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# Feasibility of the Lilium α-200 portable ultrasound bladder scanner for accurate bladder volume measurement

**Tsuyoshi Majima[1]** , **Yumi Oota[2]** , **Yoshihisa Matsukawa[1]** , **Yasuhito Funahashi[1]** , **Masashi Kato[1]** ,
**Hiromitsu Mimata[3]** , **Momokazu Gotoh[1]**

[1]Department of Urology, Nagoya University Graduate School of Medicine, Nagoya, [2]Department of Urology, Oita Oka Hospital, Keiwakai, [3]Department of Urology, Oita University Faculty of Medicine, Oita, Japan

**Purpose:** The aim of this study was to investigate whether data obtained from the Lilium α-200 (Lilium Otsuka Co., Ltd., Japan) correlated with conventional frequency-volume chart (FVC) and post-void residual urine volume (PVR) obtained by urethral catheterization.

**Materials and Methods:** This was a prospective multicentre study. Patients hospitalized for the treatment of lower urinary tract symptoms were included. Patients were evaluated with conventional FVC and Lilium α-200 for 2 days. PVR was measured by urethral catherization after urination at the end of the 2 day evaluation period.

**Results:** A total of 42 patients were enrolled in this study. Voided volume and PVR measured by Lilium α-200 were significantly correlated with voided volume obtained from conventional FVC and PVR measured by urethral catheterization, respectively. There was considerable measurement error in voided volume measured by Lilium α-200 (-21.0±102.0 mL). In contrast, the error between PVR measured by the Lilium α-200 and PVR obtained by urethral catheterization was 2.4±52.0 mL. Additionally, high body mass index, but not sex, benign prostate hyperplasia, time zone of measurement (daytime vs. nighttime), and examiners (a urologist versus other healthcare providers) were significantly associated with inaccurate results in voided volume.

**Conclusions:** Voided volume and PVR measured by the Lilium α-200 were correlated with voided volume obtained from conventional FVC and PVR measured by urethral catheterization, although accuracy of the measurements was not high. The Lilium α-200 is a useful device to easily measure approximate bladder volume.

**Keywords:** Ultrasonography; Urinary bladder; Urination disorders/diagnosis

## INTRODUCTION

In most developed countries, the ageing population is increasing [1]. The prevalence of lower urinary tract symptoms (LUTS) increases with age [2]. It is well known that LUTS are not only associated with quality of life [3,4], but also with depression, anxiety [3,5], and social restriction [6]. These psychosocial disturbances can lead to appetite loss, malnutrition, and decreases in activities of daily life, resulting in the development of sarcopenia or frailty [7,8]. Hence, appropriate
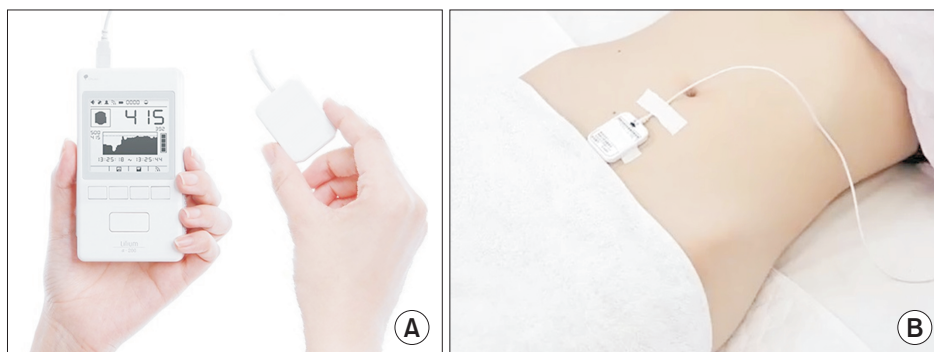
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**Fig. 1.** (A) The Lilium α-200 portable ultrasound bladder scanner consists of the main body (120×68×27 mm, 150 g) and a flat ultrasound probe (45×33×8 mm). (B) The flat ultrasound probe (45×33×8 mm) is attached to the suprapubic area of a patient. Bladder volume is automatically and periodically measured every minute by A-mode ultrasound, which can generate a frequency-volume chart and residual urine volume after urination.

care for LUTS could not only improve the quality of life but also contribute to extending healthy life expectancy in older adults.

