International Journal of Science and Research (IJSR)
ISSN: 2319-7064
SJIF (2022): 7.942

Exploring the Use of a Novel Remote Monitoring Device to Evaluate Storage Symptoms in Patients with Benign Prostatic Hyperplasia from At-Home Uroflows and Frequency Volume Charts

Gregg R. Eure[1], Jamie Giovanelli[2], Samay Sappal[3], Daniel Godelfer[4], Ilya Sobol[5]

[1]Department of Urology, University of Virginia, Culpeper, VA, USA
Email: greure[at]me.com

[2, 3, 5]Urology of Virginia PLLC, Virginia Beach, VA, USA

[4]Dabl Solutions LLC, Alexander, AR, USA

Abstract: ***The purpose of this study is to evaluate storage symptoms in men with benign prostatic hyperplasia (BPH) from uroflow and frequency-volume data collected using the CarePath remote monitoring device. A total of 5,197 voids were analyzed across 576 men with BPH during a 24-hour period. An exploratory retrospective analysis was performed to summarize void characteristics for men with and without urinary frequency. Approximately 52% of men were found to have urinary frequency (>8 voids in 24 hours) and 93% of these had nocturia (≥1 nighttime void). Men with urinary frequency had a lower peak flow rate (average daytime Qmax 10.5 ml/s vs 12.7 ml/s) and voided smaller volumes (average daytime void volume 142.1 ml vs 178.4 ml) compared to those without urinary frequency. Home uroflow devices that facilitate studies over a 24-hour period can provide insights into male voiding patterns and supplement the clinical diagnostic process.***

Keywords: remote monitoring, uroflowmetry, overactive bladder, lower urinary tract symptoms, benign prostatic hyperplasia

1. Introduction

Overactive bladder (OAB) has been defined as urinary urgency, with or without urinary incontinence, usually with frequency and nocturia, in the absence of proven infection or other obvious pathology [1]. The prevalence of OAB in adult men has been estimated at 11-16% and increases with age [2, 3]. This chronic condition significantly impacts quality of life, with nocturia reported as one of the most bothersome symptoms [4].

In men, OAB is often under-recognized and undertreated. Lower urinary tract symptoms (LUTS) are typically associated with prostatic obstruction as the prevalence of both LUTS and benign prostatic hyperplasia (BPH) increase with age. The diagnosis of OAB in men is further complicated by the concurrent presence of both storage and voiding symptoms, making it difficult to distinguish between BPH and OAB. While BPH is characterized by voiding problems (e.g., urinary hesitancy, weak stream, terminal dribble), storage problems typical of OAB (e.g., urgency, frequency, nocturia) can also occur. The rate of coexisting bladder outlet obstruction (voiding problems) and OAB (storage problems) has been reported in approximately 45-75% [5-8]. A potential bias toward a BPH diagnosis and the large overlap of symptoms has likely led to the potential undertreatment of OAB for men with overlapping symptoms [3, 9].

Frequency volume charts (FVC) and bladder diaries are noninvasive, simple assessment tools to evaluate symptoms and can aid in the diagnosis and management of OAB [10-12]. Data from FVCs include daytime and nighttime voiding frequency, total voided volume, and volume of individual voids. While paper-based or digital diaries have often been used to document this information, data collection can be cumbersome and patient compliance can be a problem. Remote diagnostic devices can aid in the automation of data collection and improve convenience by simplifying the patient experience. Such technologies can provide clinicians with a summary of voiding behavior to inform patient management. The aim of this exploratory analysis was to evaluate the presence of storage symptoms in men with BPH utilizing frequency-volume data collected with an at-home uroflow device.

