uricap Female

The new and safe way to sample urine in women, with a low rate of contamination

The UriCap Female has a soft and comfortable design that creates a secure seal around the urethral opening. The design of the UriCap Female shields the urethra and urine from contaminants in the area. It connects to a standard urine drainage bag.

The UriCap Female offers a new way to safely replace invasive catheters or beakers for urine sampling, urine collection and urine monitoring.

In addition, the UriCap Female has the following advantages for urine sampling:

- Low rate of contamination compared to Mid Stream Urine Collection
- An external and clean procedure with no risk of causing UTI
- Easy to apply at the A&E, Pre-Surgery or at an outpatient clinic/family office
- Can be used on all women when an uncontaminated sample is of importance
- Can stay on, if the patient can't get out of bed and wants to stay dry.

The UriCap Female is especially useful for women experiencing urinary incontinence who are physically impaired, partially mobile, able to sit, or bedridden. UriCap is often used at night-time to have an uninterrupted sleep whilst staying dry. It can however be used by all women to safely collect an uncontaminated urine sample.

> *It is clear to everyone that the use of an invasive method for taking a urine sample should be reduced to a minimum.*
> *The UriCap Female provides an excellent, reliable, and safe solution as an alternative.*
> *Today, when there is a need to collect urine for culture, both in the internal department and in the general emergency department, we use the "UriCap Female" external catheter and are very satisfied.*

Batsheva Kloyzner - Epidemioligy Nurse
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For more information:

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SAFETY, PERFORMANCE AND USABILITY ASSESSMENT OF A NOVEL STERILE DEVICE FOR URINE CULTURE SAMPLING IN WOMEN

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HYPOTHESIS / AIMS OF STUDY

There is a need for a novel, safe approach to non-invasive urine collection and containment. Urine samples should be collected by a protocol that minimizes contamination from the genital mucosa and perineal skin. Urinary tract infections (UTIs) are one of the most common types of healthcare-associated infections (1). However, urine-culture contamination rates are high and diagnostic accuracy does not vary significantly in self-collected MSSC with or without prior cleansing (2). A urine culture from incontinent women, especially elderly women in a hospital setting is usually obtained by an invasive catheterization with the risk of causing a UTI and CAUTI occurring in up to 75% of placements (3). Not all UTI-symptomatic women are diagnosed with UTI thus the diagnostic process may lead to preventable infections.

The aims of this clinical investigation were first to evaluate the performance, safety, and usability of the sterile, single-use urinary collection and containment device for sampling urine for culture in the hospital setting in women who were able to void completely or have mild bladder incontinence and second, to identify a simple non-contaminating urine collection method that is safe with no risk of complications that can be easily used in a busy clinical environment.

STUDY DESIGN, MATERIALS AND METHODS

This was a prospective, single-arm, open-label, interventional, pilot clinical investigation approved by the Institution's Independent Ethics Committee to evaluate the collection of non-contaminated urine samples for culture in adult female subjects who are able to void completely or had mild urinary incontinence. The performance of the device was evaluated by the number and proportion of contaminated and non-contaminated urine samples collected using the device and compared to data collected over the years in multiple studies and surveys performed on the same target population using the same urine collection method (i.e., Midstream Clean Catch), albeit with different urine collection devices. The safety of the device was evaluated by the number and proportion of device-related Adverse Events (AEs) reported during the clinical investigation. The usability of the device was evaluated using the health care professional Treatment Satisfaction Questionnaire (hcpTSQ).

For this single-center investigation, healthy female volunteers that were invited for observation prior to surgery, or that were hospitalized in the Medical Center Urology Department for any reason except urinary or other suspected infections, were invited to participate in the clinical investigation. Subjects that provided their consent were screened for their eligibility. The novel device (figure 1) used in the study is a patented small, soft cup made from medical-grade silicone which is attached to a short silicone tube and a standard urinary drainage bag. The device does not require skin adhesives or an external suction source, making it unique from other external urinary collection devices. It is applied directly to the skin around the urethra and is designed to stay in its application location using naturally occurring adhesive forces for up to 24 hours. Once applied, the first urine specimen can be utilized for a clean catch or mid-stream specimen.

