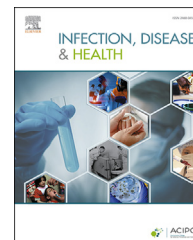


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Research paper

Effect of external urinary collection device implementation on female surgical patients

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Abstract *Background:* The Centers for Disease Control and Prevention reports that catheter-associated urinary tract infections (CAUTIs) are the most common hospital-acquired infection. Female external urinary collection devices (EUCDs) may be an alternative to indwelling urethral catheters (IUCs), thereby decreasing CAUTIs. However, no study has demonstrated that EUCDs can help reduce CAUTIs in female surgical patients. We sought to compare CAUTI rate and the median number of days an IUC was used before and after availability of this female EUCD for surgical patients.

Methods: A retrospective analysis of adult female surgical patients admitted to a single academic institution who received an IUC and/or EUCD was performed. Patients who received an IUC three months before (PRE) EUCD availability (08/2017–10/2017) were compared to patients receiving an IUC and/or EUCD 12 months after (POST) (11/2017–11/2018).

Results: From 906 surgical patients receiving an IUC/EUCD, 127 received an EUCD in the POST cohort. Compared to the PRE, the POST had a higher rate of CAUTIs (infections per 1000 catheter days, 11.2 vs. 4.6, $p = 0.017$) and overall UTI rate (infections per 1000 catheter days, 5.4 vs. 4.8, $p = 0.036$), whereas IUC days were similar between cohorts (median, two vs. two days, $p = 0.18$). The POST cohort rate of EUCD UTI was 4.6 infections per 1000 device days.

Conclusion: While EUCDs appear to be a promising alternative to IUCs for female surgical patients, this study found increased CAUTIs after introduction of an EUCD. Further research is needed to clarify if female EUCDs are effective in decreasing CAUTI prior to widespread adoption.

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Highlights

- Indwelling urinary catheters increase female catheter-associated UTI (CAUTI) risk.
- Female external urinary collection devices (EUCD) may decrease CAUTI risk.
- Implementation of EUCD did not decrease CAUTI rates in female surgical patients.

Introduction

Urinary tract infections (UTI) are among the most prevalent healthcare-associated infections reported to the Center for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) [1]. Furthermore, UTI can lead to significant complications including pyelonephritis, meningitis, sepsis, bacteremia, and death [2]. Nationally, hospital-acquired UTI results in 13,000 patient deaths each year and increases healthcare costs by more than \$400 million per year, with each UTI costing between \$500-\$1000 [2-4]. Moreover, the CDC reports that 75% of hospital-acquired UTIs are a direct result of an indwelling urinary catheter (IUC), also known as a catheter-associated UTI (CAUTI) [1].

In order to decrease the duration of IUC, the incidence of UTI, and circumvent a direct path for bacteria into the urinary tract of male patients, the condom catheter, a type of external urinary collection device (EUCD), was first introduced in the 1970s [5]. Compared to the condom catheter, IUCs have been demonstrated to increase the risk of symptomatic UTI, bacteriuria, or death by five times [6]. However, the condom catheter is limited by female anatomy, which is noteworthy as females are more affected by UTIs than men due to a shorter urethra and proximity of the urethra to the vagina and rectum. In fact, 50% of females are expected to have a UTI at least once in their lifetime with more than a three-fold increased risk of CAUTI, compared to males [3,7]. In order to mitigate risk of UTI, it is important to remove IUCs as soon as possible; however, incontinence-associated dermatitis and re-catheterization are potential risks after removal in hospitalized patients [8,9]. To date, female EUCDs, such as heavy pads and an adhesive collection device similar to an ostomy bag, have been trialed unsuccessfully [10]. In 2017, *PureWick*® was invented as an EUCD for females [11]. This device is comprised of a curved wicked fabric which is placed in between the labia and gluteus muscles and a plastic portion aligned with the pubic bone (Fig. 1) [12,13]. A continuous suction device is then attached, draining to a wall vacuum (Fig. 2) [12,13].

