Mangosteen-Derived Mangostin as a Topical Prophylaxis Against Catheter-Related Infections: A Multicenter, Double-Blind Randomized Placebo-Controlled Trial

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Abstract

Background: Non-tunneled hemodialysis (HD) catheters (NTHCs) are associated with high rates of systemic and localized infections. Mangostin, a xanthone derived from mangosteen, exhibits antimicrobial and anti-inflammatory properties; however, its clinical efficacy in preventing exit site infection (ESI) and catheter-related bloodstream infection (CRBSI) has not been established. The present study evaluated the efficacy of topical mangostin ointment in preventing systemic and local infection.

Methods: This multicenter, double-blind, randomized, placebo-controlled trial enrolled 66 acute and chronic HD patients from 3 hospitals. Participants were randomized to receive topical mangosteen-derived mangostin ointment (mangostin group) or a placebo, applied at the catheter exit site immediately following insertion, and were monitored until catheter removal.

Results: The composite incidence of ESI and CRBSI was significantly lower in the mangostin group than in the placebo group (P=0.025), corresponding to a 78% risk reduction. Furthermore, a higher proportion of patients in the mangostin group had mild inflammation (exit-site inflammation score ≤2) (p=0.008).

Conclusion: Topical mangostin significantly reduces the combined incidence of local and systemic infection and inflammation in patients with NTHC. Further studies are needed to explore its efficacy in patients with a tunneled HD catheter or a peritoneal dialysis catheter.

Keywords: bacteremia; double lumen catheter; septicemia; dialysis; sepsis; DLC

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ประสิทธิภาพของยาขี้ผึ้งมังคุดในการป้องกันการติดเชื้อของสายฟอกเลือดแบบชั่วคราว: การศึกษาแบบสุ่มอำพรางสองฝ่ายและมีกลุ่มควบคุม

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บทคัดย่อ

บทนำ: การใช้สายฟอกเลือดชนิดชั่วคราวแบบ non-tunneled hemodialysis catheters มีความเสี่ยงสูงต่อการติดเชื้อบริเวณทางออกของสาย (Exit-site infection) และการติดเชื้อในกระแสเลือดที่สัมพันธ์กับการใช้สายฟอกเลือด (Catheter-related bloodstream infection) แมงโกสติน (Mangostin) ซึ่งเป็นสารกลุ่มแซนโทน (Xanthone) สกัดจากมังคุด มีคุณสมบัติต้านเชื้อจุลชีพและลดการอักเสบ ทว่าประสิทธิภาพทางคลินิกในการป้องกันการติดเชื้อจากสายฟอกเลือดยังไม่ได้รับการพิสูจน์อย่างชัดเจน จึงเป็นที่มาของการศึกษาประสิทธิภาพของยาขี้ผึ้งมังคุดในการป้องกันการติดเชื้อจากสายฟอกเลือดแบบชั่วคราว

ระเบียบวิธีวิจัย: การศึกษาแบบสุ่มที่มีกลุ่มควบคุมในผู้ป่วยที่ได้รับการใส่สายฟอกเลือดชั่วคราวรายใหม่ จำนวน 66 ราย สุ่มให้ทายาขี้ผึ้งมังคุดหรือยาหลอกบริเวณทางออกของสายฟอกเลือด จากนั้นติดตามผู้ป่วยจนกระทั่งมีการเอาสายฟอกเลือดออก

ผลการวิจัย: อุบัติการณ์รวมของการติดเชื้อที่ทางออกของสายฟอกเลือดและการติดเชื้อในกระแสเลือดของกลุ่มยาขี้ผึ้งมังคุดต่ำกว่ากลุ่มยาหลอกอย่างมีนัยสำคัญ (P=0.025) คิดเป็นความเสี่ยงที่ลดลงร้อยละ 78 นอกจากนี้ยาขี้ผึ้งมังคุดมีสัดส่วนผู้ป่วยที่มีคะแนนการอักเสบของผิวหนังรอบทางออกของสาย ≤2 (exit site inflammation score ≤2) มากกว่ากลุ่มยาหลอกอย่างมีนัยสำคัญ (P=0.008)

