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A single institution pre-/post-comparison after introduction of an external urinary collection device for female medical patients

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Abstract

Background: External urinary collection devices (EUCDs) may serve as an alternative to indwelling urinary catheters (IUCs) and decrease the rate of catheter associated urinary tract infections (CAUTIs). *PureWick*® is a novel female EUCD; however, no study has definitively proven benefit regarding reduction of CAUTIs.

Aim: We sought to compare the CAUTI rate and IUC days before and after availability of the *PureWick*® EUCD at a single institution. We provide a descriptive analysis of female medical patients receiving an EUCD.

Methods: A retrospective review of adult female patients admitted to a single institution on a medical service who received an IUC and/or an EUCD was performed. Patients who received an IUC in the 3 months before EUCD availability (PRE) were compared to patients who received an IUC and/or EUCD in the 12 months after (POST).

Results: Out of 848 female patients, 292 received an EUCD in the POST cohort and overall, 656 received an IUC (259 (100%) PRE vs. 397 (67.4%) POST). Compared to the PRE cohort, the POST cohort had a higher number of IUC days (median, 3 vs 2 days, $p = 0.001$) and a higher rate of CAUTI (infections per 1000 catheter days, 9.3 vs 2.3, $p = 0.001$). The rate of UTI associated with EUCD use was 9.8 infections per 1000 device days.

Discussion: While EUCDs might appear to be a promising alternative to IUCs for female patients, this single center pre-/post-analysis found that both the number of IUC days and the CAUTI rate increased after introduction of a female EUCD.

Keywords

Catheter associated urinary tract infection, external urinary collection device, indwelling urinary catheter

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Background

Hospital-acquired urinary tract infections (UTIs) are one of the most common healthcare associated infections (Titsworth et al., 2012). Up to 80% of hospital-acquired UTIs are associated with indwelling urinary catheter (IUC) use, making catheter associated UTIs (CAUTIs) the most common hospital-acquired infection tracked by the Centers for Disease Control and Prevention (CDC) (Foxman, 2002; Lo et al., 2014; Stone et al., 2014). CAUTIs can lead to even further morbidity including pyelonephritis, bacteremia, endocarditis, vertebral osteomyelitis, septic arthritis, and meningitis (CDC, Ncezid and DHQP, n.d.). In addition, CAUTIs account for an estimated 13,000 deaths annually in the United States (CDC, Ncezid and DHQP, n. d.; Eliakim-Raz et al., 2019). Furthermore, CAUTIs contribute to substantial healthcare costs and, with value-based payment schemes emerging, this constitutes a significant concern for healthcare providers. This has led hospitals to dedicate resources to develop CAUTI prevention programs (R Douglas Scott II, 2009).

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The most important modifiable risk factor for the development of CAUTI is the duration of IUC (Chenoweth and Saint, 2013; Chenoweth et al., 2014; Davis, 2019; Galiczewski, 2016; Li et al., 2019). There is a direct relationship between duration of catheterization and risk of developing CAUTI, with a risk of 3%–10% per day of catheterization (Lo et al., 2014). Therefore, it is important to find alternatives to IUCs. External urinary collection devices (EUCDs) have been proposed as an alternative to IUCs. Studies in male patients have shown that EUCDs can be safe and effective in reducing CAUTI (Gray et al., 2016; Saint et al., 2008). While several types of EUCDs have been successfully implemented for male patients, to our knowledge, no EUCD has demonstrated a clear benefit in reducing CAUTIs for female patients (Beeson and Davis, 2018). *PureWick®* is a novel female EUCD, allowing for management of incontinence and measurement of strict ins and outs in female patients of all sizes, with early case studies demonstrating safe and efficacious use (Eckert et al., 2020; Newton et al., no date). However, no study has reported that *PureWick®* consistently reduces the rate of CAUTIs. We sought to compare the CAUTI rate and median IUC days before and after availability of the *PureWick®* EUCD at a single academic institution, as well as provide a descriptive analysis of female medical patients receiving an EUCD.

Methods

This research was approved by the Institutional Review Board at our institution. We followed the guidelines outlined in the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement. We performed a retrospective analysis of adult (≥18-years-old) female patients admitted to the internal medicine, family medicine, and neurology services at our institution from 2017 to 2018. Adult female patients receiving an IUC and/or EUCD admitted in the 3 months before (PRE) and 12 months after (POST) *PureWick®* availability were included. The longer POST period was planned to allow for collection of sufficient EUCD data. Of note, this is the only available EUCD for female patients at this institution. Pregnant patients, prisoners, and patients admitted to other medical specialty services or a surgical service were excluded.

