Received: 7 October 2021 | Revised: 8 December 2021 | Accepted: 4 January 2022

DOI: 10.1111/luts.12426

ORIGINAL ARTICLE

WILEY

Freeflow: The novel portable uroflowmeter can help to realize practical urinary conditions at home

Shinobu Kato[1] | Hajime Watanabe[1] | Kotaro Yamasue[2]

[1]Medical Cooperation Kato Urological Clinic, Hiratsuka, Japan

[2]Public Health and Preventive Medicine, Yokohama City University Graduate School of Medicine, Yokohama, Japan

Correspondence
Kotaro Yamasue, Yokohama City University Graduate School of Medicine, 3-9 Fukuura, Kanazawa-Ku, Yokohama, 236-0004, Japan.
Email: yamasuek@yokohama-cu.ac.jp

Abstract

Objectives: To evaluate the effectiveness of a novel portable urine flowmeter, Freeflow, for examining the actual state of urination at home.

Methods: Forty-three patients with benign prostatic hyperplasia used the Freeflow uroflowmeter in the hospital and at home without accumulating urine. We created a nomogram for each patient's urine volume and maximal urinary flow rate (Qmax). Furthermore, we investigated the actual state of each patient's urination. We also investigated the differences in the micturition status between daytime and nighttime.

Results: Of the 43 patients, 40 were able to provide the necessary data in the hospital, and all patients provided data measured at home. The trial period of the home assessment was 2-7 days. Regarding the average urine volume, no significant difference was observed between in-hospital and at-home patients; however, Qmax and mean flow rate (Qave) were significantly higher at home. The average coefficient of variation was very large. The relationship between daytime and nighttime was observed in 30 patients; urine volume increased significantly at nighttime; however, no significant difference was observed in Qmax and Qave. The nomogram for several days and a completed urinary diary helped to display daytime and nighttime urination characteristics.

Conclusions: Freeflow, the newly developed uroflowmeter, enabled us to determine the fluctuations in the measurements recorded at home and the differences between daytime and nighttime. Thus, creating a nomogram for objectively examining nighttime urination status and utilizing a urination diary was found to be effective for providing correct diagnosis and treatment of lower urinary tract symptoms.

KEYWORDS
LUTS, nomogram, portable uroflowmeter, urination diary

1 | INTRODUCTION

Noninvasive assessment of prostatic obstruction with lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia has been previously developed. van Venrooij et al[1] reported that the prediction of the probability of a man with LUTS suggestive of benign prostatic hyperplasia could be deduced from a diagram based on a formula composed of three readily available parameters: prostate volume, maximal urinary flow rate (Qmax), and mean voided volume (VV).

Uroflowmeters are noninvasive instruments that measure the amount and speed of urination and have long been used in hospitals and homes for diagnosing LUTS.[2] Hospitals tend to use a fixed type of uroflowmeter, which is often installed in the toilet; in this context, it may not be possible to obtain accurate measurements because of tension during examinations. In addition, it has been reported that measurement at home is necessary.[2-7] However, this mode of urine measurement is not very popular in homes because, in Japan, home-based urine flow measurement cannot be claimed as an insured mode of medical treatment; its value for home use is not well known. Many urine flowmeters often store urine in containers. An inexpensive method that can obtain relevant measurements without collecting the urine—a funnel-shaped method that approximately measures Qmax—is known[8]; however, this method cannot measure urine volume. Our report in the journal the of Japanese Continence Society (Japanese) discussed our use of a newly developed urine flowmeter (Freeflow) for measuring urine flow characteristics, including urine volume, without collecting urine. We used it simultaneously with the existing in-hospital urine flowmeter for comparison purposes. We also compared the effectiveness of the Freeflow meter's assessments between in-hospital and home-based use; its accuracy was not significantly different from that of the existing stationary type. A large variation in terms of urination at home was reported, and it was not possible to determine the actual condition of the patient based on a single measurement in the hospital.[9]

In this current study, we increased the number of participants in our assessment, reconfirmed the difference between in-hospital and at-home use of the Freeflow device, and investigated the urination data of each participant, including nighttime, in the home utilizing a nomogram and urinary diary.

A flowrate nomogram was developed to aid the interpretation of urinary flow rate data.[10] This research aimed to create an overall nomogram based on the relationship between Qmax and urine volume and make use of a urinary diary to examine the micturition status of each patient and differences between daytime and nighttime urine flow.

