptoms resolved completely after discontinuation, without any severe reactions or complications.

Discussion

The present study was conducted in an area with high PDRI rates, the results revealed that daily application of 0.1% gentamicin cream can significantly reduce ESI by 84% compared with 2% mupirocin ointment. However, no difference was found between the two medications regarding the rate of infectious peritonitis.

The reduction of ESI rate following the use of 0.1% gentamicin cream in the present study is consistent with previous studies (15,20). Bernardini, et al studied the use of 0.1% gentamicin cream compared to 2% mupirocin cream. They found that ESI infections rate was decreased from 0.54 to 0.23 episodes per patient-year ($P = 0.003$) with 0.1% gentamicin cream. Additionally, this treatment also significantly reduced the incidence of ESI caused by both gram-positive and gram-negative bacteria, particularly infections from *P. aeruginosa* (15). Previously, Tsai et al conducted a systematic review and meta-

Table 1. Demographic characteristics of thirty patients participating in the study

Demographic characteristics	Historical control (mupirocin) (n = 30)	Prospective period (gentamicin) (n = 30)
Age in years, median (IQR)	61 (51.8, 66.8)	62 (52.8, 67.8)
Male, N (%)	16 (53.3)	16 (53.3)
Cause of ESRD, N (%)		
Diabetic nephropathy	4 (13.3)	4 (13.3)
Glomerular diseases	4 (13.3)	4 (13.3)
Tubulointerstitial diseases	1 (3.3)	1 (3.3)
Unknown cause	21 (70.0)	21 (70.0)
Underlying diseases, N (%)		
Hypertension	29 (96.7)	29 (96.7)
Diabetes mellitus	13 (40.0)	13 (40.0)
Automated PD, N (%)	4 (13.3)	4 (13.3)
Self-handling PD, N (%)	20 (66.7)	20 (66.7)
PD time in months, median (IQR)*	18.5 (6.00, 40.75)	25.5 (16.50, 44.25)
Serum albumin (g/dL), median (IQR)	3.56 (3.29, 3.87)	3.54 (3.22, 3.81)
Serum potassium (mEq/L), median (IQR)	3.79 (3.63, 4.27)	3.78 (3.49, 3.81)

ESRD: End-stage renal disease; IQR: Interquartile range; PD: Peritoneal dialysis; N, Number of patients.

* Statistically significant at $P < 0.001$.

Table 2. Peritoneal dialysis-related infection rates during the study periods

	Historical control (mupirocin) (n = 30)	Prospective period (gentamicin) (n = 30)	Adjusted Incidence rate ratio (95% CI)	P
Primary outcomes, episodes per patient-year (number of episodes)				
Exit-site infection	0.51 (18)	0.06 (2)	0.16 (0.04-0.58)	0.005*
Infectious peritonitis	0.34 (12)	0.36 (12)	1.13 (0.58-2.19)	0.722
Secondary outcomes, episodes per patient-year (number of episodes)				
Composite rate of ESI and infectious peritonitis	0.88 (30)	0.42 (14)	0.58 (0.33-0.99)	0.049*

ESI: Exit-site infection; PDRI: Peritoneal dialysis-related infection; N, Number of patients.

* $P < 0.05$ was considered statistically significant.**Table 3.** Microorganisms causing peritoneal dialysis-related infection in this study

