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Original Article

Ultrasound-Tuned Antimicrobial Hydrogel–Coated Urinary Catheters Reduce Catheter-Associated Urinary Tract Infection: A Randomized Controlled Trial

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ABSTRACT

Background: Catheter-associated urinary tract infection remains a frequent healthcare-associated infection, largely driven by microbial adhesion and biofilm formation on catheter surfaces. Conventional antimicrobial coatings have shown inconsistent effectiveness because of passive release kinetics and declining activity over time. Objective: To compare catheter-associated urinary tract infection rates between ultrasound-tuned antimicrobial hydrogel–coated urinary catheters and standard uncoated silicone catheters. Methods: This prospective parallel-group randomized controlled trial enrolled 60 hospitalized adults requiring indwelling urinary catheterization for at least 72 hours. Participants were allocated equally to an ultrasound-tuned antimicrobial hydrogel–coated catheter group or a standard catheter group. The intervention group received daily low-intensity ultrasound activation, while both groups received standardized catheter care. The primary outcome was clinically assessed and microbiologically confirmed catheter-associated urinary tract infection. Secondary outcomes included urine colony count, time to infection onset, symptomatic infection, and adverse events. Results: Catheter-associated urinary tract infection occurred in 1/30 participants (3.3%) in the ultrasound-tuned hydrogel group and 5/30 participants (16.7%) in the standard catheter group, representing an absolute risk reduction of 13.4 percentage points and an estimated relative risk of 0.20. Mean urine colony count was lower in the intervention group ($2.1 \times 10^4 \pm 0.8 \times 10^4$ CFU/mL) than in the control group ($6.7 \times 10^4 \pm 1.9 \times 10^4$ CFU/mL; $p = 0.01$). No catheter-related or ultrasound-associated complications were reported. Conclusion: Ultrasound-tuned antimicrobial hydrogel–coated catheters were associated with reduced infection risk and bacterial burden during short-term inpatient catheterization. Keywords: Antimicrobial Coatings; Catheter-Associated Urinary Tract Infection; Hydrogels; Ultrasound Therapy; Urinary Catheters; Randomized Controlled Trial.

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INTRODUCTION

Catheter-associated urinary tract infection remains a major healthcare-associated infection among hospitalized patients requiring indwelling urinary catheterization, with microbial adhesion and biofilm formation on catheter surfaces serving as central mechanisms in its pathogenesis. Although catheter care bundles, aseptic insertion, closed drainage systems, and early removal protocols have reduced avoidable risk, the catheter surface itself continues to provide a favorable interface for bacterial attachment, colonization, and ascending infection. Once microorganisms establish a biofilm, they become less susceptible to host immune defenses and antimicrobial agents, making surface-level prevention an important priority in device-centered infection control (1). Standard silicone and latex-

based catheters are widely used because of their mechanical suitability and relative biocompatibility, but they do not actively prevent microbial attachment or biofilm maturation (2,3).

Several antimicrobial catheter technologies, including silver-based, antibiotic-impregnated, antiseptic-coated, and other modified biomaterial surfaces, have been developed to address this limitation. However, their clinical effectiveness has remained variable, partly because many coatings rely on passive antimicrobial release, which may decline over time and may not adequately suppress biofilm development during the later period of catheterization (4,5). Additional concerns include coating durability, local cytotoxicity, alteration of microbial ecology, and possible contribution to antimicrobial resistance when antimicrobial exposure is sustained or poorly controlled. These limitations support the need for catheter coatings that provide localized antimicrobial activity while minimizing unnecessary systemic exposure and preserving safety (6,7).

Hydrogels have emerged as promising biomaterials for medical device coatings because of their high water content, tissue-like surface characteristics, biocompatibility, and capacity to incorporate antimicrobial components. Their hydrated structure can reduce protein adsorption and bacterial adhesion while allowing controlled interaction with therapeutic agents or external stimuli (6,7). More recently, responsive or tunable hydrogel systems have been explored as a strategy to improve antimicrobial performance by activating or enhancing local effects only when needed. Ultrasound is particularly relevant in this context because it is non-invasive, clinically familiar, and capable of influencing biomaterial behavior, antimicrobial diffusion, and early biofilm disruption without necessarily increasing systemic antimicrobial exposure (8,9).