สรุป: ยาขี้ผึ้งมังคุดสามารถลดการอุบัติการณ์รวมของการติดเชื้อที่ทางออกของสายฟอกเลือดและการติดเชื้อในกระแสเลือด รวมไปถึงการอักเสบบริเวณทางออกของสายในผู้ป่วยที่ใช้สายฟอกเลือดแบบชั่วคราวได้ ควรมีการศึกษาประสิทธิภาพของขี้ผึ้งมังคุดในผู้ป่วยที่ใช้สายสวนฟอกเลือดแบบ tunneled cuffed catheter หรือ สายฟอกไตทางช่องท้องต่อไปในอนาคต

คำสำคัญ: ติดเชื้อ; สายสวนหลอดเลือดดำ; สายฟอกไต; ติดเชื้อรุนแรง

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Background

According to the 2023 Annual Report of the Nephrology Society of Thailand, over 30% of hemodialysis patients still rely on non-tunneled hemodialysis catheters (NTHCs) for primary vascular access[1]. Furthermore, there is a substantial demand for urgent hemodialysis among patients with acute kidney injury (AKI). Multi-center data from 16 hospitals across Thailand (2013–2015) indicated that approximately 8% of hospitalized patients developed AKI requiring the insertion of NTHC[2].

NTHCs are associated with a significantly elevated risk of catheter-related infections—ranging from 2 to 5 times greater than with arteriovenous fistulas (AVFs)— and are linked to increased mortality compared to both AVFs and arteriovenous grafts[3]. Infection rates have been reported as 3.25-13.6 per 1,000 catheter-days[4-7]. Consequently, the 2019 KDOQI guidelines recommend restricting the duration of NTHC use to a maximum of two weeks and advocating for the application of topical antiseptic or antibiotic ointments at the catheter exit site until complete wound healing to mitigate infection risks[8]. However, this recommendation is based primarily on expert opinion and has not yet been incorporated into the routine standard clinical practice. Furthermore, comparative studies evaluating various topical agents, including mupirocin, Polysporin triple ointment, and povidone-iodine, have demonstrated no statistically significant differences in clinical efficacy. Despite their potential benefits, the routine use of topical antibiotics is increasingly constrained by concerns over antimicrobial resistance and the imperative need for broader-spectrum antimicrobial activity[8-10].

Consequently, xanthone compounds extracted from mangosteen pericarp have attracted considerable interest due to their diverse pharmacological activities. Among these, α-mangostin is the most prevalent and extensively documented, exhibiting potent antibacterial, antifungal, anti-inflammatory, and antioxidant properties[11-13]. Research indicates that α-Mangostin accelerates wound healing by enhancing bacterial clearance, stimulating collagen synthesis, facilitating re-epithelialization, and modulating inflammatory responses[14]. Notably, it demonstrates potent antibacterial activity, particularly against gram-positive pathogens such as *Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus* spp., *Enterococcus* spp., and *Propionibacterium acnes,* and is effective against methicillin-resistant *Staphylococcus aureus* (MRSA) by disrupting bacterial cell membranes[11]. A systematic review of 30 studies further revealed that α-mangostin's antibacterial efficacy was comparable to that of conventional antibiotics, underscoring its potential as an alternative antimicrobial agent[15].

Thailand serves as a major global producer of mangosteen in Southeast Asia. Utilizing α-mangostin extracted from mangosteen pericarp not only significantly increases the economic value of agricultural byproducts but also fosters sustainable support for local farming communities. Currently, α-mangostin extracts have been successfully used in the treatment of periodontal diseases and acne, yielding high patient satisfaction[16]. Despite these established therapeutic applications, the potential of α-mangostin to mitigate catheter-related infections and suppress inflammation at hemodialysis catheter exit sites remains unexplored. Consequently, this study represents the first clinical investigation into the efficacy of α-mangostin in reducing inflammation and preventing infection associated with non-tunneled hemodialysis catheters (NTHCs).