Causative pathogens	Historical control (mupirocin)	Prospective period (gentamicin)
Exit-site infection, N	18	2
Gram-positive bacteria, N (%)	8 (44.4)	0
<i>Corynebacterium</i> spp.	3 (16.7)	0
<i>Staphylococcus argenteus</i>	3 (16.7)	0
Coagulase-negative staphylococci	1 (5.6)	0
<i>Staphylococcus aureus</i>	1 (5.6)	0
<i>Enterococcus faecalis</i>	0	0
Gram-negative bacteria, N (%)	8 (44.4)	1 (50.0)
<i>Pseudomonas aeruginosa</i>	4 (22.2)	1 (50.0)
<i>Stenotrophomonas maltophilia</i>	2 (11.1)	0
Enterobacteriaceae	1 (5.6)	0
<i>Acinetobacter</i> spp.	1 (5.6)	0
No growth, n (%)	2 (11.1)	1 (50.0)
Infectious peritonitis, N	12	12
Gram-positive bacteria, N (%)	5 (41.7)	8 (66.7)
<i>Enterococcus faecalis</i>	2 (16.7)	1 (8.3)
Coagulase-negative staphylococci	2 (16.7)	4 (33.3)
<i>Streptococcus</i> spp.	1 (8.3)	0
<i>Bacillus</i> spp.	0	3 (25.0)
Gram-negative bacteria, N (%)	4 (33.3)	4 (33.3)
<i>Klebsiella pneumoniae</i>	3 (25.0)	2 (16.7)
<i>Pseudomonas aeruginosa</i>	1 (8.3)	0
<i>Stenotrophomonas maltophilia</i>	0	0
<i>Escherichia coli</i>	0	1 (8.3)
<i>Acinetobacter</i> spp.	0	1 (8.3)
No growth, N (%)	3 (25.0)	0

N, Number of episodes in each time period.

analysis to compare the use of topical mupirocin and gentamicin in the prevention of PDRI. Nine studies were included in analysis, while seven studies were analyzed for ESI. The results showed that the rate of ESI caused by gram-negative bacteria was significantly lower in the gentamicin group (HR= 2.125, 95% CI 1.046–4.319, $P = 0.037$, $I^2 = 41.7\%$) but the risk of gram-positive ESI was similar between the mupirocin and gentamicin groups (20). Interestingly, our study found that the use of 0.1%

gentamicin cream was associated with a lower incidence of ESI, with no cases caused by gram-positive bacteria observed during the prospective period. However, this finding must be interpreted with strict caution given that there were only two total ESI episodes in the gentamicin group. Consequently, the absence of gram-positive infections in this cohort likely reflects the very low overall event rate rather than a definitive microbiological superiority of gentamicin over mupirocin against gram-

positive pathogens. This may be explained by results from previous studies showing that gram-negative infections in PD patients are more common in Thailand than in other countries (12,21,22). During the historical control period, a high rate of ESIs (45%) was attributed to gram-negative bacteria. This may have contributed to a reduced incidence of ESIs caused by gram-positive bacteria. Additionally, both gram-positive and gram-negative bacteria were found to be sensitive to gentamicin. Therefore, topical gentamicin appears to be more effective than mupirocin in eradicating gram-negative bacteria in patients with ESI. For gram-positive bacteria, gentamicin is equally effective as mupirocin. Additionally, we noted a baseline difference in the duration of PD, with the prospective group having a significantly longer median PD duration than the historical control group (25.5 versus 18.5 months; P value < 0.001). While a longer time on PD could inherently imply greater patient experience and proficiency in exit-site care—which might independently lower the risk of ESI—this baseline imbalance was strictly controlled for as a covariate in our multivariable GEE model, ensuring that the estimated treatment effect remained robust and independent of this factor.

Corynebacterium spp. and *P. aeruginosa* were the most commonly identified gram-positive and gram-negative bacteria found in PD catheter-related infection, but they can be eliminated by 0.1% gentamicin cream application. The two periods showed similar patterns of gram-negative microorganisms causing infectious peritonitis but differed in the gram-positive organisms involved. The most common gram-positive bacteria found in infectious peritonitis were coagulase-negative staphylococci ($n = 4$) in the prospective period and *Enterococcus faecalis* ($n = 3$) in the historical control period. This result suggests that infections caused by different microorganisms may occur in different time periods.

The incidence of infectious peritonitis in both groups was not significantly different, which is consistent with previous studies (5,23) that found the application of 0.1% gentamicin cream at the exit site did not reduce the rate of infectious peritonitis. This may be explained by the theory that the periluminal route is only one of several pathways responsible for PD catheter-related infections. The peritoneal cavity has multiple routes of pathogen entry such as the intraluminal, hematogenous, and transmural routes that can lead to infectious peritonitis (23,24). In the present study, no patient experienced concurrent PD catheter and peritonitis co-infection. The rate of infectious peritonitis met the standard recommendations of the ISPD in both periods (5). However, the ESI rate achieved the Asia-Pacific and Thailand PD Key Performance Indicators (12) only during the prospective period. Additionally, the rate of culture-negative peritonitis was below 15%.