While there have been previous single institution retrospective and observational studies examining the implementation of female EUCDs, these have often been in heterogeneous or solely intensive care unit populations. [4,14-17]. Surgical patients, who may simply need accurate monitoring of urine output, might be a more ideal population. Additionally, avoidance of infection is

paramount for surgical outcomes. Surgical patients have a high percentage of IUC usage, with 86% of patients undergoing major surgery receiving an IUC perioperatively and 50% of those patients retaining an IUC for greater than two days postoperatively [18]. Post-operative patients who have an IUC for longer than two days have an increased likelihood of developing a CAUTI [18].

Therefore, this study sought to compare the CAUTI rate and median number of days a patient uses an IUC (IUC days) for surgical patients before and after availability of this EUCD at a single academic institution, hypothesizing decreased CAUTI rate and median IUC days after implementation of this female EUCD.

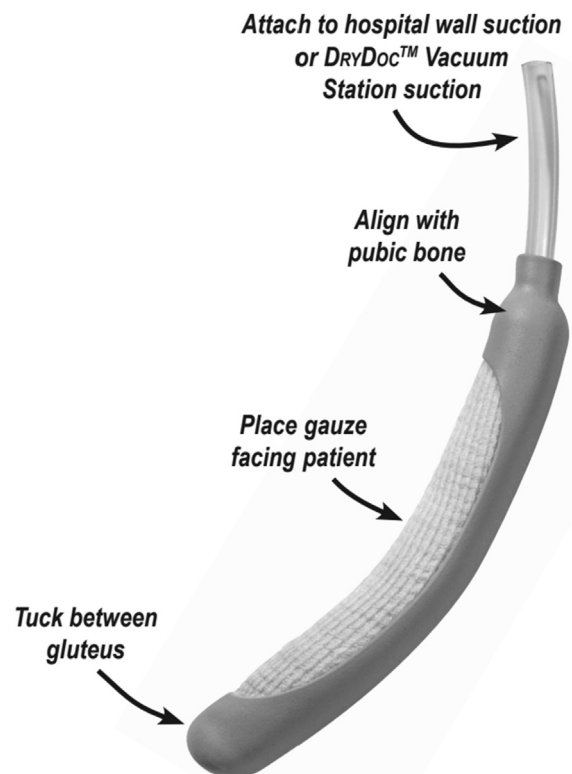


Fig. 1 Female external urinary collection device (*PureWick*®) that was implemented at the single institution. ©2021 BD. Used with permission.

