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Corresponding author:
Dongmei He

407994894@qq.com

Author Affiliation:
West China School of Medicine,Sichuan University, Sichuan University affiliated Chengdu Second People's Hospital,Chengdu Second People's Hospital.

Non-antibiotic catheter care and maintenance strategies for preventing infection in hemodialysis catheters: a retrospective protocol registration for a stratified exploratory systematic review and meta-analysis

He, D; Tian, M; Liu, Y; Yaang, S; Yang, M; Li, Q.

ADMINISTRATIVE INFORMATION

Support - No support.

Review Stage at time of this submission - Data analysis.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 1 September 2026 and was last updated on 1 September 2026.

INTRODUCTION

Review question / Objective Among adults or children receiving hemodialysis through a tunneled, cuffed, long-term, or otherwise clearly identified dialysis catheter, are non-antibiotic catheter care and maintenance strategies associated with fewer catheter-related infections than usual care, an alternative non-antibiotic strategy, or a pre-intervention period? Patient-level risk ratios and catheter-day incidence rate ratios are synthesized separately.

Rationale Hemodialysis catheters remain exposed to microbial entry at the exit site, tunnel or cuff, hub, connector, and intraluminal surface. Existing evidence syntheses largely address broader central venous catheter populations, specific dressings, barrier caps, or antimicrobial locks. A dialysis-specific synthesis of non-antibiotic catheter care is needed because intervention mechanisms, infection definitions, denominators, and study designs vary. This review therefore separates clinical outcome domains, patient-level and catheter-day denominators, intervention mechanisms, and study-design strata. PROSPERO and INPLASY were searched on 20 August 2026, and no completely overlapping review or protocol registration was identified.

Condition being studied Catheter-related infection in patients receiving hemodialysis, including exit-site infection, tunnel infection, bloodstream infection or catheter-related bloodstream infection, and composite or total catheter infection. The review preserves the diagnostic wording used by each source report and does not impute an operational threshold when none was reported.

METHODS

Participant or population Adults or children receiving hemodialysis through a tunneled, cuffed, long-term, or otherwise clearly identified dialysis catheter. Mixed central venous catheter or

temporary-catheter reports were eligible only when the relevant hemodialysis subgroup and its direct comparison could be separately extracted. No restrictions were imposed by age, sex, ethnicity, or language.

Intervention Non-antibiotic catheter care and maintenance strategies, including exit-site dressing or skin antisepsis, chlorhexidine-containing dressings, gauze or transparent coverage, hub or barrier technology, connector or cap systems, and multicomponent catheter-care bundles involving aseptic access, hub disinfection, dressing protocols, education, surveillance, feedback, or related maintenance elements. Antibiotic ointments and antibiotic lock solutions are outside the primary definition.

Comparator Usual care, standard dressing, standard antisepsis, an alternative non-antibiotic catheter-care strategy, or a pre-intervention period with a comparative denominator.

Study designs to be included Individually randomized trials, crossover trials, cluster-randomized trials, controlled before-and-after comparisons, interrupted practice comparisons, and quality-improvement studies with comparative denominators. Non-comparative reports, rate-only reports without an extractable comparison, and overlapping reports without independent data are excluded after full-text assessment. Systematic reviews are used for reference-list screening and contextual interpretation, not as primary studies.

Eligibility criteria Studies were eligible when they enrolled the target hemodialysis population, evaluated a non-antibiotic catheter-care or maintenance strategy, included an eligible comparator, and reported a direct comparison with an effect estimate or sufficient events and denominators for calculation. Outcomes were eligible when they addressed exit-site infection, tunnel infection, bloodstream infection or CRBSI, or composite or total catheter infection. Studies were excluded for non-comparative design, no extractable direct comparison, non-target population without separable data, antibiotic-only intervention, or non-independent overlapping data.

Information sources PubMed, Embase, Cochrane Library, Web of Science, Scopus, and CNKI were searched from database inception to 20 August 2026. Reference-list screening and other prespecified methods were also used; eight additional reports were identified through other methods. PROSPERO and INPLASY were searched on 20 August 2026 for ongoing reviews and protocols.

