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# Effectiveness of an External Urinary Device for Female Anatomy and Trends in Catheter-Associated Urinary Tract Infections

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## ABSTRACT

**PURPOSE:** The purpose of this study was to examine the effectiveness of an external female urinary management system (external urinary device for female anatomy [EUDFA]) in critically ill women unable to self-toilet and to identify rates of indwelling catheter use, catheter-associated urinary tract infections (CAUTIs), urinary incontinence (UI), and incontinence-associated dermatitis (IAD) before and after the introduction of the EUDFA.

**DESIGN:** Prospective, observational, and quasi-experimental design.

**SUBJECTS AND SETTING:** The sample comprised 50 adult female patients in 4 critical/progressive care units using an EUDFA at a large academic hospital in the Midwestern United States. All adult patients in these units were included in the aggregate data.

**METHODS:** Prospective data collected from the adult female patients over 7 days included urine diverted from the device to a canister and total leakage. Aggregate unit rates of indwelling catheter use, CAUTIs, UI, and IAD were retrospectively examined during 2016, 2018, and 2019. Means and percentages were compared using *t* tests or chi-square tests.

**RESULTS:** The EUDFA successfully diverted 85.5% of patients' urine. Indwelling urinary catheter use was significantly lower in 2018 (40.6%) and 2019 (36.6%) compared with 2016 (43.9%) ($P < .01$). The rate of CAUTIs was lower in 2019 than in 2016, but not significantly (1.34 per 1000 catheter-days vs 0.50, $P = .08$). The percentage of incontinent patients with IAD was 69.2% in 2016 and 39.5% in 2018-2019 ($P = .06$).

**CONCLUSIONS:** The EUDFA was effective in diverting urine from critically ill female incontinent patients and indwelling catheter utilization.

**KEY WORDS:** Catheter-associated urinary tract infections, External catheter for female anatomy, External urinary device, Female external catheter, Incontinence-associated dermatitis, Indwelling urinary catheter, Urinary incontinence.

## INTRODUCTION

Bladder management for critically ill females in the acute care setting includes use of indwelling urinary devices and diversion of urine to avoid incontinence-associated dermatitis (IAD) and pressure injuries.[1] Use of an indwelling urinary device in the acute and critically ill female is a common practice. However, instrumentation of the urinary tract with an indwelling catheter can result in mechanical stress or trauma as well as histological changes that can affect the bladder and even kidneys.[2,3] Catheter-associated urinary tract infections (CAUTIs) are a major source of patient morbidity; they account for approximately 70% to 80% of all healthcare-acquired infections.[3] There are an estimated 449,334 CAUTI-related harm events per year, costing more than $340 million to the healthcare system[4] and resulting in more than 13,000 deaths.[5] The per patient cost to treat a CAUTI varies considerably by acuity and comorbidity, but the direct attributable costs can range from under $1000 to over $10,000 per case.[6,7] The National Health Safety Network (NHSN) reports average CAUTI rates from 3.1 to 7.4 per 1000 catheter-days within critical care units, although rates within individual units are often higher.[8]

Longer duration of catheter use is a primary risk factor for CAUTIs,[9] with the risk for bacteriuria increasing 3% to 7% each day.[2] As a result, effective efforts to reduce CAUTIs typically include strategies to reduce the use and duration of indwelling catheters.[9] Regulatory bodies like the NHSN and the Centers for Medicare & Medicaid Services track catheter use and CAUTI rates as part of national quality improvement initiatives.[10,11]

Depending on the strategy used for bladder management, critically ill patients are also at an increased risk for IAD, a form of irritant contact dermatitis that occurs when skin is exposed to urine or fecal matter. The prevalence of IAD ranges

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from 3% to 50% depending on the population, setting, and age group; the highest prevalence is observed in critical care units.[12-14] Incontinence and IAD, in particular, are associated with an increased risk for pressure injury; IAD also causes pain, itching, burning, and infection, which are significant patient experience indicators.[14-18]