Materials and methods

Study Design and Setting

This multicenter, randomized, double-blind, placebo-controlled trial was conducted across three clinical sites in Thailand: Phramongkutklao Hospital and College of Medicine, Fort Suranari Hospital, and Ananda Mahidol Hospital, between July 2024 and February 2025. The study protocol was reviewed and approved by the Institutional Review Board of the Royal Thai Army Medical Department. In accordance with the Declaration of Helsinki, written informed consent was obtained from all participants prior to their enrollment in the study.

Study population

Eligible participants included adult patients diagnosed with AKI or end-stage kidney disease who required renal

replacement therapy via a newly inserted NTHC and were eligible for enrollment in the study. Exclusion criteria were predefined as follows: (1) history of mangosteen allergy; (2) ongoing continuous renal replacement therapy; (3) known colonization with multidrug-resistant organisms; or (4) concurrent use of systemic antibiotic therapy at the time of enrollment.

Trial procedure

Participants were randomized into two groups: the intervention group received topical mangosteen-derived mangostin ointment (mangostin group), while the control group received a placebo ointment. Randomization was performed using a computer-generated random number list with a permuted block design (block size of four). Allocation concealment was ensured by sequentially numbered, sealed envelopes distributed to each participating center. This concealment was maintained until the point of treatment assignment. Both participants and outcome assessors were blinded to the group allocation. Prior to the intervention, all participants underwent an initial hypersensitivity test. The investigator applied a 2-cm diameter area of either mangostin or placebo ointment to the participant's inner forearm. The site was observed 30 minutes later for signs of allergic reaction, including erythema, wheal formation, or pruritus.

All participants underwent ultrasound-guided insertion of NTHCs by either a nephrology fellow or an attending nephrologist, using the aseptic Seldinger technique. Catheters were placed in either the internal jugular or femoral vein based on clinical indication and vascular accessibility.

Post-procedure, standard exit-site care was performed by hemodialysis nurses under aseptic conditions. The catheter exit site was disinfected with a 2% chlorhexidine solution in 70% alcohol. In the intervention group, approximately 5 mm of mangostin ointment was applied directly to the catheter exit site using a 15 g tube with a 10 mm outlet. In the control group, an identical procedure was performed using a placebo ointment. Applications were performed immediately after catheter insertion and at the end of each hemodialysis session. Finally, the cannulation site, catheter hub, and connections were covered with sterile gauze dressings, in accordance with institutional catheter care protocols **(Figure 1)**.

