External Collection Devices as an Alternative to the Indwelling Urinary Catheter

Evidence-Based Review and Expert Clinical Panel Deliberations

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ABSTRACT

Multiple evidence-based guidelines have suggested clinicians consider external collection devices (ECD) as alternatives to indwelling catheters. Nevertheless, there is a dearth of evidence-based resources concerning their use. An expert consensus panel was convened to review the current state of the evidence, indications for ECDs as an alternative to an indwelling urinary catheter, identify knowledge gaps, and areas for future research. This article presents the results of the expert consensus panel meeting and a systematic literature review regarding ECD use in the clinical setting.

KEY WORDS: CAUTI prevention, External collection device

INTRODUCTION

Catheter-associated urinary tract infections (CAUTIs) are the most frequently reported hospital-acquired infection in the National Health Safety Network. They are associated with multiple clinically relevant complications such as pyelonephritis, urosepsis, and bacterial endocarditis. In addition to concerns over patient safety associated with CAUTI development, there is a growing concern over the prevalence of multi-drug-resistant infections. A national study analyzed the number of CAUTIs associated with multidrug-resistant organisms in long-term acute care hospitals, and found vancomycin resistance among Enterococcus faecalis in 44% of cases reported in 2010, and 25% of Pseudomonas aeruginosa infections. It is estimated that at least 13,000 deaths are attributable to urinary tract infections (UTIs) each year. Based on these associations, the Centers for Medicare and Medicaid Services named hospital-acquired UTI as one of the original “never events.”

Effective prevention of CAUTI relies on an intervention bundle, similar to prevention guidelines for other never events such as facility-acquired pressure ulcers. A bundle is defined as 3 to 5 interventions that, when implemented collectively, improve patient outcomes. Saint and colleagues identified 4 elements of an intervention bundle for prevention of CAUTI: (1) urinary catheter reminders or stop orders; (2) nurse-initiated discontinuation of indwelling urinary catheters; (3) portable ultrasound to determine postvoid residual; and (4) external continence devices (ECDs) in men. The 2009 Centers for Disease Control and Prevention CDC Guidelines also included a statement about use of ECDs, “Consider using external catheters as an alternative to indwelling urethral catheters in cooperative male patients without urinary retention or bladder outlet obstruction [pg.38].” This statement is categorized as category II, indicating the recommendation is supported by weak evidence suggesting a reasonable balance of likely benefits versus harm. External collection devices are also advocated in guidelines from the Infectious Diseases Society of America, European and Asian infection control societies, Wound Ostomy and Continence Nurses Society, and the American Nurses Association.

External Collection Devices

External collection devices are defined as a category of devices that adhere to the external genitalia or pubic area and collect urinary output (Figure 1). They are distinguished from indwelling catheters that are inserted into the bladder vesicle using a transurethral or suprapubic route. They can be divided into several device categories, condom catheters, reusable body-worn urinals, and a nonsheath, glans-adherent ECD.