2. Materials and Methods

The CarePath device (iO Urology, Knoxville, TN, USA) has been developed to collect data on multiple naturally occurring voids throughout the day which can be performed over several days or weeks (Figure 1). The device consists of a handle and a bucket that is disposed of after patient evaluation is complete. It is simple to use, with no buttons, no charging, and no upfront preparation required. Data recording starts automatically when liquid is detected passing through the unit. The device is rinsed with water and stored in its pouch after each use. Utilizing accelerometers and a high-precision liquid float, the device allows for accurate, high resolution inflow measurements for flows up to 40 ml/s. Information from calibrated instruments indicate that the device can achieve accuracy of within ±1% for flow and ±5% for volume measurements. An embedded cellular connection allows

summary reports to be sent directly to a patient's electronic medical record or uploaded to a web portal for immediate clinician review. Previous experience with the device has shown that data collected over a 24-hour period can provide a reasonable estimate of uroflow variability and similar average peak flow rate (Qmax) compared to data collected over several days or weeks [13]. This study expands on the previously published data set to provide additional insights into male voiding behavior based on urinary frequency.

Figure 1: CarePath device including disposable bucket and handle

Newly diagnosed and follow-up adult male patients with BPH who had not had a flow study in the last year were prescribed the remote monitoring device at 2 urological clinics in the US. Men were instructed to void normally into the device and to use the device to collect all voids within one 24-hour period, with at least one void collected on all other study days. Data from the 24-hour period was analyzed in this study. Daytime and nighttime voids were summarized based on patient-specific wake times and bedtimes provided by each individual. De-identified data was available for analysis utilizing a proprietary algorithm.

A cut-off of approximately 8 voids per 24 hours is generally used to define urinary frequency [3, 11, 14]. Therefore, daytime and nighttime frequency, volume, and flow rate were summarized for patients reporting more than 8 voids within 24 hours compared to those reporting 8 or fewer voids. Voiding parameters were first averaged within subjects and then data was averaged over all patients and summarized with descriptive statistics. To assess impact of age, patients were divided into five groups and void characteristics were then evaluated by frequency subgroup (≤8 vs >8 voids per day).

3. Results

Void data was collected from adult men with BPH from October 2021 to April 2024. A total of 5,197 void segments were identified and evaluated across 576 men during a 24-hour period. Approximately 52% (299/576) of men were found to have urinary frequency (>8 voids per 24-hour period). The average age was 66.9 (SD 8.9) and 67.8 (SD 8.2) for the group without and with urinary frequency, respectively. The group of men with urinary frequency had a greater number of both daytime and nighttime voids, had a lower Qmax (which may be suggestive of obstruction), and voided smaller volumes compared to men classified as not having urinary frequency (Table 1). Based on these findings, we developed a metric of the ratio of average Qmax to the number of voids as a potential measure of obstruction and overactivity which was found to be lower in men with storage symptoms: 0.9 vs 2.6 (Table 1).

Table 1: Void Characteristics in Men With and Without Urinary Frequency

Characteristic	*≤8 Voids in 24 Hours*	*>8 Voids in 24 Hours*
Number of patients	277	299
Age (years)	66.9 ± 8.9	67.8 ± 8.2
Mean Qmax/# of Voids	2.6 ± 2.4	0.9 ± 0.4
Wake time voids		
Number of voids	4.5 ± 1.6	9.1 ± 3.0
Qmax (ml/s)	12.7 ± 5.3	10.5 ± 4.2
Void volume (ml)	178.4 ± 85.5	142.1 ± 64.6
Void duration (s)	29.2 ± 11.2	27.8 ± 9.8
Nighttime voids		
Number of voids	1.9 ± 1.0	3.1 ± 1.8
Qmax (ml/s)	12.3 ± 5.8	10.0 ± 1.8
Void volume (ml)	215.3 ± 110.9	177.4 ± 92.9
Void duration (s)	37.3 ± 17.8	37.1 ± 16.0

The vast proportion of men with urinary frequency were classified as having nocturia, defined as waking up to void one or more times during the night (93%, 279/299); in addition, 78% (232/299) recorded at least 2 voids during the night compared to 47% (129/277) in the group of men without urinary frequency [1].

