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Impact of micro-hole zone catheters *vs.* conventional eyelet catheters on bladder emptying, flow stops, and microtrauma in adults with neurogenic or non-neurogenic lower urinary tract dysfunction requiring clean intermittent catheterization: a systematic review and meta-analysis

Branson Thamran,[1] Bungaran Sihombing,[1] Steven Steven[2]

[1]Department of Urology, Haji Adam Malik Hospital, Medan; [2]Department of Urology, Universitas Indonesia, Dr. Cipto Mangunkusumo Hospital, Jakarta, Indonesia

Abstract

Intermittent catheterization is the gold standard method for bladder emptying in neurogenic and non-neurogenic lower urinary tract dysfunction patients. Despite their usage, eyelet catheters are associated with frequent flow stops, incomplete bladder emptying, and mucosal trauma that leads to patients' discomfort and contributes to chronic urinary tract infections. This systematic review and meta-analysis aim to assess the safety and impact of the micro-hole zone catheter in this population. Several databases were widely searched for studies through 2025. The primary outcome was bladder emptying, and secondary outcomes were flow stops and microtrauma. The Cochrane risk of bias tool 2.0 was used to assess the risk of bias. We identified four publications with a total of 253 patients. There was a significant difference in the residual urine volume between the two groups [mean difference: -21.40 mL; 95% confidence interval (CI): -40.03 to -2.80, p=0.0005]. The mean difference in flow stop rate was 0.20 (95% CI: 0.12 to 0.34, p=0.3173), and the mean difference in microtrauma was 0.15 (95% CI: 0.09 to 0.26, p=0.628). All favor the micro-hole zone catheter. The micro-hole zone catheter demonstrated a safety option compared to the eyelet catheter with regard to microtrauma, residual urine volume, and fewer flow stops that lead to better emptying of the bladder.

Key words: micro-hole zone catheter, intermittent catheterization, urinary tract dysfunction, eyelet catheter, conventional urinary catheter.

Correspondence: Branson Thamran, Department of Urology, Haji Adam Malik Hospital, Medan, Indonesia. E-mail: dr.bransontham@gmail.com

Introduction

Clean intermittent catheterization (CIC) is globally regarded as the gold standard for bladder management of lower urinary tract dysfunction patients, including both neurogenic and non-neurogenic disorders, as it enables effective bladder emptying and reduces the risk of complications.[1,2]

Neurogenic bladder, commonly resulting from conditions such as spinal cord injury, multiple sclerosis, or diabetes-related neuropathy, and non-neurogenic causes such as bladder outlet obstruction or detrusor underactivity, may both lead to chronic urinary retention requiring catheterisation.[3] In these populations, CIC plays a critical role in preserving renal function, preventing bladder overdistension, and maintaining urinary continence.[3]

Despite the therapeutic effect, CIC is also associated with several complications. Among these complications, urinary tract infections (UTIs) lead to the highest mortality rate, with reported incidence rates of up to several episodes per patient per year in long-term users.[4-6]

Recurrent UTIs not only impair quality of life but are also associated with increased healthcare utilization, antibiotic exposure, and the risk of antimicrobial resistance.[4,7] In vulnerable populations, particularly those with neurogenic bladder, recurrent or complicated UTIs may contribute to urosepsis, hospitalization, and increased mortality risk, especially in individuals with multiple comorbidities.[6-8] In addition to infection risk, incomplete bladder drainage, residual urine, and catheter-related microtrauma remain persistent challenges that may further predispose CIC users to complications.[2,9] Residual urine serves as a reservoir for bacterial growth and colonization; on the other hand, repeated trauma to the urothelium during catheterization may facilitate bacterial entry and inflammation.[2,9] Together, these factors contribute to an infection sequence, mucosal injury, and impaired bladder function, which handicapped patient outcomes and quality of life.[2,9]

Conventional eyelet catheters (CEC) have been associated with mucosal suction during bladder emptying, where the bladder mucosa is drawn into the drainage eyelets.[2,9] This phenomenon can result in urinary flow interruptions, increased intra-catheter pressure, and the need for catheter repositioning, potentially leading to microtrauma and suboptimal bladder drainage.[2,9] To address these limitations, a novel intermittent catheter incorporating micro-hole zone technology has been developed. This design features multiple

micro-holes distributed along the catheter tip, which may facilitate more uniform drainage and reduce focal suction forces.[1,9]

Evidence from laboratory studies and early clinical investigations suggests that this technology may improve bladder emptying performance and reduce catheter-related microtrauma.[1,2,9]