The primary outcome was the rate of CAUTI before and after EUCD introduction. UTIs associated with EUCD use were not considered CAUTIs and were recorded separately. Secondary outcomes included IUC days, EUCD-associated UTI rate, and general UTI rate. UTI and CAUTI were defined according to the CDC National Health Safety Network definition (CDC, Ncezid and DHQP, n. d.). CAUTI and EUCD-associated UTI rates were calculated as both infection episodes per 1000 catheter days as well as infection episodes per 10,000 patient days (Wright et al., 2011).

Patient demographic information was collected including age, body mass index (BMI), and medical comorbidities including diabetes, congestive heart failure (CHF), end stage renal disease (ESRD), dementia, current malignancy, and human immunodeficiency virus (HIV) infection.

Complications occurring during hospitalization were also recorded including deep venous thrombosis (DVT), pulmonary embolism (PE), acute renal failure, and *Clostridium difficile* infection. Additional data collected included the indication for IUC placement; the provider service ordering the catheter; the causative organism of the CAUTI/UTI; antibiotic use in the 72 hours prior to CAUTI/UTI; and hours from catheter placement to CAUTI/UTI. Urine cultures growing *Candida* species or other fungus were not considered a true CAUTI/UTI and were excluded (CDC, Ncezid and DHQP, n. d.).

Two groups were compared, the PRE patients who received an IUC and the POST patients who received an IUC and/or EUCD. Descriptive statistics were performed for all variables. A chi-square test was used to compare categorical variables and a Mann–Whitney U test was used to compare continuous variables. Categorical data was reported as percentages and continuous data was reported as medians with interquartile range. All p-values were two-sided, with a statistical significance level of <0.05. All statistical analyses were performed with IBM SPSS Statistics for Windows, version 24. (Armonk, NY: IBM Corp).

Results

Demographics, primary and secondary outcomes

Out of 848 female patients, 292 received an EUCD in the POST cohort. Overall, 656 patients received an IUC (259 (100%) PRE vs. 397 (67.4%) POST) (Table 1). There were no differences in the cohorts regarding age, BMI, and comorbidities (all $p > 0.05$) (Table 1). Compared to the PRE cohort, the POST cohort had a greater number of IUC days (median, 3 vs 2 days, $p = 0.001$) (Table 1) and a higher rate of CAUTI by both calculation methods (infections per 1000 catheter days, 9.3 vs 2.3, $p = 0.001$; infections per 10,000 patient days, 70.7 vs 15.4, $p = 0.001$), while the overall UTI rate was similar between cohorts (infections per 1000 patient days, 15.5 vs 21.4, $p = 0.40$) (Table 2). The POST cohort also had a longer duration of hospitalization (median, 6 vs 5 days, $p = 0.002$). In the POST cohort, the rate of UTI associated with EUCD use was 9.8 infections per 1000 device days and 33.9 infections per 10,000 patient days (Table 2). There were no differences between the cohorts in regard to the specialties ordering catheters, with medicine ordering the most devices in both the PRE and POST cohorts (74.3% vs 78.2%, $p = 0.173$).

Complications and microbiological data

Patients in the POST cohort were more likely to develop acute renal failure (17.5% vs. 11.6%, $p = 0.038$), but rates of other complications were similar between the groups. The most common organisms isolated in urine cultures in the

Table 1. Characteristics of female catheterized patients admitted to a medical service before (PRE) and after (POST) external urinary collection device implementation.

Characteristic	PRE (*n* = 259)	POST (*n* = 589)	*p*-value
Age, year, median (IQR)	70 (53, 81)	73.0 (59, 82)	0.197
BMI, median (IQR)	24.7 (21.4, 29.0)	25.0 (21.3, 30.7)	0.683
Hospital LOS, days, median (IQR)	5 (3, 8)	6 (4, 12)	0.002
Indwelling catheter days, median (IQR)	2 (1, 4)	3 (1, 7)	0.001
PureWick catheter days, median (IQR)	N/A	2 (1, 5)	N/A
PureWick, n (%)	N/A	292 (49.6%)	N/A
Indwelling urinary catheter, n (%)	259 (100%)	397 (67.4%)	<0.001
Medical comorbidities, n (%)			
Diabetes	94 (36.3%)	195 (33.1%)	0.410
CHF	50 (19.3%)	128 (21.7%)	0.479
Current malignancy	60 (23.2%)	124 (21.1%)	0.550
Dementia	29 (11.2%)	63 (10.7%)	0.923
ESRD	19 (7.3%)	36 (6.1%)	0.606
HIV infection	1 (0.4%)	2 (0.3%)	1.000

BMI = body mass index, LOS = length of stay, IQR = interquartile range, CHF = congestive heart failure, ESRD = end stage renal disease, HIV = human immunodeficiency virus.

