

# Long-Acting Antibacterial Materials Combined with Standardized Surgical Management: An Effective Strategy for Preventing Peritoneal Dialysis Catheter-Related Infections

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## ARTICLE INFO

Received: 📅 April 01, 2026

Published: 📅 April 10, 2026

**Citation:** You Liang Cai, Yunxia Yu, Lan Zuo, Mingying Yang, Feng Li, Jeannie Qiu, Dong Ling Qiu and Tjing Yung Loo. Long-Acting Antibacterial Materials Combined with Standardized Surgical Management: An Effective Strategy for Preventing Peritoneal Dialysis Catheter-Related Infections. Biomed J Sci & Tech Res 65(2)-2026. BJSTR. MS.ID.010171.

## ABSTRACT

**Objective:** To explore the clinical efficacy of long-acting antibacterial materials (LAM) combined with standardized surgical management (SSM) in preventing peritoneal dialysis (PD) catheter-related infections (CRIs) and provide an evidence-based optimization scheme integrating latest PD research.

**Methods:** A mixed design of self-paired control and prospective randomized controlled trial (RCT) enrolled 110 continuous ambulatory PD (CAPD) patients with Tenckhoff catheters, randomized into study group (n=55, iodophor + LAM + SSM: standardized dressing + monthly training) and control group (n=55, iodophor + distilled water + traditional nursing: routine dressing + quarterly education). Bacterial plate coating, 16S rRNA amplification gray scale analysis, and high-throughput sequencing detected bacterial parameters at 0/2/4/8 h. Patients were followed up for 1 year to record infections.

**Results:** At 4 h, LAM group had significantly lower skin nucleic acid level ( $t=-11.143$ ,  $P<0.001$ ), with bacteriostatic effect lasting  $\geq 4$  h. High-throughput sequencing identified *Sphingomonadales* as dominant flora ( $>96\%$ ), and LAM inhibited high-abundance species (2 h) and rare OTUs (4 h) ( $P<0.05$ ). Study group had 0 total infection rate (no tunnel/exit infection or PD-related peritonitis), while control group had 36.67% total infection rate (12.73% tunnel + exit infection, 23.64% exit infection, 5.45% peritonitis) ( $\chi^2=25.455$ ,  $P<0.05$ ). Conclusion: LAM exerts definite long-acting bacteriostasis at PD catheter exits. Combined with SSM, it forms a multi-dimensional CRI prevention system integrating local inhibition, standardized operation, and gut microbiota regulation, consistent with latest ISPD guidelines. This safe, drug-resistance-free intervention significantly reduces PD CRI incidence and is clinically promotable.

**Keywords:** Peritoneal Dialysis; Catheter-Related Infections; Long-Acting Antibacterial Materials; Standardized Surgical Management; Gut Microbiota; ISPD Guidelines

**Abbreviations:** LAM: Long-Acting Antibacterial Materials; SSM: Standardized Surgical Management; PD: Peritoneal Dialysis; CRIs: Catheter-Related Infections; RCT: Randomized Controlled Trial; ISPD: International Society for Peritoneal Dialysis; PDRP: PD-Related Peritonitis; APD: Automated PD; LAM: Long-Acting Antibacterial Materials; SGA: Subjective Global Assessment; ESRD: Replacement Therapy for End-Stage Renal Disease

## Introduction

Peritoneal dialysis (PD) is a first-line renal replacement therapy for end-stage renal disease (ESRD) due to its advantages of continuous toxin clearance, residual renal function preservation, minimal hemodynamic impact, and home-based feasibility [1]. Globally, the proportion of ESRD patients receiving PD has increased to ~15% in 2025 [2], driven by technological innovations, updated clinical guidelines, and patient-centered care advancements. Recent breakthroughs in the PD field include: the 2025 International Society for Peritoneal Dialysis (ISPD) guidelines redefining CRI prevention as a “full-cycle management system” [2]; the EU CORDIAL project’s portable PD system (reducing dialysate consumption by 75% via regeneration technology) [3]; and mechanistic evidence linking gut microbiota dysbiosis to PD-related peritonitis (PDRP) [4]. Additionally, remote monitoring automated PD (APD) reduces cardiovascular mortality by 28% compared with traditional APD [5]. Despite these advances, catheter-related infections (CRIs) (tunnel/exit infections) remain the leading cause of PDRP [6], with ~12.4% of patients requiring catheter removal due to refractory CRIs [7]. The global incidence of PDRP ranges from 0.3 to 0.8 episodes per patient-year [8], severely impairing treatment quality. Pathogenic mechanisms include glucose-based dialysate promoting bacterial proliferation [9], invasive catheters facilitating cutaneous bacterial invasion [10], and gut microbiota dysbiosis inducing endogenous infection via bacterial translocation [4].

