




ORIGINAL CLINICAL ARTICLE

Are three-day voiding diaries feasible and reliable? Results from the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) cohort

Anne P. Cameron¹ | Jonathan B. Wiseman² | Abigail R. Smith² | Robert M. Merion² | Brenda W. Gillespie¹ | Catherine S. Bradley³ | Cindy L. Amundsen⁴ | Claire C. Yang⁵  | Henry H. Lai⁶  | John O.L. DeLancey¹ | Margaret E. Helmuth² | Megan S. Bradley⁴  | Nnena Agochukwu¹ | Victor P. Andreev² | Ziya Kirkali⁷ | J. Quentin Clemens,¹ The LURN Study Group

¹Departments of Urology and Obstetrics and Gynecology, University of Michigan, Ann Arbor, Michigan

²Arbor Research Collaborative for Health, Ann Arbor, Michigan

³Iowa Department of Obstetrics and Gynecology, University of Iowa Carver College of Medicine, Iowa City, Iowa

⁴Duke Department of Obstetrics and Gynecology, Duke University Medical Center, Durham, North Carolina

⁵Department of Urology, University of Washington, Seattle, Washington

⁶Department of Urology, Washington University School of Medicine, St Louis, Missouri

⁷National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, Maryland

Correspondence

Anne P. Cameron, 1500 East Medical Center Dr, Taubman Center 3875, Ann Arbor, MI, 48109-5330.
Email: annepell@med.umich.edu

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Abstract

Aims: The aims of this study were to assess the completeness of voiding diaries in a research context and to correlate diary data with patient-reported questionnaires.

Methods: Men and women enrolled in the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) were given a 3-day voiding and fluid-intake diary to fill-out. Diaries were assessed for completeness and intake-output imbalances. They were assigned to one of four categories based on a percentage of missing data and fluid imbalance: no diary submitted, unusable (>40% missing void or intake volumes, or unphysiological fluid imbalance), usable but not complete, and complete.

Results: A total of 1064 participants were enrolled and 85% (n = 902) returned the bladder diary. Of the diaries returned, 94% (n = 845) had data on three separate days, 87% (n = 786) had no missing intake volumes, 61% (n = 547) had no missing voided volumes, and 70% (n = 635) had a fluid imbalance within 3 L across the 3-day time period, resulting in 50% (n = 448) of participants with 100% complete diaries. Younger age was associated with a higher likelihood of not submitting a diary, or submitting an unusable diary. Women had a higher likelihood of submitting an unusable diary or a usable but incomplete diary.

Conclusion: Overall, 50% of LURN participants returned voiding diaries with perfectly complete data. Incomplete data for voided volumes was the most common deficiency. There was only a moderate correlation between diary data and questionnaire responses, indicating that diaries are a source of unique information.

KEYWORDS

humans, questionnaires, surveys, urinary bladder

1 | INTRODUCTION

Bladder diaries are a rich source of relatively objective information on the voiding and fluid consumption habits of patients with lower urinary tract symptoms (LUTS). They are useful in identifying potential causes of LUTS, guiding behavior modifications, and assessing treatment outcomes. However, the usefulness of bladder diaries is largely dependent upon complete and accurate data. Diaries require significant patient effort to complete, which can result in missing data.¹

Several studies have assessed the utility of bladder diaries but most were limited by inclusion of single-sex,²⁻⁷ a single disease process, or a small study population.¹⁻¹¹ Self-reported measures of urinary symptoms are much faster to complete, but it is also not known whether these are sufficient to establish a clear clinical picture or if the diary is also needed.¹² Some studies that have compared bladder diaries and symptom scores derived from self-report items suggest that the bladder diary is superfluous at least for overactive bladder⁵ and incontinence⁷ in women, but this needs to be assessed in a larger mixed sex population with different LUTS. The primary aim of this study was to describe the completeness and accuracy of a three-day bladder diary in a large cohort of men and women seeking care for LUTS. Our hypotheses were that (a) most patients can accurately capture voiding habits and fluid intake in a diary, (b) voiding diary data and questionnaire data will correlate highly for daytime symptoms, and (c) voiding diary data and questionnaire data will correlate poorly for nighttime symptoms.