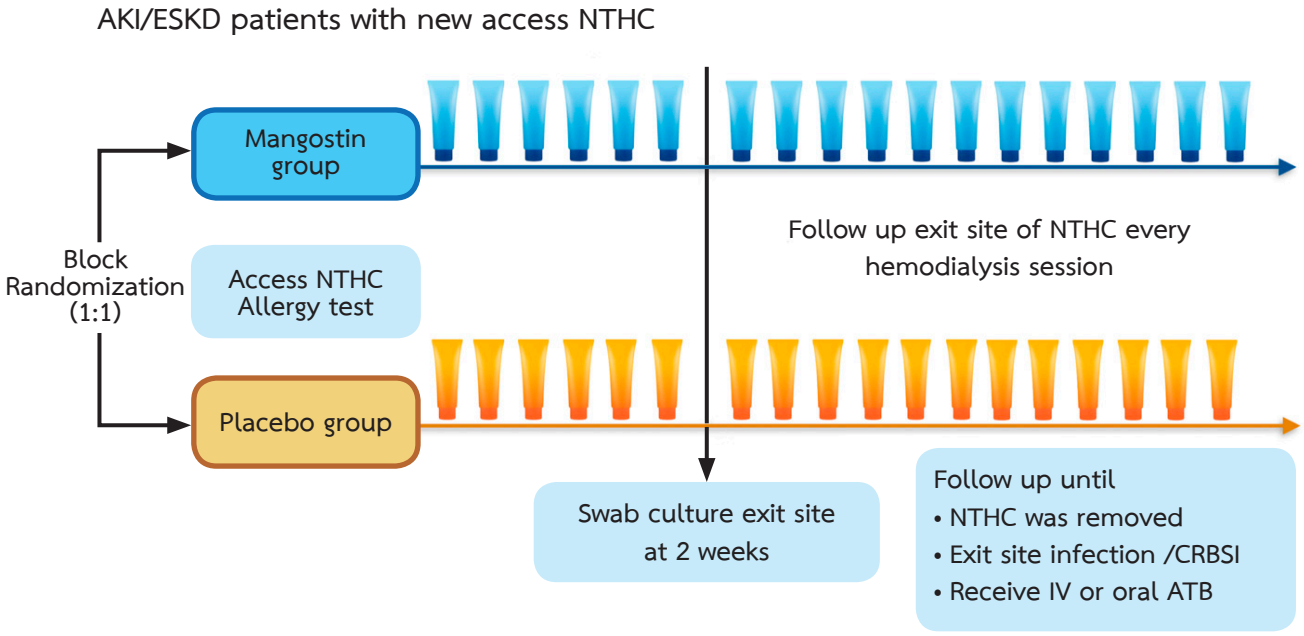

Figure 1 Study protocol

AKI, acute kidney injury; ESKD, end-stage kidney disease; NTHC, non-tunneled hemodialysis catheters; CRBSi, catheter-related bloodstream infection; IV, intravenous; ATB, antibiotics

The topical mangostin formulation used in this study was Kapioku Acne Gel, developed through a collaboration between Kasetsart Agricultural and Agro-Industrial Product Improvement Institute, Kasetsart University, and Quality Plus Biomedtech Co., Ltd. The formulation underwent stability testing and dermatological safety evaluation in human volunteers and is registered with the Thai FDA under license number 10-1-6500016681. The active formulations consisted of Garcinia mangostana peel extract (α-mangostin, 0.5%), water (94.2%), Carbopol Ultrez (0.5%), triethanolamine (0.5%), panthenol (0.5%), dimethicone (2%), Germaben II (0.8%), and Polysorbate 20 (1.0%). The placebo gel, provided by the same manufacturer, was identical in appearance and composition to the active gel but omitted the α-mangostin extract. Both formulations were manufactured by Quality Plus Biomedtech Co., Ltd. in strict compliance with GMP, ISO 22716, and ISO 9001 standards.

Evaluation of catheter exit-site inflammation and infection

At each hemodialysis session, the catheter exit site was systematically evaluated by trained nurses prior to dialysis initiation and before dressing replacement. Clinical parameters, including edema, erythema, tenderness, crusting, and purulent discharge, were recorded. In the absence of a validated scoring system specifically for NTHCs, the Exit Site Scoring System from the 2012 International Society for Peritoneal Dialysis (ISPD) Guidelines/Recommendations[17] was adapted to standardize wound evaluation and documentation **(Table 1)**.

Table 1 Exit Site Scoring System from 2012 ISPD Guidelines/Recommendations

Feature	0 Point	1 Point	2 Point
Swelling	No	Exit only; <0.5 cm	>0.5 and/or tunnel
Crust	No	<0.5 cm	>0.5 cm
Redness	No	<0.5 cm	>0.5 cm
Pain	No	Slight	Severe
Drainage	No	Serous	Purulent

Outcomes

The primary outcome was the time to the occurrence of a composite endpoint, defined as either exit-site infection (ESI) or catheter-related bloodstream infection (CRBSI). The secondary outcome was the severity of exit-site inflammation, quantified using the adapted exit-site scoring system. Patients were followed from the time of catheter insertion until the occurrence of the composite endpoint, catheter removal, or the initiation of systemic antibiotic therapy.