Men were split into five different age groups (<60, 61-65, 66-70, 71-75, and >75 years) and void parameters were examined by urinary frequency group. Trends within each age group were similar to those reported for the overall cohort, namely, more frequent daytime and nighttime voiding with lower volumes in the urinary frequency cohort (Figure 2). A qualitative comparison across age groups indicates a greater number of nighttime voids and lower Qmax with increasing age.

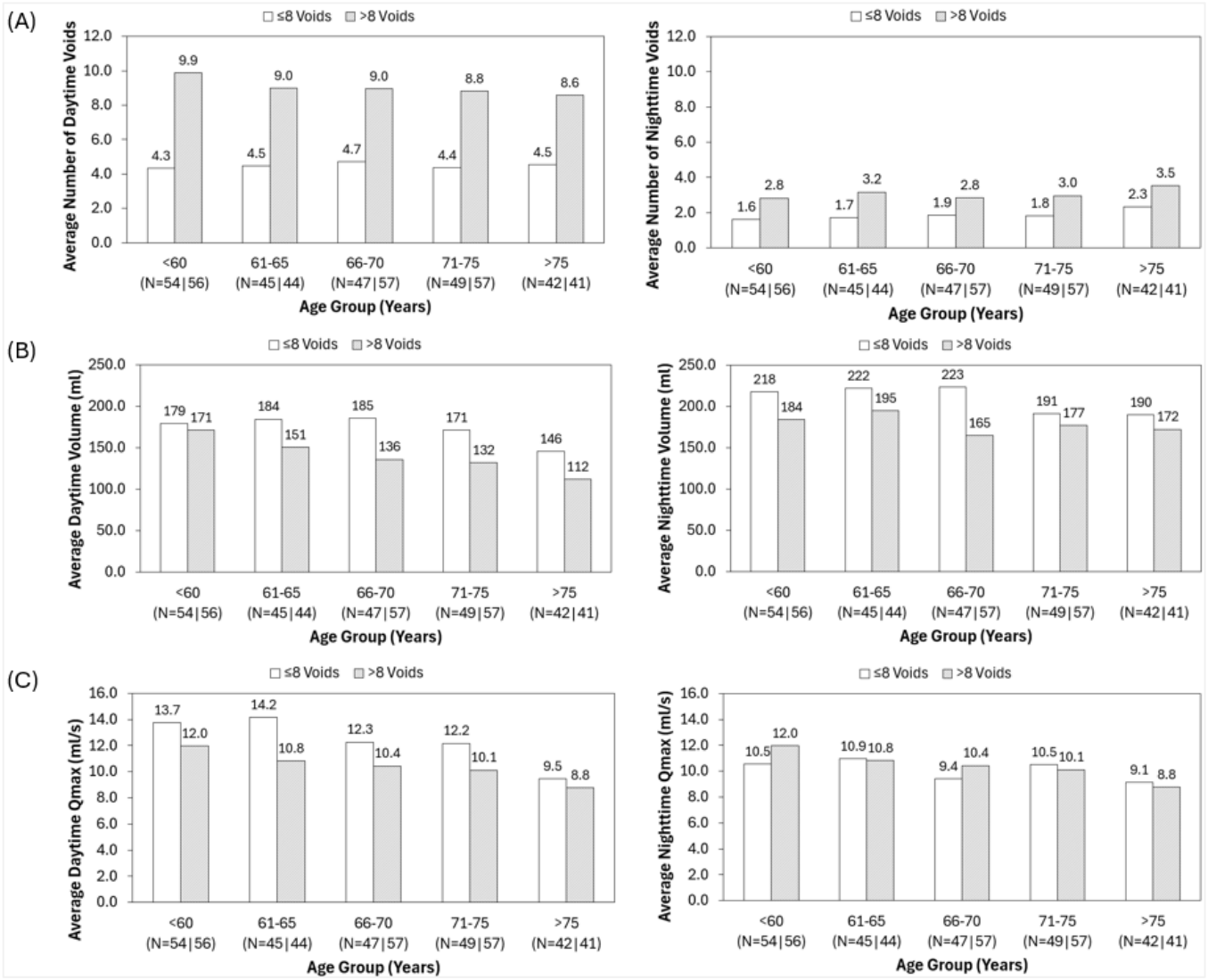

Figure 2: (A) Daytime and nighttime frequency, (B) volume and (C) Qmax by age subgroup