Originally constructed of latex, many condom catheters are now constructed from one of several alternative substrates such as silicone. Single-use condom catheters (sometimes referred to as Texas catheters) adhere to the penile shaft via an adhesive applied to the interior surface of the device, or a
| Category                        | Description                                                                 | Application                                                                 | Image Url                                                                 |
|--------------------------------|-----------------------------------------------------------------------------|-----------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Latex-based sheathed devices   | External catheter with latex sheath, Available with and without separate adhesive liner. | Sheath is held at the tip of the penis and rolled down the penile shaft. Appropriate sizing is necessary. | [Image 1]                                                                |
|                                | External catheter with latex sheath and adhesive lining.                     |                                                                             |                                                                          |
|                                | External catheter with foam adhesive strap                                  | Sheath is held at the tip of the penis and rolled down the penile shaft. An adhesive strap is wrapped around the device to provide occlusion. Appropriate sizing is necessary. | [Image 2]                                                                |
|                                | External catheter with sheath made of PSX silicone material and adhesive lining. |                                                                             |                                                                          |
|                                | External catheter with silicone sheath and adhesive lining.                 |                                                                             |                                                                          |
|                                | External catheter with silicone sheath and adhesive lining.                 |                                                                             |                                                                          |
|                                | External catheter with hydrocolloid sheath and adhesive lining.             |                                                                             |                                                                          |
|                                | External catheter with silicone sheath and adhesive lining.                 |                                                                             |                                                                          |
|                                | External catheter with silicone sheath. Adhesive free.                     | Sheath is held at the tip of the penis and rolled down the penile shaft. A foam velcro strap is wrapped around the device to provide occlusion. Appropriate sizing is necessary. | [Image 3]                                                                |
|                                | Inflatable external catheter with silicone sheath. Adhesive free.           | The inflatable retention ring secures the catheter and can be easily detached for removal. Appropriate sizing is necessary. | [Image 4]                                                                |
|                                | Retracted Penile pouch                                                      | The penis is placed in the opening of the pouch and the wafer adheres to the skin at the base of the penis. Wafer can be cut to accommodate different sized anatmoshes. | [Image 5]                                                                |
|                                | Glans-adherent device                                                       | The device secures to the glans only by first adhering the faceplate, then overlapping and securing with the seal straps. One-size-fits-all and no sizing necessary. | [Image 6]                                                                |
|                                | Non-sheath, glans-adherent ECD with integrated hydrocolloid and adhesive.   |                                                                             |                                                                          |

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measuring the penile diameter at the base of the penile shaft, gently cleansing and drying the penile skin, and clipping any hair growing on the shaft to enhance adherence between the condom catheter or adhesive strap and skin.14 Some clinicians use a liquid polymer acrylate (liquid skin barrier) to protect the underlying skin and promote adherence; our literature review identified no studies supporting or refuting the need for adding this step to the application process. Anticipated wear times for condom catheters are 24 to 72 hours.15

The nonsheath, glans-adherent ECD is a fully external, one-size-fits-all, device that can be applied to males who are circumcised and uncircumcised, as well as those who have smaller penile circumferences or leaks and obese men with retracted penile shafts. This device differs from traditional condom catheters because of the one-size-fits-all design with technology that bypasses the need to cover the penile shaft and associated risk of skin damage.15,16 A brief overview of device application is presented in Table 1.

Obese men and those with shorter penile shafts may also be fitted with a 1- or 2-piece penis pouch, sometimes referred to as a retracted penis pouch.14–16 These devices attach to the pubis via a hydrocolloid wafer barrier. The base of the penile shaft is assessed and a hole is cut in the barrier wafer that allows the penis to pass through the pouch. The skin at the base of the penis is held taut to enhance adherence. Urine drains into a collection pouch that is incorporated into the product, or a pouch that is attached to the wafer barrier via a flange. The pouch has a distal port that attaches to a drainage bag. Preparation of the skin requires cleansing and removal of pubic hair. Anticipated wear time is 2 to 3 days for a 1-piece system and 5 to 7 days for a 2-piece system.17

External collection devices have been developed for women, but none have gained widespread use in the clinical setting.18,19 Despite a number of innovative designs, the considerable challenges of designing a device that effectively contains urinary output while avoiding damage to the pubic skin or vaginal mucosa remains elusive. As a result, commercially available ECDs are currently limited to male patients.

In addition to its indication as part of a care bundle for prevention of CAUTI, ECDs have been used in a variety of other situations (Table 2). These indications include long-term drainage in men with neurogenic bladder dysfunction and reflex urinary incontinence, short-term drainage in men who experience cognitive dysfunction due to acute or chronic illness, and short-term drainage in the ambulatory surgical setting or diagnostic suite.20-23

While evidence-based intervention bundles have been shown to reduce CAUTI incidence, a 2014 analysis by the National Hospital Safety Network revealed that only 6% to 27% of hospitals reported adherence to CAUTI prevention policies.1 This disparity between evidence and practice may be due, in part, to patient and caregiver preference based on discomfort, application challenges associated with appropriate application for small and retracted male anatomy, and difficulties with leak prevention.31

In order to more fully address widespread adoption of ECDs as an alternative to the indwelling catheter, a roundtable discussion of clinicians with expertise in indwelling catheter management, prevention and treatment of CAUTI, and use of ECDs was convened. The purpose of that meeting was to identify ECD knowledge gaps and indications for ECD use as an alternative to the indwelling urinary catheter.