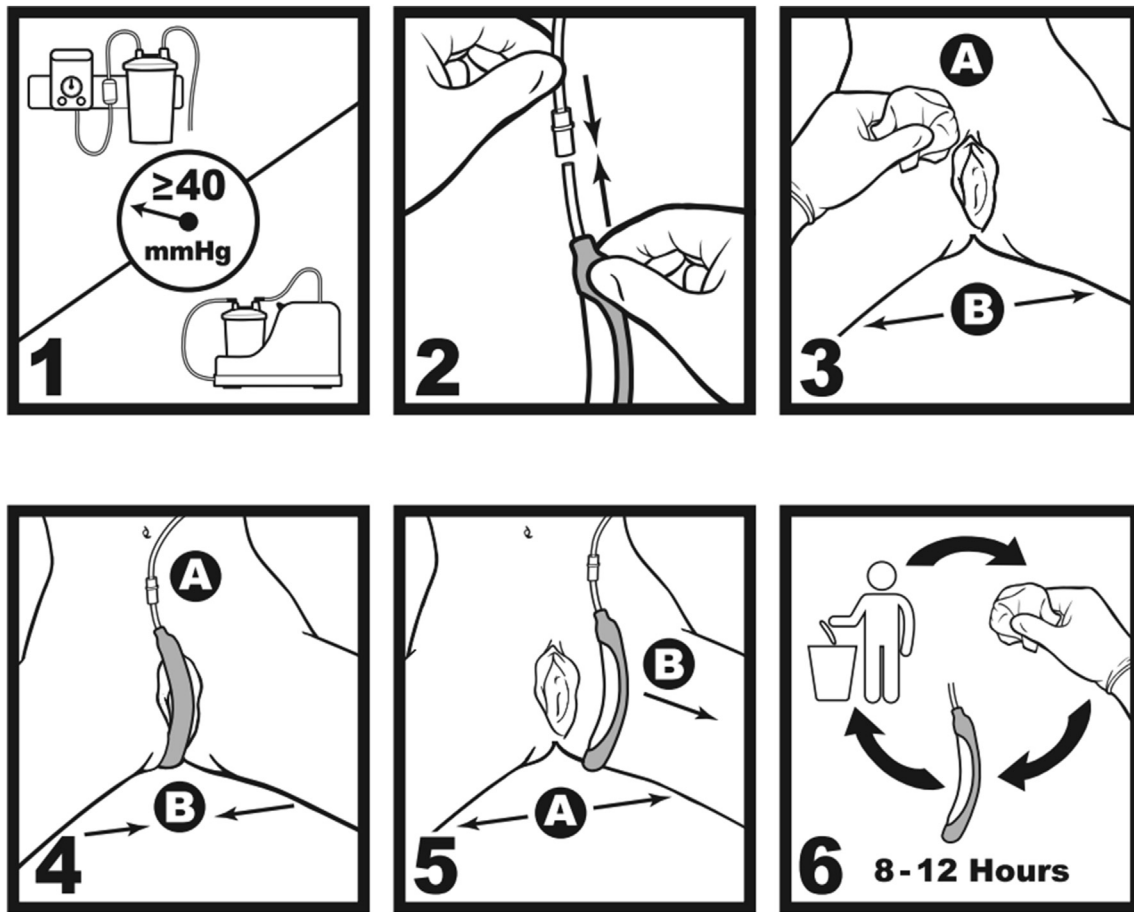


Fig. 2 Instructions for use of the PureWick® female external urinary collection device. ©2021 BD. Used with permission.

Methods

A retrospective analysis of adult (≥ 18 years old) female patients who were admitted to general surgery or a surgical subspecialty at a single large academic institution from August 2017 to November 2018 was performed. This study was approved by the Institutional Review Board and deemed exempt from need for consent.

Adult female patients who received an IUC in the three months before (PRE) and an IUC and/or EUCD in the 12 months after (POST) female EUCD availability were included. During the PRE period, there were no alternatives to IUC for female patients. Prisoners and patients admitted to all other services (i.e., Internal Medicine, Family Medicine, Obstetrics, Gynecology, and other medical subspecialties) were excluded. The longer POST period (12 months vs. 3 months) was to allow for sufficient EUCD data collection as the implementation was gradual and the decision for ordering an EUCD was left solely to the providers' discretion with no formal protocol. There was, however, didactic education and information provided to all hospital staff (i.e., physicians, nurses and trainees) regarding the new EUCD. This information included specific care and maintenance instructions given to the nurses and clinicians in the form of an electronic mail with pertinent information about this newly available device. In addition, nursing

received "hands-on" training with nursing educators and instructed that the EUCD could be used instead of an IUC in situations where accurate urinary measurements were needed but that one to two-hour monitoring, as for an IUC, was not needed. The instructions also included information on changing EUCDs at least every 8–12 h and contraindications for EUCD use, such as urinary retention, agitation or confusion, fecal incontinence, heavy vaginal bleeding, recent surgery of external urogenital tract, perineal skin breakdown, and latex or adhesive allergy. This study aims to examine if the option of EUCD availability at a large medical center would change decision-making for IUC placement and/or earlier removal and thereby effect total IUC days, which may theoretically lead to a decreased CAUTI rate.

The primary outcome was the rate of CAUTI before and after EUCD introduction. Secondary outcomes included EUCD-associated UTI (EUCD-AUTI), IUC days, and overall general UTI rate before and after EUCD introduction. The NHSN CDC definitions of symptomatic and asymptomatic bacteremic UTI were used for UTI, CAUTI, and EUCD-AUTI [2]. The criteria for CAUTI were utilized to determine EUCD-AUTI except that the patient had an EUCD instead of an IUC. Additional data including indication for catheterization, provider service ordering the catheter, the causative organism of the CAUTI/UTI, antibiotic use in the 72 h

prior to CAUTI/UTI, and hours from catheter placement to CAUTI/UTI were also collected.