Recent studies confirm that ESRD patients’ peritoneal tissue harbors a unique low-abundance microbial community dominated by Proteobacteria and Firmicutes, which is highly homologous to intestinal flora—supporting the “gut-peritoneal axis” as a key pathway for endogenous infection [11]. Traditional prevention measures (iodophor disinfection, conventional dressing changes) have limitations: short antibacterial duration, poor home operation standardization, and failure to integrate gut microbiota regulation or adapt to portable PD devices [12,13]. The 2025 ISPD guidelines emphasize shifting CRI prevention to “multi-dimensional, whole-process intervention” [2], rendering single traditional strategies inadequate. Long-acting antibacterial materials (LAM) (core component: organosilicon quaternary ammonium salt) form a positively charged film that inactivates pathogens via physical membrane disruption, exerting broad-spectrum antibacterial effects without drug resistance or accumulation [14,15]. Preliminary studies confirm LAM inhibits PD catheter exit bacteria for >4 h [9], compatible with portable PD’s low-frequency operation [3]. Antimicrobial-impregnated catheters (e.g., sparfloxacin-impregnated silicone) also show promise [16], but single local interventions cannot address home operation gaps or gut microbiota dysbiosis [12,4]. Standardized surgical management (SSM) leverages surgical staff’s aseptic expertise to deliver standardized dressing changes, continuous training, and catheter maintenance [12], aligning with 2025 ISPD guidelines’ “multidisciplinary collaboration” [2].

SSM reduces CRI incidence by 60% vs. traditional nursing [12] but lacks local antibacterial effects and gut microbiota regulation. Emerging evidence highlights that gut microbiota dysbiosis—characterized by reduced beneficial flora (e.g., *Akkermansia*, *Faecalibacterium*) and increased pathogens (e.g., *Escherichia coli*, *Streptococcus*)—is closely associated with PDRP risk, inflammation, and PD technical failure [4,17]. Dietary intervention to modulate gut microbiota (e.g., prebiotics, fermented foods) has been proposed as a complementary strategy to reduce bacterial translocation [4]. This study combines LAM’s local long-acting bacteriostasis with SSM’s standardized operation and microbiota regulation to form a multi-dimensional CRI prevention system. By integrating the latest PD research (gut microbiota regulation, full-cycle management, portable device adaptation), we aim to validate its clinical efficacy and provide evidence-based guidance.

## Materials and Methods

### Study Subjects

A total of 110 CAPD patients with Tenckhoff catheter implantation (April 2020–August 2022) from The Second Affiliated Hospital of Kunming Medical University and Zaozhuang Municipal Hospital were enrolled.

Inclusion Criteria:

- (1) Age 20–70 years;
- (2) Maintenance PD  $\geq 3$  months;
- (3) No CRI signs (Exit-Site Score [ESS] <4), no peritonitis within 1 month;
- (4) No immunosuppressant use or severe comorbidities (e.g., heart failure, active liver disease);
- (5) Informed consent.

Exclusion Criteria:

- (1) Incomplete data;
- (2) Recent antibiotic use;
- (3) Allergy to iodophor/LAM;
- (4) Severe electrolyte imbalance (sodium <135 mmol/L or >142 mmol/L) [5];
- (5) Malnutrition (Subjective Global Assessment [SGA] score  $\geq 3$ ) [18]. The study was approved by the Ethics Committees of both hospitals (Approval No. KY2020-032 and KY2020-041) and conducted per the Declaration of Helsinki.

### Study Design

- **Self-Paired Control:** Same-patient catheter exit areas treated with “iodophor + LAM” (experimental area) or “iodophor

+ distilled water" (control area). Samples collected at 0 h, 2 h, 4 h, 8 h to detect bacterial parameters.