**EXPERT PANEL PROCEEDINGS**

Eight clinicians were selected to serve on the round table based on their complementary areas of expertise to serve as consensus panel members (Table 3). The majority of consensus panel members (n = 7, 87.5%) were RNs; the panel member who was not an RN has expertise in epidemiology and infection control. The expertise represented by this panel was broad and included 1 member with expertise in urology, 2 in quality improvement, 5 in infection prevention, and 1 in epidemiology.

The expert panel met in Anaheim, California, on June 8, 2014, to consider the current state of the science and evidence-based literature surrounding ECDs, and to identify knowledge gaps and indications for usage. Each individual provided rationales and recommendations, and consensus on agenda

**TABLE 1.**

| Application Procedure |
|-----------------------|
| 1. If the patient is uncircumcised, retract foreskin to expose the glans. |
| 2. Clean and dry the glans. |
| 3. Use alcohol wipe to remove cleanser’s moisturizing agents and natural oils from the skin. |
| 4. Apply small amount nonwater-soluble liquid adhesive to the glans, avoiding urethral opening and allow to dry for 30 s. |
| 5. Remove paper tabs from faceplate (“daisy”) and apply the device to ensure primary securement. |
| 6. Remove paper tabs from one section of the seal (“bowtie”) at a time and apply circumferentially by overlapping the exposed petals. |
| 7. Apply gentle pressure with one hand around the new seal, holding for 10 s to promote device adherence. |
| 8. For uncircumcised anatomy, return the foreskin to natural resting position, which may overlap the seal. |
| 9. Attach drainage bag to universal adapter at distal end of device and secure with the hydrocolloid stabilization securement device.16 |

From Lucas and colleagues.16

*Mas lists Liquid Adhesive, Eloquest Healthcare, Inc, Ferndale, Michigan.

*CathGrip, Bioderm, Inc, Largo, Florida.

**TABLE 2.**

| Indications for ECD Use in Men |
|-------------------------------|
| • Patients requiring ECD when indwelling catheter is not appropriate17,20,23 |
| • Long-term care patients who experience urinary incontinence without retention18 |
| • Long-term urinary containment for selected men with neurogenic bladder dysfunction and incontinence without sensory awareness due to paralyzing spinal disorders such as spinal cord injury, transverse myelitis, or progressive multiple sclerosis24 |
| • Patients with delirium tremens |
| • Patients on powerful diuretic medications such as furosemide who require accurate documentation of fluid intake and urinary output (vs strict intake and output)21,23 |
| • Patients requiring procedural drainage such as after outpatient surgeries such as discectomy, arthroscopic surgeries |
| • Patients on observation for 6- to 8-h period postprocedure when deemed appropriate (observation for urinary retention) |

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topics was achieved. The agenda included 3 main topics: (1) urinary management and the impact on overall wellness; (2) current urinary management algorithms; (3) the benefits of implementation of male ECDs within a urinary management algorithm. They reviewed evidence-based literature on ECDs as an alternative for incontinence management prior to the round-table discussion.

A moderator guided the discussion, she was selected based on expertise in the process of consensus construction, and was an individual who was neutral to the topic. Consensus for each statement was obtained based on general principles outlined by Murphy and colleagues,32 using 80% agreement for each statement was obtained based on general principles on expertise in the process of consensus construction, and as an alternative for incontinence management prior to the algorithm. They reviewed evidence-based literature on ECDs implementation of male ECDs within a urinary management algorithm. Th ey reviewed evidence-based literature on ECDs as a minimum criterion for consensus. If consensus was not achieved after initial discussion, the statement was modified based on panel member input and a second, and sometimes third, consensus votes were taken until consensus was achieved.32

Discussion initially focused on ECD as part of an evidence-based care bundle for prevention of CAUTI. Panel members recognized that current evidence demonstrates effective prevention of CAUTI primarily relies on a reduction in the number of indwelling urinary catheter days. For example, a study on the relationship between indwelling urinary catheter use and the incidence of CAUTI showed a strong linear correlation ($r^2 = 0.79; P < .0001$).33 Additional articles were reviewed regarding the negative outcomes associated with CAUTI, such as increased morbidity, extended hospital length of stay, decreased health-related quality of life, and increased costs.2,4,14,23,31