4. Discussion

In a group of men with a BPH diagnosis that received a home uroflow device, over half (52%) recorded more than 8 voids in 24 hours and were classified as having urinary frequency. This subgroup of men voided more during the daytime and nighttime, had lower Qmax, and voided lower volumes compared to the group of men voiding 8 or fewer times in 24 hours. Data from home uroflow devices with the ability to capture multiple voids over 24-hours or longer can provide insights into urinary habits to inform the clinical diagnostic process.

While several other home uroflow devices are available to record frequency volume charts or bladder diaries, they may be more difficult to use, reducing patient compliance for studies requiring data for 24-hours or longer. These technologies require placing devices in the toilet or setting up a receptable to collect void data, require assembly prior to use, require the use of batteries, or must remain in or close to the toilet between uses [15-18]. On the other hand, the device used in the study is hand held and requires no upfront preparation or charging by the patient, the device detects the start of a void automatically, and summary reports are sent directly to the clinician for review. Such a home uroflow tool may remove barriers to patient compliance that may be present when using paper or digital frequency volume charts or bladder diaries.

Both BPH and OAB are common causes of LUTS, increase in prevalence with age, and may have a similar clinical presentation, including nocturia, frequent micturition, and dribbling. The main trends observed in this study are similar to trends reporting in studies evaluating BPH and OAB, including lower voided volumes in those with BPH+OAB compared to those with BPH alone [6, 19]. Bladder outlet obstruction during voiding that can occur in patients with BPH is characterized by increased detrusor pressure and reduced urinary flow rate. On the other hand, OAB is characterized by detrusor overactivity based on urodynamics with involuntary detrusor muscle contractions during the filling phase and is often associated with bladder outlet obstruction and benign prostatic enlargement. Structural changes to the bladder as a result of benign prostatic obstruction, aging, or neurogenic insults may lead to bladder wall hypertrophy, progressive denervation, and heightened detrusor muscle excitability resulting in OAB symptoms [20]. A stiffer bladder wall may lead to reduced voided volumes and heightened excitability

can result in urinary frequency as observed in the cohort of men with greater than 8 voids in this study.

Due to overlapping symptoms, BPH with OAB may present in a similar fashion or in varying degrees of each condition contributing to the overall patient clinical presentation. It is important to make an accurate diagnosis, as different treatment strategies may be used to target different symptoms and/or conditions [10]. Further, while voiding problems may be present, storage symptoms such as urgency, frequency, and nocturia have been shown to be more bothersome to men; these symptoms tend to be more disruptive to everyday life or cause social embarrassment [4, 21]. Therefore, such symptoms may potentially be more important to address when creating a patient treatment plan. Given the undertreatment of male OAB reported in several studies, use of home uroflow devices that facilitate accurate measurement of urinary frequency and volume in a normal environment can provide useful information to aid in better understanding of male voiding patterns to supplement clinical diagnostic information [9, 22].

The hallmark symptom of OAB per the International Continence Society definition is urgency which cannot be evaluated utilizing the device, but rather relies on patient self-report or can be captured via bladder diaries or questionnaires. On the other hand, frequency and volume are accurately captured with the device which can inform the clinician on patient voiding behavior for consideration in their patient evaluation. In other studies, it was uncommon to find urgency as an isolated symptom in OAB, but rather frequency or nocturia in addition to urgency were the more prevalent OAB symptoms [3, 14]. Urodynamic or other physiological data were not available for men included in this study to inform bladder status. The retrospective study design and lack of information on symptom severity further limits interpretation of the results. Future studies may evaluate use of the remote monitoring device and the potential utility of the Qmax to void ratio prospectively to determine whether uroflow and frequency-volume information collected with the device can help in patient diagnosis, treatment, and care management decisions.