Table 2. UTI rates of female catheterized patients PRE and POST external urinary collection device implementation.

Characteristic	PRE (*n* = 259)	POST (*n* = 589)	*p*-value
Urine cultures performed, n (%)	112 (43.2%)	338 (57.4%)	<0.001
CAUTI, n (*)	2 (2.3)	25 (9.3)	0.001
CAUTI, n (**)	2 (15.4)	25 (70.7)	0.001
PAUTI, n (*)	N/A	12 (9.8)	N/A
PAUTI, n (**)	N/A	12 (33.9)	N/A
UTI, n (***)	36 (21.4)	95 (15.5)	0.408

CAUTI = catheter-associated urinary tract infection, PAUTI = PureWick-associated UTI, UTI = urinary tract infection.
* CAUTI and PAUTI rate are presented as number of infections per 1000 catheter days.
**CAUTI and PAUTI rate presented as number of infections per 10,000 patient days.
*** UTI rate is presented as number of infections per 1000 patient days.

POST group were *Escherichia coli* (*E. coli*) (56.8%) and *Enterococcus* species (13.5%).

Descriptive analysis of EUCD patients in the POST cohort

An EUCD was in place for a median of 2 days (Table 1). In the POST cohort, 104 patients (35.6%) received both an IUC and an EUCD (Table 3). Measurement of strict ins and outs (57.2%) was the most common indication for use of EUCD (Supplemental Table 1). The most common causative organism of UTI and CAUTI in EUCD patients was *E. coli* (55.9% and 53.3%, respectively) (Supplemental Table 2). The most common hospital-acquired complication in the EUCD patients was acute renal failure (16.1%) (Supplemental Table 3).

Discussion

While much attention has been given to the problem of hospital-acquired infections, and there has been some progress for hospitalized male patients, there is a paucity of interventions taken to minimize CAUTIs in female patients.

Table 3. Characteristics of female patients admitted to a medical service receiving an external urinary collection device.

Characteristic	POST (*n* = 292)
Age, year, median (IQR)	76 (63, 85)
BMI, median (IQR)	24.7 (21.5, 30.2)
Hospital LOS, days, median (IQR)	6 (3, 11)
Indwelling catheter days, median (IQR)	2 (1, 5)
PureWick catheter days, median (IQR)	2 (1, 5)
Indwelling urinary catheter, n (%)	104 (35.6%)
PureWick, n (%)	292 (100%)

IQR = interquartile range, BMI = body mass index, LOS = length of stay.

This study examined the effect of the implementation of a novel EUCD on the rate of CAUTI and number of IUC days for inpatient female medical patients at a single academic institution. Surprisingly, after the introduction of the EUCD, the rate of CAUTI more than tripled, and the median number of IUC days increased by a full day.

It is known that duration of IUC is an important risk factor for CAUTI (Chenoweth and Saint, 2013; Chenoweth et al., 2014; Davis, 2019; Galiczewski, 2016; Li et al., 2019). In a meta-analysis of observational studies of hospitalized floor and intensive care unit patients, Li et al. (2019) reported that patients who developed CAUTI had a significantly increased duration of IUC, with a mean difference in duration of catheterization of +6.99 days compared to patients without CAUTI (Li et al., 2019). This corroborates findings reported by Crouzet et al. (2007) who found at a single institution, decreasing the duration of IUC significantly decreased the rate of CAUTI (Crouzet et al., 2007). Our results support these findings as the POST group in our study had a significantly longer duration of IUC, as well as a significantly higher CAUTI rate. In contrast to the aforementioned studies, the duration of catheterization in the POST group in our study only increased by 1 day, suggesting that even minimal increases in duration of catheterization can significantly increase CAUTI risk. This lends further support to guidelines recommending that IUCs be removed as soon as possible (Hooton et al., 2010; Lo et al., 2014). The increase in IUC days is likely related to the significantly longer duration of hospitalization in the POST cohort. Due to the increase in CAUTIs, our hospital has initiated a hospital-wide nursing driven protocol to more expeditiously remove IUCs.

