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NOTE

URIKA, continuous ultrasound monitoring for the detection of a full bladder in children with dysfunctional voiding: a feasibility study

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Abstract

Objectives. To assess the feasibility of a new wearable, wireless ultrasonic device, the URIKA bladder monitor (UBM), in the detection of a full bladder in children with dysfunctional voiding (DV). *Methods.* This observational study included 14 children with DV who were subjected to an UBM monitoring session of 1.5–2 h. Transabdominal ultrasound (TUS) images were made as reference. The UBM measured the anterior–posterior bladder dimension by an ultrasound transducer, mounted in an elastic belt around the lower abdomen. Level of agreement between both methods was estimated by Bland–Altman analysis. Receiver operating characteristics (ROC) analysis was performed to determine a full bladder threshold for the studied population. *Results.* In 13 out of 14 patients, the UBM measured properly. Maximum bladder dimensions detected by the UBM and TUS were 6.69 $\pm$ 1.53 cm and 4.79 $\pm$ 0.99 cm respectively. Bland–Altman analysis showed a negative bias of -0.90 cm (limits of agreement: $-4.1/+2.3$ cm). ROC analysis resulted in a sensitivity and specificity of 78.3% and 100%, for a bladder dimension threshold of 5.03 cm. When this threshold was implemented *a priori*, the full bladder detection rate would have been 71%. In children younger than 10 years, this would be 100% ($n = 5$). *Conclusion.* The UBM is able to detect a full bladder with a detection rate of 71%, if a 5.03 cm threshold would be implemented. In patients younger than 10 years, the detection rate would be 100%. Future research will focus on increasing the UBM's accuracy and investigating the effect of UBM alarm treatment in children with urinary incontinence.

Introduction

Urinary incontinence (UI) is a common problem in children [1]. The prevalence of UI in children between the age of 6–10 years, equals 6%–9% [2]. It is important to treat UI effectively, because of the major social impact on the child's quality of life. Children rated 'wetting their pants in class' repeatedly in the top 5 of most stressful life events between 'losing my mother or father' or 'going blind' [3, 4]. Dysfunctional voiding (DV) is a form of lower urinary tract dysfunction resulting in recurrent urinary tract infections and/or UI. DV refers to children who habitually contract the external urethral sphincter or pelvic floor during the voiding phase, resulting in a staccato or interrupted uroflow pattern [5, 6]. DV is often experienced simultaneously with other storage or bladder filling symptoms, such as postponing micturition resulting in a sudden, unexpected need to void [5, 7]. The current non-pharmacological treatment options for these children are behavioural alarm treatment (clockwise voiding), cognitive treatment and pelvic floor exercises [6]. These treatments aim to improve bladder control by neglecting the full bladder and instead, void at preselected times [8]. Behavioural alarm treatment is based on the concept of negative reinforcement, in which the child responds to an alarm alerting urinary leakage by contracting the pelvic floor muscles which will avoid setting of the alarm [9]. It is suggested that positive

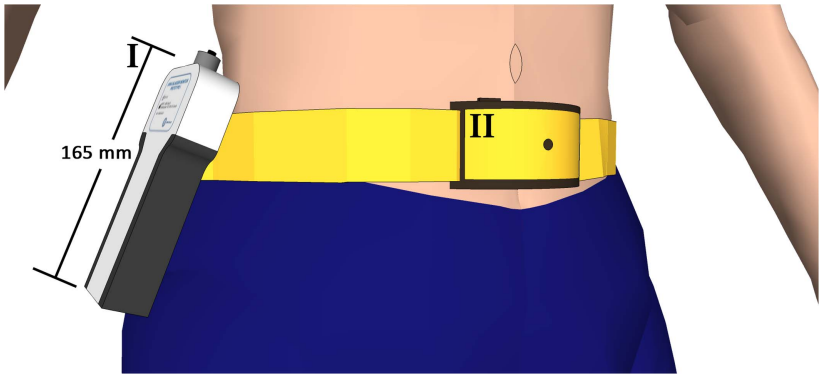

Figure 1. The electronic case (I) and the transducer assembly (II) of the UBM. In the centre of the assembly (II), the single-element transducer is positioned.

reinforcement, by alarming the patient when the bladder is at near maximum capacity, would increase the effectiveness of the current treatment options [10]. Possible devices that are clinically used to determine the full bladder volume are conventional B-mode ultrasound and the BladderScan® (Verathon Inc., Bothell, WA). However, these systems are not able to alarm the patient of having a full bladder prior to micturition. Furthermore, each individual measurement requires actions by a trained professional and also the size of these systems is not optimal for continuous monitoring, especially in children. Small, wearable bladder monitors to automatically detect a full bladder have been developed in the past [10–13]. These systems were based on a single-element ultrasound transducer which detected the posterior bladder wall, when it rose above the symphysis pubis [14]. However, these systems were not clinically evaluated during natural bladder filling or used in children for prolonged periods. None of these systems made their way to the daily clinical practice.