Randomized controlled crossover studies have demonstrated that micro-hole zone catheters (MHZC) are associated with significantly fewer urinary flow stops and lower residual urine volumes compared with CEC, enabling more continuous bladder emptying without the need for catheter repositioning.[10,11]

These findings have been observed in both male and female CIC users under healthcare professional surveillance. In particular, lower intra-catheter pressure peaks observed with MHZC suggest reduced mucosal suction, which decreased catheter-related microtrauma.[12,13]

Despite these promising findings, there are no systematic reviews and meta-analyses on this topic synthesizing clinical evidence. Therefore, this study aimed to evaluate the effectiveness of MHZC in patients with lower urinary tract dysfunction undergoing CIC, focusing on urinary flow stops, catheter-related microtrauma, and residual urine volume.

Materials and Methods

Search strategy

This systematic review and meta-analysis strictly followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines and was registered in the PROSPERO record book (CRD420251266851).[14] From the database's inception through 2026, a comprehensive literature search was conducted using PubMed, Google Scholar, and the Cochrane Library. Search keywords included "micro-hole zone catheters", "eyelet catheters", and "lower urinary tract dysfunction". Additionally, the other database search algorithm was adapted using the PubMed search strategy. The *Supplementary Material* contains the search strategy.

Inclusion and exclusion criteria

Studies were included according to the following criteria: i) study design – prospective trials, retrospective cohort studies, or case series; ii) the population is patients with lower urinary tract dysfunction; ii) the intervention is the use of MHZC; iii) comparison of CEC. The primary outcome is bladder emptying assessed using post-voidal residual volume. Secondary outcomes are flow stops and microtrauma. Exclusion criteria included: animal or preclinical studies, reviews, publications in languages apart from English, and abstract-only or poster presentation studies.

Data extraction

All retrieved titles, abstracts, and complete texts were independently reviewed by two reviewers. Disagreements were settled through the third author. The following sequence was used to extract the overall data: study characteristics, clinical parameters, type of intervention, and important outcomes (flow stop, residual urine, and microtrauma).

Risk of bias assessment

The Cochrane risk of bias tool 2.0 (RoB2) was used for this risk of bias assessment to improve the quality assessment of randomised clinical trials in several ways.[15] After the inclusion criteria were met, 4 studies were included. RoB2 is presented in *Supplementary Figure 1*. The overall risk of bias across the 4 included studies was low to moderate. All studies were randomized crossover trials, reducing the risk of bias introduced by randomization.

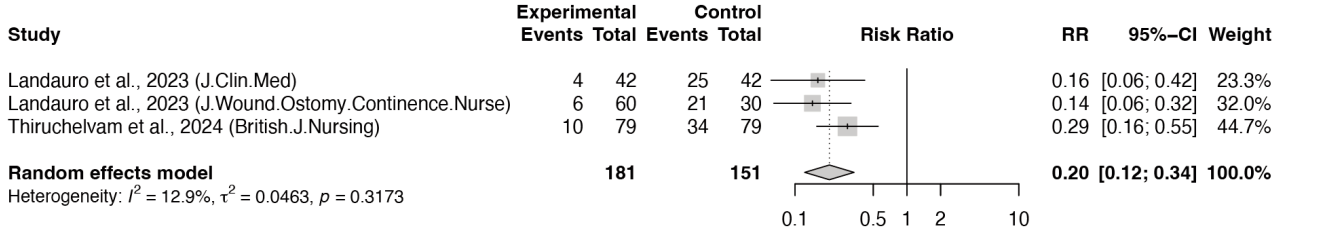

Figure 1. Forest plot providing flow stop events. RR, risk ratio; CI, confidence interval.

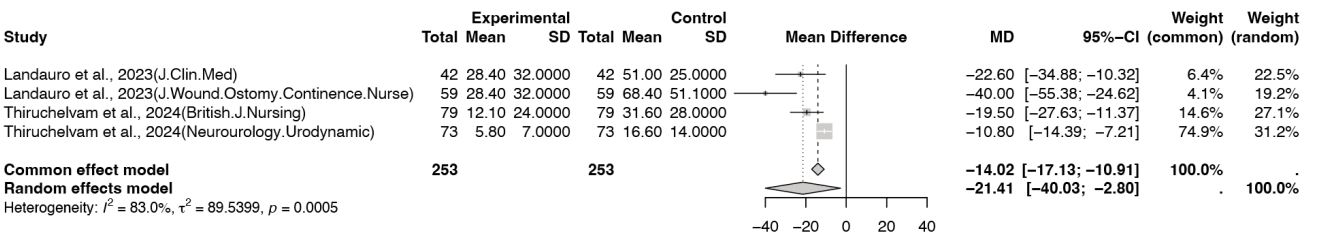

Figure 2. Forest plot displaying residual urine volume. SD, standard deviation; MD, mean difference; CI, confidence interval.