An external urinary device (EUD), also referred to as an external catheter, is one of a variety of alternative bladder management strategies to minimize indwelling catheterization in the acute or critically ill patient.[19] Unlike the array of options designed for male anatomy, there is a paucity of available EUDs designed to capture, divert, or contain urine in persons with female anatomy. In the past decade, several EUDs for female anatomy (EUDFAs) have been developed that have been found to reduce the use of indwelling catheters.[20-22] The importance of having a clinically useful EUDFA is imperative to reducing patient harm and reduce indwelling urinary catheter-days. The purpose of this study was to examine the effects of an EUDFA in critically ill women unable to self-toilet and to describe rates of indwelling catheter use, CAUTIs, urinary incontinence (UI), and IAD before and after the introduction of the device at a large academic hospital in the Midwestern United States.

## METHODS

This study employed a prospective, observational methodology; multiple cohorts were identified to achieve study objectives. First, to examine the effectiveness of the EUDFA, we prospectively studied 50 critically ill female patients hospitalized in either the intensive care unit (ICU) or progressive care unit of a large Midwestern academic hospital between December 2019 and April 2021. Adult (aged >18 years) females who were receiving inpatient critical or progressive care, incontinent of urine, unable to self-toilet, and using the EUDFA as defined by the study protocol were eligible. Those with an indwelling urinary catheter were excluded from this cohort.

We also examined trends in the rates of indwelling urinary catheter use, CAUTIs, UI, and IAD using a quasi-experimental, retrospective, cross-sectional comparison of male and female patients cared for in the critical care units of the same hospital during 2016, 2018, and 2019. These years were chosen to reflect periods before (2016) and after (2018, 2019) introduction of the EUDFA. For this portion of the study, all adult (male or female) patients who were receiving inpatient critical or progressive level of care for any amount of time during the study month were eligible (available data did not allow us to limit data capture to female patients). Catheter use and CAUTI rates were calculated using a full year of data. Incontinence and IAD data are not collected every month; in reviewing the available data, it was discovered that a particular month contained complete data for each of the observation years. Therefore, a decision was made to examine UI and IAD during that same month in each year.

### Study Device

The device studied was the Sage PrimaFit External Urine Management System for the Female Anatomy (Sage Products, a business unit division of Stryker, Cary, Illinois). This system is placed in the perineal area between the labia, against the urethra conforming to the female anatomy, and connected to low continuous suction providing a sump mechanism to divert urine into an external canister (Figure).

### Data and Outcome Measures

Patient demographics and clinical characteristics at enrollment were collected from patient medical records. The effectiveness of the EUDFA was operationally defined as the percentage of urine diverted by the system in relation to the volume of urine collected in the incontinence pads and liners. The total volume of urine represented the volume of urine remaining in the EUDFA, standard incontinence pads, soft incontinence liners, and the volume of urine collected in the canister. Dry weights of each were subtracted from wet weights (in grams, which equals milliliters) to determine the portion of urine output diverted by the device. Data regarding indwelling catheter usage, CAUTIs, UI, and IAD were obtained from documentation related to hospital quality monitoring criteria. The CAUTI rate was calculated as the number of CAUTIs per 1000 indwelling catheter-days during the year. Indwelling catheter use was calculated as the total number of indwelling catheter-days

