

Evaluation of a New, Novel Male External Urinary Management Device

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Background

Reducing the risk of catheter-associated urinary tract infections (CAUTI) by using condom catheters as an alternative to indwelling urinary catheters (IUC), when applicable, is well-supported in the literature^{1,2}. Health risks secondary to the invasive nature of IUCs are well-known. However, utilization of condom catheters for non-dementia, spontaneously urinating and incontinent patients is low. This is typically due to issues with fit and performance of current condom catheter options and the added convenience afforded to HCPs when using IUCs. At this time, viable options and research regarding alternative urinary management devices are limited¹. Very few advances have been made in recent years to address these needs:

- Alternative to condom catheters for satisfactory performance
- Alternative to indwelling catheters to reduce risk of associated infections

A new, novel male external urinary management device that is currently marketed in non-acute care settings for males with chronic urinary incontinence was identified as a possible alternative for use in the acute care setting.

Objectives

1. Develop performance data for a sample of patients to assess functionality and performance of the new male external urinary management device compared to traditional condom catheter options.
2. Obtain feedback from nursing staff to measure their acceptance and interest in adoption of the new product.

Method

A total of 3 units, each representative of a different tier of acuity at a Michigan healthcare system, that had a measurable baseline utility of traditional condom catheters and willingness to participate were selected to evaluate the new device. The 3 units included one (1) of each: medical-surgical, progressive care and intensive care. Product education, which included review of the algorithm for patient selection (Fig.1) was provided by the company representative, a RN. The algorithm is based on the 2009 CDC Guidelines for Prevention of Catheter-associated Urinary Tract Infections³. A data collection form was completed by the nurse at the time of device application and removal. To limit the risk of bias, forms were faxed to a third party for data aggregation. A goal of the evaluation was to identify 10 patients per unit, apply the new urinary management device and monitor the patient and device. At the end of the trial, all participating HCPs were asked to complete a survey to assess the caregiver's experience, level of satisfaction, measure preference and likeliness to advocate for it's use. This survey was also performed by the third party.

Poster presented at Cleveland Clinic's Spring WOC Nursing Symposium: April 12, 2013; Cleveland, OH.

