Nova metoda merjenja urodinamike, primerna za domačo uporabo na osnovi kapacitivnosti

A Novel Capacitive Method for Urodynamic Measurements That is Suitable for Home Use

Avtor / Author

Ustanova / Institute

Gregor Nikolić[1], Igor But[2], Andraž Stožer[3], Iztok Kramberger[1]

[1]Univerza v Mariboru, Fakulteta za elektrotehniko, računalništvo in informatiko, Laboratorij za elektronske in informacijske sisteme, Maribor, Slovenija; [2]Univerzitetni klinični center Maribor, Klinika za ginekologijo in perinatologijo, Oddelek za splošno ginekologijo in ginekološko urologijo, Maribor, Slovenija; [3] Univerza v Mariboru, Medicinska fakulteta, Inštitut za fiziologijo, Maribor, Slovenija;

[1]University of Maribor, Faculty of Electrical Engineering and Computer Science, Laboratory for Electronic and Information Systems, Maribor, Slovenia; [2]University Medical Center Maribor, Division of Gynecology and Perinatology, Department of General Gynecology and Gynecologic Urology, Maribor, Slovenia; [3] University of Maribor, Faculty of Medicine, Institute of Physiology, Maribor, Slovenia;

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Izvleček

Namen: *Urinska inkontinenca prizadene velik del ženske in moške populacije in eden prvih presejalnih testov so urodinamske meritve. Med najpreprostejšimi napravami, ki ne dajejo zadostne količine podatkov, in napravami, ki dajejo kopico podatkov, a so cenovno nedostopne in se uporabljajo le v kliničnih testih, je velik prepad. Cilja raziskave sta bila preučiti obstoječe metode merjenja urodinamike in razviti metodo, ki bi zmanjšala prepad med prej omenjenimi napravami ter omogočila široko dostopnost.*

Metode: *Raziskava je vključevala pregled obstoječih urodinamskih metod in odločitev za kapacitivno metodo kot metodo, s katero bi lahko dosegali zastavljene cilje. Izdelali smo pripomoček za validiranje kapacitivne metode z namestitvijo elektrod na zunanjo stran zbirne*

Abstract

Background: *Urinary incontinence is highly prevalent in both women and men. Urodynamic testing is essential for diagnosis, but a gap exists in the usefulness of simple assessments that do not provide sufficient data, and devices that provide the necessary data, but are used primarily in clinics and clinical trials. This study considered the existing methods of urodynamics testing and developed a device that was both effective and suitable for home use.*

Methods: *A review of existing urodynamic methods led to development of a capacitive device. We created a device with sensor electrodes placed on the outside of a specimen container. The functionality of the electrodes and performance of the novel capacitive device were compared with that of a gravimetric device (Dorado KT, Laborie Medical Technologies,*

Naslov za dopisovanje / Correspondence

Dr. Iztok Kramberger, Univerza v Mariboru, Fakulteta za elektrotehniko, računalništvo in informatiko, Laboratorij za elektronske in informacijske sisteme, Koroška cesta 46, 2000 Maribor, Slovenija
E-pošta: iztok.kramberger@um.si

Dr. Andraž Stožer, Univerza v Mariboru, Medicinska fakulteta, Inštitut za fiziologijo, Taborska ulica 8, 2000 Maribor, Slovenija
E-pošta: andraz.stozer@um.si

posode. Kapacitivna metoda velja za potrjeno, vendar zanjo še ni literature o morebitnih kliničnih validacijah. Zato smo izvedli primerjavo razvite kapacitivne naprave z validirano gravimetrično napravo Dorado KT, ki se uporablja v Univerzitetnem kliničnem centru Maribor.

Rezultati: *Rezultati meritev kažejo precejšnje ujemanje med obema napravama pri merjenju volumna (p = 0,936) ter pri merjenju maksimalnega (p = 0,327) in povprečnega pretoka (p = 0,136). Grafična poteka spreminjanja volumna in pretoka v času kažeta veliko stopnjo prekrivanja.*

Zaključek: *Metoda merjenja glede na zgodovinski razvoj tovrstnih naprav kaže na razvojni korak v prihodnost, kljub temu da meritve v dani obliki še v celoti ne dosegajo priporočil, ki jih je izdalo mednarodno združenje za inkontinenco. V primeru uporabe večjega števila elektrod je pričakovati izboljšanje omenjene pomanjkljivosti, možna pa je tudi razširitev funkcionalnosti, in sicer v primeru izdelave samostojne naprave na principu kapacitivne metode, ki je predstavljena v prispevku.*

Mississauga, ON, Canada) used at the University Clinical Center, Maribor.