Patient demographic information collected included 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). Hospital length of stay, admitting service, and complications including deep venous thrombosis (DVT), pulmonary embolism (PE), acute renal failure, and *Clostridium difficile* infection were recorded.

Two groups were compared, the PRE group that received an IUC and the POST group that received an IUC and/or EUCD. Guidelines described in the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement were followed. Categorical variables were reported as percentages and compared by a chi-square test. Continuous data was reported as medians with interquartile range or minimum and maximum if less than seven data points and was compared by Mann-Whitney-U test. Statistical significance level was set at <0.05 with two-sided p-values. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 24 (Armonk, NY: IBM Corp).

Results

Patient demographics, primary and secondary outcomes

A total of 906 adult female patients were admitted to a surgical service and received an IUC and/or an EUCD during the study period. The PRE cohort included 435 patients and the POST included 471 patients, with 127 POST patients receiving EUCDs (27% of POST patients). There were no differences in age and most comorbidities, including

diabetes, CHF, dementia, current malignancy, and HIV infection (all $p > 0.05$). There was a higher prevalence of ESRD comorbidity in the POST cohort (6.8% POST vs. 3.7% PRE, $p = 0.036$) and higher BMI in the PRE cohort (27.5 vs. 25.5 mg/kg², $p = 0.005$) (Table 1). Urinary retention and surgery were the most common indications for catheterization for both PRE and POST groups (59.5% PRE and 51.4% POST, 25.1% PRE and 22.9% POST) (Table 2). Neurosurgery was the most common service ordering IUC in the PRE and both urinary catheter types in the POST cohort (22.8% of all surgical services in PRE and 23.4% in POST), with trauma, critical care, burn surgery as the second most common service (12.0% PRE and 21.7% POST) (Table 2).

Compared to PRE patients, POST patients had nearly triple the rate of CAUTIs (infections per 1000 catheter days, 11.2 POST vs. 4.6 PRE, $p = 0.017$) and increased UTI rate (infections per 1000 catheter days, 5.4 POST vs. 4.8 PRE, $p = 0.036$) (Table 1). Of the 127 EUCD surgical patients, there were eight cases of CAUTI (12.3 infections per 1000 catheter days) and four cases of EUCD-AUTI (4.6 infections per 1000 catheter days) (Table 3). There was a similar median IUC days between cohorts (two days vs. two days, $p = 0.18$) (Table 1).

Complications and microbiological data

Compared to the PRE cohort, the POST cohort had an increased length of hospital stay (median, seven days POST vs. four days PRE, p value < 0.001) and DVT events (11 events POST vs. 3 events PRE, $p = 0.045$) (Tables A1). There were no differences in PE, acute renal failure, and *C. difficile* infection between PRE and POST groups (all $p > 0.05$).

POST patients had an increased rate of urine culture orders (32.3% POST vs. 17.7% PRE, $p < 0.001$) compared to PRE patients (Table 1). There were no differences in predominant organisms of CAUTI/UTI, antibiotic use in the 72 h

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

Characteristic	PRE (n = 435)	POST (n = 471)	p-value
Age, year, median (IQR)	58.0 (44, 70)	60.0 (48, 70)	0.058
BMI, median (IQR)	27.5 (22.9, 32.6)	25.5 (21.8, 30.1)	0.005
Hospital LOS, days, median (IQR)	4 (3, 7)	7 (3, 14)	<0.001
Indwelling catheter days, median (IQR)	2 (1, 3.5)	2 (1, 5)	0.188
Indwelling urinary catheter, n (%)	–	446 (94.7%)	<0.001
EUCD days, median (IQR)	–	3 (1, 6)	
EUCD, n (%)	0 (0%)	127 (27.0%)	
Urine culture, n (%)	77 (17.7%)	152 (32.3%)	<0.001
CAUTI, n (^a)	6 (4.6)	19 (11.2)	0.017
EUCD-AUTI, n (^a)	N/A	4 (4.6)	N/A
UTI, n (^b)	13 (4.8)	28 (5.4)	0.036

BMI = body mass index, LOS = length of stay, IQR = interquartile range, CAUTI = catheter-associated urinary tract infection, EUCD-AUTI = External Urinary Collection Device-associated UTI, UTI = urinary tract infection.