Fig.1: Algorithm for Patient Selection

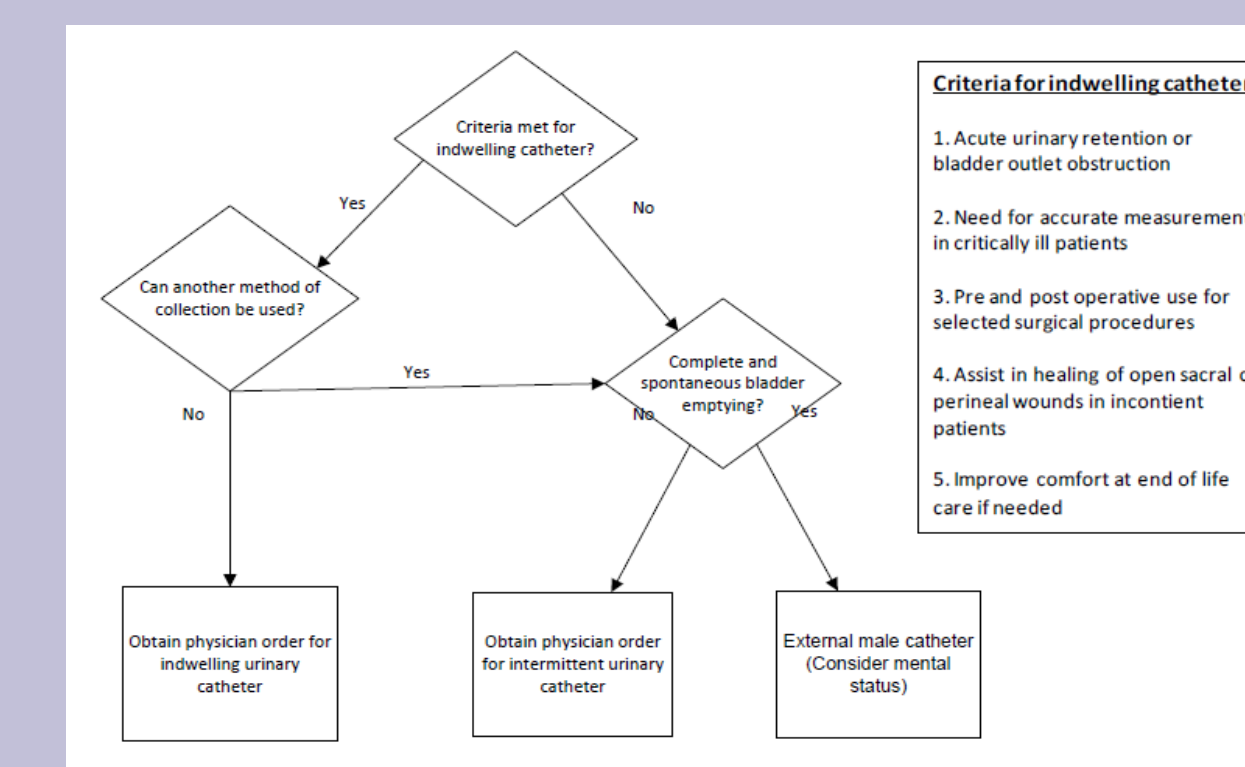


Fig.3: Wear Time Despite Some Premature Removals (n=42 applications)