Results: *Measurements of fluid volume (p = 0.936), maximum (p = 0.327), and mean (p = 0.136) flow observed with the two devices were not significantly different. Graphical analysis of collected volumes and flow variation over time show a high degree of overlap.*

Conclusions: *Compared with previously developed urodynamics testing devices, the capacitance method and the performance of this device represent an advance. The precision of the measurements needs improvement and did not fully address the recommendations of the International Continence Society, but he use of additional sensor electrodes is expected to improve performance. Extending the functionality as a standalone capacitive device for home use and upgrading with wireless access by mobile systems would allow for additional benefits beyond current voiding diaries.*

INTRODUCTION

Lower urinary tract symptoms (LUTS) reflect complex problems in either the storage or voiding phases of the micturition cycle. The most common symptoms are urinary incontinence (UI), overactive bladder (OAB), and difficulty passing urine. UI has an estimated prevalence in 25% to 45 % in women, with leakage of urine during physical, sports, or sexual activity, and may occur with urgency (1,2). OAB is slightly less prevalent, accounting for 7.7% to 31.3% of LUTS, without a significant difference in gender prevalence (1). The primary symptom of OAB is urgency, which is a sudden strong need to urinate that requires the immediate interruption of activity. LUTS also include increased daytime micturition (frequency) and voiding at night (nocturia). Unlike women, the most common symptom in men is UI with difficulty emptying the bladder because of benign prostatic hyperplasia (3). Three percent of men between 45 and 49 years of age report suffering from LUTS, and the prevalence exceeds 30% in men over 85 years of age (4). Both the prevalence and psychological burden of LUTS increase with age and can significantly impair quality of life.

The medical history, urinalysis, responses to various questionnaires, a voiding diary, and urinary flow measurement are helpful for diagnosis. The most common diagnostic tool is the voiding diary in which patients record their 24-hour voiding frequency and urine volume while at home. Flow measurement is a reliable indicator of LUTS, and unlike the voiding diary, provides an objective measurement of urine volume and flow. Unfortunately, flow meters are only available in outpatient clinics or hospitals and are not widely available to the general public. To provide better access to this diagnostic method, we designed a device that is intended for home use. The flow meters used in medical facilities are gravimetric and measure the weight of the voided urine, or use a rotating disk, or measuring rods. Our flow meter is a capacitive device made of a light plastic material that is placed under the toilet bowl ring. This study compared the reliability of the novel device with that of an existing flowmeter and assessed its potential utility for diagnosing LUTS.

Materials and Methods

The device that was constructed and tested includes a standard urine or stool specimen container and is placed in a standard toilet bowl for use. The device

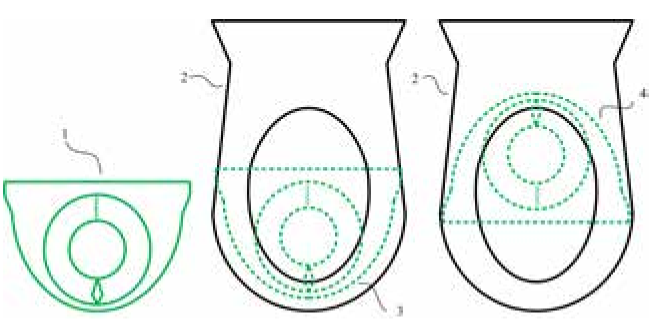

Figure 1. The specimen container[1] can be positioned in the toilet[2] to collect either urine[3] or stool[4]. The urine collection position was selected for this evaluation.

and its installation are shown in Figures 1 and Figure 4.

The device has two pairs of sensor electrodes that detect the presence of urine, measure the urine level, and indirectly determine the urine volume and flow rate from those data. The electrodes are located on the outer surface of the specimen container, as shown in Figure 2.