2 | METHODS

2.1 | Ethics

The study protocol was approved by the Ethics Committee of Kanagawa Prefecture Insurance Medical Association. All procedures were carried out in accordance with the principles of the Declaration of Helsinki. All participants in the study gave informed consent.

2.2 | Patients

Among the 43 patients included in this study, 40 who visited the clinic for the diagnosis and treatment of benign prostatic hyperplasia were treated with oral medications, and three were being followed up. Patients with inflammatory diseases, such as neurogenetic bladder, cancer, and acute cystitis, were excluded.

2.3 | Uroflowmetry and assessment

The structure of the Freeflow device (GEO System Co. Ltd., manufactured by Japan)[11] is shown in Figure 1 and a short video clip can be found on the GEO System homepage (http://www.geo-system.co.jp/nyoryukei/movie/movie.html).

This device measures the flow velocity by optically reading the rotation speed of the built-in impeller; 100 measurement data were stored. When the patient visited the hospital, their urine flow rates were measured; thereafter, they took the device home for home measurement. After the home measurements, the patients were brought to the clinic, and their data were transmitted wirelessly to the tablet, portable computer (PC), and printing machine from which they were analyzed. The date and time of urination, micturition volume, Qmax, average micturition rate (Qave), hesitation time, and micturition curve were all displayed. When the patient entered the sleep start time, the daytime and nighttime minutes were displayed separately in a urination diary. Correlation and t-test analysis were applied to the difference between the mean values to compare the urine volume, Qmax, and Qave between the mean values in the hospital and those found at home. The average value ± SD of each person's micturition characteristics at home was examined, and the coefficient of variation was calculated. We investigated the relationship between each patient's micturition volume and Qmax, created a nomogram for all patients, and investigated their urination symptoms.

The difference between daytime and nighttime urination statuses was investigated by re-setting nighttime from 12:00 AM to 7:00 AM. Patients with benign prostatic hyperplasia have been reported to have lower Qmax values at night compared to their Qmax values during the day[4]; therefore, we investigated the relationship between the ratio of Qmax at nighttime and daytime as well as the prostate volume. The prostate volume was estimated by conducting a transabdominal echography with a Hitachi Aloka Prosound α (HITACHI Co Ltd, Japan). In addition, the volume of the prostate was calculated by multiplying the vertical, horizontal, and diagonal by 0.52.[12] During the consultation, we asked the International Prostate Symptom Score (IPSS), quality of life (QoL) score, and overactive bladder symptoms score (OABSS) questions through a questionnaire, provided scores, and investigated the relationship with the average Qmax value.

3 | RESULTS

3.1 | Implementation status

Of the 43 participants, three were unable to obtain data in the hospital, and all provided data at home. The average age was 70.4 ± 7.1 (50-85) years, the average device usage period at home was 4 (1-5, 8, 9) days, and the average number of measurements was 12.1 (2-68) times. Prostate volume was 29.4 ± 14.2 (12.3-72.9) mL, IPSS was 10.7 ± 5.5 (1-25), QoL score was 2.9 ± 1.2 (0-6), and OABSS was 4.3 ± 2.6 (0-11).

3.2 | Difference between in-hospital and at-home measurements

Table 1 shows a comparison of in-hospital and home-based averages. There was no difference in urine volume, but Qmax and Qave were