The combination of an antimicrobial hydrogel coating with low-intensity ultrasound stimulation may therefore provide a biologically plausible method for reducing catheter-associated infection. Ultrasound may enhance local antimicrobial activity, interfere with bacterial adhesion, improve antimicrobial penetration into early biofilm structures, and alter microbial membrane permeability at the catheter–tissue interface (9–11). Unlike passive coatings, an ultrasound-tuned system offers the potential for externally modulated protection, allowing antimicrobial activity to be reinforced during catheterization while limiting continuous drug release. This mechanism is clinically relevant because catheter-associated urinary tract infection is largely driven by surface colonization and biofilm progression rather than systemic infection at the time of insertion.

Despite encouraging developments in antimicrobial biomaterials and responsive drug-delivery systems, clinical evidence evaluating ultrasound-tuned antimicrobial hydrogel–coated urinary catheters remains limited. Existing evidence is largely derived from laboratory, biomaterial, or preclinical infection models, while randomized clinical data assessing clinically confirmed catheter-associated urinary tract infection are scarce. In particular, there is a lack of patient-level randomized evidence comparing ultrasound-responsive antimicrobial hydrogel-coated catheters with standard uncoated silicone catheters under routine inpatient conditions. This gap is important because reductions in bacterial adhesion or colony counts in experimental settings do not always translate into clinically meaningful reductions in catheter-associated urinary tract infection.

Therefore, the present randomized controlled trial was designed using a PICO framework in which the population comprised hospitalized adults requiring indwelling urinary catheterization for at least 72 hours, the intervention was an ultrasound-tuned antimicrobial hydrogel–coated urinary catheter with daily low-intensity ultrasound exposure, the comparator was a standard uncoated silicone catheter, and the primary outcome was clinically assessed and microbiologically confirmed catheter-associated urinary tract infection. The study hypothesis was that ultrasound-tuned antimicrobial hydrogel–coated catheters would reduce catheter-associated urinary tract infection rates and bacterial burden compared with standard uncoated catheters during short-term inpatient catheterization.

MATERIALS AND METHODS

This prospective, parallel-group randomized controlled trial was conducted in the Islamabad–Rawalpindi region over a four-month period among hospitalized adult patients requiring short-term indwelling urinary catheterization. The trial was designed to compare the clinical effectiveness and safety of ultrasound-tuned antimicrobial hydrogel–coated urinary catheters with standard uncoated silicone urinary catheters for the prevention of catheter-associated urinary tract infection. Eligible participants were adults aged 18 years or older who required an indwelling urinary catheter expected to remain in place for at least 72 hours and who had no clinical or laboratory evidence of urinary tract infection at baseline. Baseline absence of infection was confirmed through clinical assessment and urinalysis before catheter insertion. Patients were excluded if they had chronic or recurrent urinary tract infection, current antibiotic therapy for any active infection, known immunosuppressive illness, pregnancy, structural urinary tract abnormality, anticipated catheterization of less than 72 hours, or previous participation in the study.

Participants were recruited consecutively from eligible inpatient units after screening against the predefined criteria. A total of 68 patients were assessed for eligibility, of whom 60 fulfilled the inclusion criteria and were enrolled after informed consent. Participants were randomly allocated in a 1:1 ratio to either the ultrasound-tuned antimicrobial hydrogel–coated catheter group or the standard uncoated catheter group using a computer-generated randomization sequence. Thirty participants were assigned to each study arm. Allocation was implemented before catheter insertion, and all participants received catheter care according to the same institutional catheter maintenance protocols to reduce performance-related variation between groups.

The intervention group received urinary catheters coated with an antimicrobial hydrogel engineered to respond to low-intensity ultrasound stimulation. Following catheter insertion, low-intensity ultrasound exposure was applied once daily using a portable therapeutic ultrasound device with standardized safety parameters. The ultrasound application protocol was kept consistent across intervention participants to ensure uniform exposure. The control group received standard silicone urinary catheters without antimicrobial hydrogel modification or ultrasound activation. Apart from the catheter type and ultrasound exposure in the intervention arm, all procedures related to catheter insertion, fixation, drainage system handling, perineal hygiene, and clinical monitoring were standardized across both groups.