In this study, a new wearable, wireless ultrasonic monitor, the URIKA bladder monitor (UBM) has been developed. This device automatically estimates the anterior–posterior (A–P) bladder dimension. When the A–P bladder dimension exceeds a critical threshold, the patient will be alarmed of a full bladder. With this positive feedback system, it is hypothesized that both the awareness of the bladder filling and the effectiveness of present treatment options will increase.

In this feasibility study, the UBM is primarily used for observational purposes to measure changes in A–P bladder dimensions over time. The aim of this study was to estimate an alarm threshold and to determine the full bladder detection rate of the UBM in a study population of children with DV.

Materials and methods

The UBM is an ambulatory A-mode based ultrasonic device, which transmits ultrasound pulses in the direction of the bladder. The UBM consists of two main parts: a transducer assembly and electronic case (figure 1).

First, the transducer assembly (90 × 72 × 21 mm) contains a single-element, 3.81 MHz ultrasound transducer (at a 0° angle) with an active diameter of 19 mm. The combination of this acoustic frequency and active diameter results in a near field length of 23 cm, which is deep enough to detect the posterior wall of the urinary bladder [15, 16]. The transducer assembly is positioned perpendicular to the skin between the symphysis pubis and the umbilicus with a belt. To minimize acoustic interference with air, a liquid coupling gel is used.

Next, the electronic case is connected with a short cable to the transducer assembly, which can be fixed to the elastic belt on the hip side. The electronic case (165 × 80 × 28 mm) consists of a printed circuit board (PCB), two AA-batteries and a micro-SD card. Figure 2 illustrates a simplified diagram of the UBM's architecture. The PCB consists of an analogue and a digital part. The analogue part contains a high voltage generator which charges a capacitor (C) of 10 nF (red box in figure 2). The capacitor is discharged by the pulse forming network (S) to excite the ultrasound transducer (X), generating a sound wave at a frequency of 3.81 MHz with a duration of 0.13 μs. A radio-frequency receiver processes the returning ultrasound reflections of the anterior and posterior bladder walls, which are amplified by a variable gain amplifier for attenuation compensation. The received digital data is stored in a memory, which is controlled by a complex programmable logic device.

The stored data can be uploaded to a PC for visual inspection through a low energy wireless link (Bluetooth®). Furthermore, the digital data is transferred to the internal micro-SD card for off-line evaluation. The distance between the A–P bladder wall is calculated through a software algorithm installed on a laptop or smartphone. First, the raw data is pre-processed by applying a low-pass filter to detect the envelope of the signal and to minimize the influence of noise. Next, a threshold value was calculated by adding the