Statistical analysis

The RStudio software package was used to conduct statistical evaluations.[16] To account for longitudinal variability, effect estimates were pooled using a random-effects model. Results have been presented as risk ratios (RR) with 95% confidence intervals (CIs) for dichotomous outcomes. I^2 and τ^2 values were used to evaluate heterogeneity, and a p-value of less than 0.05 was deemed significant. To identify possible causes of inaccuracies, sensitivity analyses were performed using leave-one-out analysis. Funnel plots were used to study publication bias and further heterogeneity.

Results

Study selection and characteristics

A total of 1672 studies were identified from databases. A total of 12 duplicate studies were detected. After deduplication, 1660 records were filtered. A total of 1631 studies were removed. No automation tools were used during the screening. The remaining 29 studies were refiltered for retrieval. A total of 19 studies were not retrieved for full text, while 10 were retrieved for full text. A total of 6 studies were excluded: one because of a different outcome, and another because it was a questionnaire-based study. Another was an *ex vivo* porcine study; one was a case report; one was a preclinical study; and the last was a single-arm study. Of these 4 studies, 256 participants were identified. The PRISMA flow chart reflects the identification of studies *via* databases and registers, rescreening, and reassessment of qualified studies (*Supplementary Figure 2*).[14] *Supplementary Table 1* consists of the general characteristics of the study.

Flow stops between the two groups

In the flow stop outcome, using a random-effects model, the pooled effect demonstrated a significant reduction in the risk of the outcome in the intervention group compared with the control (RR=0.20; 95% CI 0.12 to 0.34, p=0.3173). Overall, these findings indicate that the intervention is consistently associated with a substantially lower risk (≈80% relative reduction) compared with the control (Figure 1).

Urine volume between the two groups

For residual urine volume assessed after the first flow stop using a bladder scanner, the intervention demonstrated a significant reduction. Due to substantial between-study heterogeneity (I^2=83.0%; τ^2=89.54), a random-effects model was applied with a mean difference of approximately -21.4 mL (95% CI -40.03 to -2.80, p=0.0005) (Figure 2).

Microtrauma between the two groups

Across all studies, the incidence of microtrauma was consistently lower in the experimental group. Microtrauma was assessed using a urine dipstick before and after catheterization. A random-effects model demonstrated a significant reduction in microtrauma with the intervention (RR=0.15; 95% CI 0.09 to 0.26, p=0.6280). Between-study heterogeneity was negligible (I^2=0%; τ^2=0), indicating a highly consistent effect across trials (Figure 3).

Leave-one-out analysis

We chose the leave-one-out analysis for the sensitivity analysis when high heterogeneity in the outcome was observed. Leave-one-out analysis works by omitting one study at a time and analyzing the remaining studies simultaneously, showing which study has the greatest impact on the high heterogeneity observed in the study. When doing leave-one-out analysis, Thiruchelvam *et al*. and Landauro *et al*. showed high heterogeneity when we omitted these two studies independently (Figure 4).[11,13]

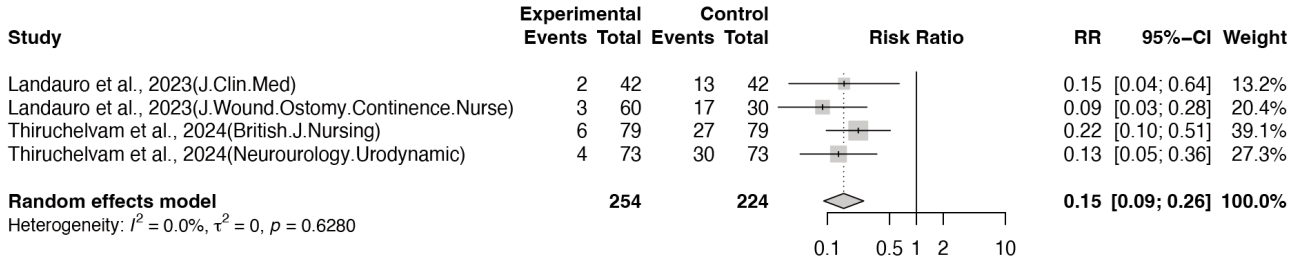

Figure 3. Forest plot showing catheter-related microtrauma events. RR, risk ratio; CI, confidence interval.