2 | MATERIALS AND METHODS

2.1 | Study design and population

The Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) recruited men and women from six US tertiary care sites as part of a 1-year prospective observational study. The study design and recruitment criteria have been previously detailed.¹³ Participants were at least 18 years of age and presented to a LURN physician with at least one LUTS as assessed by the LUTS Tool¹⁴ using a 1-month recall period. Participants with neurogenic bladder, major psychiatric disorders or other medical issues that might interfere with study participation (eg, dementia, psychosis, etc), as well as those who had difficulty reading or communicating in English, were excluded from the study. Data collected at a baseline visit included demographics, medical history, the Functional Comorbidity Index¹⁵ (FCI), body mass index (BMI), a three-day bladder diary,

patient-reported urinary symptoms, psychological symptoms, and quality of life.

2.2 | Measures

Bladder diaries in the LURN Observational Cohort Study were collected using a modified International Consultation on Incontinence Questionnaire (ICIQ) bladder diary,⁸ a validated diary with detailed information on participant intake and output over a three-day period. Study participants were instructed to enter the void and intake amount, intake type, the time each void and intake took place, and record their bladder sensation at the time of voiding (eg, none, normal, urgency), pad changes, and incontinence episodes (“stress” or “urge” or “unknown”). Participants reported the times they went to bed and woke up for the day, allowing for the classification of daytime and nighttime events.

Diary quality was assessed using the following metrics: void and intake data on three separate days, proportions of voids and intakes with a missing volume, and fluid imbalance over the 3-day period (calculated as total volume consumed minus total volume voided). Diaries with at least one void and intake recorded on three separate days and less than 40% missing void and intake volumes were classified as “usable”, while any returned diaries that did not meet these criteria were classified as “unusable”. Among the “usable” diaries, those with no missing volume data and a physiologically feasible fluid imbalance (<3 L across all 3 days) were considered “complete,” while others were defined as “usable, but not complete.” Hence all complete diaries had to be a full 33-day long, have all voided volumes and intake volumes recorded accurately with no checkmarks or simple statements such as “a lot” or “little” and be fluid balanced on average over the 3 days with no more than 1 L/d of imbalance indicative of missed recordings.

For the complete diaries, the following measures were derived (average per 24-hour period and total over the three 24-hour periods): number of voids, total voided volume, number of intakes, total intake volume, fluid balance, and number of incontinence episodes. Maximum voided volume and average volume per void were also calculated. Voids were split into day and night components for each 24-hour period, with day voids occurring during awake hours and night voids during sleeping hours. If waking and sleeping times were not indicated for a given 24-hour period, participant averages from other 24-hour periods were used. If waking and sleeping times were not indicated for a given diary, waking times of 6 AM and bedtimes of 12 AM were used for each of the three 24-hour periods in that diary. These

times were selected a priori as conservative estimates of typical waking and bedtimes.

Participants completed the LUTS Tool, a 44-item questionnaire assessing the frequency and both of LUTS over the preceding week. LUTS Tool question #2, “During a typical day in the past week, how many times did you urinate during waking hours?” and question #3, “During a typical night in the past week, how many times did you wake up because you needed to urinate?” were used for self-reported measures of average number of day and night voids, respectively.

2.3 | Statistical methods

A multinomial logistic regression model was fitted to assess factors significantly associated with the probability of membership in each category of bladder diary completion (complete, usable, unusable, and not submitted). Candidate covariates included age, sex, race, BMI category, education level, employment status, FCI, and history of a psychiatric diagnosis. Metrics derived from the bladder diary were summarized with means, standard deviations, quartiles, and ranges. The association between bladder diary metrics was explored using R^2 and polychoric correlation coefficients were used to evaluate associations between metrics derived from the bladder diary and self-reported urinary symptoms. All statistical analyses were completed using SAS 9.4 (Cary, NC).

