
Patient and caretaker satisfaction with the PureWick system

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Introduction: The BD PureWick System (PureWick) allows for non-invasive management of urinary incontinence (UI) by using a low-pressure suction to wick urine from an external catheter into a collection canister. The purpose of this study was to assess satisfaction of using PureWick for management of UI in the outpatient setting based on patient and caregiver feedback.

Materials and methods: Patients and caregivers utilizing PureWick completed an online questionnaire between August and October 2020. Factors evaluated included demographics, satisfaction, recommendations, and claims using multiple choice questions, checklists, 6-point Likert Scale, and open-ended questions. Patient and caregiver responses were compared using the independent samples *t*-test and *z*-test.

Results: Of the 119 patients and 205 caregivers completing the questionnaire, > 80% indicated

satisfaction, comfort benefits, continued future use, and likelihood of recommendation despite > 70% reporting increased expense compared to diapers. Additionally, > 20% indicated sleep benefits. Compared to patients, caregivers found PureWick easier to use (3% vs. 20%, $p < 0.001$) and associated with less perceived UTI and skin infections (7% vs. 17%, $p = 0.008$). Claims, using the 6-point Likert Scale, with mean ratings ≥ 5 included PureWick being easy to set up, empty, clean, and, compared to diapers, requiring leaving the bed less to use the bathroom. Caregivers gave higher ratings than patients to claims on PureWick being easy to set up and allowing for feelings of increased rest the morning after use.

Conclusions: Patients and caregivers using PureWick in the outpatient setting reported convenience in managing UI, intended future use, and more satisfaction in comparison to adult diapers.

Key Words: urinary incontinence, lower urinary tract symptoms, nocturia, sleep quality, urinary tract infection

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Introduction

Urinary incontinence (UI) is one of the most common lower urinary tract symptoms (LUTS) in women, affecting an estimated 30%-51% of women.¹⁻³ The distribution of the major subtypes of UI differ, with more than half of the women experiencing

stress incontinence, a quarter experiencing urge incontinence, and the rest experiencing mixed and functional incontinence.^{4,5} Rarer causes of UI include postural incontinence, continuous incontinence, and coital incontinence.⁶ UI is considered one of the most bothersome LUTS, especially impacting quality of life.⁷ Since UI leads to body image concerns, avoidance of social settings, and other psychosocial effects, effective management of UI becomes important especially beyond the clinical setting.

Many strategies, including options for conservative management, medications, and surgery, exist for UI; however, these options may fail in some patients or patients may not be candidates for them.⁸ Most patients try conservative approaches such as scheduled voiding, fluid intake control, smoking cessation, caffeine reduction, pelvic floor muscle therapy, incontinence pads, or other containment devices.^{8,9} Patients and patient caretakers may not be satisfied with these approaches since they can be difficult to set up and maintain, negatively impact user feelings and experience, or be costly. Indwelling catheters may be utilized for all causes of UI but are plagued with issues, including the risk of catheter associated urinary tract infections (CAUTIs).

The PureWick device (BD, Franklin Lakes, NJ, USA), used by women, utilizes a continuous low-pressure suction to wick urine away from the body and into a canister.¹⁰ The BD PureWick Catheter system has been studied in the inpatient setting and has been found to reduce UTI rates and maintain skin integrity, and accurately quantify urine output.¹¹

The purpose of this study was to assess patient and caregiver satisfaction of using the BD PureWick System based on feedback.

Materials and methods

A cross-sectional study was done to assess patient and caregiver feedback on the BD PureWick System (PureWick). Caregivers were defined as anyone helping the patient with activities of daily life and had no specific professional training, therefore almost all were informal caregivers. All patients or caregivers that utilized a PureWick system in the home setting were recruited between August 2020 and October 2020. An online survey was sent during the time period by the manufacturer and respondents were included in the study; respondents identified as either patients or caregivers for the patients. Multiple caregivers for the same patient were not surveyed. Survey questions were chosen to understand product benefits and user experience. Standard research questions were used

for the survey questionnaire. Pre-alignment with regulatory, legal, and medical reviewers took place to review, revise, and approve survey questions and ensure construct, content, and face validity. Informed consent was obtained from survey participants and a gift card was provided for participation. IRB exemption was obtained (WCG #1-1487865-1).