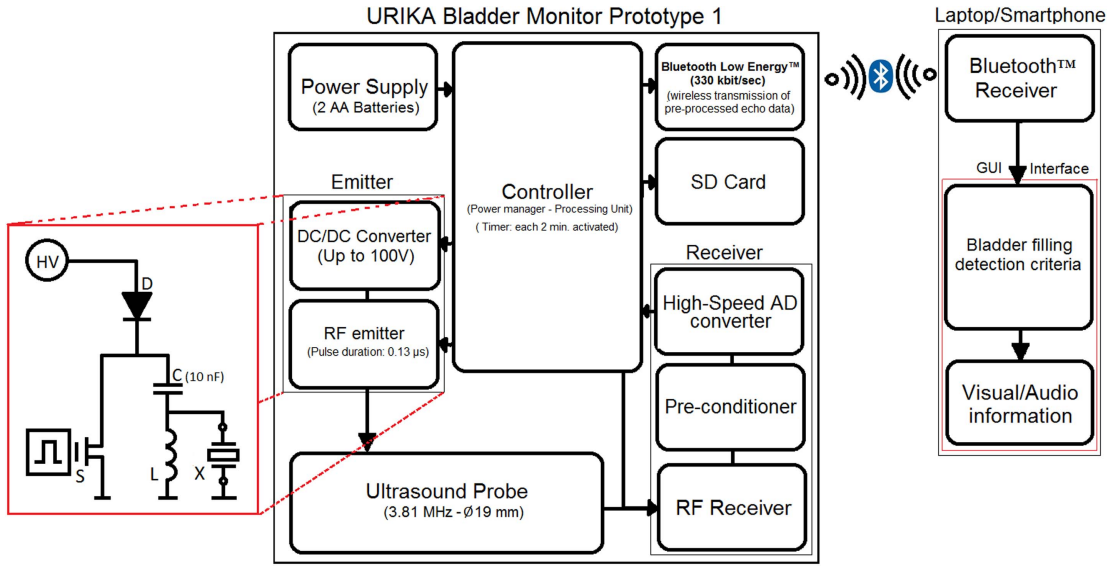

Figure 2. Diagram of the internal electronic structure—red box: circuit for discharge of a 10 nF capacitor (*C*) for generation of a high-voltage (HV) pulse (*S*) to the transducer (*X*).

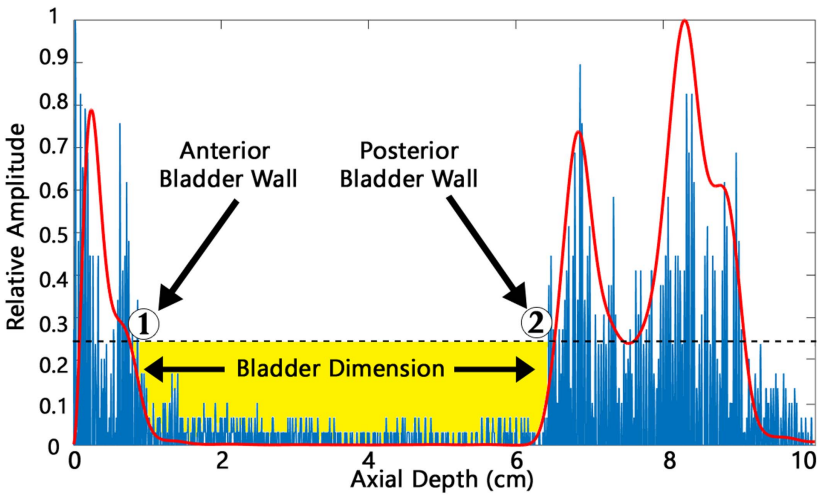

Figure 3. The normalized raw data (blue) and the envelope data (red) of a full bladder in patient 2. The axial position of the anterior (1) —and posterior (2) wall of the bladder are found by comparing the filtered echo to the detection threshold (horizontal, broken line). When the amplitude exceeds the threshold, the position of the bladder walls are found.

minimum value of the signal to its standard deviation [17]. The position of the anterior wall is detected when the first time-sample of the envelope is below the threshold value (for an axial depth >0.5 cm). Secondly, the posterior wall is detected when the next consecutive time-sample exceeds the threshold value [17]. The time difference between the recorded reflections of both bladder walls (Δt) is transposed to an estimated A–P bladder dimension, based on a speed of sound (c) in urine of 1540 m s^{-1} (equation (1)).

$$\text{A–P bladder dimension} = \frac{c \cdot \Delta t}{2} \qquad (1)$$

Figure 3 shows a received signal of a full bladder from one of the patients.

Experimental protocol

To evaluate the UBM, a feasibility study for the UBM was conducted in a group of children with DV who were scheduled for clinical bladder training at the department of Pediatric Urology. After approval from the Local Ethical Committee of the University Medical Centre Utrecht, written informed consent was obtained. Children were included between the ages of 6 and 12 years with a positive diagnosis for DV, based on their patient history and repeated staccato uroflow measurements [6]. Patients with a history of constipation and a transverse rectum diameter of more than 35 mm, measured by ultrasonography, were excluded. An enlarged rectum will displace the posterior wall of the bladder, which will influence the detection of the A–P bladder dimension [18].