3 | RESULTS

The LURN Observational Cohort Study enrolled 1064 participants (519 men and 545 women) with a mean age of 58.8 ± 14.1 SD years. Most participants (83%) were white, and the mean BMI was 30.1 ± 6.9 kg/m² with 43% classified as obese (BMI, >30 kg/m²). Participants had few comorbidities with a mean FCI of 2.3 ± 2.0 , including 19% with self-reported diabetes mellitus. About two-thirds of participants reported incontinence on the LUTS Tool. Details of the enrollment, patient demographics, and clinical symptoms were reported previously.¹³

Among the participants, 902 (84.8%) returned a baseline bladder diary. Diaries were excluded for the following reasons (not mutually exclusive): having fewer than 3 days completed ($n = 57$), failing to record an amount for more than 40% of voiding episodes ($n = 48$) or intake volumes ($n = 4$). This yielded 796 usable diaries (88%). When stringent criteria were applied, 49.7% (448 of 902 diaries returned) had complete volume data for all recorded intake and voiding events and had negligible fluid balance differences (ie, <3 L across all 3 days).

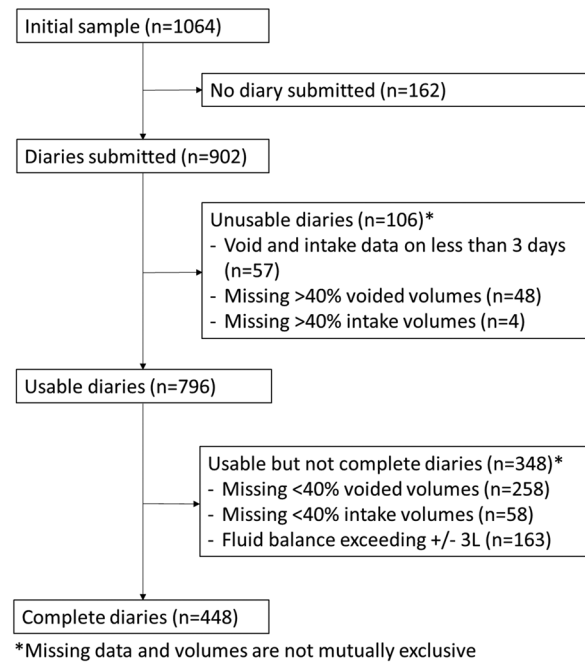


FIGURE 1 STROBE diagram of bladder diary completion.

Strengthening the reporting of observational studies in epidemiology (STROBE) diagram of how participant’s bladder diaries were categorized into “none submitted,” “unusable,” “usable,” or “complete.” Bladder diary groups and reasons for exclusion from groups are accompanied by relative sample sizes

Among those excluded from this category, the most common reason was missing a voided volume ($n = 258$) (Figure 1).

Younger age was associated with a higher likelihood of not submitting a diary, or submitting an unusable diary. Female sex was associated with a higher likelihood of submitting an unusable diary or a usable but incomplete diary. Lower education level was associated with a higher likelihood of submitting an unusable diary (Table 1).

Among the complete diaries, participants reported a mean of 8.8 ± 3.2 voids per 24-hour period with a mean total voided volume of 1769 ± 701 mL. They reported an average of 1.1 ± 2.0 incontinence episodes per 24-hour period. In terms of intake, participants consumed an average of 1812 ± 681 mL per 24-hour period with an average of 6.3 ± 2.2 separate intakes. This yielded an average fluid imbalance of -43 ± 458 mL per 24-hour period (Table 2). The distribution of average 24-hour fluid imbalance among all complete diaries is shown in Figure 2, and complete descriptive statistics on voiding and intake information is available in Table S1.