The primary outcome was the occurrence of catheter-associated urinary tract infection during the catheterization period. Catheter-associated urinary tract infection was operationally defined as the presence of compatible clinical features with microbiological confirmation on urine culture obtained after catheterization. Clinical monitoring was performed daily for symptoms and signs suggestive of urinary tract infection, including fever, suprapubic discomfort, dysuria after catheter removal where applicable, and other clinically relevant urinary symptoms. Secondary outcomes included quantitative urine colony count, time to infection onset, symptomatic catheter-associated urinary tract infection, catheterization duration, and catheter- or ultrasound-associated adverse events. Quantitative urine culture results were recorded as colony-forming units per milliliter, and time to infection onset was calculated in days from catheter insertion to the first confirmed infection event.

Baseline data included age, sex, indication for catheterization, baseline urinalysis, study group allocation, and expected duration of catheterization. Clinical and microbiological data were recorded using standardized data collection forms to maintain consistency and reduce information bias. The main exposure variable was catheter type, categorized as ultrasound-tuned antimicrobial hydrogel–coated catheter or standard uncoated catheter. The principal dependent variable was catheter-associated urinary tract infection status, recorded as present or absent. Continuous variables included age, duration of

catheterization, time to infection onset, and urine colony count. Categorical variables included sex, catheterization indication, study group, symptomatic infection, and adverse events.

Bias was addressed through random allocation, comparable eligibility criteria, standardized catheter care protocols, baseline screening to exclude pre-existing urinary infection, and use of microbiological confirmation for outcome ascertainment. Baseline characteristics were compared between groups to assess allocation comparability. Confounding was minimized by applying identical catheter care procedures across both arms and by excluding patients with major infection-related risk modifiers such as current antibiotic use, immunosuppressive conditions, pregnancy, and structural urinary tract abnormalities. All enrolled participants completed follow-up, and therefore the final analysis included all randomized participants.

The final sample comprised 60 participants, with 30 participants per group. The sample size reflected the number of eligible patients recruited during the defined study period and was considered sufficient for preliminary evaluation of clinically meaningful differences in catheter-associated urinary tract infection between groups. Data were analyzed using statistical software. Continuous variables were summarized as mean and standard deviation, while categorical variables were presented as frequencies and percentages. Between-group comparisons for continuous variables were performed using independent-samples t-tests after assessment of distributional suitability. Categorical variables, including catheter-associated urinary tract infection rates, were compared using the chi-square test. Statistical significance was set at $p < 0.05$. Missing outcome data were not encountered because all enrolled participants completed follow-up.

Ethical conduct was maintained throughout the study through informed consent, baseline infection screening, standardized clinical monitoring, and documentation of adverse events. Participant confidentiality was preserved during data collection and analysis. Data integrity was supported by prospective recording, consistent operational definitions, standardized microbiological confirmation, and inclusion of all enrolled participants in the final analysis.

RESULTS

A total of 68 patients were screened, of whom 60 met the eligibility criteria and completed follow-up. Thirty participants were randomized to the ultrasound-tuned antimicrobial hydrogel–coated catheter group and 30 to the standard catheter group. Baseline characteristics were comparable between groups, with no meaningful imbalance in age, sex distribution, catheterization indication, baseline urinalysis, or catheterization duration.

Table 1. Baseline Demographic and Clinical Characteristics by Study Group

Variable	Ultrasound-Tuned Hydrogel (n=30)	Standard Catheter (n=30)	Total (N=60)	p-value
Age, years, mean ± SD	55.7 ± 13.8	56.9 ± 14.6	56.3 ± 14.2	0.74
Male sex, n (%)	18 (60.0)	19 (63.3)	37 (61.7)	0.79
Female sex, n (%)	12 (40.0)	11 (36.7)	23 (38.3)	0.79
Postoperative retention, n (%)	13 (43.3)	13 (43.3)	26 (43.3)	1.00
Medical monitoring, n (%)	17 (56.7)	17 (56.7)	34 (56.7)	1.00
Baseline urinalysis normal, n (%)	30 (100.0)	30 (100.0)	60 (100.0)	—
Duration of catheterization, days, mean ± SD	5.6 ± 1.4	5.8 ± 1.6	5.7 ± 1.5	0.62

During follow-up, catheter-associated urinary tract infection occurred in 1 of 30 participants in the ultrasound-tuned hydrogel group and 5 of 30 participants in the standard catheter group, corresponding to infection rates of 3.3% and 16.7%, respectively. This represented an absolute risk reduction of 13.4 percentage points and an estimated number needed to treat of approximately 8 patients to prevent one catheter-associated urinary tract infection. The relative risk was 0.20, indicating an estimated 80% lower infection risk in the intervention group; however, the confidence interval was wide because of the small number of infection events.