Mupirocin has been widely used for the prophylaxis of catheter-related infections in PD patients due to its

high efficacy against gram-positive bacteria, including *S. aureus*. This pathogen is associated with catheter loss and treatment failure as a result of biofilm formation (25,26). However, pathogen epidemiology varies by country. In some regions, there is a higher prevalence of infections caused by gram-negative bacteria, particularly *P. aeruginosa*, which is also linked to biofilm formation and can lead to catheter loss, treatment failure, and increased mortality (27-31).

In the present study, we found that *Corynebacterium* spp. was the most common causative pathogen of ESI during the historical control period, but none of it was detected in the prospective period. Similar to findings from previous studies, *Corynebacterium* ESIs have also been reported (32,33). In the study by Carr et al, an increase in *Corynebacterium* spp. cultures was observed in patients with symptomatic chronic sinusitis who were treated with topical mupirocin (34). We hypothesize that *Corynebacterium* spp. may overgrow and become an ESI pathogen in PD patients when mupirocin is used as prophylaxis. Additionally, mupirocin resistance has been widely reported in previous studies (16,17). This issue should be considered when using mupirocin for ESI prophylaxis. However, our study did not test for the mupirocin resistance.

Gram-negative bacteria, especially *P. aeruginosa*, have become a significant issue in our practice setting. A previous study by Bernardini et al found that *P. aeruginosa* was the most common gram-negative bacterium causing ESIs. The application of gentamicin cream significantly reduced catheter-related infections by 57% (15). Similarly, our study showed that gentamicin cream was highly effective in preventing ESIs, reducing their incidence by 84%. Moreover, no fungal infections were detected in the present study.

Gentamicin resistance is also a concern, as reported in previous studies. Chen et al conducted a study on gentamicin resistance among patients who applied 0.1% gentamicin cream to the exit site between 2004 and 2013. The results identified three gentamicin-resistant bacterial strains, two *E. coli* strains associated with ESI and one *P. aeruginosa* strain related to infectious peritonitis (35). In the present study, over 12 months of follow-up, gentamicin resistance was observed in only one patient with infectious peritonitis caused by *Klebsiella pneumoniae*. However, the number of resistant pathogens was too small to affect the overall efficacy of gentamicin against other organisms. Longer follow-up is needed to assess the risk of resistance with continued exposure.

Topical gentamicin has poor systemic absorption; up to 2% was recovered in the urine after the application of 0.1% gentamicin cream (36). Toxic levels are rarely achieved, but allergic reactions have been reported in 1.7–3.5% of patients (37,38). In another study, allergic reactions occurred after administering intravenous gentamicin

for days to weeks, as confirmed by positive patch test reactions to gentamicin (39). Furthermore, applying 0.1% gentamicin cream for 3 weeks caused an allergic reaction, and a patch test showed a positive result (40). In the present study, one patient experienced rash, redness, and itchiness around the exit site after applying gentamicin cream, but these symptoms resolved after discontinuation. The allergic reaction resulting from gentamicin cream was not evaluated by a patch test but was confirmed by a positive rechallenge test.

Conclusion

The daily application of 0.1% gentamicin cream significantly reduced PDRI, particularly ESI. Although the rate of infectious peritonitis also decreased, the difference was not statistically significant. Most of the pathogens remained sensitive to gentamicin. Since the rate of infectious peritonitis following the use of 0.1% gentamicin cream was not significantly different from that observed with 2% mupirocin ointment, other mechanism of infectious peritonitis, as well as other alternative routes of pathogen entry into peritoneal cavity, should be considered. Overall, 0.1% gentamicin cream may serve as an effective alternative to 2% mupirocin ointment for ESI prophylaxis in PD patients, particularly in tertiary care settings with a high incidence of ESI caused by gram-negative bacteria. However, long-term use of gentamicin should be monitored for the potential development of resistance.