The median time for completion of the survey was 6 minutes. Multiple choice and checklist questions assessed factors such as patient and caregiver demographics, length of time of care, reason for stopping PureWick (if stopped), time of daily use, level of mobility of user, other incontinence products used, and cost; the demographics and baseline characteristics questions asked to the caregivers were in reference to the patients they were caring for. A 6-point Likert Scale was used to assess PureWick satisfaction, recommendation to friends and family, continued use of PureWick in the future, and claims related to Purewick use (e.g., rested, dryness, attitude towards product, cleaning, set up, ease, sleep disruption, comfort, using bathroom, comparison to adult diapers, skin irritation, preference). All surveys were completed anonymously and no personally identifiable information on respondents was collected.

The main outcomes of interest were to assess patient experiences (by comparing impact on life, likelihood of continuing use, and recommending to others) with PureWick and agreement with key claims about PureWick among patients and caregivers. Data was compared between patients and caregivers to understand direct and indirect benefits of PureWick. Data analysis was conducted by grouping respondents by patient and caregiver status. The independent samples t-test was used to compare means and the independent samples z-test was used to compare percentages using WinCross and Q Research Software.

Results

The survey was sent to 3,388 patients. Of these, 324 patients and caregivers responded (9.6% response rate; 5.2% margin of error). This included 119 patients (112 current and 7 former users) and 205 caregivers (182 current and 23 former users). Average patient age was 75.5 years old. Majority (> 50%) of participants in both groups were current users, 65 and older, Caucasian, and retired. The majority also had limited mobility and prior history of use of adult diapers or absorbent sheets/pads. In terms of using PureWick, most of the participants had used it during nighttime (> 60%)

TABLE 1. Characteristics of survey respondents

| Characteristic | Patients, n (%) | Caregivers, n (%) | p value |
|------------------------------|-----------------|-------------------|---------|
| User status | | | |
| Current | 112 (94) | 182 (89) | .110 |
| Former | 7 (6) | 23 (11) | .110 |
| User age | | | |
| < 65 years | 35 (29) | 23 (11) | .000 |
| 65-79 years | 52 (44) | 80 (39) | .409 |
| ≥ 80 years | 32 (27) | 102 (50) | .000 |
| Race | | | |
| Caucasian | 96 (81) | 149 (73) | .106 |
| African American | 14 (12) | 20 (10) | .570 |
| Hispanic | 0 (0) | 11 (5) | .010 |
| Asian | 0 (0) | 6 (3) | .060 |
| American Indian | 2 (2) | 2 (1) | .580 |
| Other | 2 (2) | 1 (0) | .280 |
| No answer | 8 (7) | 21 (10) | .284 |
| Usage needs | | | |
| Day only | 3 (3) | 6 (3) | .830 |
| Night only | 87 (73) | 133 (65) | .126 |
| Day and night | 29 (24) | 66 (32) | .136 |
| Time of use | | | |
| < 3 months | 36 (30) | 86 (42) | .036 |
| 3-5 months | 60 (50) | 88 (43) | .192 |
| 6-8 months | 11 (9) | 14 (7) | .432 |
| 9-11 months | 0 (0) | 2 (1) | .280 |
| ≥ 1 year | 3 (3) | 5 (2) | .963 |
| Not currently using | 9 (8) | 10 (5) | .321 |
| Level of mobility of patient | | | |
| Limited mobility | 63 (53) | 138 (67) | .010 |
| Full mobility | 46 (39) | 28 (14) | .000 |
| Immobile | 10 (8) | 39 (19) | .010 |
| Prior product used | | | |
| Adult diapers | 70 (59) | 157 (77) | .001 |
| Absorbent sheets/pad | 79 (66) | 146 (71) | .363 |
| Protective underwear | 56 (47) | 75 (37) | .064 |
| Medication | 26 (22) | 33 (16) | .196 |
| Surgery | 9 (8) | 6 (3) | .056 |
| Foley catheter | 5 (4) | 10 (5) | .780 |

and for 3-5 months (> 40%), Table 1. In statistically comparing these characteristics between patients and patients being taken of by caregivers, more patients were present in both the < 65 years age (29% vs. 11%) and employed groups (4% vs. 0%) while more patients taken care of by caregivers were present in the ≥ 80 years age (50% vs. 27%), Hispanic (5% vs. 0%), and retired groups (72% vs. 58%). In addition, more patients were

present in the full mobility group (39% vs. 14%) and more patients taken care of by caregivers were present in the limited mobility (67% vs. 53%) and immobile (19% vs. 8%) patient groups. More patients taken care of by caregivers had used adult diapers for management compared to patients (77% vs. 59%), Table 1.