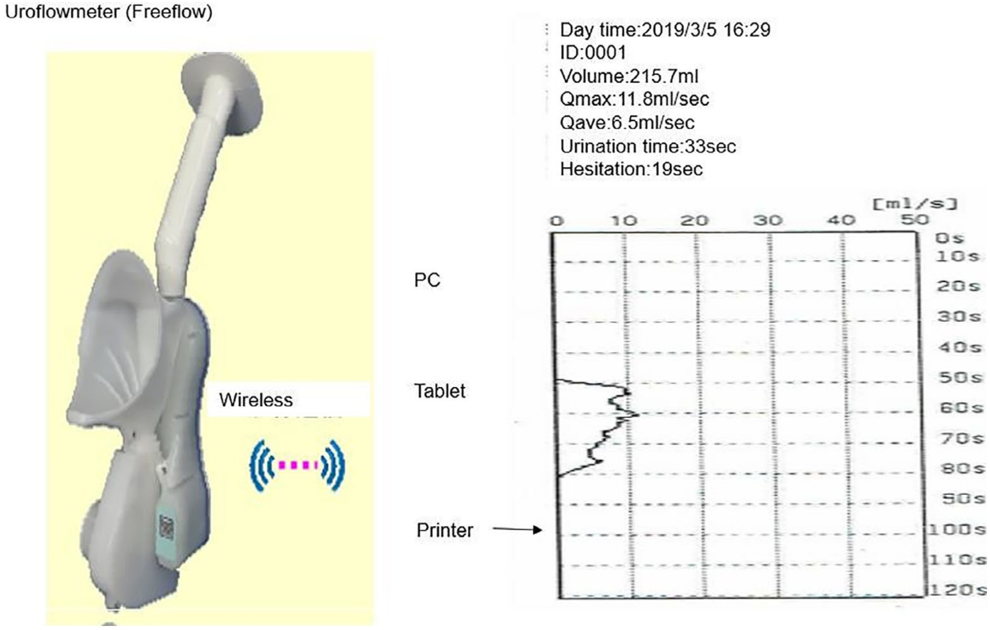

FIGURE 1 Freeflow system (portable uroflowmeter and printed chart). Qave, mean flow rate; Qmax, maximum flow rate

TABLE 1 Difference between home and office uroflowmetry

	Home	Office	Mean difference (95% CI)	*P*-value
Qmax (mL/s)	17.5 ± 7.8	14.6 ± 8.9	2.8 (0.8–4.7)	<0.01**
Qave (mL/s)	7.9 ± 3.6	6.7 ± 3.8	1.2 (0.38–1.97)	<0.01**
VV (mL)	207 ± 14	200 ± 18	6.6 (−24 to 38)	0.67

Abbreviations: Qave, mean flow rate; Qmax, maximal urinary flow rate; VV, voided volume.

TABLE 2 Comparison of voiding parameters between daytime and nighttime

	Daytime	Nighttime (12:00 AM to 7:00 AM)	Mean difference	*P*-value
Qmax (mL/s)	17.1 ± 7.3	16.7 ± 8.3	0.42 (−1.5 to 2.3)	0.65
Qave (mL/s)	7.9 ± 3.7	7.6 ± 4.3	0.25 (−0.66 to 1.17)	0.59
VV (mL)	193 ± 85	266 ± 139	73.4 (38 to 109)	<0.001**

Abbreviations: Qave, mean urinary flow rate; Qmax, maximal urinary flow rate; VV, voided volume.

significantly higher at home. Although the Qmax in the hospital and at home showed a significant correlation ($r = 0.75$, $P < 0.001$), patients who had low levels of Qmax in the hospital tended to show increased levels at home.

3.3 | Measurement status at home

The home-based urinary flowmeter data were stored in a small printing machine, tablet, or directly on a PC; the measurement time and various urine volume characteristics are displayed as shown in Figure 1. The average coefficient of variation for each patient at home was as follows: Qmax: 0.42 ± 0.2; the amount of urination was 0.45 ± 0.19, which was quite large.

Table 2 shows the average value of each patient's urine flow rate during the daytime and at nighttime (12:00 AM to 7:00 AM). Thirty patients provided measurements during the nighttime. Qmax and Qave were not significantly different, but the urine volume was significantly higher at nighttime.

Table 3 shows a urination diary, which distinguishes between the daytime and nighttime flow measurements of patient A, who experiences frequent urination 68 times over 5 days.

Figure 2 shows the relationship between the urine volume and the Qmax of patient A; this is created based on the 5-day urination diary. The coefficient of variation for each urination is very large, the Qmax is 0.69, and the urination volume is 0.62; it is clear from these results that urine flow rate characteristics cannot be judged based on only one measurement (x mark) in the hospital. There is often a higher urinary volume at nighttime and frequent urination as well.