When assessing the utility of voiding diaries for guiding behavioral modification, 51% of participants with complete diaries had an average 24-hour number of voids exceeding 8, the typical threshold for defining urinary

TABLE 1 Associated factors of having a complete diary (results of multinomial logistic regression)

Variable	Not submitted vs complete			Unusable vs complete			Usable but not complete vs complete		
	Odds ratio estimate	95% confidence interval	P value	Odds ratio estimate	95% confidence interval	P value	Odds ratio estimate	95% confidence interval	P value
Age (per 10-y increase)	0.739	0.646, 0.845	<.001	0.738	0.633, 0.859	<.001	0.933	0.838, 1.038	.201
Sex (female vs male)	0.891	0.605, 1.311	0.557	2.188	1.378, 3.475	<.001	1.844	1.377, 2.468	<.001
Education (high school or less vs more than high school)	2.337	1.398, 3.904	0.001	1.320	0.663, 2.627	.430	1.166	0.733, 1.854	.516

frequency¹⁶ (Figure 3). About a third of participants reported an average 24-hour intake volume over 2 L, and 93 (64%) of these participants had urinary frequency (≥ 8 voids per day). Among these 93 participants, 57 (61%) reported being at least “somewhat” bothered by their urinary frequency. There was a statistically significant association between the average 24-hour number of voids and intake volume ($P < .001$); however, the R^2 value of 0.037 indicated that only 4% of the variance in voided volume was explained by intake volume (Table 3). Sixty-seven percent of participants consumed less than 2 L/d suggesting that they were possibly fluid restricting.

Comparing the average number of day and night voids to self-reported day and nighttime frequency on the LUTS Tool showed statistically significant and positive polychoric correlation coefficients ($P < .001$). However, polychoric correlation coefficients were below 0.500 (0.454 for average day voids and 0.493 for average night voids) (Figure 4). Furthermore, most patients recorded values in their bladder diaries outside of the range indicated on the corresponding response to the LUTS Tool question (59% for the average number of day voids and 69% for night voids) (Figure 5). Specifically, for average number of day voids, 85% of patients answering “1 to 3 times”, 77% answering “8 to 10 times”, 83% answering “11 to 13 times”, and 95% answering “14 or more times” had diary values outside of the range in their response. Similarly, for average number of night voids, 56% of patients answering “1 time”, 79% answering “2 times”, 88% answering “3 times”, and 87% answering “4 or more times” had average diary values (rounded up to the nearest whole void) not matching these responses.

4 | DISCUSSION

Although clinically helpful, bladder diaries are often viewed as burdensome to patients and study participants. We demonstrated that the vast majority (85%) of LURN participants were willing to fill out a 3-day fluid-intake and voiding diary.

Despite the strict criteria used to classify a diary as “complete,” almost 50% of diaries met this threshold. An additional 39% yielded incomplete but usable data. This is not to say that the other diaries were uninterpretable (and may have had clinical utility), but for research purposes, they were deemed not useful for this analysis. The most common missing data point was voided volume (ie, participant recorded that they voided but did not measure the volume). This would be expected in a LUTS population where 66% have urgency¹³ since it is difficult to measure urine output when rushing to void, or when urgency incontinence occurred before measuring. Also, it

TABLE 2 Bladder diary metrics per 24-hour period (complete diaries only, n = 448)

	Minimum	First quartile	Median	Third quartile	Maximum	Mean	Standard Deviation
Average number of voids	2.7	6.7	8.3	10.3	39.3	8.8	3.2
Total number of voids	8.0	20.0	25.0	31.0	118.0	26.3	9.5
Average voided volume, mL	386.9	1237.2	1700.5	2139.2	4377.0	1768.6	701.3
Total voided volume, mL	1160.8	3711.5	5101.5	6417.6	13130.9	5305.9	2103.9
Maximum voided volume (single void), mL	118.3	300.0	414.0	591.5	1419.6	466.2	207.1
Average number of intakes	1.7	4.7	6.0	7.5	19.7	6.3	2.2
Total number of intakes	5.0	14.0	18.0	22.5	59.0	18.9	6.7
Average intake volume, mL	522.5	1321.0	1725.2	2188.5	4495.2	1812.1	680.5
Total intake volume, mL	1567.4	3962.9	5175.5	6565.4	13485.7	5436.2	2041.5
Average fluid balance (out minus in), mL	-995.7	-386.9	-49.8	285.9	966.1	-43.4	458.4
Total fluid balance (out minus in), mL	-2987.0	-1160.8	-149.3	857.6	2898.3	-130.3	1375.1
Average number of leaks	0.0	0.0	0.0	1.0	13.3	1.1	2.0
Total number of leaks	0.0	0.0	0.0	3.0	40.0	3.2	6.0