^a CAUTI and EUCD-AUTI rate are presented as number of infections per 1000 device days.

^b UTI rate is presented as number of infections per 1000 patient days.

Table 2 Catheterization characteristics of female patients admitted to a surgical service before (PRE) and after (POST) external urinary collection device (EUCD) implementation. EUCD patients only include POST patients who were given an EUCD.

Characteristic	PRE (n = 435)	POST (n = 471)	EUCD (n = 127)
<i>Indication for catheterization, n (%)</i>			
Urinary retention	22 (5.1%)	74 (15.7%)	33 (26.0%)
Accurate Measurement of Urinary Output	259 (59.5%)	242 (51.4%)	75 (59.1%)
Incontinence	2 (0.5%)	12 (2.5%)	9 (7.1%)
Intravesical pharmacologic therapy	1 (0.2%)	0 (0%)	0 (0%)
Neurogenic bladder	1 (0.2%)	0 (0%)	0 (0%)
Hematuria with clots	2 (0.5%)	0 (0%)	0 (0%)
Surgery	109 (25.1%)	108 (22.9%)	4 (3.1%)
Management of immobilized patient	37 (8.5%)	29 (6.2%)	3 (2.4%)
Comfort	2 (0.5%)	6 (1.3%)	3 (2.4%)
<i>Provider service ordering catheter</i>			
Anesthesiology	0 (0%)	1 (0.2%)	1 (0.8%)
Emergency medicine	1 (0.2%)	12 (2.5%)	3 (2.4%)
Family medicine	0 (0%)	1 (0.2%)	0 (0%)
Medicine	7 (1.6%)	14 (3.0%)	4 (3.1%)
Neurology	9 (2.1%)	8 (1.7%)	5 (3.9%)
Neurosurgery	99 (22.8%)	110 (23.4%)	24 (18.9%)
Orthopedic surgery	82 (18.9%)	53 (11.3%)	9 (7.1%)
Otolaryngology	8 (1.8%)	10 (2.1%)	3 (2.4%)
Plastic surgery	16 (3.7%)	22 (4.7%)	1 (0.8%)
Cardiothoracic surgery	18 (4.1%)	18 (3.8%)	3 (2.4%)
Colorectal surgery	51 (11.7%)	28 (5.9%)	2 (1.6%)
Hepatobiliary surgery	16 (3.7%)	20 (4.2%)	3 (2.4%)
Surgical oncology	11 (2.5%)	14 (3.0%)	7 (5.5%)
Transplantation surgery	14 (3.2%)	18 (3.8%)	0 (0%)
Trauma, critical care, burn surgery	52 (12.0%)	102 (21.7%)	56 (44.1%)
Vascular surgery	16 (3.7%)	9 (1.9%)	3 (2.4%)
Urology	35 (8.0%)	31 (6.6%)	3 (2.4%)

prior to CAUTI/UTI, and time from catheter placement to CAUTI/UTI between the cohorts (all $p > 0.05$). *Escherichia coli* was the most common causative organism in all groups.

Additionally, while there were no specific reports of adverse events from EUCD use provided to our Epidemiology and Infection Prevention Department, there was a reportable pressure dermatologic injury that led to additional nursing in-services in 2019.

Descriptive analysis of EUCD patients

The POST patients who received EUCDs had a median age of 63 years and median BMI of 24.4 mg/kg² (Table 3). The two most common comorbidities were diabetes (14.2%) and current malignancy (18.1%). The trauma, critical care, and burn surgery service was the most common service ordering EUCDs (44.1% of EUCD), with neurosurgery being the second most common (18.9%) (Table 2).