Frequency-volume charts (FVCs) and residual urine measurements have been widely used for the evaluation of lower urinary tract dysfunction. The FVC provides much useful information such as voided volume, 24-hour urine production, and the nighttime urine production rate. However, it is sometimes bothersome for patients or caregivers to measure and record voided volume and the time at every urination, especially at night. Postvoid residual urine volume (PVR) is easily measured with an ultrasound instrument by medical staff [9], but cannot be done by patients themselves. Therefore, simpler bladder monitoring methods, which can be easily performed by any patient, are needed.

The Lilium α-200 (Lilium Otsuka Co., Ltd., Kanagawa, Japan) is a new bladder volume ultrasound imaging device that monitors not only PVR but also 24-hour urine production and automatically calculates voided volume from data measured every minute. Hence, this new ultrasound imaging device could be used as a substitute for conventional FVCs and ultrasound bladder scanners. However, the accuracy of the data obtained using this device remains unclear. Therefore, to verify the accuracy of the device, we investigated whether data obtained by use of the Lilium α-200 portable ultrasound bladder scanner correlated with data collected by use of conventional FVCs and PVR measured by urethral catheterization.

## MATERIALS AND METHODS

This was a prospective multicenter study performed according to the ethical principles of the Declaration of Helsinki and approved by the ethics committee of Nagoya University Graduate School of Medicine (approval number: 2015-03926779).

Patients who were hospitalized in Nagoya University Hospital or Oita Oka Hospital, Keiwakai, for the treatment

of LUTS, such as benign prostatic hyperplasia or overactive bladder, were included in this study from January 2016 to April 2018. Patients needed to be over 20 years old and give written informed consent. Patients were evaluated using conventional FVCs and the Lilium α-200 device (Lilium Otsuka Co., Ltd., Kanagawa, Japan) for 2 days. The Lilium α-200 consists of the main body (120×68×27 mm, 150 g) and a flat ultrasound probe (45×33×8 mm) which is attached to the suprapubic area by a urologist or another health care provider (Fig. 1). The bladder volume is automatically and periodically measured every minute by A-mode ultrasound, which can generate an FVC and residual urine volume after urination. PVR was also measured by urethral catherization after urination to evaluate device accuracy at the end of the 2-day evaluation period.

### 1. Statistical analysis

Spearman's correlation analysis was performed to assess the correlation between voided volume obtained from the portable ultrasound bladder scanner and that assessed by conventional FVCs as well as between PVR measured by the portable device and that obtained by urethral catherization. In addition, Bland and Altman plots were used to evaluate the degree of agreement between data obtained from these methods. According to a previous study that examined the accuracy of a portable abdominal ultrasound machine, the bladder reading was considered accurate if it was within 25% of the PVR obtained by catheterization [10]. Based on this study, in our study, data from the portable scanner within ±30% of data from conventional FVCs were defined as "accurate", whereas data with greater measurement error were defined as "inaccurate". Univariate logistic regression analysis was performed to evaluate predictive factors for "inaccurate" results using sex (male vs. female), body mass index (BMI) (<18.5 kg/m$^2$ vs. 18.5 to 25.0 kg/m$^2$ vs. >25.0 kg/m$^2$), benign prostatic hyperplasia, time zone of measurement (daytime vs. nighttime), and examiner (a urologist vs. other health care providers).

**Table 1.** Characteristics of the patients included in the study

| Characteristic | Value |
|---|---|
| Age (y) | 71 (69–74) |
| Sex (male:female) | 32:10 |
| Body mass index (kg/m$^2$) | 22.7±3.1 |
| Primary disease | |
| Benign prostatic hyperplasia | 24 |
| Neurogenic bladder | 3 |
| Overactive bladder | 11 |
| Nocturnal polyuria | 3 |
| Stress urinary incontinence | 1 |