Definitions

Exit site infection (ESI) was defined as the presence of hyperemia, induration, and/or tenderness within 2 cm of the catheter exit site. This condition may be accompanied by drainage from the site and may or may not be associated with bacteremia[8]

Catheter-related blood stream infection (CRBSI) was defined as clinical manifestations and at least one positive bacterial culture (BC) from a peripheral source (dialysis circuit or vein) and no other apparent source, with either positive semiquantitative (>15 CFU/catheter segment, hub or tip) or quantitative (>10^2 CFU/catheter segment, eg, hub or tip) culture, where by the same organism (species and antibiogram) is isolated from the catheter segment (eg, hub or tip) and a peripheral source (dialysis circuit or vein) blood sample. If available, the following would be supportive: Simultaneous quantitative cultures of blood samples with a ratio of ≥3:1 (catheter hub/tip vs peripheral [dialysis circuit/vein]); differential period of catheter culture versus peripheral BC positivity of 2 hours[8]

Sample Size Calculation

The sample size was determined based on a previous study by Sesso et al. (1998)[18], using time-to-event (survival) analysis. Assumptions included a two-sided α=0.05 (Z=1.96), a power of 80% (Z=0.84), a hazard ratio (HR) of 7.2, and equal allocation between groups (k = 1.0). The estimated probabilities of catheter-related infection were 0.057 in the experimental group and 0.388 in the control group. Using the standard formula for survival analysis, the required sample size was calculated to be 31 participants per group.

Statistical Analysis

Descriptive statistics were used to summarize baseline characteristics. Continuous variables were assessed for normality and reported as mean ± standard deviation for normally distributed data. Categorical variables were presented as frequencies and percentages. Between-group comparisons for continuous variables were performed using the independent Student's t-test or the Mann–Whitney U test, as appropriate. Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate. All analyses were conducted according to the intention-to-treat principle. Time-to-event outcomes were evaluated using the Kaplan–Meier method, with differences assessed by the log-rank test (Mantel–Cox). All statistical tests were two-sided, and a p-value < 0.05 was considered statistically significant.

Results

Baseline characteristics

A total of 66 participants were randomized equally to the mangostin and placebo groups (n = 33 per group). In the mangostin group, one participant was lost to follow-up, and one participant died from causes unrelated to the study intervention. In the placebo group, two participants were lost to follow-up, and two participants had their NTHCs removed after only one dialysis session **(Figure 2)**. All randomized participants were included in the intention-to-treat analysis.