Table 2. Catheter-Associated Urinary Tract Infection by Study Group

Outcome	Ultrasound-Tuned Hydrogel (n=30)	Standard Catheter (n=30)	Effect Estimate	95% CI	p-value
CAUTI present, n (%)	1 (3.3)	5 (16.7)	RR = 0.20	0.03–1.61	0.046*
CAUTI absent, n (%)	29 (96.7)	25 (83.3)	—	—	—
Absolute risk reduction	—	—	13.4 percentage points	—	—
Number needed to treat	—	—	≈8	—	—

*The manuscript reports p = 0.046. This value should be statistically verified because recalculation from the displayed 2×2 counts may yield a less significant result depending on whether chi-square, continuity correction, or Fisher's exact test is used.

Quantitative urine culture results showed a lower bacterial burden in the ultrasound-tuned hydrogel group. Mean colony count was $2.1 \times 10^4 \pm 0.8 \times 10^4$ CFU/mL in the intervention group compared with $6.7 \times 10^4 \pm 1.9 \times 10^4$ CFU/mL in the standard catheter group, giving a mean difference of -4.6×10^4 CFU/mL. This represented approximately a 69% lower mean colony count in the intervention group.

Table 3. Quantitative Urine Culture Results

Variable	Ultrasound-Tuned Hydrogel	Standard Catheter	Mean Difference	Relative Reduction	p-value
Mean colony count, CFU/mL ± SD	**$2.1 \times 10^4 \pm 0.8 \times 10^4$**	**$6.7 \times 10^4 \pm 1.9 \times 10^4$**	**-4.6×10^4 CFU/mL**	**68.7% lower**	**0.01**

Secondary outcomes supported the primary findings. Among participants who developed infection, mean time to infection onset was longer in the ultrasound-tuned hydrogel group than in the standard catheter group, suggesting delayed microbial progression. Symptomatic catheter-associated urinary tract infection was also less frequent in the intervention arm, although this comparison did not reach statistical significance.

Table 4. Secondary Clinical Outcomes

Outcome	Ultrasound-Tuned Hydrogel	Standard Catheter	Effect Estimate	p-value
Time to infection onset, days, mean ± SD	6.0 ± 0.0	4.4 ± 0.9	Mean difference = +1.6 days	0.04
Symptomatic CAUTI, n (%)	1 (3.3)	4 (13.3)	RR = 0.25	0.16
Catheter-related adverse events	0	0	No events	—
Ultrasound-associated complications	0	—	No events	—

Overall, the intervention demonstrated a consistent clinical pattern: lower CAUTI incidence, reduced urine bacterial burden, delayed infection onset, and no reported catheter- or ultrasound-related complications.

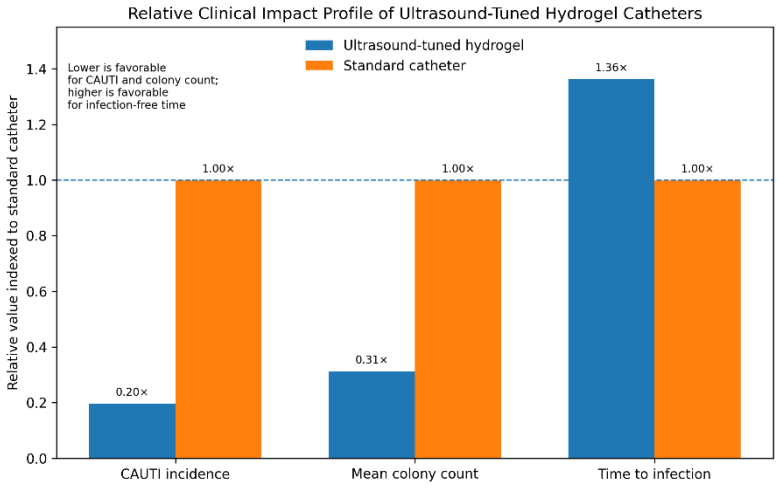

Figure 1 Relative Clinical Impact Profile of Ultrasound-Tuned Hydrogel Catheters

The relative clinical impact profile showed that ultrasound-tuned hydrogel catheters reduced CAUTI incidence to 0.20× of the standard catheter group and lowered mean urine colony count to 0.31× of the

control value, while extending infection-free time among infected participants to 1.36× of that observed with standard catheters. This combined pattern indicates that the intervention was associated not only with fewer infections but also with a lower bacterial burden and delayed progression to clinically confirmed infection.