5. Conclusion

Home uroflow devices that enable studies over a period of 24 hours or longer can provide insights into male voiding patterns and provide supplemental information to inform the clinical diagnostic process.

References

[1] Abrams P, Cardozo L, Fall M, et al. The standardisation of terminology in lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. Urology. 2003;61(1):37-49.
[2] Eapen RS, Radomski SB. Review of the epidemiology of overactive bladder. Res Rep Urol. 2016; 8: 71-76.
[3] Milsom I, Abrams P, Cardozo L, Roberts RG, Thuroff J, Wein AJ. How widespread are the symptoms of an overactive bladder and how are they managed? A population-based prevalence study. BJU Int. 2001;87(9):760-766.
[4] Van Dijk MM, Wijkstra H, Debruyne FM, De La Rosette JJ, Michel MC. The role of nocturia in the quality of life of men with lower urinary tract symptoms. BJU Int. 2010;105(8):1141-1146.
[5] Irwin DE, Milsom I, Kopp Z, Abrams P, Artibani W, Herschorn S. Prevalence, severity, and symptom bother of lower urinary tract symptoms among men in the EPIC study: impact of overactive bladder. Eur Urol. 2009; 56(1):14-20.
[6] Knutson T, Edlund C, Fall M, Dahlstrand C. BPH with coexisting overactive bladder dysfunction--an everyday urological dilemma. Neurourol Urodyn. 2001; 20(3):237-247.
[7] Abrams P. Detrusor instability and bladder outlet obstruction. Neurourol Urodyn. 1985;4:317-328.
[8] de Nunzio C, Franco G, Rocchegiani A, Iori F, Leonardo C, Laurenti C. The evolution of detrusor overactivity after watchful waiting, medical therapy and surgery in patients with bladder outlet obstruction. J Urol. 2003;169(2):535-539.
[9] Burnett AL, Walker DR, Feng Q, et al. Undertreatment of overactive bladder among men with lower urinary tract symptoms in the United States: A retrospective observational study. Neurourol Urodyn. 2020;39(5):1378-1386.
[10] Gacci M, Sebastianelli A, Spatafora P, et al. Best practice in the management of storage symptoms in male lower urinary tract symptoms: a review of the evidence base. Ther Adv Urol. 2018;10(2):79-92.
[11] Leron E, Weintraub AY, Mastrolia SA, Schwarzman P. Overactive bladder syndrome: Evaluation and management. Curr Urol. 2018;11(3):117-125.
[12] Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA guideline amendment 2023. J Urol. 2024;211(1):11-19.
[13] Kaplan SA, Molnar GC, Shen J, Eure GR. The role of remote diagnostics to better assess uroflow variability: insights from combining at home uroflows and frequency volume charts from 19,868 voids using a novel, hand held, cellular embedded device. Urology. 2024:S0090-4295(24)00294-2. Epub ahead of print.
[14] Irwin DE, Abrams P, Milsom I, Kopp Z, Reilly K, Group ES. Understanding the elements of overactive bladder: questions raised by the EPIC study. BJU Int. 2008;101(11):1381-1387.
[15] Chun K, Kim SJ, Cho ST. Noninvasive medical tools for evaluating voiding pattern in real life. Int Neurourol J. 2017;21(Suppl 1):S10-16.
[16] Porru D, Scarpa RM, Prezioso D, Bertaccini A, Rizzi CA, Group HS. Home and office uroflowmetry for evaluation of LUTS from benign prostatic enlargement. Prostate Cancer Prostatic Dis. 2005;8(1):45-49.
[17] De La Rosette JJ, Witjes WP, Debruyne FM, Kersten PL, Wijkstra H. Improved reliability of uroflowmetry investigations: results of a portable home-based uroflowmetry study. Br J Urol. 1996;78(3):385-390.