Main outcome(s) The five main estimable outcomes are: (1) patient-level total or composite catheter infection, summarized as a risk ratio; (2) patient-level exit-site infection, summarized as a risk ratio; (3) patient-level bloodstream infection or CRBSI, summarized as a risk ratio; (4) bloodstream infection per catheter-day, summarized as an incidence rate ratio; and (5) exit-site infection per catheter-day, summarized as an incidence rate ratio. Lower values favor the non-antibiotic strategy. Patient-level and catheter-day outcomes are never pooled together.

Additional outcome(s) Tunnel infection and other outcome domains not meeting quantitative compatibility criteria will be reported as structured or exploratory evidence. Single-study estimates, adjusted-effect pools, crude event-rate estimates, temporary-catheter evidence, hub or barrier evidence, and multicomponent-bundle evidence will be presented separately when quantitative pooling is not justified.

Data management Two review authors independently screened titles and abstracts, assessed potentially eligible full texts, extracted data using a piloted standardized form, adjudicated study design, and assessed risk of bias. Disagreements were resolved by discussion and consensus. NoteExpress was used for reference management and deduplication by title and author overlap. Analyses were conducted in R 4.6.1 using the metafor package. Extracted fields included study characteristics, intervention and comparator details, follow-up, infection definitions, event counts, participant denominators, catheter-days, effect estimates, confidence intervals, and risk-of-bias information.

Quality assessment / Risk of bias analysis Risk of bias was assessed independently by two review authors using RoB 2 for individually randomized studies, the RoB 2 cluster-randomized extension for cluster-randomized studies, and ROBINS-I for non-randomized intervention studies. Disagreements were resolved by consensus. The three patient-level primary pools excluded high-risk RoB 2 studies and serious-risk ROBINS-I studies; all eligible studies were retained in full-pool sensitivity analyses. Certainty of evidence was assessed with GRADE for the five estimable outcomes.

Strategy of data synthesis Patient-level dichotomous outcomes will be synthesized as risk

ratios and catheter-day outcomes as incidence rate ratios. Log-transformed effects will be pooled using REML random-effects models with Knapp-Hartung confidence intervals. Sparse or zero-event cells will use a 0.5 continuity correction in the prespecified primary model. Supportive sensitivity analyses will retain zero-event studies using a GLMM, exclude studies with zero events, and exclude the reconstructed catheter-day denominator sensitivity. Adjusted effects will be pooled only with compatible adjusted effects and crude estimates only with compatible crude estimates. RCT, cluster-randomized, and non-randomized strata will be described separately without formal interaction testing. I-squared of 0% will be interpreted as no statistically detected heterogeneity in a small pool, not clinical homogeneity or equivalence.

Subgroup analysis Prespecified mechanism-based strata are: (1) exit-site dressing or skin antisepsis; (2) hub or barrier device or connector systems; (3) multicomponent catheter-care bundles; and (4) other non-antibiotic strategies when a mechanism-specific classification is not possible. Study-design strata are individually randomized, cluster-randomized, and non-randomized studies. Patient-level RR and catheter-day IRR are separate strata. Temporary-catheter evidence is kept separate from long-term tunneled-catheter evidence. No formal interaction test is planned or interpreted.

Sensitivity analysis Sensitivity analyses include reintroducing studies excluded from risk-restricted primary pools, leave-one-out analyses, a GLMM retaining zero-event studies, exclusion of studies with zero events, and exclusion of studies with reconstructed catheter-day denominators. Adjusted and crude estimates remain separate. Alternative rare-event models are supportive robustness checks and do not replace the prespecified primary model or determine GRADE certainty.

Language restriction No language restrictions will be imposed.

Country(ies) involved China.

Keywords hemodialysis; tunneled catheter; catheter-related infection; exit-site care; bloodstream infection; non-antibiotic prevention; exploratory meta-analysis.

Contributions of each author

Author 1 - Dongmei He.
Email: 407994894@qq.com
Author 2 - Min Tian.
Author 3 - Yan Liu.
Author 4 - Siqi Yaang.
Author 5 - Minghui Yang.
Author 6 - Qin Li.