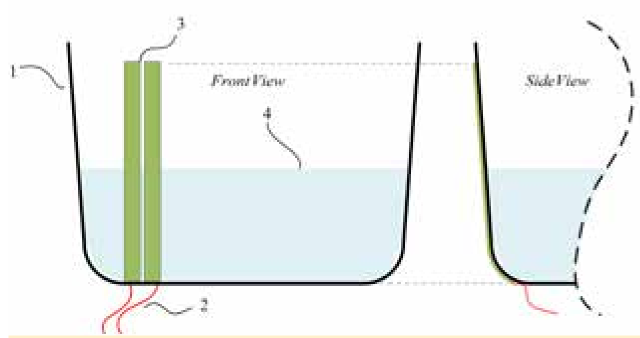

Figure 2. Copper tape electrodes[3] on the outside of the container[1] are placed over contacts on the device[2] and are not in direct contact with the collected fluid[4].

Data captured by the sensor electrodes are transferred by a wire connection to a processing unit containing a capacitance-to-digital converter and then sent to a computer for storage via an electrical interface. Data measurement and conversion and the appearance of the electrodes are shown in Figures 4 and 5. The specimen container is conical and rounded at the bottom, which results in a nonlinear relationship between the measured capacitance and the liquid level. To determine the equation for the calculation of the urine volume, the device was calibrated with fluid samples of known volume. The equation describing the flow curve was determined by the known volumes and the measured capacitance and is shown in Figure 3. The volume can be determined for each capacitance value.

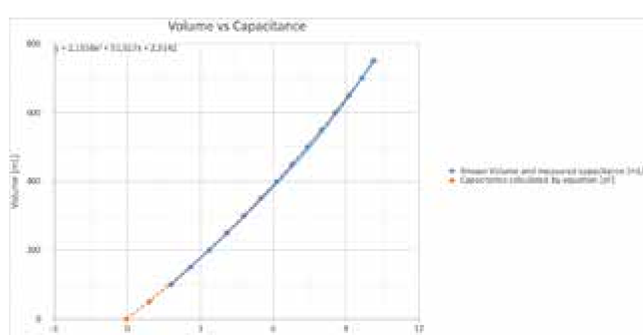

Figure 3. Measured (blue) and calculated (red) capacitance with known fluid volumes.