The relationship between each patient's VV and Qmax average was not significant ($r = -0.1$, $P = 0.52$), and the relationship between

TABLE 3 Example of a urinary diary

No.		Voiding time (s)	VV (mL)	Qmax (mL/s)	Qave (mL/s)	Hesitate time (s)
Daytime						
1	5:38	29	124	8.8	4.3	7
2	7:23	4	27	13.6	6.6	0
3	8:33	31	125	6.3	4	11
4	10:02	40	90	7.2	2.3	9
5	12:27	32	170	13.6	5.3	2
6	15:02	34	135	10.2	4	1
7	16	22	149	14.7	6.8	4
8	17:19	34	112	6	3.3	8
9	18:45	20	127	11.8	6.3	5
10	20:11	49	136	6.3	2.8	10
11	22:19	54	512	22	9.5	0
Sum			1707			
Mean				11	5	5.2
Nighttime						
12	23:57	35	281	13.6	8	2
13	1:33	30	296	19	9.9	1
14	2:44	74	204	10.2	2.8	3
15	4:04	40	131	7.2	3.3	10
16	5:07	20	164	14.7	8.2	0
Sum			1076			
Mean		39.8	215	12.9	6.4	3.2
Total			2783			
Mean		34.3	174	11.6	5.5	4.8

Abbreviations: Qave, mean urinary flow rate; Qmax, maximal urinary flow rate; VV, voided volume.

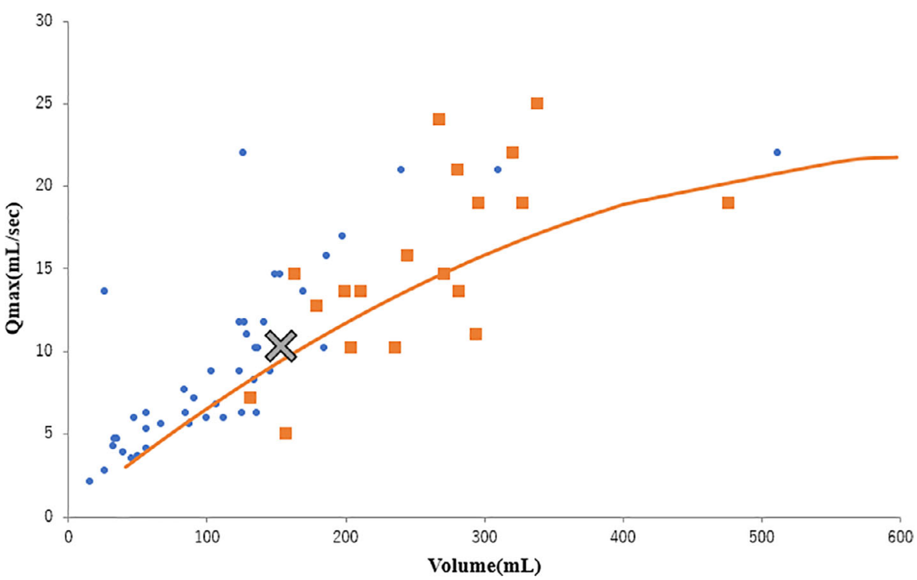

FIGURE 2 Relationship between voided volume and Qmax Patient A, 81 y of age (for 5 d). ●, daytime data; ■, nighttime data; ×, measured value in hospital; Qmax, maximum flow rate

the Qmax ratio at nighttime and daytime and the prostate volume was not significant, but this ratio tended to decrease when the prostate volume was large.

The relationship between the IPSS and Qmax showed a significantly negative correlation ($r = -0.42$, $P < 0.01$); however, some patients showed low Qmax, even when the IPSS was low.

4 | DISCUSSIONS

The effectiveness of a newly developed portable uroflowmeter, Freeflow, which measures urine flow characteristics without collecting urine, was assessed by applying it among patients with benign prostatic hyperplasia in hospital and home settings.

Several reports have compared the performances of urinary flowmeters with regard to in-hospital and home measurements.[4,6,13,14] Matzkin et al reported a similar result after they investigated the fluctuation of Qmax over a period of 6-12 months.[12] Recently, Summers et al collected urine in a cup and used a urine flowmeter called Stream DX, which is used at home with a disposable sensor, to make urine flow measurements and collected the data of 637 people for 19 284 times over an average of 5 days. They reported considerable fluctuations between successive days and emphasized the significance of measuring urine flow at home for obtaining a more accurate diagnosis of urinary function.[15] We examined the comparison between in-hospital and home measurements; we also examined the difference between daytime and nighttime measurements at home, created a nomogram for recording the relationship between each person's urine volume and Qmax, and maintained a urination diary. The average urine volume of the participants' home measurements was not significantly different from that in the hospital, but Qmax and Qave were significantly higher at home. It was reconfirmed that a single measurement in the hospital was insufficient for making an accurate diagnosis. A portable urine flowmeter can be used for measuring urine flow at home (it involves taking urine in a cup and examining the change in weight in many cases); in other cases, a special liquid level sensor can be inserted, and this change is measured. The newly developed Freeflow did not require urine collection; therefore, it carried less risk of urine spillage on the floor and was easy to wash. It posed no usability problems, which was a concern for use among elderly patients. People with dysuria tend to have less urine output, shorter urination time, and higher Qmax in the early afternoon than in the morning and evening, and it has been reported that there is a circadian rhythm in the micturition status.[16] Porru et al reported that people with benign prostatic hyperplasia have a large circadian rhythm. Examination of the urination statuses between the daytime and at nighttime by using a urinary flowmeter showed that the urine volume was large and urination time was longer at nighttime, and urination rate and Qmax were low during sleep; thus, it could be a useful diagnostic tool for LUTS caused by benign prostatic hyperplasia.[5]