In evaluation of user experience for patients, 36% reported sleep benefit (improved quality of sleep), 27%

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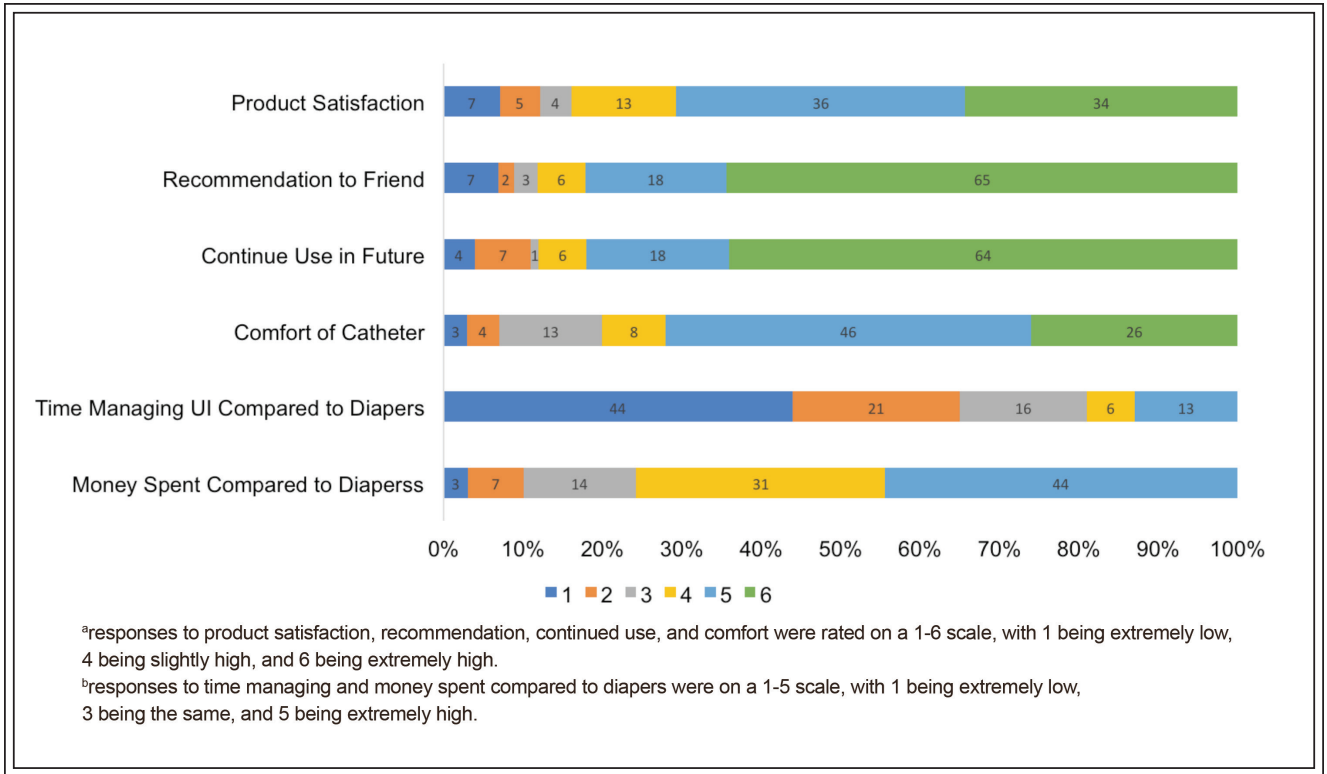


Figure 1. Patient ratings of product experience.