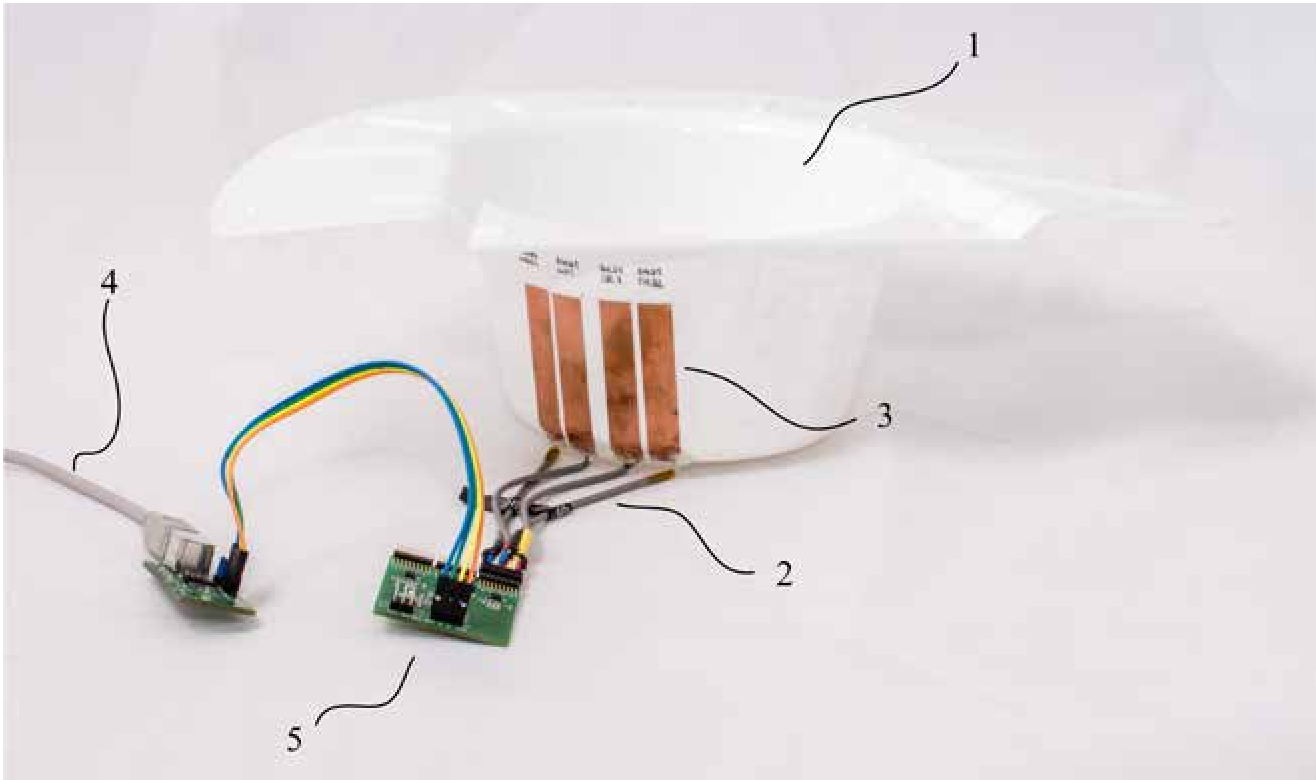

Figure 4. The specimen container[1] attached electrodes[3], and wire[2] connection to a capacitive-to-digital converter, processing unit,[5] with data transfer to a computer[4].

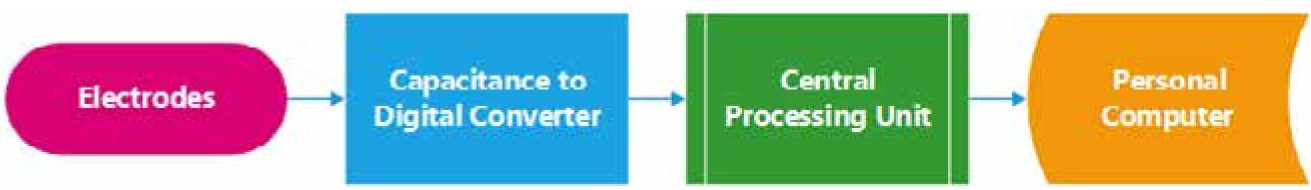

Figure 5. Connectivity diagram of the specimen container utility.

The reliability of the novel device was evaluated by comparing its performance with that of the Dorado KT (Laborie Medical Technologies, Mississauga, ON, Canada), which is used for urodynamic testing at the Department of General Gynecology and Gynecological Urology in the University Clinical Center, Maribor. The Dorado KT system is widely adopted and certified, provides a number of different urodynamic tests, and is upgradable. One of the options is measurement the flow rate and the amount of excreted urine using a weight-sensing cell that is placed under a collecting funnel. The device is shown mounted on a simulated toilet bowl ring in Figures 6 and 7.

Figure 6. The Dorado KT system is shown with a toilet stand[4] and funnel[3]. Our specimen container[2] is placed on the weight cell[1] of the Dorado KT system.

The capacitive device was installed on the weight cell of the Dorado KT system as shown in Figure 6, a configuration in which the flow of fluid into the measuring system was the same for the Dorado KT and our system, which allowed direct comparison of the results. Eight consecutive measurements of simulated urine excretion were performed without the use of an intermediate funnel so that the comparison could be made without the interference of objects that could influence the measurements. The liquid test volumes were chosen to simulate the average adult bladder volume of 300–400 mL (5). A plastic bag filled with water was used to simulate voiding. An opening was made at one of the bottom corners of the bag through which the water flowed into the measuring system. The opening was positioned at approximately the same distance from the measuring device as the funnel of the Dorado KT system. We measured the volume increase and flow as a function of time, the total volume, and the maximum and average flow rates of the liquid were determined.

RESULTS

Validation of the novel capacitive device was carried out at the Department of General Gynecology and Gynecological Urology, University Medical Center, Maribor. The results of standard tests, including uroflowmetry, cystometry (CMG), urethral pressure profile (UPP), leak point pressure (LPP), and complete micturition studies with electromyography (EMG) and video following Incontinence Society (ICS) standards and guidelines were performed in both the capacitive device and the Dorado KT for comparison. For testing, the Dorado KT container was replaced with the novel device as shown in Figure 7. Eight urodynamics measurements of simulated fluid excretion were performed using each system. The results are shown in Table 1.