is not surprising that women struggled more with measuring voided volume since urgency incontinence is more common in women and urine collection in the seated position is more challenging than for men who can collect urine in the standing position. This highlights the need for a method to collect voided volume that is easier for participants to use, particularly women.

Few studies have addressed diary completeness, with most relying on test-retest variability as a marker of completeness.^{2,8} However, reliability only reflects similarities between days, and not necessarily a patient's ability

(or willingness) to complete the diary. Two studies in LUTS patients reported on diary completeness, with "complete" diaries (based on various measures) in 53% (214 of 400) of men and women⁸ and 57% of 110 women,² similar to our results.

Analysis of voiding diary data collected from both men and women is not commonly performed^{1,5,11} and no studies have objectively compared the completeness of the collection. Ku et al¹ assessed the subjective burden of voiding diaries among 57 men and 105 women with LUTS on a 2-, 3-, or 7-day diary. Diary completeness was

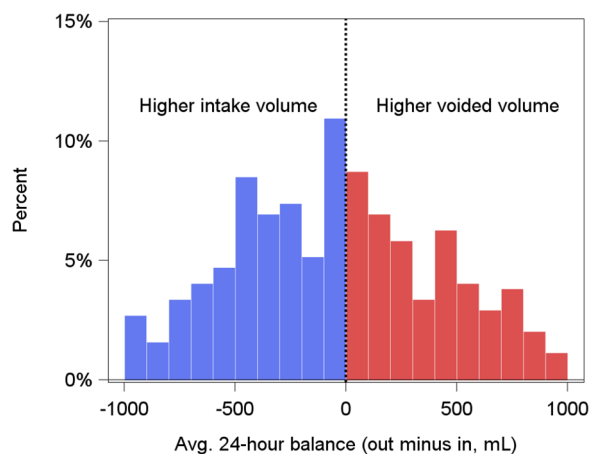


FIGURE 2 Distribution of avg. 24-hr. fluid balance (output minus input, mL, complete diaries only, n=448). Distribution of average 24-hour fluid balance (mL), defined as average voided volume minus average intake volume, among complete diaries only (n = 448). Blue bars represent values with higher average intake volume and red bars represent values with higher average voided volume