Values are presented as median (interquartile range), number only, or mean±standard deviation.
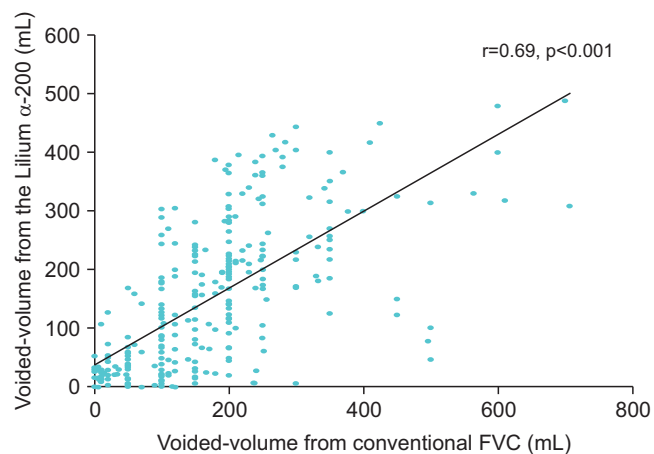


**Fig. 2.** Scatter plot of voided volume from the portable bladder scanner and that from conventional frequency-volume charts (FVCs). Spearman's correlation analysis showed a significant correlation between voided volume measured by the portable device and that measured by conventional FVCs (r=0.69, p<0.001).



**Fig. 3.** Scatter plot of postvoid residual urine volume (PVR) from the portable bladder scanner and that obtained by urethral catheterization. Spearman's correlation analysis showed a significant correlation between PVR measured by the portable device and that obtained by urethral catheterization.



**Fig. 4.** Bland–Altman plot of difference in voided volume (the portable device measurement minus conventional frequency-volume chart [FVC] measurement) against the mean of the two measurements. SD, standard deviation.

## RESULTS

A total of 42 patients were enrolled in this study. The patients' characteristics are shown in Table 1. Because 8 of 42 patients refused urethral catheterization, data were analyzed on the number of times the 42 patients urinated (316 times) and on PVR in 34 patients (34 times). There was significant correlation between voided volume measured by use of the portable ultrasound bladder scanner and conventional FVCs (r=0.69, p<0.001; Fig. 2). A significant correlation was also found between PVR measured by use of the portable device and PVR obtained by urethral catheterization (r=0.74, p<0.001; Fig. 3). The measurement error between voided volume measured by the portable scanner and conventional FVCs was -21.0±102.0 mL (mean±standard deviation [SD]) (Fig. 4). Conversely, the error between PVR measured by the portable scanner and PVR obtained by urethral catheteriza-
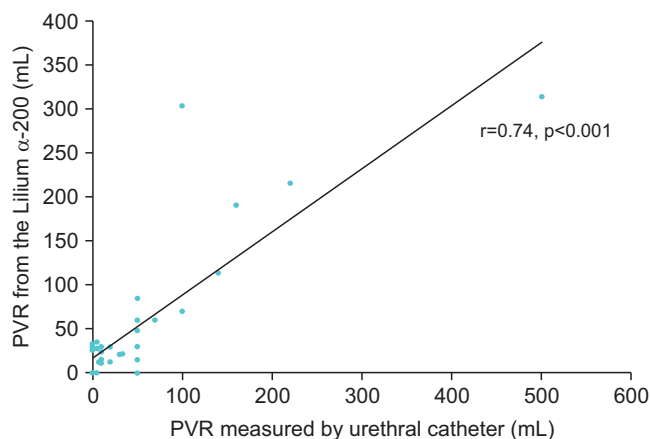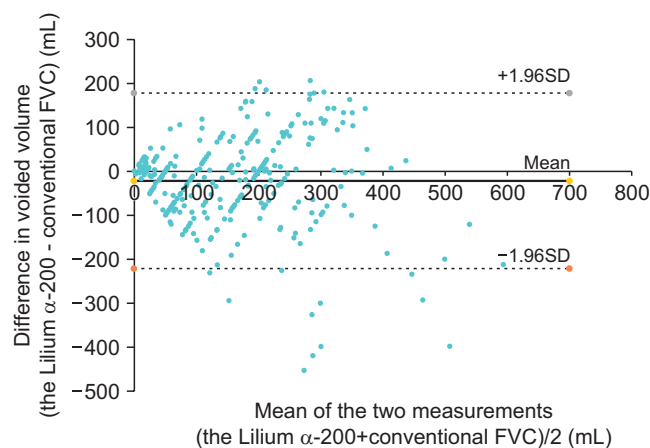
tion was 2.4±52.0 mL (mean±SD) (Fig. 5). The measurement error of "accurate" results between voided volume from the portable scanner and conventional FVCs was 4.3±53.3 mL, whereas the measurement error of "inaccurate" results was -55.2±136.3 mL (Table 2). Univariate logistic regression analysis indicated that BMI >25.0 kg/m$^2$ was significantly associated with "inaccurate" results of the portable scanner compared with BMI <18.5 kg/m$^2$. However, sex, benign prostatic hyperplasia, time zone of measurement (daytime vs. nighttime) and examiner were not significantly associated with "inaccurate" results of the portable device (Table 3).
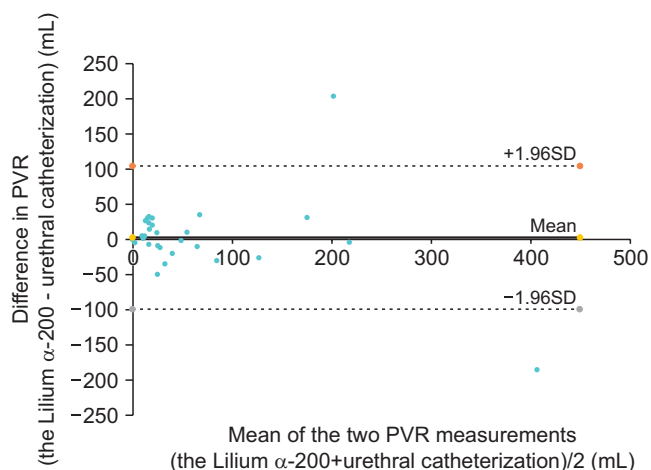
**Fig. 5.** Bland–Altman plot of difference in postvoid residual urine volume (PVR) (the portable device measurement minus urethral catheterization measurement) against the mean of the two measurements. SD, standard deviation.