The most common indication for EUCD was for accurate measurement of urinary output (59.1%) (Table 2). Most patients who received an EUCD also received an IUC (80.3%) (Table 3). The median time from catheter placement to CAUTI/UTI was 51 h for surgical EUCD patients. The most common complications in EUCD patients were DVT (7.1%) and acute renal failure (7.9%).

Discussion

Surgical patients with IUCs have an increased rate of UTI with a subsequent increased duration of hospital stay, higher incidence of surgical site and prosthetic infections, and increased mortality [3]. However, IUCs may be necessary post-operatively to closely monitor urine output, prevent bladder distention, and avoid wound contamination. This study sought to evaluate if EUCDs can provide an alternative to IUCs and truncate IUC usage, which was expected decrease IUC days and CAUTI-related morbidity. This single center study unexpectedly showed that, after implementation of the female EUCD, the rate of CAUTI more than tripled and the median number of IUC days did not change. Additionally, the rate of overall UTIs and urine culture orders both increased, with urine culture orders more than doubling that of the PRE group. There was also dermatologic injury from the pressure and stiffness of the device.

One potential explanation is that there was no change in duration (days) of IUC usage. This may suggest that instead of using EUCDs for patients who would have previously received an IUC, providers used EUCDs for patients who would not have received an IUC. Thus, the EUCD would introduce a potential infectious source where there would

Table 3 Characteristics and urinary tract infection rates of female patients admitted to a surgical service before (PRE) and after (POST) external urinary collection device (EUCD) implementation who were given an EUCD.

Characteristics	EUCD (n = 127)
Age, year, median (IQR)	63.0 (52, 74)
BMI, median (IQR)	24.4 (20.2, 29.4)
Hospital LOS, days, median (IQR)	14 (7, 25)
Indwelling catheter days, median (IQR) ^(c)	4 (1, 8)
Indwelling urinary catheter, n (%)	102 (80.3%)
EUCD catheter days, median (IQR)	3 (1, 6)
EUCD, n (%)	127 (100%)
Urine culture, n (%)	59 (46.5%)
CAUTI, n ^(a)	8 (12.3)
EUCD-AUTI, n ^(a)	4 (4.6)
UTI, n ^(b)	13 (5.5)

BMI = body mass index, LOS = length of stay, IQR = interquartile range, CAUTI = catheter-associated urinary tract infection, EUCD-AUTI = External Urinary Collection Device associated UTI, UTI = urinary tract infection.

^a CAUTI and EUCD-AUTI rate are presented as number of infections per 1000 device days.

^b UTI rate is presented as number of infections per 1000 patient days.

^c Indwelling catheter days are the days of indwelling catheter use in patients who have used an indwelling urinary catheter in addition to an external urinary collection device.

have not been, instead of decreasing UTI risk by removing an IUC. This contrasts with Rearigh's studies which showed a decrease in IUC days with EUCD introduction despite no change in CAUTI [14,17]. In support of this, the majority of patients who received an EUCD previously received an IUC. Furthermore, this may imply that the EUCD-AUTIs may have been truly related to the previous catheters.

Alternatively, differences seen in this study could be related to the difference in medical and surgical populations. This study contrasts with prior predominantly medical population single-institution studies that have demonstrated a decrease in CAUTI rates after EUCD introduction [14–17]. Zavodnick et al. showed that EUCD implementation in a medical ICU decreased CAUTI rates by more than half [14]. Eckert et al. found similar results at a community hospital with the CAUTI rate decreasing from 1.11 device-days to zero in the year following EUCD implementation [15]. However, in the year following, this improvement was not sustained [15]. Though, similar to our findings, Warren et al. found EUCD implementation in all female inpatient settings at a large academic medical center had no effect on the rate of CAUTI [16]. Rearigh et al. showed the same result, with no change in CAUTI rates in their single medical institution after EUCD [17]. Specifically, surgical patients have different indications for urinary collection devices, such as to avoid bladder distention and acute urinary retention post-operatively [19]. This may explain why the most common service ordering IUCs was neurosurgery while the most common

service ordering EUCD was trauma, critical care, burn surgery. Neurosurgery may use IUCs more frequently due to neurogenic bladder or postoperative urinary retention while trauma, critical care, burn surgery may use EUCDs to monitor resuscitation [20].