Figure 7. *The Dorado KT system is shown equipped with a simulated toilet stand, funnel, and weight cell. The novel capacitive device is shown (left) with the specimen container positioned on the weight cell of the Dorado KT system (right) as it was for the comparative evaluation.*

Table 1. Results of eight measurements of voided volume, maximum flow rate, and average flow rate obtained with the novel specimen container utility and the Dorado KT system. The percent errors and average percent errors are shown. Differences were compared by Mann–Whitney U tests and are reported as p-values.

	Voided Volume (V_{void}) [mL]			Maximum Flow Rate (Q_{max}) [mL/s]			Average Flow Rate (Q_{av}) [mL/s]		
n	SC Utility	Dorado KT	Percent error	SC Utility	Dorado KT	Percent error	SC Utility	Dorado KT	Percent error
1	344,79	339,06	1,69	37,11	47,00	21,04	26,81	29,53	9,22
2	428,56	432,31	0,87	29,75	24,10	23,43	19,77	18,52	6,74
3	462,03	463,88	0,40	18,29	16,00	14,33	9,66	9,38	2,93
4	470,54	480,17	2,01	99,36	105,80	6,09	47,97	61,31	21,77
5	460,66	481,02	4,23	79,77	85,20	6,38	48,71	65,42	25,54
6	468,82	468,12	0,15	80,90	103,20	21,61	50,57	66,22	23,64
7	476,10	478,79	0,56	76,75	89,30	14,05	48,91	62,84	22,17
8	518,36	506,10	2,42	73,68	71,30	3,33	36,97	41,11	10,07
	Average Percent Error:		1,54	Average Percent Error:		13,78	Average Percent Error:		15,26

There was a small difference the total excreted urine volumes determined by the capacitive and standard methods, with an average the error of only –0.48%. Differences in the determination of maximum (–3.51%) and the average flow (–12.83%) were larger, but not statistically significant ($p > 0.05$). The size of the differences of maximum and average flow rates observed with the two devices can be explained by uncontrolled changes in the simulated urine excretion. The level of the fluid in the container was measured with only one electrode placed on one side of the container. Variation in the measurements was most likely the result of deviation of the position of the container from vertical or waves in the container occurring during simulated excretion. Differences in flow rates and fluid volumes observed in the second and eighth measurement in Table 1 are shown graphically in Figures 8 and 9.

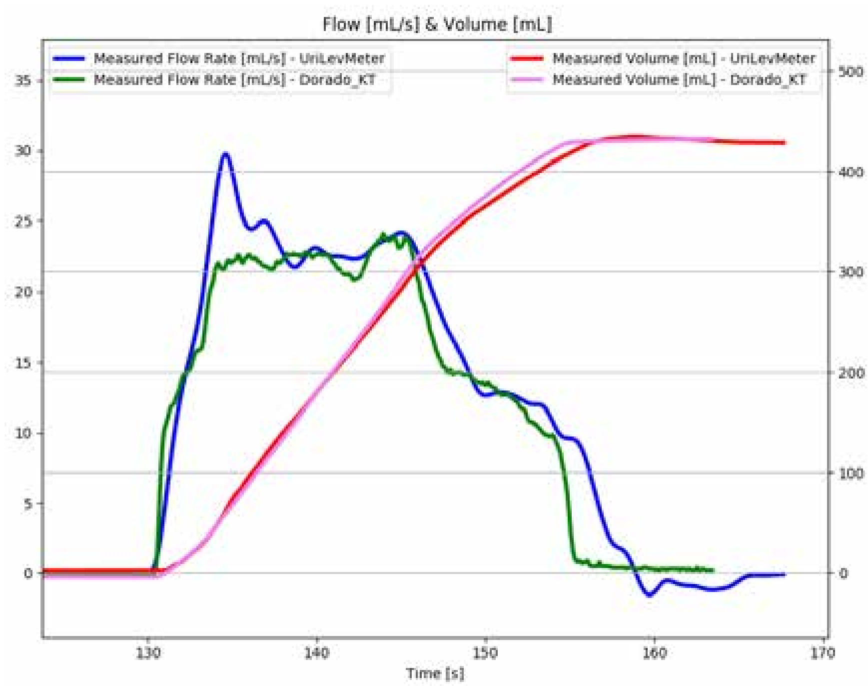

Figure 8. Flow rates and volumes obtained with the novel specimen container and the Dorado KT obtained in the second measurement of the device comparison (from Table 1).

