A comparative study of the efficacy and comfort of the Purewick™ male external catheter in healthy volunteers

#645

Adrian Wagg, Department of Medicine, University of Alberta, Edmonton, Alberta, Canada
Maria-Victoria Sena, Joulé Healthcare, Edison, N.J.,USA

Hypothesis / aims of study

Prolonged use of indwelling catheters is associated with urinary tract infection and urethral trauma in men. The use of an external urine collection device may avoid these complications. For males, condom catheters are an option for external drainage, however, there are limitations to their use. The increasing prevalence of men with a buried or hidden penis secondary to obesity or, in the acute hospital setting, with generalized oedema is an increasing problem. Obesity has a prevalence of up to 40.8% in middle-aged men in the United States and, in one series, 87% of men who went surgical management for their acquired buried penis was obese [1,2].

An alternative device, the PureWick male external catheter is intended for non-invasive urine output management in male patients may be suitable for use in obese men. There are no data on the performance of this device in men unable to use conventional condom catheters. This study sought to assess the efficiency of urine collection over two voids in a group of obese and non obese men.

Study design, materials and methods

In this prospective, post-market, crossover, single-blind, single center study, healthy male volunteers were randomized 1:1 to a treatment sequence using two devices (PureWick Male External Catheter and Sage PrimoFit) and were followed through 2 voids. Performance was defined *a priori* as the percentage capture of urine following a voluntary void.

Secondary aims comprised assessment of the performance of the system in men unable to use traditional sheath style condom catheters, participant comfort after using the device and health care providers' perspectives on ease of use in placing and removing the device, both measured by 5-point Likert scale.

Men had to be 18 years of age or older, to have the ability to speak and understand English, to adhere to the required study procedures and to independently void urine. Men with urinary incontinence which prevented spontaneous voiding; urinary retention, frequent episodes of bowel incontinence, any irritation, wound, open lesion, at the device application site, or on the genitalia, an inability to comply with study procedures independently were excluded. Approximately 50% of the men recruited were obese so that potential differences based on anatomy could be examined. Men were divided into non-morbidly obese men (BMI <40 kg/m^2) or morbidly obese men (BMI ≥40 kg/m^2). Participants were randomized 1:1 to one of the two treatment sequences. Randomization was stratified by non-morbidly obese or morbidly obese men.

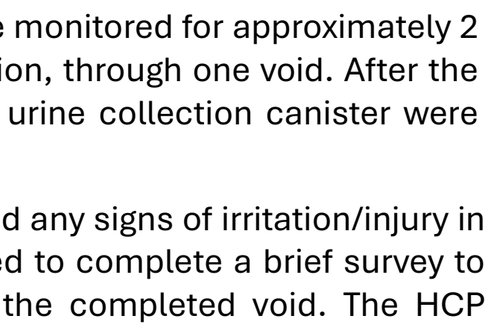
A sample size of 44 provided 90% power to detect a mean paired difference in capture rate of half of the standard deviation of the paired difference in capture rate of 5% using a two-sided paired t-test at significance level of 0.05.

Prior to arrival, participants were instructed to come to the study site with a full bladder. Once the participant felt need to void, depending on randomized treatment order, the HCP placed either the PureWick MEC or the Sage PrimoFit device. Participants were monitored for approximately 2 hours from the time of the device application, through one void. After the void, the pre-weighed absorbent pad and urine collection canister were reweighed.

The device was removed, and the HCP noted any signs of irritation/injury in the perineal area. The participant was asked to complete a brief survey to assess device comfort immediately after the completed void. The HCP completed a brief survey to assess device ease of use for the participant. Following process, participants were asked to drink and when the participant felt the need to void a second time, the HCP confirmed that the bladder volume was >125mL by portable bladder scanner. Void 2 was repeated using the 2nd device. Participant and HCP surveys were repeated.

Race, N (%)	
Black / African American	30 (50.8)
Native Hawaiian or other Pacific Islander	1 (1.7)
White	22 (37.3)
Not reported	1 (1.7)
Unknown	5 (8.5)
Weight, kg	
Mean (SD)	98.2 (26.5)
Median	92.1
Range	56.8-169.1
Height (cm)	
Mean (SD)	176.5 (8.04)
Median	175.3
Range	160.0-205.7
BMI, (kg/m^2)	
Mean (SD)	31.6 (8.6)
Median	28.4
Range	18.0-55.0
BMI ≤ 40, n(%)	44 (74.6)
BMI ≥ 40, n(%)	15 (25.4)
Buried penis	
Yes, n(%)	2 (3.4)
No, n(%)	57 (96.6)
Compatible with Traditional Sheath-style Catheter	
Yes, n(%)	57 (96.6)
No, n(%)	2 (3.4)