In an effort to decrease duration of IUCs and CAUTI rates, EUCDs have been proposed as an alternative to IUCs (Eckert et al., 2020; Gray et al., 2016; Saint et al., 2006, 2008). In a study of paraplegic male patients, Esclarin De Ruz et al. (2000) reported that patients using a condom catheter had a significantly lower rate of UTIs than patients using an IUC (Esclarín De Ruz et al., 2000). Saint et al. (2006) performed a small randomized controlled trial comparing condom catheters to IUCs and found patients without dementia using an IUC had a four times increased risk of bacteriuria, UTI, or death, although this finding was no longer significant when generalized to all patients including patients with dementia (Saint et al., 2006). More recently, Eckert et al. (2020) implemented a CAUTI prevention program utilizing *PureWick*® at a single community hospital (Eckert et al., 2020). After 1 year, the CAUTI rate had significantly decreased from 1.11 to 0 infections per 1000 indwelling catheter days; however, the following year the CAUTI rate increased to 0.90 per 1000 catheter days, which was not significantly lower than the first-year baseline rate. They also noted a significant decrease in IUC utilization after implementation of the *PureWick*® EUCD. However, they did not track number of patients receiving an EUCD or the duration of EUCD use and there was no description of patients receiving an EUCD or patients who developed CAUTI. In contrast, our study demonstrated that both the number of IUC days and the CAUTI rate increased significantly after *PureWick*® implementation. As the duration of IUC use is the most important risk factor for CAUTI, it is likely that the increased number of IUC days contributed to the higher CAUTI rate, though the increase in IUC duration by 1 day may not fully explain the 6 infections per 1000 catheter days increase in CAUTI after EUCD implementation. Additionally, it has been reported that UTI incidence may follow a seasonal pattern, with cases increasing in warmer weather (Rosello et al., 2018; Simmering et al., 2021). This may have affected our results, as the data collection for the PRE group was during autumn, when temperatures are warmer in our location, while data collection for the POST group was over the course of 12 months. This suggests that the infection rates in the PRE group may, in fact, have been even lower if collected over the course of a year. Also, our study was completed at a large, quaternary care academic center with high volumes of medically complex patients which may have influenced the rate of CAUTI relative to that observed by Eckert et al. (2020).

Additionally, the rate of UTI associated with EUCD was similar to the CAUTI rate in the POST group, suggesting that even if EUCD use decreases IUC days, it may not decrease CAUTI incidence. While some studies demonstrated a benefit with EUCDs reducing CAUTIs (Gray et al., 2016; Saint et al., 2008), one study evaluating patients in hospitals, nursing homes, or receiving home health, reported that male patients with condom catheters had double the probability of developing a UTI compared to patients with an IUC (Zimakoff et al., 1996). One proposed reason for this was reverse causality: patients with recurrent UTIs related to an IUC may have been more likely to receive an EUCD. This may also have contributed to the high UTI rate associated with EUCDs

in our study, as over one-third of EUCD patients also had an IUC during their hospitalization. The UTI in these cases may then have been related to bacteriuria induced by the IUC rather than a UTI purely secondary to EUCD use. In addition, less attention to local hygiene may have occurred in the EUCD patients. Regardless, this study suggests that the benefits of EUCDs in reducing IUC days and CAUTI rates may not be as straightforward as previously surmised, especially in females.

To date, this study is the most detailed analysis of patients receiving a *PureWick®* catheter. Previous studies examining the usage of female EUCDs were predominantly case series or quality improvement projects that did not report detailed characteristics of the patients receiving the EUCD. This study is consistent with prior studies in that measurement of strict ins and outs and urinary incontinence were the two most common indications for EUCD usage. Interestingly, urinary retention was also documented as an indication in 13.4% of patients. However, this may reflect incorrect documentation of overflow incontinence or documentation that was not updated when an IUC was removed and an EUCD placed.

Limitations

This study is a retrospective chart review and is therefore inherently susceptible to numerous limitations. This includes missing data, inconsistencies in charting, and reporting bias. However, the same data abstractors worked on both the PRE and POST cohorts, and it is thus unlikely that these limitations affected one group disproportionately. As a chart review, this study also did not allow for the collection of data regarding UTI or asymptomatic bacteriuria prior to device placement, which may have influenced CAUTI rate. Also, more urine cultures were ordered in the POST cohort, perhaps because of the longer duration of hospital stay in the POST group, which may have contributed to the higher rates of infection. In addition, use of this novel EUCD was not protocolized and thus left to provider discretion and therefore placement may not have replaced use of IUC, instead adding more patients with an external form of urinary collection. Also, EUCD use has been promoted by nursing staff at our institution, which may have led them to pressure physicians to order EUCDs on a population that may not have benefited from them, such as patients that would not otherwise have had a catheter. Additionally, due to a relatively low number of patients who received an EUCD, this study may be underpowered. Finally, qualitative feedback from nurses and patients is also lacking.

Conclusion

While EUCDs might appear to be a promising alternative to IUCs for female patients, this single center pre-/post-analysis found that both the median number of IUC days and the CAUTI rate increased after introduction of the *PureWick®* EUCD. While this may not be directly related to use of this EUCD, this study did not show a significant reduction in the number of CAUTIs after EUCD introduction in this female medical population. This highlights the importance of identifying which female patients will benefit from an EUCD with prospective randomized trials prior to widespread adoption.

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Supplemental material

Supplemental material for this article is available online.

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