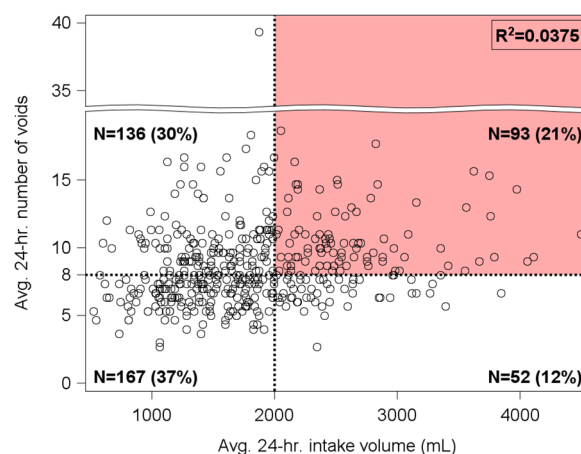
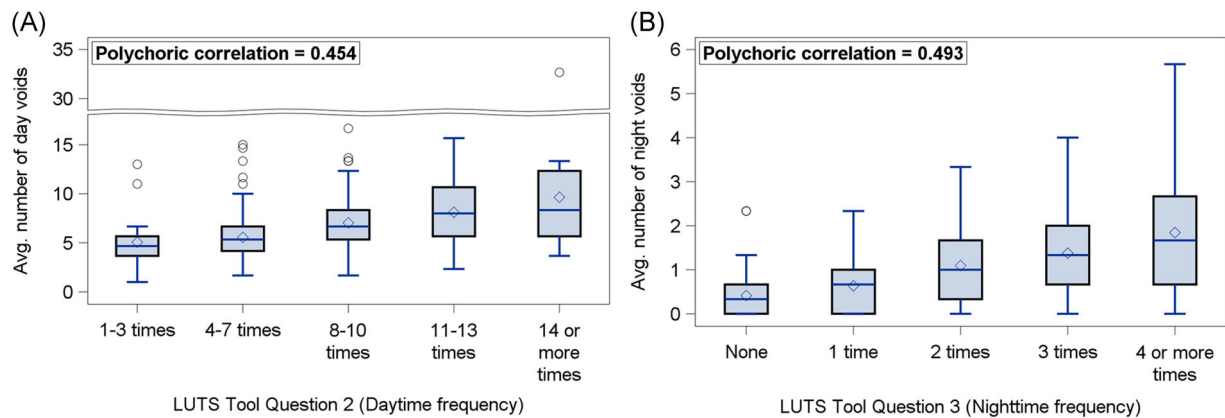
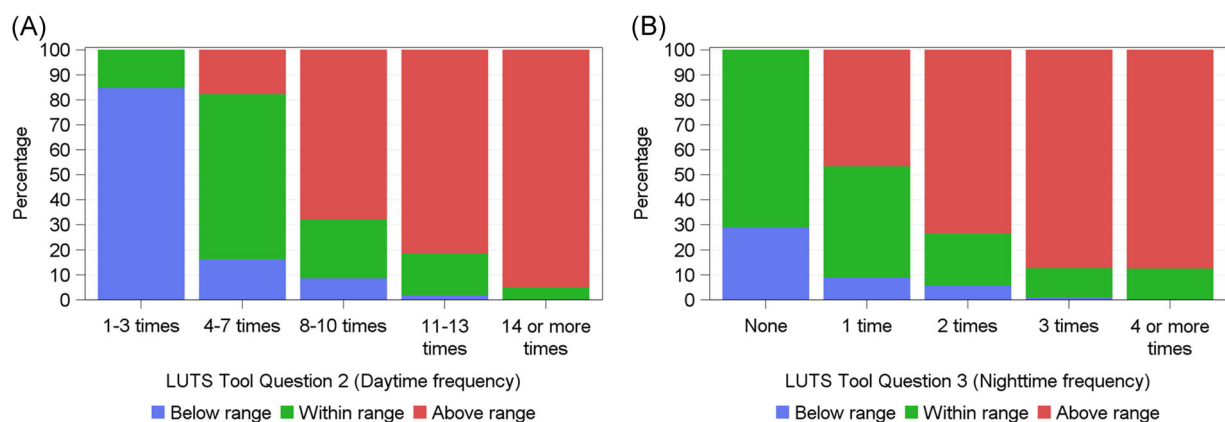


FIGURE 3 Scatterplot of avg. 24-hr. number of voids vs. intake volume. Scatterplot of average 24-hour number of voids vs. intake volume, among complete diaries only (n = 448). Dotted line on the x- and the y-axis represents typical thresholds for defining urinary frequency and excessive fluid intake, respectively. Shaded region represents participants with urinary frequency and excessive fluid intake

TABLE 3 Medians and interquartile ranges of bladder diary metric differences (complete diaries only, for each pairwise difference among the three 24-hour blocks)