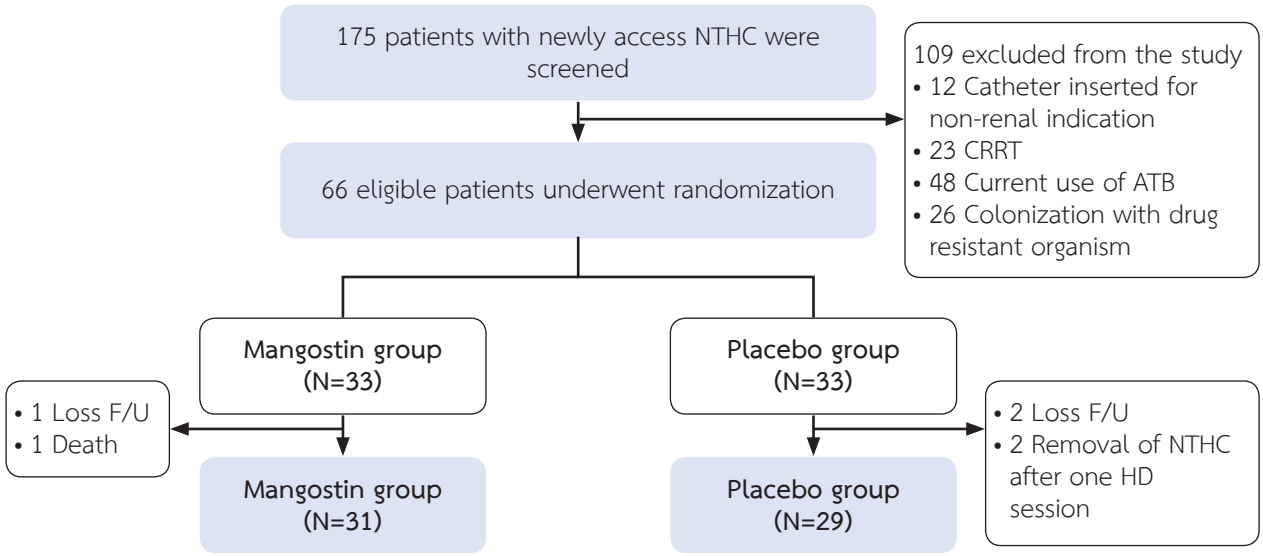

Figure 2 Study Flow Diagram

NTHC, non-tunneled hemodialysis catheters; F/U, follow-up; HD, hemodialysis; CRRT, continuous renal replacement therapy; ATB, antibiotics

Baseline characteristics and laboratory parameters for the mangostin and placebo groups are shown in **Table 2**. Catheter characteristics are presented in **Table 3**. Regarding the type of kidney disease, ESKD accounted for 80% of NTHC use in both groups. The right internal jugular vein (Rt. IJV) was the most common catheter insertion site in both groups.

Table 2 Baseline characteristics of all patients by the treatment group

Variables	Mangostin (n = 33)	Placebo (n = 33)
Sex, Male (N/%)	20 (60.6%)	19 (57.6%)
Age, years (mean ± SD)	67.3±12.46	60.1±16.09
Body mass index, kg/m² (mean ± SD)	23.94±4.4	23.86±5.0
Comorbidities (N/%)		
• Diabetes mellitus	18 (54.5%)	15 (45.5%)
• Hypertension	28 (84.8%)	30 (90.9%)
• Dyslipidemia	19 (57.6%)	16 (48.5%)
• Ischemic heart disease	3 (9.1%)	4 (12.1%)
• Atrial fibrillation	3 (9.1%)	2 (6.1%)
• Heart failure	3 (9.1%)	2 (6.1%)
• Cerebrovascular accident	2 (6.1%)	3 (9.1%)
• Cancer	2 (6.1%)	0 (0%)
• Viral hepatitis	1 (3%)	2 (6.1%)
Use of Immunosuppressive drugs (N/%)	3 (9.1%)	4 (12.1%)
Laboratory Parameters (mean ± SD)		
• Hemoglobin (g/dL)	9.1±2	9.3±2.1
• Serum albumin (g/dL)	3.45±0.64	3.52±0.53
• Blood urea nitrogen (mg/dL)	76.4±35.3	86.6±31.6
• Serum creatinine (mg/dL)	8.95±5.62	9.31±5.63

Table 3 Characteristics of the catheter by the treatment group

Variables	Mangostin (n = 33)	Placebo (n = 33)
History of central venous catheter (%)	10 (30.3%)	9 (27.3%)
Types of kidney disease (%)		
• End-stage kidney disease	27 (81.8%)	27 (81.8%)
• Acute kidney injury	6 (18.2%)	6 (18.2%)
Catheter Insertion Site (%)		
• Right internal jugular vein	23 (69.7%)	28 (84.8%)
• Left internal jugular vein	2 (6.1%)	2 (6.1%)
• Right femoral vein	8 (24.2%)	3 (9.1%)
Indication for catheter placement (%)		
• Short-term use in new chronic hemodialysis patients	17 (51.5%)	19 (57.6%)
• Thrombosis of AVF/AVG	8 (24.2%)	7 (21.2%)
• Switching from HD to PD	2 (6.1%)	0 (0%)
• Acute kidney injury	6 (18.2%)	7 (21.2%)

HD, hemodialysis; PD, peritoneal dialysis; AVF, arteriovenous fistula; AVG, arteriovenous graft