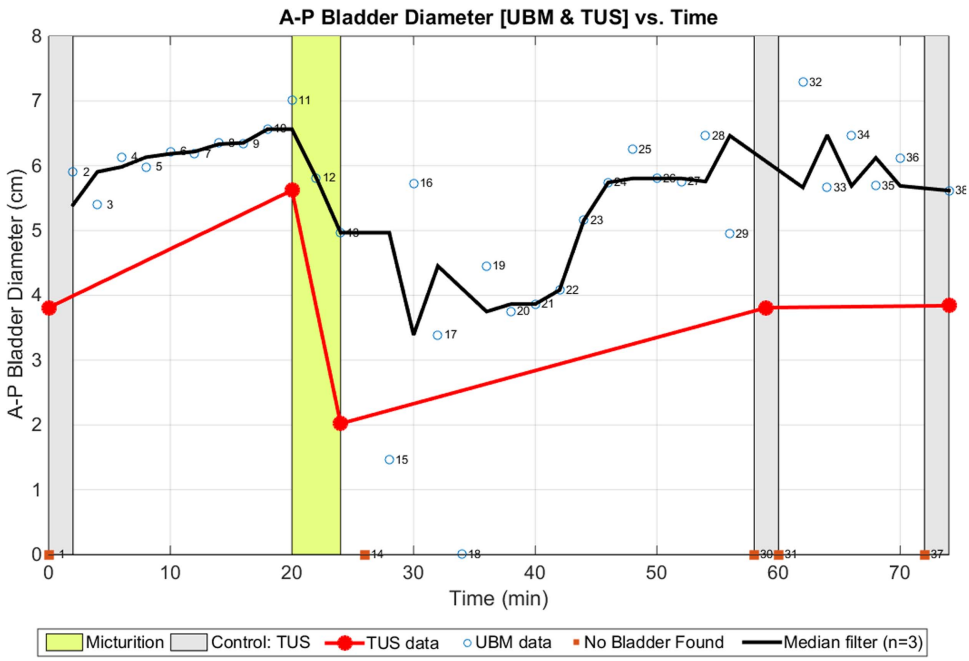

Figure 4. Results of a 7 year old girl showing a correlation between the bladder filling and the estimated bladder dimension over time, for the UBM and TUS. Yellow area: period of micturition (residu present), grey area: period of transabdominal ultrasound.

At study entrance, the patients presented on the ward and an initial transabdominal ultrasound image (TUS) of the bladder was obtained. For TUS, conventional 4 MHz convex probe (Philips Medical Systems HD11 XE) was applied to the lower abdomen above the symphysis with the patient lying supine, corresponding to standard clinical practice. By using the digital calliper system, the A–P bladder dimension was measured by the researcher. Next, the UBM was placed on the abdomen of the patient recording the A–P bladder dimension every 2 min. As a reference, TUS of the bladder was performed every half hour to monitor the A–P bladder dimension. When the patient felt the urge to void, TUS was performed before and after micturition. To minimize the impact of the study procedure on the bladder training, the patients were free to move around while wearing the UBM.

The measured A–P bladder dimensions were analysed by descriptive statistics, calculating the maximum and standard deviation, which will serve as an indication for the future alarm threshold. To determine the level of agreement between the UBM and TUS, Bland–Altman analysis was performed. Due to the same transducer position of the UBM and the TUS probe, it was not possible to record the bladder dimension for both methods simultaneously. For this reason, the calculated A–P bladder dimensions of the UBM were averaged, using the data before and after TUS. But in case the UBM was repositioned too high on the abdomen after TUS, the UBM measured above the superior dome of the bladder. As a result, the A–P bladder dimension could not be detected. In this situation, only one measurement was used for the Bland–Altman analysis.

To determine a full bladder alarm threshold for the UBM, a receiver operating characteristics (ROC) analysis was performed. In the ROC analysis, the UBM was compared to TUS, calculating sensitivity, specificity and the Area under the curve (AUC). Based on the estimated full bladder alarm threshold, the full bladder detection rate will be determined.

Results

A total of 14 patients (12 girls, 2 boys) [mean age: 9.2 $\pm$ 1.8 years] have been enrolled in this study. With a sample size of 14 patients, it is possible to estimate a full bladder detection rate of 85% within a 90% confidence interval of $\pm$15%, which is considered to be acceptable in this first feasibility study [19]. Before conducting descriptive analysis, the first patient was excluded due to an internal malfunction of the UBM. Furthermore, UBM data was excluded when the bladder was temporarily out of the detection range due to incorrect repositioning. When the bladder was out of range, a measurement error of less than one centimetre was found corresponding to the abdominal wall thickness. For this reason, all calculated A–P bladder dimension values below 1 cm were excluded.