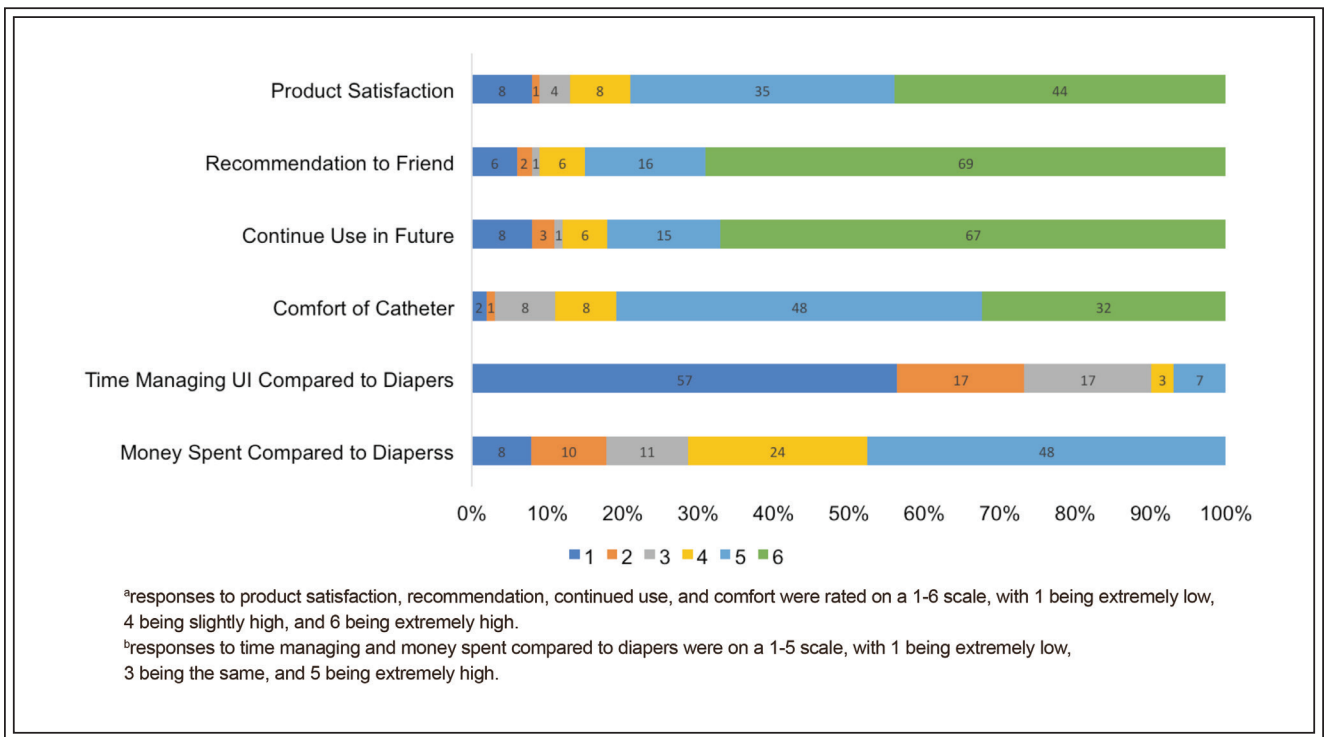


Figure 2. Caregiver ratings of product experience.

found that there was an improvement in staying dry, and 76% continued use of diapers with PureWick, Table 2. Using the 6-point Likert Scale, patients indicated at least satisfaction (83%), likelihood of recommendation to friend (89%), continued use of PureWick in the future (88%), at least slight comfort (80%), less time managing UI compared to using diapers (65%), using the product at night (73%) over all day (24%) and saving ≥ 3 hours (33%), Tables 1 and 2. However, most patients reported continued concurrent diaper use (76%) and spending more money compared to diapers (75%), Figure 1.

For patients being taken care of by caregivers, sleep benefits were noted for 14% of patients and 23% of caregivers. In addition, these caregiver-dependent patients found that the product helped them stay dry (18%) but required continued use of diapers (78%), Table 2. Using the 6-point Likert Scale, caregivers indicated slight satisfaction (87%), likelihood of recommendation to a friend (91%), continued use of PureWick in the future (88%), at least slight comfort (88%), less time managing UI compared to using diapers (74%), using the product at night (65%) over all day (32%) and saving ≥ 3 hours using PureWick (34%). However, most caregivers reported continued concurrent diaper use for the patients (78%) and

spending more money compared to diapers (72%), Figure 2.

Altogether, $\leq 5\%$ of participants found benefits in increasing peace of mind. Respondents who stopped PureWick use, and indicated a reason, did so because they no longer needed an incontinence product (3% patients, 1% caregivers), switched to a different product (4% patients, 2% caregivers), or the person under the care passed away (2% caregivers). In comparing user experience between patients and caregivers, more caregivers found benefit for ease of use (20% vs 3%) and noted less UTI and skin infections in their patients (17% vs. 7%), Table 2.

Patients and caregivers rated several claims relating to PureWick on a 6-point Likert Scale, with 1 representing strongly disagree and 6 representing strongly agree, which were averaged and compared between patients and caregivers, Table 3. All claims had a mean rating of ≥ 4 , meaning that participants on average showed some level of agreement on all claims. Claims with mean ratings ≥ 5 included PureWick being easy to set up, empty, clean, and, in comparison to diapers, not requiring patients to get out of bed as much to void. In addition, caregivers gave higher ratings to claims on PureWick being easy to set up, allowing for more personal rest, and being easy to place into position.