Discussion then turned to the use of ECDs as an alternative for indwelling catheterization. Panel members concurred that evidence concerning the efficacy of ECD as an alternative to the indwelling urinary catheter is sparse, especially when compared to the current focus on timely catheter removal protocols. Given the dearth of existing research on the use of ECD and the poor uptake for intervention bundles for CAUTI prevention, the group discussed strategies for improving ECD use (Table 4).34-39 These strategies include incorporating ECD use into education about CAUTI prevention, and emphasizing the ability of ECD use in reducing indwelling catheter days while maintaining the ability to accurately measure fluid intake and urinary output.

Individual panel members observed that introduction of ECDs into their facilities sometimes met with resistance from nursing staff owing to concerns about application of an ECD, its ability to effectively contain urinary output, and prevention of potential complications such as urethral obstruction or local tissue damage if devices were applied too tightly. Panel members with experience introducing ECDs in acute care facilities

| TABLE 3. Clincians, Credentials, Affiliations, and Facilities of Consensus Panel Members |
|-----------------------------------------------|
| First name | Last Name | Credentials | Title/Role | Facility/Organization |
|-------------|-----------|-------------|------------|----------------------|
| Mike  | Gray | PhD, APRN, FNP-BC, CURNP, CCN | Nurse practitioner and professor | University of Virginia School of Nursing |
| Claudia  | Skinner | DNP, RN, CCRN, CNML, BC-NE | Director of Center of Excellence | St. Jude Medical Center |
| Shannon  | Davila | RN, MSN, CIC, CPCH | Clinical quality improvement manager | New Jersey Hospital Association |
| Brenda  | Helms | RN, BSN, MBA/HCM, CIC | Manager infection prevention, employee health, accreditation | Baylor Medical Center at McKinney |
| Wendy  | Kaler | CLS, MPH, CIC | Manager infection control | St. Francis Memorial Hospital |
| Valerie  | Lowe | RN, BSN, CIC | Infection preventionist | California Hospital Medical Center |
| Susan  | Viker | RN, CIC | Manager of infection prevention | California Hospital Medical Center |
| Vicki  | Warnock | RN, CIC | Director of infection prevention | Dignity Health |

| TABLE 4. Recommendations for Improving Use of ECD as a Component of an Intervention Bundle for Prevention of CAUTI |
|-----------------------------------------------|
| 1. Incorporating ECDs into discussions of CAUTI prevention, emphasizing the need to avoid unnecessary Foley catheters while maintaining the ability to capture accurate intake and output.24,30 |
| 2. Ensuring adequate buy-in of clinical team members when introducing an ECD; addressing key stakeholders and team at correct time points; engaging medical director and nursing director, WOC nurses as stakeholders, nurse educators, and CAUTI prevention champions.24,30 |
| 3. Identifying champions/superusers as part of the quality improvement initiative.2,38 |
| 4. Setting appropriate expectations regarding the learning curve for application of ECDs by nurses and presentation of the device as an evidence-based solution for CAUTI prevention; presenting the learning curve associated with ECDs as investment, which is part of the solution vs part of the problem. |
| 5. Setting appropriate expectations regarding duration of ECD use and potential changes on a case-by-case basis; emphasizing evidence-based nursing.26,37 |
| 6. Setting specific expectations for ECDs in unique patient populations in which application may be more complex (eg, obese/uncircumcised). |
| 7. Develop a customizable nurse-driven protocol for ECD usage in clinically appropriate situations.24,30 |
| 8. Develop tools to demonstrate value of ECDs (cost avoidance).49,52 |
| 9. Developing tools to ensure education/re-education on every 6-mo basis (potentially annual basis) focused on appropriate ECD application to avoid rare complications.9,50 |
| 10. Collect patient survey information in ambulatory patients (satisfaction, comfort, health-related quality of life) to measure patient satisfaction.28,30 |

Abbreviations: CAUTI, catheter-associated urinary tract infection; ECD, external collection device.
emphasized the need to set appropriate expectations regarding the learning curve required for application of ECDs by nurses, identifying indications for their use, appropriate application methods, expected wear time for a typical device, and anticipated duration for ECD use in acutely or critically ill patients.