	24-h Block 1 to block 2		24-h Block 1 to block 3		24-h Block 2 to block 3	
	Median	Interquartile range	Median	Interquartile range	Median	Interquartile range
Number of voids	0.0	-1.0 to 2.0	1.0	-1.0 to 3.0	1.0	-1.0 to 2.0
Voided volumes, mL	-29.6	-407.0 to 354.9	236.6	-207.0 to 650.6	218.1	-147.9 to 709.8
Number of intakes	0.0	-1.0 to 2.0	1.0	-0.5 to 2.0	0.0	-1.0 to 2.0
Intake volumes, mL	59.1	-321.4 to 436.2	147.9	-236.6 to 642.9	88.7	-244.0 to 532.3
Fluid balance (in minus out), mL	-110.9	-532.3 to 421.4	29.6	-480.6 to 517.5	113.3	-412.8 to 621.1
Number of leaks	0.0	0.0 to 0.0	0.0	0.0 to 0.0	0.0	0.0 to 0.0

**FIGURE 4** Distribution of bladder diary metrics within LUTS Tool response levels (complete diaries only). Panned graphic for distributions of (A) the average number of day voids by LUTS Tool question 2 response level, and (B) the average number of night voids by LUTS Tool question 3 response level. Diamonds within each box represent the mean for each response level and circles represent outliers. Lower, upper, and middle lines of the box represent the first quartile, median, and third quartile, respectively. LUTS, lower urinary tract symptoms**FIGURE 5** Comparison between bladder diary metrics and LUTS Tool responses (complete diaries only). Panned graphic for stacked bar charts of (A) percentage of participants with LUTS tool question two responses higher, lower, or within range compared to bladder diary average number of day voids, and (B) percentage of participants with LUTS tool question three responses higher, lower, or within range compared to bladder diary average number of night voids. Blue bars represent participants with LUTS tool responses lower than indicated on their bladder diary, green bars represent responses within range of their bladder diary, and red bars represent responses higher than their bladder diary metric. The average number of night voids were rounded to the nearest whole void. LUTS, lower urinary tract symptoms

assessed by asking the patients, “Do you believe that you recorded the diary accurately?” and, “How often did you omit to record?” and there was no difference between diary length, but these responses were not compared between sexes.¹ There was no difference in patient-reported burden between the sexes, based on age or education, but 7-day diaries were perceived as more burdensome compared to 2 or 3 days; however, based on the subjective assessment, the 7-day diary was not determined to have more omissions. In another small study of 21 men and 133 women with LUTS who completed a 7-day diary on two separate occasions, the test-retest reliability was similar between men and women but no other assessment of diary completeness was performed.¹¹ Our approach to assessing the quality of data collection did not rely on participant recollection of their ability to complete the diary but on objective assessments of the data collected, which likely explains our low “complete” diary rate.

When the data from the bladder diary were compared to questionnaire responses, the polychoric correlations did not indicate a strong relationship between the two instruments for both day and night voids, and most patients had mismatching responses between the bladder diary and questionnaire for the two LUTS Tool questions considered. This was in contrast to our hypothesis that daytime frequency would be well captured by patient questionnaires. For both day and night frequency, there appears to be a tendency on questionnaire responses for patients at the low end of the spectrum to minimize the reported number and those at the higher end of the spectrum to exaggerate their symptoms. This is in contrast to other studies^{3,5,11} that correlated symptom scores of nocturia and frequency to bladder diaries where good correlations were found on the frequency of voids reported as a mean; however, these studies combined all patient answers which include those who under- and over-report. We have instead stratified those specific patients who are not reliable at reporting their urinary frequency that are at both ends of the spectrum.

A notable finding was that even with careful fluid-intake and voids recorded many patients had significant fluid imbalances over the study period of 3 days (Figure 2). Given that these were community-dwelling adults who had not started any new medications such as diuretics per protocol this is difficult to explain but is a common clinical frustration when the volumes do not match. These imbalances are worthy of future investigation.

This analysis has several limitations. All participants volunteered for this study and received a monetary incentive to complete the voiding diary; we cannot conclude that similarly well-completed diaries could be produced from clinical patients. However, all of these

participants were also treatment-seeking patients and if patients were made aware of the clinical benefit of this exercise they would hopefully be as compliant. Also, we noted limited variability among diary variables across the 3 days and concluded that perhaps 1 day of collection is enough, but we did not compare participants collecting 1 day of data to those collecting all three since there may be a learning phenomenon. Also, our only method of detecting a completely missed (no checkmark) entry for a void or a fluid intake was a fluid imbalance of over 1000 mL on 1 day. If a patient missed a single void or intake this would likely not result in such a large imbalance and could be missed.