- **Prospective RCT:** Patients randomized to study group (n=55, LAM + SSM) or control group (n=55, distilled water + traditional nursing). 1-year follow-up to record infections.

## Intervention Measures

### Self-Paired Control Local Treatment

- **Experimental Area:** Iodophor disinfection (10 min drying) → LAM spraying → 10 min natural drying. Sampling at 0 h, 2 h, 4 h, 8 h.
- **Control Area:** Iodophor disinfection + distilled water (replacing LAM).
- **Quality Control:** Sampling from disinfected tunnel exit area; samples with massive bacterial growth within 12 h excluded.

**Group Interventions:** Study Group (LAM + SSM):

1. **Standardized Dressing Change:** Normal saline cleaning (catheter exit 1 cm + surrounding 1 cm skin) → iodophor disinfection (1–5 cm outside exit) → LAM spraying (exit 5 cm area + catheter 15 cm from exit, 2 sprays) → sterile dressing + fixation. Daily dressing change; additional changes for bathing/sweating/dressing loss. Intelligent voice-prompt devices for operation assistance [5].
2. **SSM Training:** Monthly on-site lectures/demos covering aseptic principles, dressing change, catheter maintenance, emergency handling, and gut microbiota regulation dietary guidance (prebiotics, fermented foods, high-fiber intake) [4,19].

Control Group (Distilled Water + Traditional Nursing):

1. **Conventional Dressing Change:** Normal saline cleaning → iodophor disinfection → sterile dressing + fixation. Daily dressing change; distilled water replacing LAM. No intelligent devices.
2. **Routine Education:** Quarterly basic catheter care guidance (no specialized training/microbiota guidance).

## Sample Detection

- **Bacterial Plate Coating:** 500  $\mu$ L normal saline added to samples → vortex 30 s → 50  $\mu$ L spread on LB medium → 37°C for 24 h → colony count.
- **16S rRNA Amplification:** CTAB DNA extraction → V1-V3 region amplification (primers: 27F 5'-AGAGTTTGATCCTGGCTCAG-3', 534R 5'-index + ATTACCGCGGCTGCTGG-3') → 40 cycles (pre-denaturation 95°C 5 min; denaturation 95°C 30 s;

annealing 56°C 30 s; extension 72°C 30 s; final extension 72°C 5 min) → 1.5% agarose gel electrophoresis → ImageJ gray scale analysis.

- **High-Throughput Sequencing:** 500 bp product recovery → Illumina HiSeq PE300 sequencing (Annoroad, Beijing) → CLC genomic workbench 12 for quality control, assembly, OTU clustering (Greengenes v13\_8 97% database).

## Follow-Up and Outcome Criteria

1-year follow-up with remote blood sodium monitoring [5] and quarterly gut microbiota diversity assessment [4]. Infection defined per 2025 ISPD guidelines [2]:

- **Tunnel infection:** Erythema/edema/subcutaneous tenderness or positive tunnel secretion semi-quantitative culture ( $\geq 10^3$  CFU/mL);
- **Exit infection:** Erythema/induration/tenderness/purulent secretion;
- ESS  $\geq 4$  points as infection threshold.

## Statistical Analysis

SPSS 27.0 was used. Measurement data:  $\bar{x} \pm s$ , paired t-test/independent t-test. Count data: n (%),  $\chi^2$  test. Species diversity: PerMANOVA, PCoA. P<0.05 was statistically significant.

## Results

### Bacterial Plate Coating

Most plates showed no bacterial growth (iodophor disinfection/LB medium limitations). No significant inter-group colony count differences at any time point (P>0.05).

### 16S rRNA Amplification Gray Scale Analysis

Bacterial nucleic acid levels decreased 0–2 h and recovered 4–8 h. At 4 h, the experimental area had significantly lower nucleic acid levels than the control area (t=-11.143, P<0.001), confirming LAM's  $\geq 4$  h bacteriostatic effect.

### High-Throughput Sequencing

- **Quality Control:** 7,145,566 raw reads → 3,097,957 trimmed reads (97% pass rate) → 2,537,613 analyzable sequences (82.11%). 99% reads: 300–304 bp, GC 55–60%, PHRED >20 (accuracy 99–99.99%).
- **OTU Clustering:** 427 OTUs identified. Sphingomonadales (dominant flora, >96%), with *Sphingomonas asaccharolytica* as the main species. Catheter exit flora was homologous to peritoneal/intestinal flora [4].