**Table 2.** The measurement error of the Lilium α-200 portable bladder scanner in voided volume or PVR

| Characteristic | Number | Measurement error (mL) (mean±SD) |
|---|---|---|
| Voided volume (all) | 316 | -21.0±102.0 |
| Voided volume (accurate) | 181 | 4.3±53.3 |
| Voided volume (inaccurate) | 135 | -55.2±136.3 |
| PVR | 34 | 2.4±52.0 |

Data from the portable device within ±30% of data for conventional frequency-volume charts were defined as "accurate", whereas data with greater measurement error were defined as "inaccurate".
PVR, postvoid residual urine volume; SD, standard deviation.

**Table 3.** Predictive factors for "inaccurate" results of the Lilium α-200 portable bladder scanner. BMI >25.0 kg/m$^2$ was the only a factor significantly associated with "inaccurate" results of the portable device

| Characteristic | Odds ratio | 95% confidential interval | p-value |
|---|---|---|---|
| Sex | 1.12 | 0.65–1.93 | 0.67 |
| BMI (kg/m$^2$) | | | |
| <18.5 | | Reference | |
| 18.5–25.0 | 2.26 | 0.87–5.88 | 0.09 |
| >25.0 | 5.69 | 2.01–16.15 | 0.01 |
| Time zone (daytime vs. nighttime) | 0.85 | 0.47–1.52 | 0.58 |
| Examiners | 0.67 | 0.41–1.09 | 0.11 |

BMI, body mass index.

## DISCUSSION

The findings of the present study demonstrated 1) a significant correlation between voided volume and PVR measured by use of the Lilium α-200 portable ultrasound bladder scanner and voided volume obtained from conventional FVCs and PVR measured by urethral catheterization, respectively; 2) considerable measurement error in voided volume measured by the portable scanner (-21.0±102.0 mL); and 3) a significant association of high BMI, but not sex, benign prostatic hyperplasia, time zone of measurement (daytime vs. nighttime), or examiner, with inaccurate results in voided volume.

Only one clinical study has investigated the accuracy of the Lilium α-200 portable scanner [11]. Those authors evaluated the correlation between bladder volumes measured periodically by the portable scanner and instilled volume during video-urodynamic study. They indicated that there were strong correlations between instilled and bladder volumes measured by the portable scanner (r=0.86, p<0.001) as well as between PVR and that obtained by catheter drainage (r=0.94, p<0.001). They reported much more accurate results than ours. Since they examined the portable scanner only during one-time urination in the supine position, the ultrasound probe should be at the same position as adjusted in the beginning of the examination. By contrast, in our study, because the portable scanner recorded continuously over 24 hours, dislocation of the probe due to daily activities could have affected the accuracy of the results. This could contribute to the difference between the previous study and ours. Hence, for obtaining the most accurate recording, the

portable scanner might be an optimal option in inactive patients such as disabled patients or older adults with fewer activities of daily living.