5 | CONCLUSIONS

Treatment-seeking participants in the LURN study were relatively successful at completing fluid-intake and voiding diaries over 3 days with 50% (of 85% who returned a diary) completing near perfect diaries. The most difficult data for participants to record was voided volume, and this was most difficult for women, likely due to the difficulty in collecting voided urine. Urinary frequency and nocturia were not well captured on patient symptom scores with participants downplaying their frequency at the low end and exaggerating their frequency at the higher end when compared to the objective voiding diary.

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MD, Nazema Siddiqui, MD, Alison Weidner, MD; Study Coordinators: Carrie Dombeck, MA, Robin Gilliam, MSW, Akira Hayes, Shantae McLean, MPH; *University of Iowa, Iowa City, IA (DK097772)*: PI: Karl Kreder, MD, MBA, Catherine S Bradley, MD, MSCE, Co-Is: Bradley A. Erickson, MD, MS, Susan K. Lutgendorf, PhD, Vince Magnotta, PhD, Michael A. O'Donnell, MD, Vivian Sung, MD; Study Coordinator: Ahmad Alzubaidi; *Northwestern University, Chicago, IL (DK097779)*: PIs: David Cella, Brian Helfand, MD, PhD; Co-Is: James W Griffith, PhD, Kimberly Kenton, MD, MS, Christina Lewicky-Gaupp, MD, Todd Parrish, PhD, Jennie Yufen Chen, PhD, Margaret Mueller, MD; Study Coordinators: Sarah Buono, Maria Corona, Beatriz Menendez, Alexis Siurek, Meera Tavathia, Veronica Venezuela, Azra Muftic, Pooja Talaty, Jasmine Nero. Dr Helfand, Ms Talaty, and Ms Nero are at NorthShore University Health System; *University of Michigan Health System, Ann Arbor, MI (DK099932)*: PI: J Quentin Clemens, MD, FACS, MSCI; Co-Is: Mitch Berger, MD, PhD, John DeLancey, MD, Dee Fenner, MD, Rick Harris, MD, Steve Harte, PhD, Anne P. Cameron, MD, John Wei, MD; Study Coordinators: Morgen Barroso, Linda Drnek, Greg Mowatt, Julie Tumbarello; *Washington University in St Louis, St Louis Missouri (DK100017)*: PI: Gerald L. Andriole, MD, H. Henry Lai; Co-I: Joshua Shimony, MD, PhD; Study Coordinators: Susan Mueller, RN, BSN, Heather Wilson, LPN, Deborah Ksiazek, BS, Aleksandra Klim, RN, MHS, CCRC; *National Institute of Diabetes and Digestive and Kidney Diseases, Division of Kidney, Urology, and Hematology, Bethesda, MD*: Project Scientist: Ziya Kirkali MD; Project Officer: Christopher Mullins PhD; NIH Personnel: Tamara Bavendam, MD, Robert Star, MD, Jenna Norton; *Arbor Research Collaborative for Health, Data Coordinating Center (DK097776 and DK099879)*: PI: Robert Merion, MD, FACS; Co-Is: Victor Andreev, PhD, DSc, Brenda Gillespie, PhD, Gang Liu, PhD, Abigail Smith, PhD; Project Manager: Melissa Fava, MPA, PMP; Clinical Study Process Manager: Peg Hill-Callahan, BS, LSW; Clinical Monitor: Timothy Buck, BS, CCRP; Research Analysts: Margaret Helmuth, MA, Jon Wiseman, MS; Project Associate: Julieanne Lock, MLitt.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

ORCID

Claire C. Yang  <http://orcid.org/0000-0002-4750-6258>
Henry H. Lai  <http://orcid.org/0000-0003-2691-994X>
Megan S. Bradley  <http://orcid.org/0000-0001-9935-5132>

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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