Level of agreement

In this study population, the UBM measured a higher maximum ($\pm$SD) A–P bladder dimension compared to TUS, respectively 6.69 $\pm$ 1.53 cm and 4.79 $\pm$ 0.99 cm. This trend is illustrated by figure 4

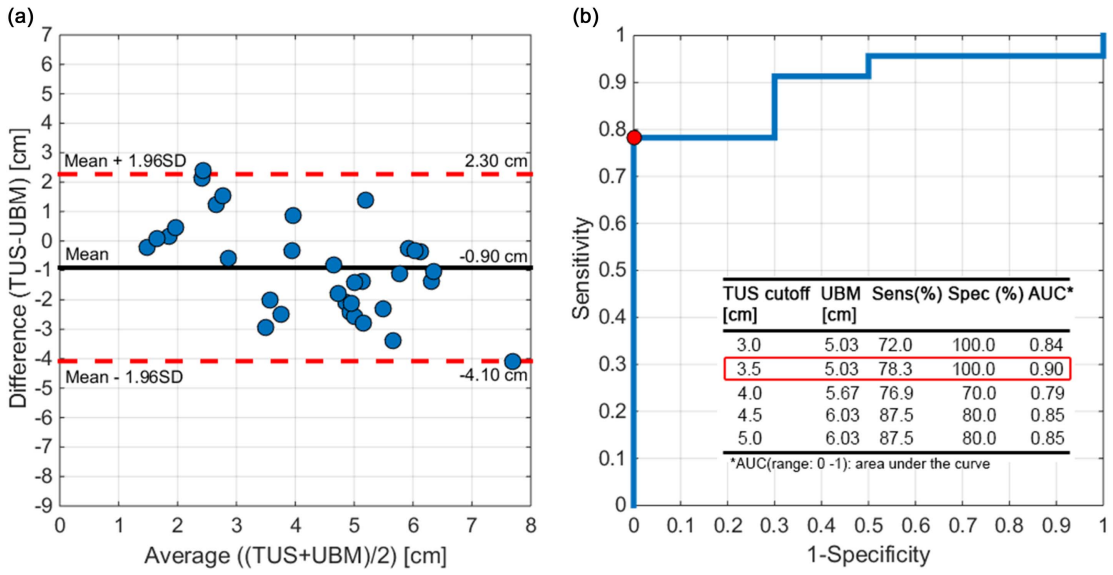

Figure 5. (A) Bland–Altman plot of estimated A–P bladder dimensions by the UBM and TUS. (B) ROC curve for TUS $>$ 3.5 cm, and the corresponding sensitivity, specificty and AUC values (TUS-cut-off values: 3–5 cm). The red dot indicate the curve value at highest accuracy.

which presents the changes in A–P bladder dimension over time, measured by the UBM and TUS. Despite this difference, both the UBM and TUS were able to estimate the filling status and detect a full bladder. Also, the decrease in A–P bladder dimension around the time of micturition is visible.

Figure 5(A) represents the results of the Bland–Altman analysis, resulting in a mean difference (d) between both methods equal to -0.90 cm. This also states that the UBM tends to measure a higher A–P bladder dimension compared to TUS. The limits of agreement were equal to -4.1 and $+2.3$ cm.

Alarm threshold

The table in figure 5(B) reports the results of the ROC analysis of the UBM, for a range of TUS cut-off values of 3–5 cm. It is noted that the highest specificity (1.00) and AUC (0.90) are found for a TUS cut-off value of 3.5 cm, which is related to an UBM alarm threshold of 5.03 cm. Figure 5(B) visualizes the corresponding ROC curve.

In this study, 17 periods of micturition were reported: five patients voided twice, one patient did not void and the remaining seven children all voided once. In 12 out of 17 times, the A–P bladder dimension of a full bladder, prior to micturition, exceeded the alarm threshold of 5.03 cm, which corresponds to a detection rate of 71%. In the five patients who voided twice, the UBM detected a full bladder in 8 out of 10 times (detection rate: 80%).

In three patients, it was not possible to detect a full bladder based on this threshold. In one patient, the full bladder was detected once, instead of the two times it was full. Comparing these four patients to the remaining population, showed that the mean age of these four patients was higher (10.7 ± 1.0 years) compared to the other subjects (8.9 ± 1.6 years). When considering the patients younger than 10 years, it was possible to detect a full bladder in all patients ($n = 5$).