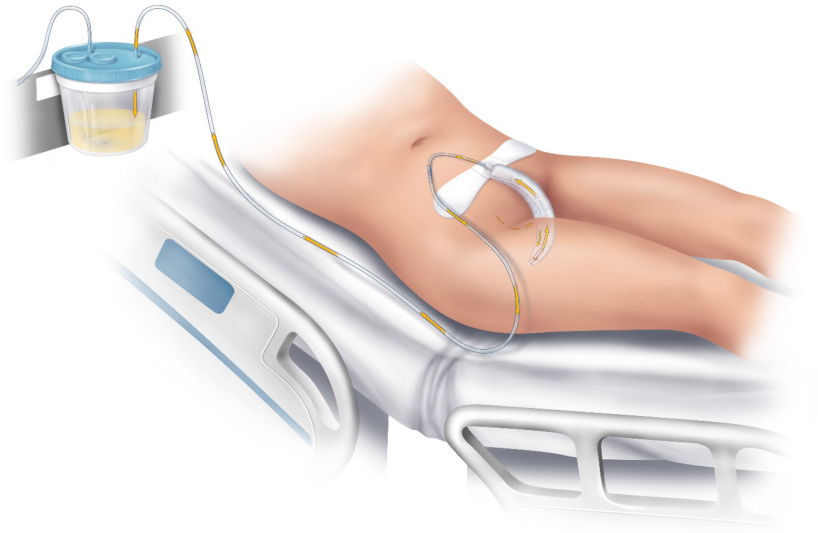

**Figure.** External female urinary device for female anatomy.

**TABLE 1.**
**Urine Containment in 50 Critically Ill Females Managed by an External Urinary Device for Female Anatomy**

| Variable | No. Nonmissing | Mean | SD | Median | Lower Quartile | Upper Quartile | Minimum | Maximum |
|---|---|---|---|---|---|---|---|---|
| Effectiveness | 43 | 83.05%[a] | 13.69% | 87.64% | 72.72% | 93.95% | 44.83% | 99.73% |
| Volume remaining in the device, mL | 43 | 24.5 | 36.5 | 10 | 4 | 28 | 1 | 205 |
| Volume collected by the canister, mL | 43 | 3,511.65 | 3,695.8 | 2,255 | 1,000 | 4,995 | 200 | 18,845 |
| Volume of urine collected on standard incontinence pads and soft incontinence liners, mL | 43 | 599.4 | 723.3 | 300 | 141 | 850 | 5 | 3,568 |
| Total volume of urine, mL | 43 | 4,135.53 | 4,193.51 | 2,805 | 1,133 | 5,554 | 375 | 19,970 |

Abbreviation: SD, standard deviation.
[a]These values reflect the average effectiveness across patients, as opposed to the overall effectiveness of 85.5% reported in the text that reflects the total mean volume of urine collected by the canister and remaining in the device (3536.15 mL) divided by the total mean volume of urine (4135.53 mL).

divided by the total number of patient-days during the year and presented as a percentage. Incontinence was defined as UI and/or fecal incontinence (FI) identified on visual inspection during the monthly pressure injury prevalence survey. Incontinence-associated dermatitis was defined as skin irritation present (yes/no) in the area of incontinence. The percentage with IAD was calculated among those with UI and/or FI.

### Data Analysis

Continuous data were summarized using descriptive statistics (mean, median, standard deviation [SD], minimum, maximum, and quartiles), and categorical data were summarized using frequencies and percentages. Differences in outcome measures between study years were compared using *t* tests (for continuous variables) or chi-square/Fisher's exact test (for categorical/count variables). A log linear model with a Poisson distribution was used to determine the differences between years for the CAUTI rates. All analyses were completed with SAS software, version 9.4 (SAS Institute, Cary, North Carolina).

## RESULTS

The 50 critically ill female patients using the EUDFA had a mean age of 66.7 (SD = 12.0) years, a mean body mass index of 32.3 (SD = 9.6); 88% were White, and the remaining 12% were African American. Because of COVID-19–related pressures on staffing and workload, urine volume data for 7 patients were incomplete. The effectiveness of the female EUD was 85.5%; thus, the EUD diverted 85.5% of patients' urine into the canister (3536.15 mL was diverted, on average, out of a total mean urine volume of 4135.53 mL (Table 1), with a loss of 14.5% of urine (collected by the standard incontinence pads and soft incontinence liners). Individual effectiveness ranged from 44.8% to 99.7%, with a median effectiveness of 87.6% and a mean effectiveness rate of 83.1% (Table 1).