The limitation of this study was that it did not acquire all micturition data; therefore, some participants did not provide their nocturnal micturition data, and we did not ask for records of bedtime and wake-up time; 12:00 AM to 7:00 AM was defined as nighttime.

As shown in Table 2, the amount of nighttime micturition increased significantly from that during the daytime, but Qmax and Qave did not increase. Half of the participants showed a decrease at night. The Qmax increased with urine volume (as can be observed based on urine volume and Qmax nomograms), suggesting that half of the participants may have had LUTS because of benign prostatic hyperplasia as is estimated by Porru et al.[5] Under this system, one can send data received from the tablet or directly from Freeflow to the PC via Bluetooth communication and enter the wake-up time and bedtime; this records the first urination characteristic data after waking up (from the daytime to sleep time), as shown in Table 2. This data is then displayed as a diary. This allows the user to note the daily urination status numerically; however, it can be difficult to determine the status for several days with this mechanism alone. In Figure 2, the data of urine volume and Qmax for several days are shown as a nomogram, and nighttime and daytime statuses are distinguished. When displayed in this way, it is easy to grasp the entire picture. At a glance, the case of participant A shows that he had polyuria and pollakiuria at nighttime and that the Qmax at nighttime was not low.It is recommended that a urine volume of ≥150 mL is necessary for making correct evaluations while using a urine flowmeter,[6] but several in-hospital patients may not have a urine volume of ≥150 mL. Therefore, for reliable uroflowmetry testing, Ceyhan et al[17] recommended that 1.5 L of water should be taken before uroflowmetry.

At home, having a urine volume of ≥150 mL is common; however, since the amount of urine discharged at nighttime is larger than that discharged during the daytime, taking measurements and recording data at nighttime will help to obtain accurate evaluations. Thus, this study confirmed the importance of taking uroflowmeter measurements at home.

The guidelines of the Japanese Society of Urology also state that the micturition diary is useful for men with LUTS, especially those with benign prostatic hyperplasia, overactive bladder, and nocturnal polyuria.[18]

Thus, the present study confirmed the effectiveness of the utilization of a urination diary that can distinguish between nighttime and daytime, such as the Freeflow system, and creating a nomogram to distinguish between nighttime and daytime measurements over several days while renting out the urine flow device to patients.

5 | CONCLUSIONS

Freeflow, the newly developed urine flowmeter, which can measure urine without collecting it, enabled us to grasp the difference between in-hospital and home flow measurements, the fluctuating state of measurements at home for several days, and the difference between daytime and nighttime flow. Creating a nomogram of the relationship between urine volume and Qmax, examining its position in the whole, objectively examining the nighttime urination status, and utilizing the urination diary, which contained such information, was found to be effective for providing correct LUTS diagnosis and treatment.

ACKNOWLEDGMENTS

We would like to thank Professor Shiroki, Department of Urology, Fujita Health University, for his advice on this paper. We would also like to thank Editage (www.editage.com) for English language editing. Cloud Funding 「FAAVO」https://camp-fire.jp/projects/view/289286

DISCLOSURE

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available in Yokohama City University at https://www.yokohama-cu.ac.jp/med/.