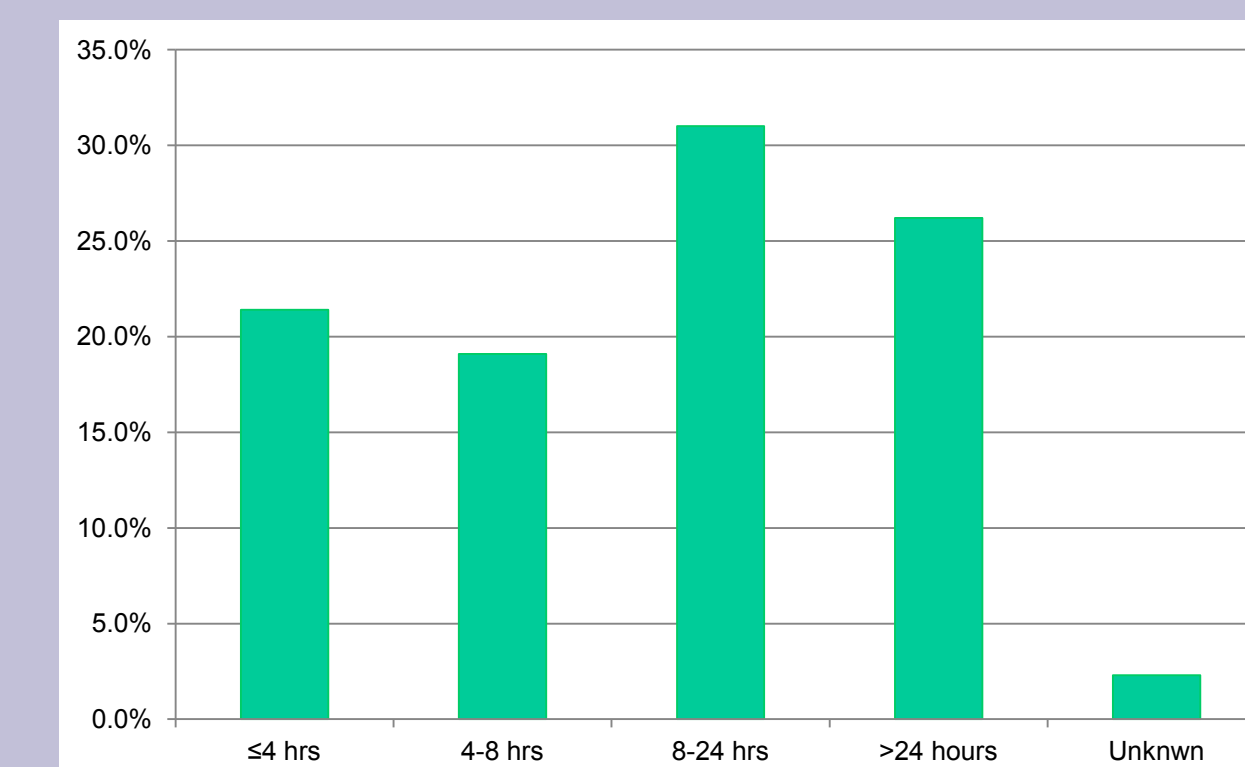


Fig.5: RNs Likely to Advocate for New Device

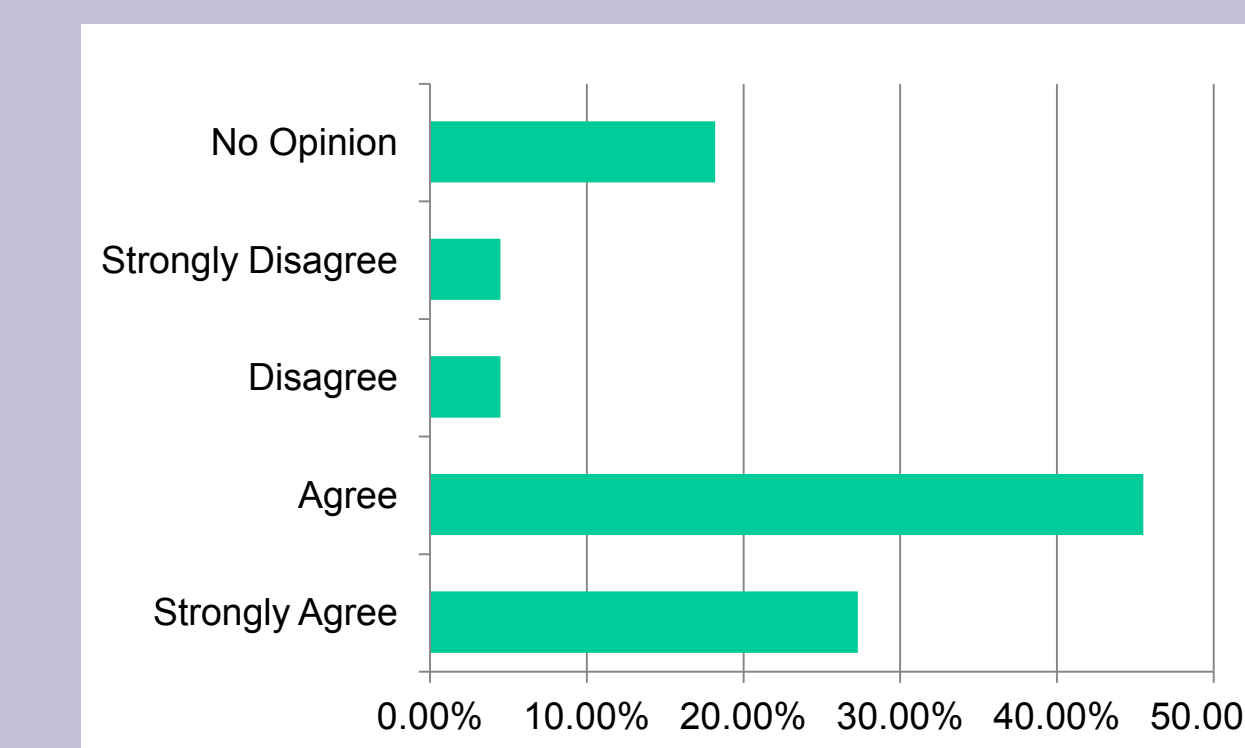