TABLE 2. User experience with PureWick

| Experience parameter | Patients | Caregivers | p value |
|--|----------|------------|---------|
| Sleep benefit (patient), n (%) | 43 (36) | 29 (14) | .000 |
| Sleep benefit (caregiver), n (%) | 3 (3) | 47 (23) | .000 |
| Staying dry, n (%) | 32 (27) | 37 (18) | .061 |
| Easy to use, n (%) | 3 (3) | 42 (20) | .000 |
| Less infections (UTIs and skin), n (%) | 8 (7) | 35 (17) | .008 |
| Less nighttime bathroom trips, n (%) | 9 (8) | 10 (5) | .321 |
| Peace of mind, n (%) | 3 (3) | 11 (5) | .225 |
| No diaper or pads needed, n (%) | 6 (5) | 8 (4) | .627 |
| Too expensive, n (%) | 3 (3) | 6 (3) | .830 |
| Continued use of diapers, n (%) ^a | 53 (76) | 122 (78) | .741 |
| Time saved using PureWick | | | |
| < 0.5 hours | 5 (11) | 12 (10) | .935 |
| 0.5-1 hours | 8 (17) | 27 (23) | .398 |
| 1-2 hours | 12 (26) | 22 (19) | .329 |
| 2-3 hours | 6 (13) | 15 (13) | 1.000 |
| ≥ 3 hours | 15 (33) | 39 (34) | .874 |

^a% is representative of patients that used diapers previously

TABLE 3. Average agreement with key claims about PureWick

| Claim ^a | Patients | Caregivers | p value |
|--|------------|------------|---------|
| PureWick system is easy to set up | 5.3 (1.10) | 5.5 (0.80) | .022 |
| PureWick canister is easy to empty | 5.1 (1.13) | 5.3 (1.01) | .093 |
| PureWick canister is easy to clean | 5.2 (1.04) | 5.1 (1.15) | .763 |
| PureWick system is quiet enough to not disturb user's sleep | 4.9 (1.43) | 5.0 (1.35) | .609 |
| I feel rested in the morning after using PureWick | 4.7 (1.46) | 5.0 (1.13) | .019 |
| Since the person I care for started using PureWick, I look forward to starting the day | 4.5 (1.47) | 4.8 (1.20) | .047 |
| PureWick Female External Catheter is easy to place into position | 4.3 (1.67) | 4.7 (1.27) | .019 |
| Claims on comparison to adult diapers | | | |
| Using PureWick is more dignified | 4.9 (1.52) | 5.2 (1.17) | .110 |
| Patient is not as concerned about limiting liquids before bed | 5.0 (1.47) | 4.9 (1.39) | .739 |
| Patient feels less embarrassed | 4.7 (1.43) | 4.5 (1.51) | .539 |
| PureWick is more preferred | 5.0 (1.49) | 4.9 (1.55) | .916 |
| PureWick disturbs sleep less | 4.6 (1.51) | 4.4 (1.41) | .397 |
| PureWick causes less skin irritation | 4.6 (1.56) | 4.8 (1.38) | .349 |
| Patient does not have to get out of bed to use the bathroom as often | 5.0 (1.63) | 5.3 (1.32) | .172 |
| Patient is more satisfied with PureWick | 4.8 (1.49) | 4.9 (1.44) | .746 |
| Using PureWick gives more confidence in managing incontinence | 4.8 (1.57) | 4.8 (1.41) | .926 |
| PureWick is easier to use | 4.6 (1.67) | 4.9 (1.38) | .210 |

^aclaims were rated on a scale of 1-6 (1 = strongly disagree, 2 = disagree, 3 = somewhat disagree, 4 = somewhat agree, 5 = agree, 6 = strongly agree) and the score was averaged

Discussion

Management of UI can be challenging, with factors impacting management ranging from practical factors like cost, time, or psychosocial factors.⁷⁻⁹ The present study aimed to evaluate the experiences of patients and caregivers in the home setting with the PureWick System. While previous inpatient studies have shown that PureWick improves safety (by reducing UTIs and maintaining skin integrity),^{10,11} we demonstrated how PureWick can have an overall positive impact from the user and caregiver perspective in the home setting. PureWick was easier to use and saved time in management compared to adult diapers, which may ease the burden of UI. In addition, for healthier older adults facing UI, saving time is an important factor to consider since they are generally busier with tasks and

increasingly continue to be involved in the workforce in the past decade.¹³ However, using PureWick was also considered to be more expensive compared to diapers, which means that it may be less accessible to patients.