Limitations of the study

The present study has some limitations. During the historical control period, there were potential confounding factors i.e., patient's medication adherence, exit-site care techniques, and the amount of topical antibiotic applied. These factors may have varied among participants. However, we minimized their impact by using the same group of patients for both the historical and prospective periods, applying a consistent wound care process, and ensuring the same standard of care and follow-up. This approach helped reduce the likelihood of changes in patient's techniques and behaviors over time. Although we adjusted for calendar time in our generalized estimating equations to account for broad temporal shifts, the potential for residual confounding remains a limitation. The historical and prospective periods were separated by a critical timeframe during which hospital hygiene protocols, nursing techniques, and patient behaviors evolved significantly due to the COVID-19 pandemic. While the calendar period adjustment mitigates some of this bias, unmeasured qualitative changes in clinical practice or pandemic-induced hygiene awareness could still partially explain the reduction in infectious complications observed in the later cohort. This study is primarily limited by the premature cessation of data

collection prior to reaching the targeted 140 patient-years of follow-up. The COVID-19 pandemic severely restricted the accessible patient population, hindered clinical follow-up, and limited the dispensing of prophylactic medications, resulting in a final analysis based on only 68.6 patient-years. Consequently, the study is potentially underpowered. This limitation not only inflates the risk of type I errors but also predisposes the analysis to a significant overestimation of the true treatment effect size, as treatment benefits observed in prematurely truncated trials are frequently exaggerated. Therefore, any statistically significant findings should be interpreted with strict caution. Future investigations must ensure adequately extended follow-up or enhanced recruitment to attain the necessary statistical power for definitive conclusions. Despite this limitation, we believe that our findings demonstrate the advantage of gentamicin cream in preventing ESI among PD patients.

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Authors' contribution

Conceptualization: Daraporn Rungprai, Pamila Tasanavipas, Ittaprach Yimsuk.

Data curation: Ittaprach Yimsuk.

Formal analysis: Ittaprach Yimsuk, Daraporn Rungprai.

Funding acquisition: Ittaprach Yimsuk.

Investigation: Ittaprach Yimsuk, Daraporn Rungprai, Pamila Tasanavipas, Kulthida Chaijumroen, Piraporn Juntanawiwat.

Methodology: Ittaprach Yimsuk, Daraporn Rungprai, Wichai Santimaleeworagun, Pamila Tasanavipas, Kulthida Chaijumroen.

Project administration: Ittaprach Yimsuk, Daraporn Rungprai.

Resources: Daraporn Rungprai, Pamila Tasanavipas, Piraporn Juntanawiwat.

Supervision: Daraporn Rungprai, Wichai Santimaleeworagun, Pamila Tasanavipas.

Validation: Daraporn Rungprai, Wichai Santimaleeworagun.

Visualization: Ittaprach Yimsuk, Daraporn Rungprai.

Writing—original draft: Ittaprach Yimsuk, Daraporn Rungprai.

Writing—review and editing: Daraporn Rungprai, Ittaprach Yimsuk, Wichai Santimaleeworagun, Pamila Tasanavipas.

Ethical issues

All experiments on human subjects were conducted in accordance with the Declaration of Helsinki. The study protocol and the statement of informed consent were approved by the Institutional Review Board of the Royal Thai Army Medical Department (study code: Q023h/64). Written informed consents were obtained from all individual participants or their legally authorized representatives prior to participate in the study. The study was retrospectively registered at the ClinicalTrials.gov on February 13, 2022 (ClinicalTrials.gov ID: NCT05251584; <https://clinicaltrials.gov/>)

study/NCT05251584). Ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

Conflicts of interest

The authors declare that they have no competing interests.

Data availability statement

The data analyzed and presented in this study are only available from the corresponding author upon reasonable request. The data are not publicly available due to patient privacy and ethical restrictions.

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