[18] El Helou E, Naba J, Youssef K, Mjaess G, Sleilaty G, Helou S. Mobile sonouroflowmetry using voiding sound and volume. Sci Rep. 2021;11(1):11250.
[19] Oelke M, Baard J, Wijkstra H, de la Rosette JJ, Jonas U, Hofner K. Age and bladder outlet obstruction are independently associated with detrusor overactivity in patients with benign prostatic hyperplasia. Eur Urol. 2008;54(2):419-426.
[20] Dmochowski RR, Gomelsky A. Overactive bladder in males. Ther Adv Urol. 2009;1(4):209-221.
[21] Peters TJ, Donovan JL, Kay HE, et al. The International Continence Society "Benign Prostatic Hyperplasia" Study: the botherosomeness of urinary symptoms. J Urol. 1997;157(3):885-889.
[22] Helfand BT, Evans RM, McVary KT. A comparison of the frequencies of medical therapies for overactive bladder in men and women: analysis of more than 7.2 million aging patients. Eur Urol. 2010;57(4):586-591.

Author Profile

Gregg R. Eure, MD is a urologist who specializes in adult urology and men's health. His expertise includes treatments for benign prostate hyperplasia (BPH), including minimally invasive and laser techniques. He is a consultant for several medical equipment companies and the author of numerous book chapters and articles. He has served on several advisory and editorial boards and frequently lectures on various topics in urology, especially BPH. After earning an undergraduate degree from the University of Virginia, he completed his general surgery training at the Medical College of Virginia and a urology residency at the Eastern Virginia Graduate School of Medicine. He was also associate professor of urology at the Eastern Virginia Medical School and now practices at UVA Health Culpeper Medical Center.

Jamie Giovanelli, PA-C, Urology of Virginia. Virginia Beach, Virginia. Jamie completed her Physician Assistant studies at Eastern Virginia Medical School. Prior to attending EVMS, she worked in the emergency room and volunteered as an EMT for the City of Virginia Beach. Jamie is dedicated to her community and has always taken pride in volunteering to serve others. After initially completing a master's degree in teaching, her passion for medicine eventually pulled her out of the classroom to allow her to prepare for her career as a physician assistant. She is now primarily focused on BPH and has become the lead BPH advanced practice provider (APP) within her practice. She is a consultant for Teleflex and has focused on educating APPs throughout the nation on the importance of BPH and bladder health in aging men.

Samay Sappal, MD earned his medical degree from the Medical College of Virginia and went on to complete his residency in urology at Penn State Health in Hershey, Pennsylvania. He is trained in the evaluation and treatment of all benign and malignant diseases of the prostate, bladder, and kidneys. Dr. Sappal's clinical interests include medical and surgical management of stone disease, multi-modal treatment of enlarged prostates, comprehensive care for urinating dysfunction, and performing stress-free vasectomies. Dr. Sappal offers Holmium Laser Enucleation of the Prostate (HoLEP), a procedure for benign enlargement of the prostate particularly suited for treating men with very large prostates or complete inability to urinate. Dr. Sappal's philosophy is to provide high level urologic care with compassion and his patients' wellbeing always at the forefront.

Daniel Godelfer is a data architect at IO Urology. Daniel has over two decades of experience working with data through all facets of its generation, transport, analysis, and consumption. Shortly after completing his master's degree in computer science from the University of Arkansas at Little Rock, he began to expand his skillset into 3D CAD modeling and design. When Daniel is not designing a data centric analytics environment, he can be found machining metal or 3D printing product prototypes. Daniel truly enjoys merging the digital world of data and the physical world of manufacturing and product design.

Ilya Sobol, MD, an assistant professor at Eastern Virginia Medical School (EVMS), specializes in endourology with a focus on BPH and kidney stone disease. Having had the opportunity to perform over 500 HoLEP procedures, Dr. Sobol continually strives to enhance patient care through ongoing learning and practice. He is grateful for the chance to contribute to several research projects and finds fulfillment in mentoring aspiring urologists.