Discussion

The purpose of this feasibility study was to determine the full bladder detection rate and the detection precision of the UBM, in a study population of children with DV. Comparing the results of the UBM and TUS showed that there is a discrepancy between these two methods. The estimated A–P bladder dimensions for the TUS were smaller compared to the UBM. This trend was also visible in the Bland–Altman analysis, resulting in a mean negative difference and the wide limits of agreement. This is partly caused by the postural position of the patient. The UBM measured the patients mostly in upright—or sitting position, while TUS was performed in supine position. Gould *et al* [20] showed that there is a two—to threefold rise in bladder pressure when tipping a subject from a supine to an upright position, due to the weight of the abdominal organs. Due to the pressure increase, the bladder expands in the A–P dimension and reduces in height. Kirchleitner *et al* [21] also showed that the A–P dimension of the bladder increases when changing from a seated to an upright position. Due to the difference in posture between both detection methods, TUS showed smaller A–P bladder dimensions compared to the UBM. This level of influence was higher than initially expected.

Furthermore, the accuracy is also influenced by movement of the transducer belt. Despite repositioning of the UBM after TUS, intermitted movement of the child resulted in an upwards movement of the

UBM, only estimating the superior dome of the bladder. As a result, the A–P bladder dimension is smaller than the present maximum dimension, which results in a positive limit of agreement (figure 5(A)). Furthermore, upwards movement could also cause loss of contact or air interference between the UBM and the skin, resulting in a dimension value equal to zero.

Alarm threshold

Despite the previous factors of influence, the UBM alarm threshold of 5.03 cm, resulted in an AUC of 0.90, a sensitivity of 78.3% and a specificity of 100%. When this threshold would have been implemented as an alarm *a priori*, a detection rate of 71% should have been found in the studied population. In four patients, the maximum A–P bladder dimension did not exceed this threshold prior to micturition. It was noted that these four patients were all familiar with a relative small bladder capacity combined with the diagnosis of DV [22]. For these four patients, the maximum voided volume during behavioural bladder training varied between 107–254 cc, compared to the age-expected volume of 330–390 cc [6]. Due to a small bladder volume for age, the bladder can be easily situated out of the UBM detection range. Furthermore, these four patients were relatively older, compared to the remaining population. In children, the bladder is considered to be abdominal organ, positioned between the pubic bone and the umbilicus. In general, the bladder can be detected with a transducer in a perpendicular position relative to the abdominal wall. When a child grows older, the full bladder is situated somewhat lower within the small pelvis, behind the pubic bone [13]. Therefore, the bladder is more difficult to detect with an ultrasound transducer positioned perpendicular to the abdominal wall [13]. In combination with a relatively obese abdomen in upright position, the UBM transducer orientation changed in a more upward direction measuring in the plane above the bladder, which resulted in a lower detection rate [13].

Due to differences in the expected—and actual bladder capacities found in the studied population, we advise to set the threshold of 5.03 cm merely as an initial threshold. To optimize the UBM for each individual patient, the healthcare specialists (e.g. urologists, urotherapists) are advised to measure the child's maximum A–P bladder dimension in supine position before micturition, by means of TUS [15]. The UBM threshold can be adjusted by adding the mean difference ($d = 0.90$ cm) to the measured TUS value.

Future research

Future research will focus on redesigning the current UBM model and adjusting the alarm algorithm to increase the UBM's stability and detection rate. First, the UBM will be combined with an adhesive silicone coupling layer, which will fixate the transducer to the skin which prevents upwards movement. Secondly, to increase the detection rate in older patients, multiple transducers will be implemented at an angle 0°–30° pointing downwards into the pelvic region [15, 23]. Furthermore, a body position sensor will be installed to change the alarm threshold in respect to body position. Finally, in order to personalize the UBM, an adaptive algorithm will be developed, which will adjust the alarm threshold based on the maximum A–P bladder dimensions previously detected before micturition. When these conditions are met, the focus will be on the clinical evaluation of this new volume-based alarm. In the near future, we hope to prove that this device will be a useful product, supporting biofeedback treatment of children with lower urinary tract symptoms.

Conclusions

This article described the URIKA Bladder Monitor, which is developed to detect a full bladder and alarm the user before micturition. In the studied population, the UBM was able to detect a full bladder with a proper sensitivity, specificity and detection rate. For children younger than 10 years, it was possible to detect a full bladder in all patients. Future research will focus on increasing the accuracy of the UBM and investigating the effect of positive alarm treatment by the UBM.

Acknowledgments

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Conflict of interest

This feasibility study was performed by P G van Leuteren, as a part of his master graduation internship for Technical Medicine (University of Twente, Enschede, The Netherlands) at the department of pediatric urology. Currently, P G van Leuteren is an employee of Novioscan. The other authors have no conflict of interest to declare.

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