Fig.2: Rationale for Urinary Management

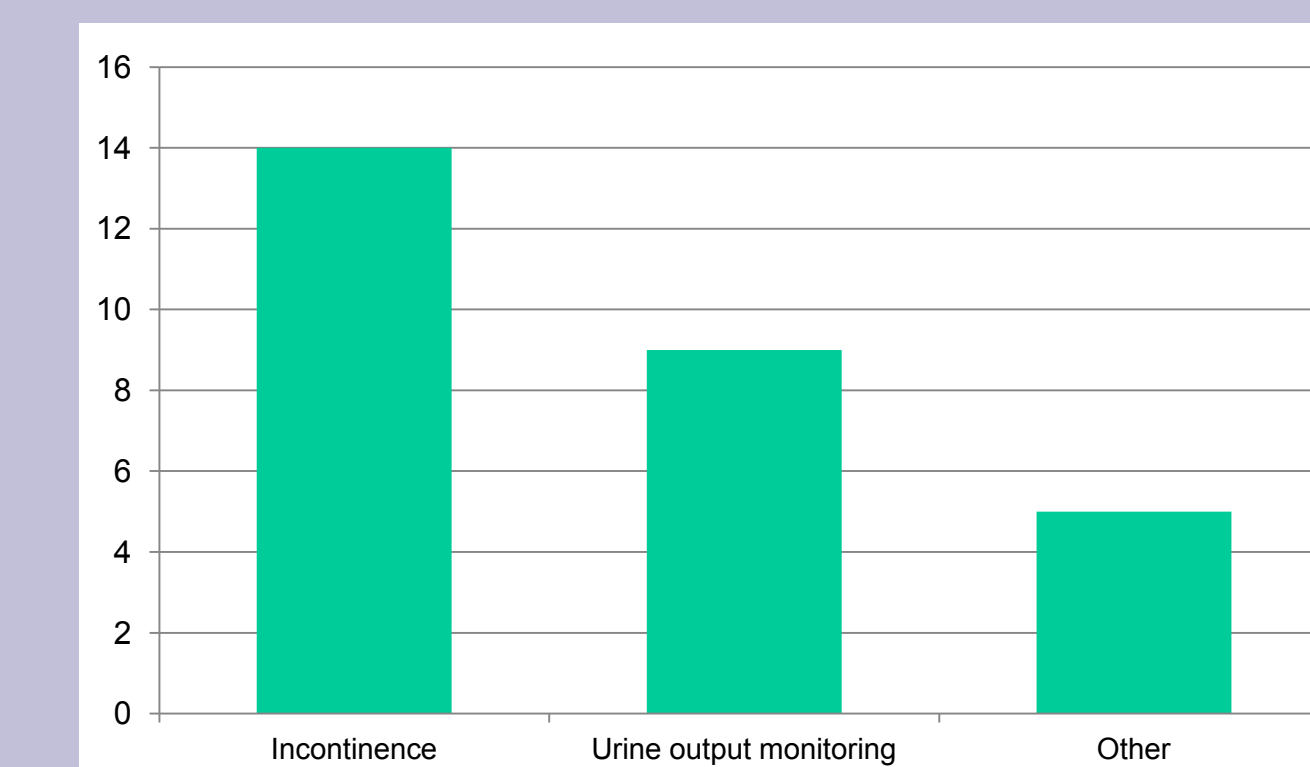
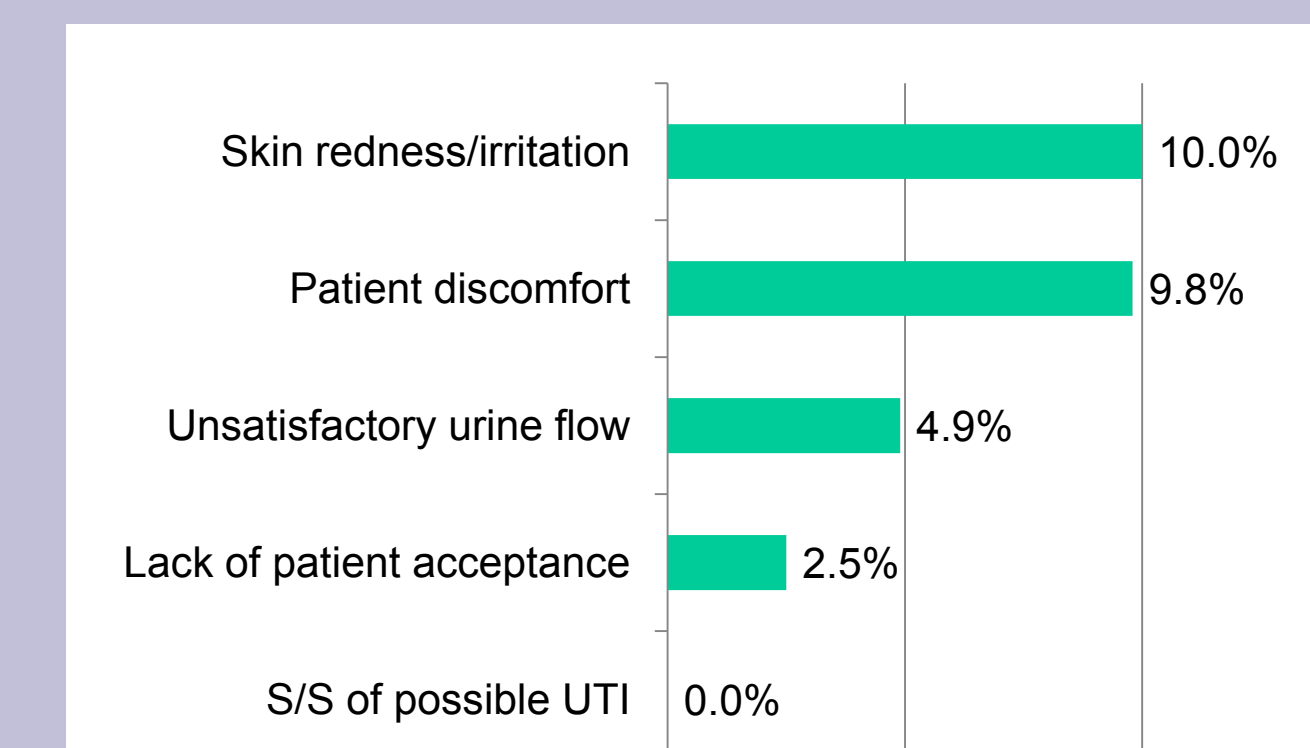