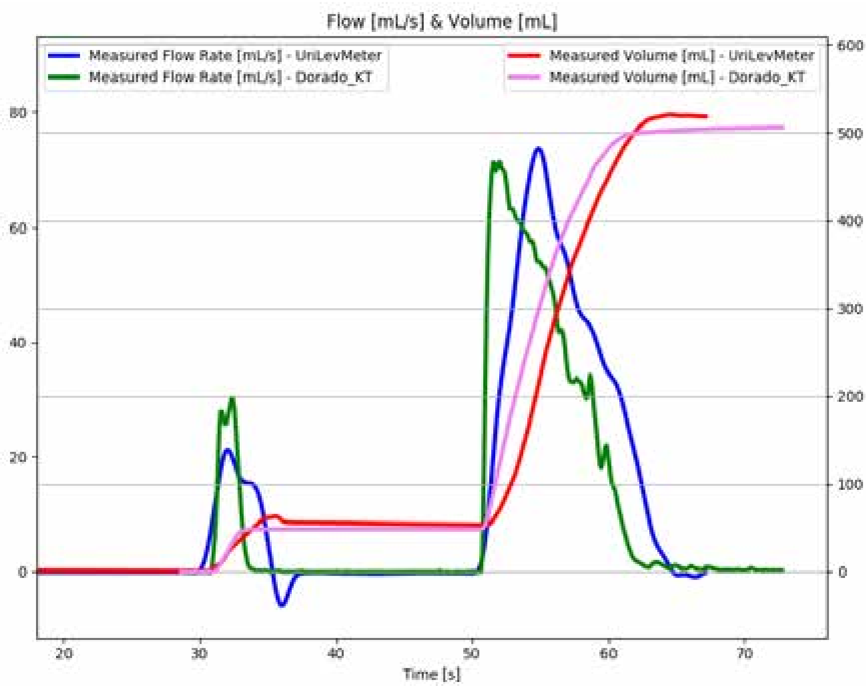

Figure 9. *Flow rates and volumes obtained with the novel specimen container and the Dorado KT obtained in the eighth measurement of the device comparison (from Table 1).*

Differences in the graphical representations of the fluid flow and collection container level were caused by signal processing by the finite impulse response filter to remove noise and calculate the average.

DISCUSSION

LUTS are common in men, women, the elderly, and children, and has a considerable psychological burden for the affected person and financial burden for the health system because of the resources needed for diagnosis and treatment. Irwin et al. estimated that the annual direct costs of OAB treatment were 262 EUR per person in Spain and 619 EUR in Sweden and that the total annual costs were 333 million EUR in Sweden and 1.2 billion EUR in Germany. The total estimated cost in the three countries was 3.9 billion euros. The costs of treatment in a home for elderly people (4.7 billion EUR) and absenteeism caused by OAB (1.1 billion EUR) should also be included (6). The annual cost of treating urgency incontinence associated with OAB, exceeded 65 billion USD in the USA in 2007 and was projected to exceed 82 billion USD in 2020 (7). Because of the high treatment costs, bladder and pelvic-floor muscle training are recommended for people with LUTS. No additional costs are incurred, both activities are effective behavioral LUTS treatments, and they are included in urology and urogynecology guidelines as the first approach to treatment. Recommended lifestyle modifications include control of fluid consumption, smoking cessation, weight reduction, and reducing alcohol consumption. Successful behavioral therapy is improved by completion of voiding diaries and clinical monitoring by urodynamic testing.

Three noninvasive methods are currently available for measuring urodynamics, gravimetric measurement of the weight of excreted urine, the rotating disk method, and capacitance measuring rods (8). The gravimetric and rotating disk methods are the most widely used, and both have drawbacks. In the gravimetric method, a funnel is attached to a specimen container located on a weight transducer. When a person voids, urine entering the funnel drains into the container. The urine volume, which is equivalent to the level of the liquid in the container can be determined from the weight and density. Flow is calculated form the change in volume over the time of collection (9,10). A schematic diagram of a gravimetric device is shown in Figure 10.