Outcomes

The primary outcome was the time to the first occurrence of either ESI or CRBSI. Kaplan–Meier survival analysis demonstrated a significantly higher infection-free survival in the mangostin group compared to the placebo group (log-rank p=0.025; **Figure 3**). The infection rate per 1,000 catheter-days was markedly lower in the mangostin group at 2.12 (95% CI: 0.53–8.49), compared to 10.90 (95% CI: 5.67–20.94) in the placebo group (p=0.025). Furthermore, the mangostin group demonstrated a 78% reduction in infection risk (Relative Risk [RR] = 0.22; 95% CI: 0.05–0.95) relative to the placebo **(Table 4)**. The number needed to treat (NNT) was 5, indicating that five participants would need to be treated with α-mangostin ointment to prevent one catheter-related infection.

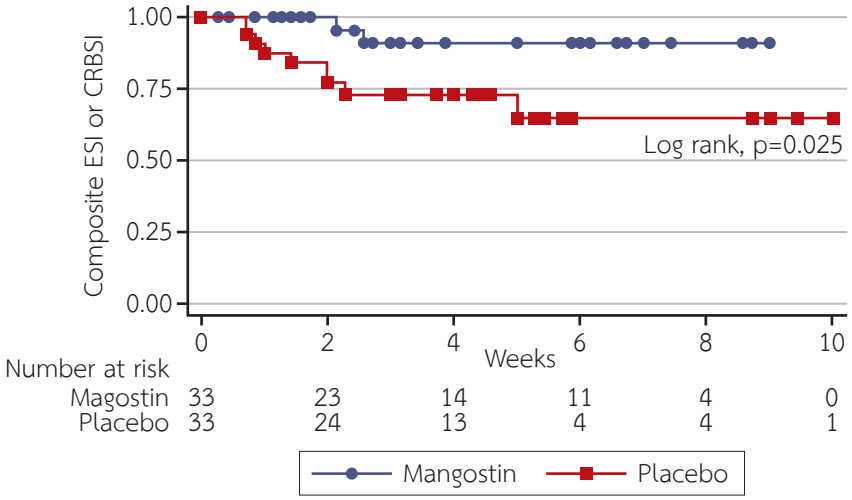

Figure 3 Kaplan–Meier survival curves for the composite outcome of exit-site infection and catheter-related bloodstream infection

ESI, exit site infection; CRBSI, catheter-related bloodstream infection

Table 4 Composite outcome of exit site infection and/or catheter-related bloodstream infection

Variables	Mangostin (N=33)	Placebo (N=33)	p-value
Composite exit site infection and/ or catheter-related bloodstream infection, n (%)	2 (6.1%)	9 (27.3%)	0.021
Infection rate per 1000 catheter-days (95% confidence interval)	2.12 (0.53, 8.49)	10.90 (5.67, 20.94)	0.025
Relative risk (95% confidence interval)	0.22 (0.05, 0.95)		

The separate outcomes of ESI and CRBSI are shown in **Supplementary Table 1** and **Supplementary Figures 1 and 2**. There were 2 (6%) and 4 (12%) ESIs in the mangostin and placebo groups, respectively (P=0.39). As for CRBSI, there was 1 episode (3%) in the mangostin group and 5 episodes (15%) in the placebo group (P=0.09).

The severity of exit-site inflammation was assessed using the Exit Site Scoring System. The detailed results on exit-site scoring (0-4) for the two groups are shown in **Supplementary Table 2**. A significantly greater proportion of participants in the mangostin group had mild inflammation (score ≤ 2) compared with the placebo group (90.9% vs. 63.6%, p = 0.008), indicating that topical mangostin application was associated with a significantly lower degree of exit-site inflammation **(Figure 4)**.