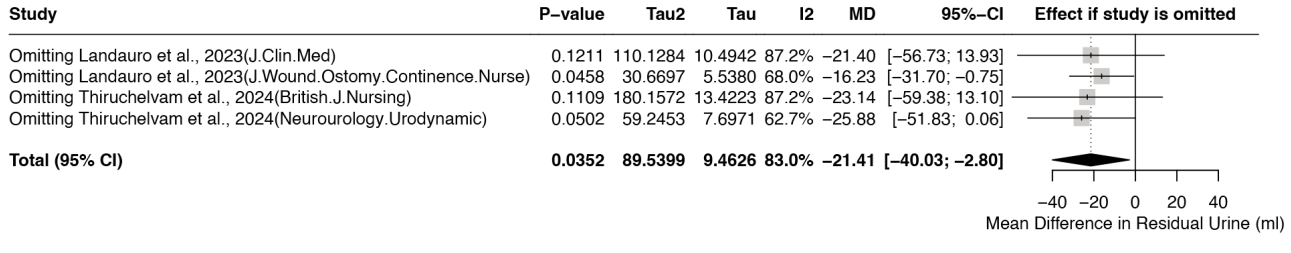

Figure 4. Sensitivity analysis using leave-one-out analysis. MD, mean difference; CI, confidence interval.

Publication of bias

The publication bias in residual urine volume can be assessed in Figure 5 (funnel plot). The plot shows the standard errors and relative risks of urine volume for each study. While we hope that a symmetrical distribution is achieved in the absence of publication bias, the funnel plot showed one study that contributed to some asymmetry, with small studies on the left and moderate variability. Although the funnel plot visually suggested a potential risk of publication bias, the small number of included studies may limit the reliability of funnel plot interpretation. Therefore, no definitive conclusion regarding the presence or absence of publication bias can be applied.

Quality of evidence

We evaluated the certainty of evidence for individual outcomes using the Grading of Assessment, Development, and Evaluation (GRADE) method.[17] Based on the GRADE criteria, the certainty of evidence supporting the use of MHZC compared with CEC is moderate. The evidence indicates a clinically meaningful improvement in bladder-emptying performance, characterized by fewer urinary flow stops and reduced residual urine, with a plausible mechanistic basis related to reduced mucosal suction. Evidence of publication bias was identified. *Supplementary Table 2* presents the GRADE criteria for the quality of evidence across different outcomes.

Discussion

Our systematic review and meta-analysis demonstrated a prominent reduction in catheter-related complications with the use of MHZC, including an 80% reduction in the risk of flow stops, a mean reduction of 21.4 mL in residual urine volume, and an 85% reduction in catheter-related microtrauma among individuals with lower urinary tract dysfunction requiring CIC. These findings collectively indicate that MHZC may offer improved bladder-emptying performance and a more continuous, uninterrupted urinary flow profile compared with CEC. From a practical standpoint, the reduction in flow stops and residual urine volume supports the hypothesis that MHZC promotes suction forces more evenly, thereby lowering mucosal blockage at the catheter-end.[10,13]

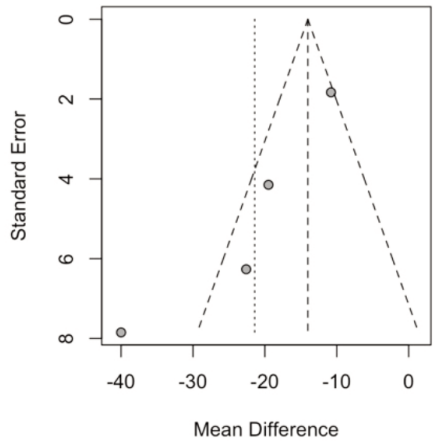

Figure 5. Funnel plot analysis of publication bias.