Another potential explanation is that the POST group was more complex and prone to complications such as CAUTI, as POST patients had a higher percentage of DVT as a hospital complication and comorbidity of ESRD compared to the PRE group. These reasons could also explain the longer length of stay of three additional days in the POST group. Regardless, this study highlights the need for high-quality randomized controlled trials to definitively evaluate the benefit of female EUCDs prior to widespread adoption.

The single center retrospective design of this study has inherent limitations including lack of generalizability, observation design, and selection bias. Although instructions for EUCD indications, contraindications, and use were provided, EUCD use was left to provider discretion, which likely led to irregular adoption and some selection bias as some providers utilized EUCDs instead of IUCs as was intended, whereas other providers likely utilized EUCDs for patients who would not have received an IUC. Additionally, in patients where both IUC and EUCD were used, the sequence of IUC and EUCD use was not recorded, so we are unable to conclude whether EUCD was placed before or after IUC. Furthermore, since EUCDs require significant nursing care that differs from IUCs, with distinct care and changing at least every 12 h, this new change in care could have varied in implementation among staff. It is important that future campaigns and programs using EUCDs have strict utilization criteria and prospectively track patients who receive these devices to provide immediate feedback to providers. Further, inaccurate data entry and inability to extrapolate cause and effect are inherent limitations to the retrospective design. In addition, despite the longer POST period due to the slow adoption by providers, the two groups had a similar number of IUC/EUCD patients which suggests a decrease use of IUC overall, though the infection rate was not improved in patients who received an IUC/EUCD. This may be related to a hospital-wide campaign to minimize use of IUCs, which EUCD implementation was part of. This study lacks details about the denominator of total female surgical patients during each time period and did not collect the standardized utilization ratio of IUC. Also, the number of patients who received only an EUCD without an IUC was also low, which decreased the power of the study. Finally, as previously mentioned, surgical subspecialty services have distinct uses for urinary catheters that may differ from medical patients, which could mandate usage of IUC and inflate CAUTI rates in this population. Despite these limitations, this is the first pre/post study on the use of EUCDs in a homogenous surgical female surgical population that provides valuable information for future prospective studies.

While the use of an EUCD is conceptually sound, the data from this single-institution study demonstrated an increase in CAUTI rates after the implementation of a female EUCD. Additionally, the adoption of EUCDs did not change the median number of IUC days. This may be related to selection bias, with EUCDs being ordered for patients who would not have otherwise received any urinary collection device.

The dermatologic injury from the pressure and stiffness of the device also should be taken into account when considering using an EUCD. Regardless, this study suggests that future prospective randomized controlled trials with explicit indications for EUCD usage are needed before widespread adoption of female EUCDs.

Authorship statement

Melinda Lem: Conceptualization, Formal analysis, Writing – Original Draft. **Nathan Jasperse:** Conceptualization, Methodology, Project Administration, Writing – Review and Editing. **Areg Grigorian:** Conceptualization, Methodology, Formal analysis, Software, Writing – Review and Editing. **Catherine M Kuza:** Conceptualization, Methodology, Investigation. **Jacob Sahag Deyell, Janani Pankajam Prasad, Charlene Yuan, Meril Tomy:** Investigation, Formal analysis. **Jeffry Nahmias:** Conceptualization, Methodology, Writing – Review and Editing, Project Administration, Supervision. All authors have approved the final article.

Conflict of interest

All authors have no conflicts of interest to disclose.

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Provenance and peer review

Not commissioned; externally peer reviewed.

Ethical considerations

This study was approved by the Institutional Review Board at the University of California Irvine and deemed exempt from need for informed consent.

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