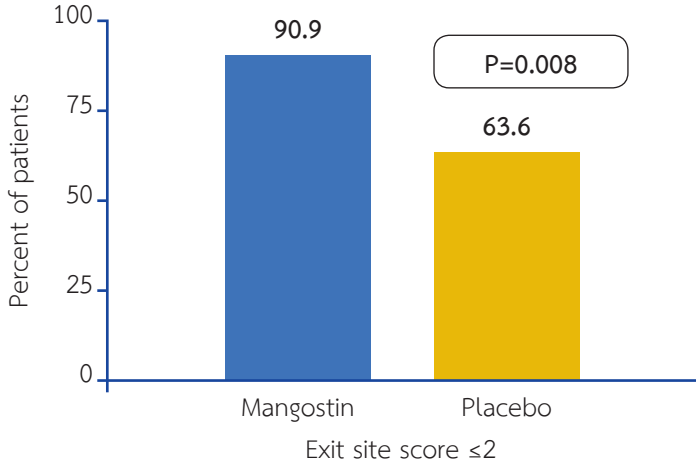

Figure 4 Proportion of patients with exit site score ≤2

At two weeks, culture results from the exit site showed no significant difference in bacterial type between the two groups (p = 0.668), and no bacterial growth was observed in over 70% of participants in both groups **(Table 5)**.

Table 5 Exit-site culture results at two weeks after catheter placement.

Bacterial culture results	Mangostin (N=33)	Placebo (N=33)	p-value
No growth	25 (75.8%)	23 (69.7%)	0.668
Staphylococcus coagulase-negative	2 (6%)	1 (3%)	
Staphylococcus epidermidis	0 (0%)	1 (3%)	
Missing	6 (18.2%)	8 (24.2%)	

Catheter survival

The average duration of NTHCs use was comparable between the two groups (P=0.46). The most common reason for catheter removal was the establishment of permanent vascular access, whereas CRBSI was the second most common cause, observed in 3% of the mangostin group and 12.1% in the placebo group **(Supplementary Table 3)**.

Discussion

The main finding of this multicenter, double-blind, randomized controlled trial is that a topical mangosteen-derived mangostin ointment significantly reduces the composite outcome of ESI and CRBSI, as well as exit-site inflammation, compared with placebo in patients with NTHCs. To our knowledge, this is the first study to evaluate the clinical efficacy of a mangosteen-derived mangostin ointment for preventing ESI and CRBSI in this population.

A previous trial by Sesso et al. established the efficacy of 2% mupirocin in reducing catheter-related infections[18]. However, the CDC's Dialysis BSI prevention Collaborative recommendations emphasize the growing concern over antimicrobial resistance associated with prolonged antimicrobial ointment use[10]. In this context, α-mangostin, a bioactive xanthone, emerges as a potent alternative. Recent in vitro studies have demonstrated that α-mangostin possesses broad-spectrum antimicrobial activity against common skin pathogens, including methicillin-resistant Staphylococcus aureus (MRSA), by disrupting bacterial cell membrane integrity[11]. Beyond its antimicrobial properties, we also evaluated exit-site

inflammation using the peritoneal dialysis catheter exit-site scoring system; a significantly greater proportion of participants in the mangostin group had minimal inflammation (score ≤2), indicating an added benefit not assessed in the earlier trial. Unlike traditional antibiotics, α-mangostin has been shown to inhibit pro-inflammatory cytokines such as TNF-α and IL-4. This dual-action mechanism may accelerate tissue healing at the exit site, creating a less hospitable environment for bacterial colonization[19]. Given its favorable efficacy profile and an observed number needed to treat of 5 for the composite outcome, mangostin ointment may represent a promising alternative for preventing catheter-related infections in patients requiring temporary hemodialysis access.

Limitations include a relatively small sample size, which may have reduced power to detect differences in individual outcomes (ESI or CRBSI), the use of a placebo rather than an active antimicrobial comparator, and the absence of reported safety data.

In summary, our study demonstrates that a topical mangosteen-derived mangostin ointment is a potentially effective intervention for reducing ESI and CRBSI, as well as exit-site inflammation, in patients with NTHCs. To build on these findings, future research should use larger sample sizes and include active comparator arms, such as antimicrobial ointments. Furthermore, expanding the study population to include patients undergoing peritoneal dialysis or those using tunneled cuffed catheters—while evaluating various catheter types—would significantly enhance the generalizability and clinical applicability of these results.

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