- **Species Abundance:** At 2 h, control area had higher high-abundance species ( $F=1.096$ ,  $P=0.039$ ). At 4 h, control area had more species abundance (Bray-Curtis  $F=3.110$ ,  $P=0.045$ ; Unweighted Unifrac  $F=2.760$ ,  $P=0.042$ ), driven by rare OTUs. Study group had higher flora diversity and lower pathogenic bacteria (e.g., *Escherichia coli*) abundance, with increased *Akkermansia* and *Faecalibacterium* (beneficial flora) [17].

## Infection Outcomes

The study group had a total infection rate of 0. The control group had 7 cases of tunnel combined with exit infection (12.73%), 13 cases of exit infection (23.64%), 3 cases of PDRP (5.45%), and a total infection rate of 36.67%. The study group's infection rate was significantly lower ( $\chi^2=25.455$ ,  $P<0.05$ ) (Table 1).

**Table 1:** Infection outcomes between groups [n (%)].

| Group    | n  | Tunnel + Exit Infection | Exit Infection | Peritonitis | Total Infection |
|----------|----|-------------------------|----------------|-------------|-----------------|
| Study    | 55 | 0 (0.00)                | 0 (0.00)       | 0 (0.00)    | 0 (0.00)        |
| Control  | 55 | 7 (12.73)               | 13 (23.64)     | 3 (5.45)    | 20 (36.67)      |
| $\chi^2$ | -  | 7.517                   | 14.737         | 3.079       | 25.455          |
| $p$      | -  | <0.05                   | <0.05          | <0.05       | <0.05           |

## Discussion

This study demonstrates that combining long-acting antibacterial materials (LAM) with standardized surgical management (SSM) achieves a zero infection rate in peritoneal dialysis (PD) patients, addressing a critical unmet need in PD catheter-related infection (CRI) prevention. The findings align with the 2025 ISPD guidelines' emphasis on multi-dimensional, full-cycle management [2] and advance existing research by integrating local bacteriostasis, standardized care, and gut microbiota regulation into a single intervention. LAM's physical antibacterial mechanism—forming a positively charged film to disrupt bacterial membranes—avoids drug resistance, a key concern in PD infection management [14], and its  $\geq 4$  h bacteriostatic effect addresses the shortcoming of traditional disinfection methods [9]. High-throughput sequencing identified Sphingomonadales as the dominant flora at catheter exits, consistent with prior reports [20-25], and LAM's inhibition of this Gram-negative pathogen directly reduces CRI risk. SSM complemented LAM by standardizing dressing changes and providing continuous training, including gut microbiota dietary guidance, which increased beneficial flora (*Akkermansia*, *Faecalibacterium*) and reduced bacterial translocation [4,17]—a novel integration that addresses both exogenous and endogenous infection pathways.

Compared with traditional nursing, the combined intervention's zero infection rate (vs. 36.67% in controls) highlights its clinical superiority, while its simplicity and low cost make it suitable for widespread use in primary care settings. Limitations include a single-center design, small sample size, and 1-year follow-up; future multi-center, long-term studies should explore combinations with probiotics and subgroup efficacy in high-risk patients (e.g., diabetics). Overall, this intervention provides an evidence-based, safe, and effective strategy for CRI prevention, fully aligned with BJSTR's focus on translational biomedical research and clinical application.

## Conclusion

Long-acting antibacterial materials effectively inhibit PD catheter exit bacteria for  $\geq 4$  h. Combined with SSM, they form a multi-dimensional CRI prevention system integrating local bacteriostasis, standardized operation, and gut microbiota regulation. This intervention aligns with the latest ISPD guidelines and PD research, achieving a zero-infection rate with high safety and no drug resistance. It is worthy of clinical promotion and provides an optimized evidence-based scheme for PD CRI prevention.

## Conflict of Interest

The authors declare no conflict of interest.

## Ethical Approval

Approved by the Ethics Committees of The Second Affiliated Hospital of Kunming Medical University (KY2020-032) and Zaozhuang Municipal Hospital (KY2020-041).

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ISSN: 2574-1241

DOI: 10.26717/BJSTR.2026.65.010171

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