Panel members also recognized the need for policies that allow individualization of ECD use based on patient needs, body habitus, and preferences. Several panel members reported improved staff acceptance of regular ECD use when they emphasized its role as an essential component of an evidence-based CAUTI prevention bundle, and when the associated learning curve was presented as an investment in the overall program’s success.

Panel members who had introduced ECDs in their facilities also discussed the need to develop a nurse-driven protocol for their use based on standardized indications, and data collection documenting its impact on CAUTI occurrences and associated costs. Nurse-driven protocols have been shown to be effective in empowering nurses to adhere to CAUTI prevention best practices.9,34-40 Reeducation focusing on techniques effective in empowering nurses to adhere to CAUTI prevention bundle. Recommended strategies included identifying key stakeholders and the team at strategic time points; and engaging support from key persons in administration such as the medical and nursing directors. Panel members also advocated early involvement of key clinical leaders within the facility such as WOC nurses, nurse educators, and CAUTI prevention champions. Identification of unit-based CAUTI prevention champions or superusers of these devices is recommended, as these individuals are ideally situated to teach others to successfully apply and manage ECD as they gain experience in their use.

Panel members practicing in ambulatory care settings also shared experiences regarding teaching patients and lay-caregivers on how to safely and effectively apply ECD, including setting expectations for a realistic learning curve, and a greater average wear time as skills applying these devices matured. In addition to collecting data about the long-term effects of ECD use on UTI rates, they also advocated investigating data on the impact of these devices on satisfaction, comfort, and health-related quality of life.

**Scoping Literature Review**

Given the lack of literature associated with ECD use, and the comparatively low uptake of CAUTI bundles in acute care facilities discussed earlier, the panel recommended appointing an editorial committee comprising 3 panel members (CS, MG, WK). The panel identified 3 aims for the literature review: (1) review evidence concerning the efficacy of ECD for prevention of CAUTI when compared to the indwelling urinary catheter, (2) review evidence concerning cost analyses associated with a CAUTI prevention bundle versus no formal program, and (3) identify knowledge gaps and prioritize research needs concerning use of ECD for prevention of CAUTI.

**METHODS**

We queried the MEDLINE database using the following parameters: research in humans published within the last 10 years, English language, both sexes, adults aged 19 years and older. Given the limited amount of research in this area, the search included all levels of studies: systematic review with and without meta-analysis of pooled data, randomized clinical trials, nonrandomized trials, prospective cohort studies and retrospective case-control studies, multiple case series, and case studies. The search also included best practice statements, clinical practice guidelines, comprehensive, and integrative reviews. MeSH terms queried were catheters; urinary catheterization; catheters, indwelling; cross infection; evidence-based nursing; and nursing assessment. Additional keyword queries were condom catheters; penile sheath; nurse-driven protocols; CAUTI; prevention; and incontinence. When searching for articles on safety of ECDs, the date range was expanded to “all dates” because of the importance of reviewing all individual reported case studies.

**Findings**

The literature review identified 86 potentially relevant articles. The editorial team then conducted a title review to eliminate duplicate articles, and articles unrelated to the stated aims, yielding 36 relevant titles. The editorial group then completed an abstract review of the 36 relevant articles, and 32 articles1-2,5,7,19,21-23,25,26,28,29,31,32,34-36 were selected that were relevant and were read in full and used for the review. An additional 20 articles3,4,6,8,10-16,18,20,24,26,27,30,31,47-51 were identified as relevant on bibliographic (ancestry) review (Figure 2).

**Efficacy and Safety of ECD**

One of the objectives of the focused (scoping) literature review was to identify clinical studies discussing the efficacy and safety of ECDs. We used the definition provided by the Cochrane: “The extent to which an intervention produces a beneficial result under ideal conditions. Clinical trials that assess efficacy are sometimes called explanatory trials and are restricted to participants who fully co-operate.”51 One randomized controlled trial26 was retrieved and 3 individual case histories47,48,50 were identified that discussed the safety of ECD use.