After obtaining the subjects' consent, subjects were screened for their eligibility. Thirty-six (n = 36) females were recruited for the collection of non-contaminated urine samples for culture in adult female subjects who are able to void completely or had mild bladder incontinence. Twenty-nine (29) subjects enrolled and completed the study. Seven (7) subjects were defined as screen failures.

As part of the screening assessment urine was collected one-time using the non-invasive novel device which was applied by a trained study staff member in an aseptic procedure, according to the device IFU. The subject urine was collected into the device's sterile urine collection bag, and the device was disconnected from the subject. The urine obtained using the device was divided into two portions: One portion was used for eligibility confirmation (i.e., visual inspection of urine and dipstick analysis). When subject eligibility was confirmed, the subject was enrolled into the study and the second portion of urine collected using the device was evaluated for contaminates at the Medical Center microbiological laboratory. The staff members who placed the device and collected the urine samples were requested to rate their satisfaction with using the device by completing the hcpTSQ straight after the urine sampling was completed. A telephonic FU visit (Visit 2) was performed 3 days (±2d) after the device displacement to monitor the subject safety. The subjects completed their participation in the clinical investigation after this visit.

In total each subject performed 2 visits during the clinical investigation over a period of approximately 3 days: One on-site visit for screening, device placement, urine sampling, enrollment, and microbiological evaluation (Visit 1) then a telephonic FU visit (visit 2) performed 3 days after the device application to monitor the subject safety. The study duration from the first subject enrolled until the last subject completed was approximately 7 months.

RESULTS

Twenty-nine (29) subjects (mean age 48; range 21-72 years; SD = 12.64 years) consented, enrolled, and completed the study. Twenty-one (n = 29) urine samples were collected using the device and analyzed at the microbiological laboratory. Twenty-eight (28) samples were not contaminated (28/29, 96.55%). One (1) sample was (1/29, 3.44%). Urine contamination was defined as "mixed growth bacteria", with a threshold of equal to or greater than (≥) 10,000 Colony-Forming Units per mL (CFU/mL), with 2 or more isolates. There were no ADEs, SADEs, or UADEs. Staff satisfaction was high 3.55 score for convenience and ease of device application device (scale 1-5). Staff satisfaction with urine sample collection time, the effectiveness of urine collection, and recommendation for using the device as the first option for urine collection the mean satisfaction scores were lower.

INTERPRETATION OF RESULTS

This is the first study to examine this novel sterile, single-use urine specimen collection device. Supporting aim 1 of the study, data presented in this study showed that the performance of this non-invasive device for urinary collection and containment in women allows for urine sampling without adding contaminations during the invasive, risk-prone process in a hospital and ambulatory settings. The device demonstrated an excellent safety profile and was not associated with any AE or complications. The satisfaction score was satisfactory; some lower user satisfaction scores, we concluded, were due to that samples were collected by MDs with limited motivation and training for the purpose. The use of the device entailed an efficient and simple procedure (see Figure 2) compared to catheterization, supporting aim 2 of the study.

Prospective studies with larger sample sizes are needed to confirm our findings. Future research should build on previous studies using the device for urine containment in the elderly and enable larger-scale evaluations demonstrating the ease of use and cost-effectiveness of a clean device as a possible "clean catch" golden standard for incontinent and bedridden women.

CONCLUDING MESSAGE

This original research provides preliminary evidence supporting the performance, safety, and usability of this novel sterile, single-use urine collection device (UCD). The contamination rates detected using the device were better than the contamination rates reported in the current literature (2). The use of this novel containment device entailed an efficient, simple, and low-risk procedure compared to catheterization that was acceptable to women. As a non-invasive device and with no adverse events reported, we concluded that the device is a safer alternative to current invasive catheterization for urine culture usually obtained from adult and older incontinent women in a hospital setting.

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