ORCID

Kotaro Yamasue http://orcid.org/0000-0003-4974-3211

REFERENCES

1. van Venrooij GE, Eckartdt MD, Boon TA. Noninvasive assessment of prostatic obstruction in elderly men with lower urinary symptoms associated with benign prostatic hyperplasia. *Urology*. 2004;63:476-480. doi:10.1016/j.urology.2003.10.021
2. Bray A, Griffiths C, Drinnan M, Pickard R. Methods and value of home uroflowmetry in the assessment of men with lower urinary tract symptoms: a literature review. *Neurourol Urodyn*. 2012;31:7-12. doi:10.1002/nau.21197
3. Chun K, Kim SJ, Cho ST. Noninvasive medical tools for evaluating voiding pattern in real life. *Int Neurourol J*. 2017;21(suppl 1):S10-S16. doi:10.5213/inj.1734860.430
4. Jørgensen JB, Jacobsen HL, Bagi P, Hvarnes H, Colstrup H. Home uroflowmetry by means of the Da capo home uroflowmeter. *Eur Urol*. 1998;33:64-68. doi:10.1159/000019534
5. Porru D, Scarpa RM, Prezioso D, Bertaccini A, Rizzi CA, HOUSE Study Group. Home and office uroflowmetry for evaluation of LUTS from benign prostatic enlargement. *Prostate Cancer Prostatic Dis*. 2005;8:45-49. doi:10.1038/sj.pcan.4500763
6. Gammie A, Rosier P, Li R, Harding C. How can we maximize the diagnostic utility of uroflow? *Neurourol Urodyn*. 2018;37(suppl 4):S20-S24. doi:10.1002/nau.23472
7. Heesakkers J, Farag F, Pantuck A, Moore K, Radziszewski P, Lucas M. Applicability of a disposable home urinary flow measuring device as a diagnostic tool in the management of males with lower urinary tract symptoms. *Urol Int*. 2012;89:166-172. doi:10.1159/000338907
8. Pridgeon S, Harding C, Newton D, Pickard R. Clinical evaluation of a simple uroflowmeter for categorization of maximum urinary flow rate. *Indian J Urol*. 2007;23:114-118. doi:10.4103/0970-1591
9. Kato S, Watanabe H, Yamasue K, Shiroki R. Evaluation of home and office uroflowmetry using the newly developed portable uroflowmeter Freeflow™. *J Japanese Contin Soc*. 2019;30:483-486. (Japanese).
10. Siroky MB, Olsson CA, Krane RJ. The flow rate nomogram: I. Development. *J Urol*. 1979;122:665-668. doi:10.1016/S0022-5347(17)56550-7
11. Shimokawa S, Udagawa H, Hara T, JP 6540795 (21 June 2019) WO2016/152847 (Geo-System Co.jp).
12. Abu-Yousef MM, Narayana AS. Transabdominal ultrasound in the evaluation of prostate size. *J Clin Ultrasound*. 1982;10:275-278. doi:10.1002/jcu.1870100606
13. Matzkin H, van der Zwaag R, Chen Y, Patterson LA, Brat Z, Soloway MS. How reliable single measurement of urinary flow in the diagnosis of obstruction in benign prostatic hyperplasia? *Br J Urol*. 1993;72:181-186. doi:10.1111/j.1464-410X.1993.tb00684.x
14. Golomb J, Lindner A, Siegel Y, Korczak D. Variability, and circadian changes in home uroflowmetry in patients with benign prostatic hyperplasia compared to normal controls. *J Urol*. 1992;147:1044-1047. doi:10.1016/S0022-5347(17)37462-1
15. Summers SJ, Armstrong JM, Kaplan SA, et al. Male voiding behavior: insight from 19,824 at-home uroflow profiles. *J Urol*. 2021;205:1126-1132. doi:10.1097/JU.0000000000001504
16. Witjes WP, Wijkstra H, Debruyne FM, de la Rosette JJ. Quantitative assessment of uroflow: is there a circadian rhythm? *Urology*. 1997;50:221-228. doi:10.1016/S0090-4295(97)00190-8
17. Ceyhan E, Asutay MK. Standardization for reliable uroflowmetry testing in adults. *LUTS*. 2021;1:45-50. doi:10.1111/lutz,12323
18. Homma Y, Gotoh M, Kawauchi A, et al. Clinical guidelines for male lower urinary tract symptoms and benign prostatic hyperplasia. *Int J Urol*. 2017;24:716-729. doi:10.1111/iju.13401

How to cite this article: Kato S, Watanabe H, Yamasue K. Freeflow: The novel portable uroflowmeter can help to realize practical urinary conditions at home. *Lower Urinary Tract Symptoms*. 2022;1-6. doi:10.1111/luts.12426