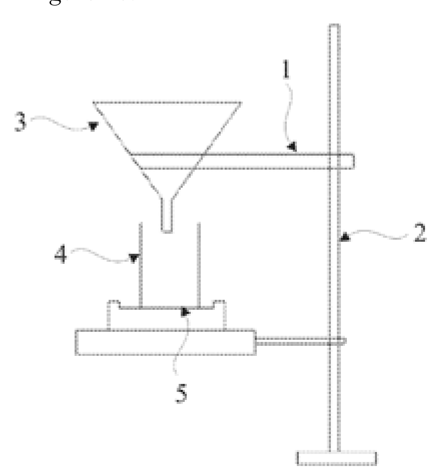

Figure 10. *A gravimetric measurement system consists of a support[1], stand[2], funnel[3], specimen container[4], and a weight transducer[5] (10).*

The Dorado KT is a gravimetric system. In rotating disc devices, the collected urine that passes over the disk has a braking effect, and the rotational speed is maintained by an increase in the power applied to it by a motor in the device. The flow rate is calculated from the power required to maintain the revolutions (9). Measuring-rod devices measure the change in capacitance in two conductive rods as the specimen container fills with urine. The volume is calculated from the height of the fluid column as a function of the change in capacitance and the cross-sectional area of the column of liquid in the container. The flow is calculated from the derivative of the volume over time (11). This method has been validated technically, but few data on its use in clinical practice are available (9). The rotating disk method is widely used, but like the gravimetric method, it depends on urinary flow rate, which makes both methods relatively difficult to implement in a home user-friendly form. For example, with the rotating disk method, a cross-sectional effect occurs with variation of the flow measurements depending on where the fluid stream lands on the disk. (8,11,12). This novel capacitive device did not satisfy the requirements or recommendations of the ICS on the accuracy of measurement (11). Nevertheless, at a given time, the volume estimate and the graphic display of flow were representative. The addition of two more electrodes would improve accuracy by eliminating the effects of waves of liquid that form during filling and of a tilted container. With three electrodes, the exact height of the surface of the liquid can be calculated.

Use of this capacitive test as an independent device, upgrading the electrodes, and improving the measurement accuracy and the battery power, would probably achieve ICS urodynamics testing targets in a device that could be used at home. Testing at home would minimize psychological effects on measurement (12). This device is hygienic, as the container can emptied after use and rinsed with running water before reuse. Its usefulness is not limited to the diagnosis of LUTS, as it could be used to monitor the success of pharmacological treatment of OAB, which is intended to reduce detrusor tonus, achieve a progressive reduction in the maximum urine flow, and prolong the interval between successive micturitions. If patients were able to record the results of urodynamics self-monitoring, physicians could use the information on the average number of micturitions in 24 hours, the amount of voided volume, and other parameters to make beneficial adjustments to therapy.

Upgrading the device with wireless communication and access by mobile systems would allow for additional benefits. Voiding diaries collect data on the times of voiding, fluid intake, daily episodes, and urgency (13). paper logs are filled out by about 90% (86% to 94%) of patients, but the percentage of accurate data entered in a specific time window is low, around 10% (8% to 14%). The accuracy of data entered in electronic journals is much higher (92% to 96%) (14,15). Using a mobile device, data can be uploaded wirelessly to an application that keeps an accurate log of the times of urination, urine volumes, when a person urinated, and flow rates. The data can be displayed graphically. If the user is reporting urgency, the application can automatically prompt uploading the event immediately after urination. People tend to forget to complete the diary unless they are prompted (16). Digitally collected data are easily processed and interpreted, made available to physicians almost immediately via the Internet, and loaded onto a server where they are available for immediate view and analysis.

CONCLUSIONS

The capacitive method of measuring UI is more suitable than weight-based, capacitance, and rotating disk methods for the development of a standalone device to measure urinary volume, flow, and other parameters at home. Improvements are needed to achieve the desired functionality, and upgrades can further reduce the existing gap between the simplest portable devices that do not provide all the desired information and expensive devices that are used only in the clinic. Even though the device cannot assess urine leakage or residual volume, it is affordable and easy to use. It provides not only quantitative urometric flow data, immediate graphical representations of flow, and allows for the simultaneous recording of an electronic voiding diary. Electronic real-time recording would increase the accuracy of the reported data compared with conventional voiding diaries.

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