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Quantification of urine capture by a novel external female catheter for accurate urine output measurement

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ABSTRACT

Indwelling catheters effectively track urine output but increase the risk of catheter-associated urinary tract infections (CAUTIs). Reducing their use, especially in female patients, is a primary clinical goal. External urinary management systems offer an alternative, but many lack the necessary accuracy for critically ill patients requiring precise urine output measurement. This study evaluates the performance of a novel external female catheter in a clinical setting. Results show the device captured an average of 97.2% of total urine output, demonstrating high accuracy. The novel external catheter system provides an effective solution for urine output measurement, reducing reliance on indwelling catheters and mitigating the risk of CAUTIs.

INTRODUCTION

In the United States, approximately 12-16% of adult hospital patients will have an indwelling urinary catheter at some point during their stay. [1] [2] Indwelling catheters are typically composed of a silicone-coated latex tube with an inflatable balloon, an access port, and a collection bag. Designed to be self-retaining, these catheters can remain in the bladder for up to 90 days. [3] They are commonly used to manage urine in incontinent patients and allow physicians to accurately track urine output, facilitating better clinical care.

Despite their utility, indwelling catheters significantly increase the risk of catheter-associated urinary tract infections (CAUTIs). Each additional day of catheterization raises the risk of CAUTI by 3-7%. [4]. Notably, failure to remove the catheter by postoperative day 3 has been directly associated with an average length of stay increase of 5.37 days, prolonging catheter use and further elevating CAUTI risk. [5] [6] Beyond clinical implications, CAUTIs can negatively impact hospital reimbursement rates. Under the CMS Hospital-Acquired Condition Reduction Program, CAUTI rates are factored into hospital performance metrics, potentially reducing reimbursement. [7]

External urinary management systems (EUMS), or external urinary catheters, have been shown to reduce catheter-associated urinary tract infections (CAUTIs) by up to 54%. This makes them a valuable alternative to indwelling catheters, particularly for nonretentive patients who do not require continuous urinary drainage.[8]

MATERIALS AND METHODS

The novel external urinary catheter system evaluated in this study was the CareDry® System (Boehringer Laboratories, LLC, Phoenixville, PA). This latex-free system is constructed from hydrophilic polyurethane foam embedded with antimicrobial compounds. Designed to be placed between the labia in contact with the urethra, the catheter utilizes suction to remove urine and moisture as it is excreted. [8] The foam conforms to patient anatomy, protecting against leaks in any position. The radial foam construction enables circumferential moisture management with a 360˚ capture surface. Captured urine is transported to a suction canister, eliminating the need for patient ambulation or repositioning during urination.

In 2024, a clinical study was conducted at Uniontown Hospital – WVU Medicine under Institutional Review Board (IRB) oversight. Patients in the Medical Intensive Care and Medical/Surgical units prescribed the CareDry® System were included. The study employed a non-randomized, observational design with informed consent waived by the IRB due to the minimal-risk nature of the intervention and the absence of identifiable patient health information collection. Output data for the study represented a retrospective collection of volume measurements without patient identifiers.

Urine capture efficacy was assessed by measuring the volume collected in the suction canister. Any urine not captured by the CareDry® System was absorbed by a pad placed beneath the patient. The volume absorbed by the pad was calculated by subtracting the pad's dry

weight from its weight after use. Capture efficacy was defined as the proportion of urine collected in the canister relative to the total urine output. Canister volume and pad weight measurements were recorded every two hours. Five (5) measurements were excluded due to stool contamination, which would have confounded absorbent pad weight calculations.

RESULTS

A total of 93 valid measurements were analyzed. The CareDry® System achieved a mean capture efficacy of 97.2% (SD: 3.15%) and a median efficacy of 98.3%. Over half (54 out of 93) of recorded measurements exceeded a capture rate of 98%. 86% of recorded measurements (80 out of 93) exceeded a capture rate of 94%.

Table 1. Summary statistics for urine volume capture.

	Urine Capture Efficacy	Urine Capture Volume
N	93	93
Mean	97.2%	283 mL
SD	3.15%	223.7 mL
Min	74.5%	20 mL
Median	98.3%	200 mL
Max	100%	1,300 mL

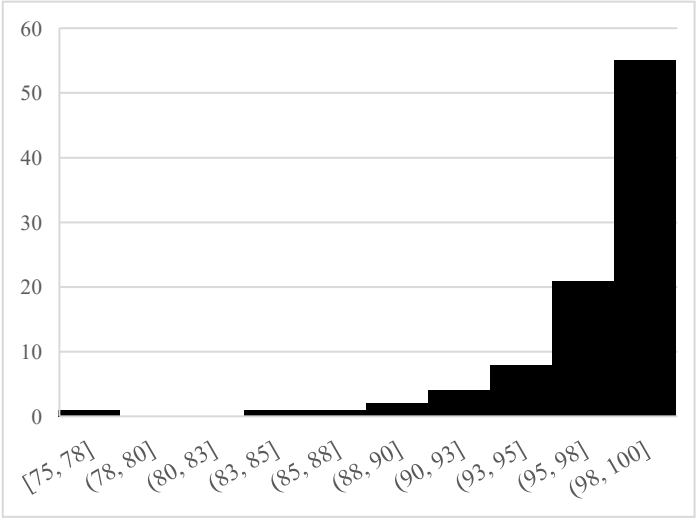

Figure 1. Urine capture percentage measurement counts.

DISCUSSION

External catheter systems are widely used in clinical settings to reduce the reliance on indwelling catheters and decrease the risk of CAUTIs. However, their adoption in critical care environments has been limited by challenges in accurately measuring urine output, which is critical for monitoring conditions like acute kidney injury (AKI). [9] [10]

One observational study of a similar external female urinary management system showed an 85.5% urine capture rate, with an overall effectiveness of 83.05%. [11] While these results are promising, they fall short of the accuracy required for detecting AKI. A urine output measurement error as small as 17 mL has been shown to impact AKI detection, emphasizing the need for improved measurement accuracy. [12] Given the average urine output volume of 283 mL recorded in the CareDry® study a 17 mL represents a 6% margin of error.

The CareDry® System has shown consistent performance in addressing urine output measurement accuracy. In over 85% of measurements (80 out of 93), CareDry® successfully captured more than 94% of urine output, remaining within the critical threshold required for AKI detection. By comparison, the competing product in a similar study exhibited an error of 16.95%, which exceeds the acceptable limit for precise urine output monitoring.

In critical care settings, the CareDry® system has proven highly effective, achieving a median capture efficacy of 98.3%. This high level of accuracy establishes CareDry® as a viable alternative to indwelling catheters, with the potential to significantly reduce CAUTI risks, shorten hospital stays, and provide the precision necessary for managing critical conditions.

By eliminating direct urethral insertion, an external urinary management system like CareDry® can significantly lower the risk of bacterial colonization, improve patient comfort and mobility, and reduce infection complications associated with prolonged catheterization. Their effectiveness in acute and critical care settings further supports their use as a safer, noninvasive solution for urine management.

Future studies should include diverse patient populations and comparative trials to validate these findings across broader clinical contexts.

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