### Rates of Indwelling Catheter Use, CAUTIs, UI, and IAD

In the yearly cross-sectional cohorts, the percentage of patient-days with an indwelling urinary catheter was significantly lower in 2018 (40.6%) and 2019 (36.6%) as compared with 2016 (43.9%, $P < .01$; Table 2). Additionally, although not statistically significant, but clinically relevant, the rate of CAUTIs was lower in 2019 compared with 2016 (1.34 vs 0.50 per 1000 catheter-days, $P = .08$) and during the combined time period of 2018-2019 than in 2016 (1.34 vs 1.08, $P = .53$).

A higher percentage of patients were incontinent of urine (either alone or in combination with FI) in the chosen observation month in 2019 (29.1%) and 2018 (17.4%) than in 2016 (5.4%, $P = .00$; Table 3); overall incontinence (fecal, urinary, or both) was highest in 2019 (37.1%) and lowest in 2016 (23.2%). The prevalence of IAD within incontinent patients was lower in 2018 (40.0%) and 2019 (39.1%) than in 2016 (69.2%). While this reflects a reduction of more than 29 percentage points, the difference was not statistically significant (2016 vs 2018, $P = .12$; 2016 vs 2019, $P = .08$; 2016 vs 2018-2019, $P = .06$; Table 3).

## DISCUSSION

In this study, we demonstrated that the EUDFA diverted a mean of 85.5% of urine into the canister. We also observed a statistically significant reduction in indwelling catheter

**TABLE 2.**
**Rates of CAUTIs Among All Patients Years: 2016 Versus 2018 and 2019**

| Variable | 2016 | 2018 | *P* Value (2016 vs 2018) | 2019 | *P* Value (2016 vs 2019) | 2018 + 2019 | *P* Value (2016 vs 2018 + 2019) |
|---|---|---|---|---|---|---|---|
| Patient-days | 23,806 | 23,792 | | 21,852 | | 45,644 | |
| Number of indwelling urinary catheter-days | 10,439 | 9,655 | | 7,993 | | 17,648 | |
| Number of CAUTIs | 14 | 15 | | 4 | | 19 | |
| Percentage of patient-days with an indwelling urinary catheter | 43.90% | 40.60% | .00[a] | 36.60% | .00[a] | 38.70% | .00[a] |
| CAUTI rate per 1000 patient-days | 1.34 | 1.55 | .69 | 0.50 | .08 | 1.08 | .53 |

Abbreviation: CAUTI, catheter-associated urinary tract infection.
[a]$P < .001$.

**TABLE 3.**
**Rates of Incontinence and IAD During a Single Month From Each Observation Year**

| Variable | 2016 | 2018 | *P* Value (2016 vs 2018) | 2019 | *P* Value (2016 vs 2019) | 2018 + 2019 | *P* Value (2016 vs 2018 + 2019) |
|---|---|---|---|---|---|---|---|
| No. patients | 56 | 69 | | 62 | | 131 | |
| Age, mean (SD), y | 57.61 (15.4) | 57.87 (16.2) | .93[a] | 57.84 (16.5) | .94[a] | | .92[a] |
| Gender, n (%) | | | .19[b] | | .96[b] | | .42[b] |
| Female | 25 (44.6%) | 39 (56.5%) | | 28 (45.2%) | | 67 (51.1%) | |
| Male | 31 (55.4%) | 30 (43.5%) | | 34 (54.8%) | | 64 (48.9%) | |
| Incontinence, n (%) | | | .0130[c] | | .0050[c] | | .0040[c] |
| Fecal | 10 (17.9%) | 3 (4.3%) | | 5 (8.1%) | | 8 (6.1%) | |
| Urinary | 0 | 6 (8.7%) | | 5 (8.1%) | | 11 (8.4%) | |
| Both | 3 (5.4%) | 6 (8.7%) | | 13 (21.0%) | | 19 (14.5%) | |
| Not incontinent | 43 (76.8%) | 54 (78.3%) | | 39 (62.9%) | | 93 (71.0%) | |
| IAD, n (%) | | | .12[c] | | .08[c] | | .06[c] |
| Yes | 9 (69.2%) | 6 (40.0%) | | 9 (39.1%) | | 15 (39.5%) | |
| No | 4 (30.8%) | 9 (60.0%) | | 14 (60.9%) | | 23 (60.5%) | |