The included randomized trials demonstrated favorable outcomes for MHZC across both male and female populations, with similar reductions in flow stops and markers of incomplete bladder emptying screened by bladder scanner.[10-13]

Notably, these results were observed in carefully regulated clinical conditions, frequently under the surveillance of medical professionals and following catheterization procedures. Although this increases internal validity and decreases variability, it may also restrict the findings' applicability to actual CIC users, where patient characteristics and technique differ greatly.[10-13]

In routine practice, patient-related factors such as dexterity, experience, and adherence to catheterization schedules may influence both performance and safety outcomes, and these factors were not fully captured in the included studies.[10-13]

The proposed mechanism underlying the improved performance of MHZC is biologically plausible and supported by both clinical and preclinical data. CEC has been associated with mucosal suction events, whereby bladder mucosa is drawn into the drainage eyelets, leading to transient flow obstruction, increased intra-catheter pressure, and the need for catheter repositioning.[12,13]

This repeated practical interaction with the urothelium may promote microtrauma, hematuria, and potentially an increased susceptibility to UTIs. On the contrary, the MCHZ design distributes drainage across multiple smaller holes, therefore reducing focal pressure and enhancing continuous flow of urine. This is reflected in the observed reductions in intra-catheter pressure peaks and flow stop frequency.[12,13]

From a clinical outcome perspective, reduced flow stops and residual urine volume lie in their potential association with complications such as UTIs, urethral trauma, and reduced quality of life. Residual urine has been identified as a modifiable risk factor for UTI in CIC users, and repeated catheter repositioning may increase the risk of mucosal injury.[10-13]

However, it is important to emphasize that much of the mechanistic understanding of mucosal suction and pressure dynamics originates from preclinical laboratory experiments and animal models**,** including *ex vivo* bladder systems and controlled experimental setups.[18-20]

While these models provide valuable insights into fluid dynamics and catheter-tissue interactions, they may not adequately replicate the complexity of human bladder physiology, including detrusor activity, bladder compliance, patient movement, and behavioral factors during catheterization.[18-20]

Consequently, the translation of these mechanistic advantages into consistent clinical benefit remains uncertain, and the reliance on such preclinical evidence introduces an element of indirectness in the overall body of evidence.[18-20]

Several methodological limitations of the included studies should also be considered. All trials employed randomized crossover designs without blinding, which may introduce performance and detection bias, particularly since there are no analyses of subjective outcomes such as discomfort and user perception.[10-13]

Furthermore, all included trials were industry-sponsored. While industry collaboration is common in device research, this raises concerns about sponsorship bias, selective outcome reporting, and the prioritization of favorable endpoints that will benefit the device company.[10-13]

The homogeneity of trials sponsored by an industrial company further limits external validity and increases the risk of evidence amplification bias, whereby pooling multiple small, similar, manufacturer-funded studies may overestimate the robustness and certainty of the evidence.[10-13]

In addition, the small sample sizes and short follow-up across studies limit the ability to detect rare or delayed adverse events. Although no serious adverse events were reported and overall adverse event rates were low, the occurrence of UTIs in a small number of participants highlights the need for cautious interpretation.[10-13] As a whole, the available evidence suggests that MHZC offers advantages in terms of catheterization performance and reduction of catheter-related trauma and complications compared with CEC.

However, these positive findings should be interpreted with care of important limitations, including non-blinded study designs, company sponsorship, short follow-up durations, and only early catheter-related complications. These factors collectively reduce confidence in the magnitude and clinical relevance of the observed effects. Future research should prioritize independent, blinded, parallel-group randomized controlled trials with longer follow-up and a focus on patient-centered outcomes, including subjective patient outcomes, such as UTI rates, quality of life, patient comfort, and long-term safety, by analyzing the availability of delayed adverse events. In addition, real-world studies evaluating device performance in routine clinical settings would provide valuable insights into generalizability and adherence. Until such data are available, the current evidence supports the potential of MHZC as a promising innovation in CIC technology, but definitive recommendations for widespread use in clinical settings should be made with caution by fellow clinicians and researchers.

Conclusions

The new MHZC technology can be an alternative for bladder management in individuals with lower urinary dysfunction that overcomes the limitations of a CEC. However, due to sponsorship trials of MHZC, future non-sponsored large trials can be made for analyzing the real impact in clinical settings to further apply this new technology for use as a standardized catheter for individuals with lower urinary dysfunction.

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Online supplementary material:

Supplementary Material. Search strategy.

Supplementary Figure 1. ROBS-2 analysis among studies.

Supplementary Figure 2. PRISMA flow chart.[14]

Supplementary Table 1. General characteristics of the study.

Supplementary Table 2. GRADE criteria table showing each criterion-related outcome.[17]

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Contributions: all authors: study concept, results' interpretation, draft of the manuscript, review and approval of the final manuscript. Branson Thamran: protocol registration. Branson Thamran, Bungaran Sihombing: literature search, study identification, study screening, and selection, data extraction. Bungaran Sihombing, Steven Steven: risk of bias assessment. Branson Thamran, Steven Steven: data synthesis and statistical analysis, critical revision. Bungaran Sihombing: supervision.

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Patient consent for publication: not applicable.

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