The benefits of PureWick extend to comfort in the patients. There was an improvement noted in the sleep quality, which is especially important since sleep disruption impacts quality of life for patients with UI, especially due to a need to use the bathroom or waking up from moisture accumulation in diapers.¹⁴ Patients often limit fluid intake to limit bathroom trips at night,⁹ but we saw that patients were less concerned about limiting this fluid intake due to the improved sleep quality and less skin irritation with PureWick use. This is important for safety in older adults, who may have higher prevalence of nocturia.¹⁵ More patients that used PureWick were in the full mobility group, which means

that there were some patients who used PureWick over toileting as a management option; further work should look to compare PureWick to other management options to evaluate potential reasons for preference.

About 17% of caregivers noticed that the patients they were caring for had less symptoms of UTIs and skin infections, which agrees with a previous study of the product.¹¹ A greater proportion of caregivers saw reduced rates of infections, suggesting that caregivers played a more active role in understanding the use of the product and may be potentially involved at healthcare visits. The health benefits extend to psychological factors; there was less embarrassment about UI experienced in patients when they were asked to compare using PureWick to their experience with diapers. The psychological stressors of UI can significantly impact quality of life in patients and easing these stressors allow for a more positive outlook on disease management.⁶ Nevertheless, only about 5% of patients and caregivers answered that they had peace of mind managing their UI using PureWick, suggesting that while PureWick use can have some benefits, it cannot eliminate all psychosocial elements associated with the condition.

While PureWick was considered to be a better alternative to diaper use in participants, it did not completely eliminate diaper use for more than 75% of patients, likely due to the PureWick cannot be used while the patient is ambulatory. In addition, despite the reduced use of diapers with PureWick, patients and caregivers found using PureWick to be more costly. This demonstrates a potential drawback and therefore not want to switch from using the less expensive methods of management.^{8,9} Nevertheless, patients and caregivers indicated that they would continue use of the product into the future and even recommend it to others, signifying the positive experience outweighed the costs.

There are several limitations to this study, including all those that would be present in a cross-sectional survey analysis and it being a primarily short term use study (most respondents had used the products for < 6 months). While the study can show some correlations in data, it can't establish any direct causations from use of PureWick. In addition, there is a potential for socioeconomic selection bias because PureWick is not covered by all insurers, including Medicare, for home use, which means that participants in lower socioeconomic groups are likely underrepresented in the study; therefore, findings may not be generalizable to all populations. While many patients indicated satisfaction with product use, not as high percentages were seen for any of the benefits, implying that no single benefit can be pointed to as the single important factor in improving patient experience. Similarly, while many users reported

sleep benefits, a lower percentage reported less bathroom trips, which opens up the possibility for other reasons for the sleep benefits that must be investigated. Additionally, questions were based in self-assessment of users and impression of caregivers rather than on measured results (e.g., sleep tracking, number of pads), limiting the amount of quantitative analysis that could be done. Those choosing to participate may have had overtly positive or negative experiences. Similarly, former users were less likely to complete the survey which can impact perspectives on the product. Recruitment by email and the use of an online survey meant that participants who have difficulty with the use of online resources may not have participated, leading to underrepresentation of these participants. The lower response rate may also result in nonresponse bias, although research has shown that the costly pursuit of a higher response rate often offers minimal to no reduction in nonresponse bias.¹⁶ Additional factors that may impact use of PureWick (e.g., BMI) or its efficacy (e.g., treatment changes) were not measured and may have led to modifications of the trends noted. Lastly, by not having data on UI subtypes, we were not able to assess whether benefits of PureWick differs by the type of UI.

Despite these limitations, the study assesses the experience with PureWick for UI management from the perspective of both the patient and caregiver. We were able to identify a variety of factors that impacted user experience and quantified the strength of the findings. We also evaluated how the product compared to diapers, and found that PureWick, despite being more expensive, was easier to set up and saved from at least 0.5 hours to more than 3 hours for the cohort.

Conclusions

Patients and caregivers using PureWick in the home setting reported more convenience in managing UI, improved sleep. Users were more satisfied with PureWick compared to adult diapers.

Disclosure

Dr. Bilal Chughtai is a consultant for Becton, Dickinson, and Company. All other authors do not have disclosures. □

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