Although we found a significant correlation between the portable scanner and conventional FVCs, there was considerable measurement error in voided volume (-21.0±102.0 mL). We found that the variation in voided volume was associated with high BMI. Since the Lilium α-200 is an ultrasound imaging device, we hypothesize that the probe dislocation rate would be increased owing to patient obesity. The device is compressed onto the lower abdomen by an abdominal bandage to obtain a clear image of the bladder; however, the probe is likely to be dislocated by changes in posture in obese patients. In addition, a clear bladder image may be difficult to obtain owing to the absorption of ultrasound energy by the abdominal adipose tissue in obese patients. Therefore, the results of the Lilium α-200 in obese patients should be interpreted with caution. However, apart from obese patients, bladder data obtained from use of the portable scanner were not affected by sex, benign prostatic hyperplasia, time zone of measurement (daytime vs. nighttime), or examiner (a urologist vs. health care providers) as

shown here. Hence, based on these results, it is assumed that the Lilium α-200 portable bladder scanner is a useful device that provides approximate bladder information regardless of sex, benign prostatic hyperplasia, time zone of measurement, or the profession of the examiners.

Because the bladder capacity or PVR of an individual could be estimated, the portable scanner can be used to evaluate patients with complaints of incomplete bladder emptying or symptoms of an overactive bladder. In addition, this device can also be used for prompted voiding in older adults. A previous randomized clinical trial showed that ultrasound-assisted prompted voiding results in significantly less daytime urine loss in older adults with urinary incontinence as well as better quality of life in care workers compared with conventional prompted voiding [12]. Hence, the Lilium α-200 portable bladder scanner may improve the quality of life of not only older patients with urinary incontinence but also their care workers through prompted voiding.

There are some limitations to this study. First, the sample size was very small. Although our study showed that obesity was the only risk factor for inaccurate results of the portable scanner, a larger cohort study might indicate other risk factors. Second, we evaluated the portable scanner for only 2 days. Because it may take time for patients to get used to handling this device, the learning curve could contribute to the measurement error of this device. Third, we did not evaluate which methods patients preferred: conventional FVC or the portable device. Fourth, the error between PVR measured by the portable device and that obtained by urethral catheterization was very small (2.4± 52.0 mL); however, the volume was not large (median, 15 mL; interquartile range, 5 to 50 mL). Hence, the accuracy of measurements of larger PVR remains unclear. Fifth, although our study indicated that the "examiners" were not associated with the measurement error of this device, we did not evaluate the inter-rater reliability of the device. Sixth, all patients had LUTS and we did not include a control population. Therefore, future studies should explore the applicability of the device in the population in general. Seventh, although we reported the impact of benign prostatic hyperplasia on the accuracy of results of the device, other conditions were not evaluated owing to the small sample size.

## CONCLUSIONS

The present study indicated that voided volume and PVR measured by the Lilium α-200 portable ultrasound bladder scanner correlated with voided volume obtained from conventional FVCs and PVR measured by urethral catheterization, although the accuracy of the measurements was not high. The portable scanner is a useful device than can easily measure approximate bladder volume and record an FVC as well as measure residual urine volume.

## CONFLICTS OF INTEREST

The authors have nothing to disclose and are not connected to Lilium Otsuka Co., Ltd.

## ACKNOWLEDGMENTS

## AUTHORS' CONTRIBUTIONS

Project development: Tsuyoshi Majima, Yoshihisa Matsukawa, and Hiromitsu Mimata. Data collection: Tsuyoshi Majima, Yumi Oota, and Yasuhito Funahashi. Data analysis: Masashi Kato. Protocol development: Yoshihisa Matsukawa. Manuscript writing: Tsuyoshi Majima. Manuscript editing: Hiromitsu Mimata and Momokazu Gotoh. Supervision: Momokazu Gotoh.

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