Fig.4: Rationale for Device Preference by RN

Attribute	Alternative Male Urinary Catheter Device	No Preference	Condom Catheter
Easy to apply	59.1%	22.7%	18.2%
Satisfactory urine flow	50.0%	40.9%	9.1%
Stays on securely	45.5%	50.0%	4.5%
No urine leakage	45.5%	40.9%	13.6%
Wear time	40.9%	50.0%	9.1%
Does not cause skin redness/irritation	40.9%	50.0%	9.1%
Patient comfort	36.4%	59.1%	4.5%
Patient acceptance	31.8%	68.2%	0.0%

Fig.6: Adverse Events & Areas of Concern (n=42 applications)



Results

The new male external urinary management device was evaluated by 31 RNs in 3 units. A total of 42 devices were used on 20 patients; and 22 RNs completed the follow-up interview or survey. Rationale for the device included incontinence, urine output monitoring and other (patient sedated and intubated; 24-hr urine collection lab; furosemide administered prior to MRI; need sample for Legionella antigen; and patient request) (Fig.2). Mean wear time of the device applied by a trained nurse (n=42 applications) was >23 hours (Fig.3).

Nurses indicated that the new device was easy to apply when compared to a traditional condom catheter. At least half of the RNs reported no device preference on a majority of attributes; and condom catheters were not preferred on any attribute (Fig.4). 72.8% of RNs were likely to advocate for use of the new device for their patients requiring urinary management (Fig.5).

Adverse events & areas of concern reported (percentage of applications) include: skin redness/irritation (10%), patient discomfort (9.8%), unsatisfactory urine flow (4.9%) and lack of patient acceptance (2.5%). Surveyed nurses were allowed to select as many adverse events and areas of concern as needed. Of note, there were no S/S of UTI attributed to the use of the new device (Fig.6).

Implications

The new device is attractive to HCPs due to ease of application, wear time, and potential to reduce the risk of CAUTI. The device may be able to replace condom catheters and reduce the unnecessary use of indwelling catheters, but challenges exist:

- Ensure adhesion of device is as consistent as possible to reduce instances of leaking
- Establish realistic expectations of performance to include approximately 24 hr wear time

The trial experience suggests that the device application and removal is not intuitive. The differences between proper and poor technique may be very subtle. Education regarding correct application is essential to successful application and wear time. Demand for this new product will be influenced by the need for a non-invasive alternative to current urinary management options as well as positive HCP and patient experiences. This will be facilitated by adequate training, use of proper technique and aggressive identification of appropriate patients.

References

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Acknowledgements

We would like to thank Eloquest Healthcare, Inc. for their support which included product, education, and 3rd party support for data aggregation and nurse surveys.