Abbreviation: IAD, incontinence-associated dermatitis.
[a]Analysis based on the *t* test.
[b]Analysis using the $\chi^2$ test.
[c]Analysis using Fisher's exact test.

utilization from 2016 to 2019 and a CAUTI rate in 2019 that was more than 60% lower than that in 2016. This time frame reflects the period during which the use of the EUDFA became more common in the critical care units. Reductions in CAUTI rates were not statistically significant. We hypothesize that the low number of events in 2019 (4 CAUTIs) influenced our ability to demonstrate statistical significance. Analysis further indicates a relative reduction of 42% in IAD prevalence from 2018 to 2019 and a reduction of 29% during the period from 2016 to 2019. While not statistically significant, we assert these differences are clinically relevant. Investigating the impact on IAD within a larger sample of female subjects with UI (for whom the EUDFA is applicable) is warranted. We also observed higher rates of UI in 2018 and 2019 compared with 2016. We believe this difference is attributable to the decrease in indwelling urinary catheter usage.

Successful strategies as well as clinical guidelines for lowering the risk of CAUTIs, including those specific for the critical care setting, suggest reducing the use and duration of indwelling urinary catheters as a main component.[9,23,24] For example, a quality improvement initiative in a medical ICU reduced indwelling catheter use by adhering to strict usage indications and observed a corresponding reduction in the rate of CAUTIs from 4.7 to 0.0 per 1000 days.[24] In 2020, a WOCN Society task force developed a clinical decision support tool (algorithm) for care following indwelling catheter removal; this tool included recommendations for use of the EUDFA and observed that these devices are particularly attractive when recording fluid intake and urinary output measurement is indicated.[19]

Multiple studies of EUDs have reported promising results regarding the reduction in indwelling catheter use and CAUTIs. For example, Eckert and colleagues[20] describe a comprehensive CAUTI prevention program at a community hospital in Southern California that included a female EUD. Indwelling catheter usage significantly declined from 31.7% to 29.7% and rates of CAUTIs significantly decreased from 1.11 to 0.0 cases per 1000 days.[20] The reduction in indwelling catheter usage was less than in the current study (from 43.9% to 36.6%), but the absolute reduction in CAUTIs was similar to what we observed. Other studies have also reported significant reductions in catheter-days associated with the use of external female urinary devices. For example, a study at a large academic medical center observed a reduction in the indwelling catheter utilization ratio among ICU patient from 0.464 to 0.401 corresponding to the introduction of an EUD.[22] In another study that included all hospitalized patients (not just ICU patients), catheter utilization per 1000 patient-days decreased in women from 71.49 to 56.15.[21] The current study adds to this literature regarding the success of EUDFA in reducing indwelling catheter use and CAUTIs.

### Strengths and Limitations

The strengths of this study include the use of a real-world setting with its clinical relevance to nursing and other clinicians. This study was limited by impacts of the COVID-19 pandemic, which interrupted and complicated patient enrollment and imposed significant burdens on staff. Additionally, data on IAD prevalence reflect only a single month in each observation year. Finally, the study time frame coincided with a period when the quality focus was on decreasing use of indwelling catheters and implementing a nurse-driven internal urinary catheter removal protocol. While the use of an effective EUDFA played a pivotal role in these initiatives, not all reductions in indwelling catheter use or CAUTIs can be attributed to the EUDFA.

## CONCLUSIONS

Study findings suggest that use of an EUDFA is an attractive alternative to extended use of indwelling catheters in the acutely and critically ill adults and results in reductions of CAUTIs and IAD. More studies, including randomized controlled trials, are needed to directly compare the use and effectiveness

of EUDFA on hospital-acquired infections and IAD in the hospital setting.

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