DISCUSSION

The present randomized controlled trial demonstrated that ultrasound-tuned antimicrobial hydrogel–coated urinary catheters were associated with a lower incidence of catheter-associated urinary tract infection, reduced urine bacterial burden, and delayed infection onset compared with standard uncoated silicone catheters. The observed CAUTI rate was 3.3% in the intervention group compared with 16.7% in the control group, corresponding to an estimated relative risk of 0.20 and an absolute risk reduction of 13.4 percentage points. Although the small sample size resulted in wide confidence limits around the effect estimate, the direction and consistency of the findings across clinical and microbiological outcomes support the biological plausibility of the intervention. The lower mean colony count in the ultrasound-tuned hydrogel group further suggests that the coating and ultrasound activation may have attenuated microbial colonization before progression to clinically evident infection.

These findings are consistent with the broader understanding that catheter-associated infection is strongly driven by microbial adhesion, biofilm formation, and progressive bacterial persistence on device surfaces. Conventional catheter materials provide limited active protection against this process, while many antimicrobial coatings depend on passive release mechanisms that may decline over time or provide insufficient activity during the critical period of biofilm maturation (12–14). The present results extend this evidence by suggesting that a responsive catheter surface, externally activated through low-intensity ultrasound, may improve local antimicrobial performance during catheterization. The longer time to infection onset in the intervention group also supports the possibility that ultrasound tuning interfered with early biofilm development or reduced microbial expansion at the catheter interface.

From a clinical standpoint, the estimated number needed to treat of approximately eight patients is potentially meaningful, particularly in settings where catheter use is frequent and CAUTI contributes to antibiotic exposure, prolonged hospitalization, and avoidable healthcare costs. A localized surface-based strategy may also support antimicrobial stewardship by reducing infection risk without increasing systemic antimicrobial use. The absence of reported catheter-related adverse events or ultrasound-associated complications further supports the short-term feasibility of this approach; however, this safety finding should be interpreted cautiously because the trial was not powered to detect rare adverse events.

The study has several strengths. Its randomized controlled design reduced selection bias, baseline urinalysis helped exclude pre-existing urinary infection, and standardized catheter care across both arms minimized differences attributable to routine nursing practice. The use of microbiological confirmation strengthened outcome assessment, while complete follow-up of all enrolled participants reduced attrition bias. At the same time, several limitations must be acknowledged. The single-region setting and small sample size restrict generalizability, and the small number of infection events limits precision around effect estimates. The study did not report allocation concealment, blinding of outcome assessors, or detailed ultrasound parameters, which may introduce performance or ascertainment bias. The absence of organism-level microbiological characterization also limits interpretation of whether the intervention had differential effects against specific uropathogens or resistant organisms.

Future studies should evaluate this technology in larger multicenter randomized trials with prespecified sample size calculations, concealed allocation, blinded microbiological assessment, and fully standardized ultrasound parameters. Longer follow-up is needed to determine whether protection persists during prolonged catheterization, particularly in critically ill, immunocompromised, postoperative, and long-term catheterized populations. Future work should also include species-level

culture reporting, antimicrobial susceptibility patterns, catheter biofilm analysis, cost-effectiveness evaluation, and implementation outcomes such as staff adherence, workflow burden, and device durability under repeated ultrasound exposure. Such evidence would clarify whether ultrasound-tuned antimicrobial hydrogel catheters can be translated from promising device innovation into routine infection-prevention practice.

CONCLUSION

Ultrasound-tuned antimicrobial hydrogel–coated urinary catheters were associated with reduced catheter-associated urinary tract infection, lower urine bacterial colony counts, and delayed infection onset compared with standard uncoated silicone catheters in hospitalized adults requiring short-term catheterization. The findings support the potential clinical value of combining responsive biomaterial coatings with non-invasive ultrasound activation as a localized device-centered infection-prevention strategy. Larger, methodologically rigorous multicenter trials are required to confirm effectiveness, define safety, optimize ultrasound parameters, and determine implementation feasibility in routine clinical care.

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