Table 1. Demographics



The PureWick external collection device

Results and interpretation

Fifty-nine men completed the study. The mean (standard deviation, SD) age of the men was 40.8 (SD12.4) years, with a median of 37.0 years. Other demographic variables are shown in Table 1. For void 1, the mean (SD) proportion of urine capture for the PureWick device was 97.8 (10.0) %, for the PrimoFit device this value was 90.7 (20.7)%. The mean (95% CI) difference between devices was 6.6 (0.18, 13.0) %, p=0.044. For the second void, the mean (SD) percentage capture was 91.1 (25.8)% for the PureWick device and 85.2 (21.7)% for PrimoFit. A 100% capture rate was seen for 39/59 (66.1%) of PureWick voids and 15/59 (25.4%) PrimoFit voids. For the morbidly obese men, for the first void, these figures were 99.7 (0.88) %, (PureWick) versus 83.5 (32.2) % (PrimoFit) and for the second void 80.8 (36.9) % (PureWick) and 79.3 (23.3) % (PrimoFit). To assess whether voided volume (weight) affected performance, the difference in the difference in mean voided urine weight (g) between devices was examined but no different, p=0.24. Given the generally lower voided weights in void 2, the difference in void weight between void 1 and 2 was assessed (mean (95%CI) difference, -63.8 (-127.7, 0.07)), but not different, p=0.05. These relationships held for the morbidly obese group. The scores for the participant comfort Scale and professional's ease of use scales are shown in Table 2. There were no adverse events reported in the study.

Participant Comfort Scale	PureWick MEC (N=38)	Sage PrimoFit (N=38)
How comfortable was the placement of the male external catheter? n,(%)		
1-Very Uncomfortable	2 (5.3)	3 (7.9)
2-Uncomfortable	0 (0.0)	2 (5.3)
3-Neither Comfortable nor Uncomfortable	5 (13.2)	6 (15.8)
4-Comfortable	9 (23.7)	11 (28.9)
5-Very Comfortable	22 (57.9)	16 (42.1)
Mean (SD)	4.3 (1.1)	3.9 (1.2)
Median	5.00	4.00
How comfortable was the device while voiding? n,(%)		
1-Very Uncomfortable	4 (10.5)	3 (7.9)
2-Uncomfortable	0 (0.0)	5 (13.2)
3-Neither Comfortable nor Uncomfortable	5 (13.2)	8 (21.1)
4-Comfortable	12 (31.6)	11 (28.9)
5-Very Comfortable	17 (44.7)	11 (28.9)
Mean (SD)	4.00 (1.3)	3.6 (1.3)
Median	4.00	4.00
How comfortable was the removal of the male external catheter? n,(%)		
1-Very Uncomfortable	1 (2.6)	2 (5.3)
2-Uncomfortable	2 (5.3)	3 (7.9)
3-Neither Comfortable nor Uncomfortable	10 (26.3)	6 (15.8)
4-Comfortable	14 (36.8)	12 (31.6)
5-Very Comfortable	11 (28.9%)	15 (39.5)
Mean (SD)	3.8 (1.0)	3.9 (1.8)
Median	4.00	4.00
How likely would you be to recommend the male external catheter to one of your loved ones? n,(%)		
1-Very Unlikely	5 (13.2)	7 (18.4)
2-Unlikely	2 (5.3%)	3 (7.9)
3-Neither Likely nor Unlikely	3 (7.9%)	4 (10.5)
4-Likely	7 (18.4)	9 (23.7)
5-Very Likely	21 (55.3)	15 (39.5)
Mean (SD)	3.9 (1.4)	3.6 (1.5)
Median	5.00	4.00

Table 2. User & HCP scales

Conclusions

There was a statistically significantly superior performance between the capture rate of the investigational device and the comparator device, regardless of voided volume (weight) order of void or BMI category. The median capture rate in morbidly obese men was higher for the PureWick device for both voids. Assessed by simple Likert Scale, healthcare professionals scored both devices as somewhat easy or easy to place in 56/59 (95%) of men. The men's opinions of ease of use of the PureWick system are in line with a recent report on patient and caregiver satisfaction with use of the system [3]. Strengths of this study include its controlled, comparative design with an adequately powered sample size but whilst intended to assess the utility of the PureWick device in men with buried penis, there were too few men with buried penis in the sample to make this assessment. The level performance of the device in morbidly obese men is, though, reassuring. This experimental study was a short-term assessment, under controlled conditions. Longer term, pragmatic studies of the use of the male device in real life clinical applications are required which take into account daily use and shifting position.

Concluding message

This single blind cross over study of the efficiency of urine capture showed a statistically significantly superior performance of the PureWick device in males versus a commercially available comparator. This relationship held regardless of voided urine volume and obesity status of the participating men

References

1. Prevalence of Obesity and Severe Obesity Among Adults: United States, 2017–2018, in NCHS Data brief 2020, Centres for Disease Control and Prevention, National Center for Health Statistics.
2. Curr Urol Rep, 2018. 19(3): p. 22.
3. Can J Urol, 2022. 29(4): p. 11216-11223

Disclosures

Funding Trial funded by Becton-Dickinson