Saint and colleagues26 compared CAUTI occurrences associated with ECD use to infections in patients managed by indwelling catheterization. The study compared indwelling urinary catheters to ECDs in 75 men aged 40 years or more who required urinary drainage during hospitalization.26 Men allocated to drainage with an ECD had a lower incidence of bacteriuria than did men randomized to the indwelling catheter group (70/1000 patient days vs 131/1000 patient days); this difference was statistically significant when adjusted for other risk factors (P = .04), including presence of dementia.26 When compared to men managed by an indwelling catheter, men using ECD has a lower hazard ratio for bacteriuria or
symptomatic UTI (hazard ratio = 4.84; 95% confidence interval = 1.46-16.02). Men without dementia using an ECD also reported higher levels of comfort and less pain associated with urinary drainage (P = .02) on a questionnaire designed for the study than men with indwelling catheters. Three case studies were published that focused on the safety of ECD use. Vaidyanathan and colleagues reported a case of localized necrosis of the scrotum in a man with a spinal cord injury. Ozkan and colleagues reported isolated gangrene of the penis in a paraplegic patient, and Kawoosa described penile strangulation and necrosis. In the first case study, the necrosis was attributed to several factors, including lack of understanding regarding the impact of urine leakage and resultant skin damage, improper personal hygiene coupled with a neurogenic bowel, and an impaired immune system. Based on these findings, the authors discussed the importance of patient and caregiver education for appropriate application, and care of an ECD in the treatment of incontinence. In the second and third case studies, adverse outcomes were attributed to improper application of the ECD; these findings highlight the importance of proper application and patient observation. Considered collectively, these case studies illustrate the importance of appropriate application of the ECD and adherence with proper care and hygiene. In addition, the lack of cases reported reinforces the clinical experiences of panel members that dispel the myth that ECDs are inherently dangerous when applied and cared for properly.

**Cost Analysis of an Evidence-Based CAUTI Prevention Bundle**

We did not find any studies that reported on the costs associated with an entire CAUTI prevention bundle of care, nor were there any articles reporting cost analyses of ECD versus IDC for CAUTI prevention. An economic analysis conducted by the CDC assessed the costs of hospital-acquired infections and the benefits of prevention, and found the attributable costs per CAUTI infection ranged from (US) $589 to $1007. The economic analysis estimated if 20% of hospital-acquired infections were prevented using evidence-based best practices, the cost benefits of prevention would reach approximately (US) $5.7 billion. Clarke and colleagues analyzed the effectiveness of a CAUTI bundle of care with 4 interventions, and reported the annualized investment of $23,924 for implementing the 4 interventions resulted in significantly higher savings as a result of CAUTI avoidance. Collectively, these studies suggest that the cost associated with an effective CAUTI prevention program is less than the cost of anticipated infections in the absence of an effective prevention program is instituted.

**Knowledge Gaps and Research Needs**

There is a significant paucity of evidence-based literature associated with ECD indications and usage. There are multiple knowledge gaps, including efficacy studies and cost analyses of CAUTI prevention bundles that incorporate ECDs. Future research should include well-designed comparative effectiveness studies to compare ECDs with indwelling urinary catheters, assessing efficacy, safety, costs, patient satisfaction, and health-related quality of life. Evidence-based guidelines should be developed to assist facilities with incorporating ECDs into CAUTI prevention bundles utilizing nurse-driven protocols.

**CONCLUSION**

This expert consensus round-table meeting resulted in a clinically meaningful discussion regarding the promotion of widespread adoption of ECDs as an alternative to the indwelling catheter. The consensus panel members successfully identified ECD knowledge gaps and indications for ECD use as an alternative to indwelling urinary catheters. An additional scoping literature review revealed existing evidence regarding the safety and efficacy of ECDs. There is a substantial clinical need for large, well-designed comparative effectiveness research studies and cost analyses, and evidence-based guidance for developing nurse-driven CAUTI prevention bundles of care, which incorporate ECDs into decision making.

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