

**Comparison of a Voiding Diary with Clinical Management Tool as an Outpatient Screening Tool
for Childhood Functional Voiding Disorders**

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Received: August 17, 2019; Initial review: November 14, 2019; Accepted: May 20, 2021.

PII: S097475591600344

Note: This early-online version of the article is an unedited manuscript that has been accepted for publication. It has been posted to the website for making it available to readers, ahead of its publication in print. This version will undergo copy-editing, typesetting, and proofreading, before final publication; and the text may undergo minor changes in the final version

ABSTRACT

Objective: To study the agreement of questionnaire-based assessment with voiding diary for differentiating primary mono-symptomatic nocturnal enuresis from voiding disorder in children. **Method:** Children 5-12 years old with bedwetting after exclusion of secondary enuresis were enrolled and parents filled a clinical management tool (CMT) questionnaire and a 48-hours voiding diary. Point prevalence and agreement of classification as primary mono-symptomatic nocturnal enuresis or voiding disorder were compared. **Results:** Of 1276 children screened, 143 (11.2%) reported enuresis. Of 100 (82 males) children finally analyzed, constipation and positive family history occurred in 14% and 37%, respectively. Questionnaire-based assessment and voiding diary identified 65% and 71%, respectively as voiding disorder [Cohen's kappa 0.542 (95%CI: 0.367-0.717)]. Discordance of classification was noted in 20%. Voiding diary identified additional 7% cases of voiding disorder. **Conclusion:** While CMT and voiding diary have moderate agreement, voiding diary should be used for cases screened negative by a questionnaire-based tool.

Keywords: *Bladder, CMT questionnaire, Enuresis, Lower urinary tract symptoms.*

Bedwetting or enuresis, due to immaturity of bladder control, occurs in ~15% children, and may persist in 2-3% into adulthood [1]. Isolated nighttime bedwetting is labeled as primary mono-symptomatic nocturnal enuresis (PMNE). Associated daytime and lower urinary tract symptoms (LUTS) may be due to functional disturbance of micturition either in filling and/or voiding phases, in the presence of an intact neuronal pathway [2,3]. Undetected voiding disorders may result in long term adverse consequences of the urinary tract, sexual and psychosocial functions [4].

In an OPD setting, voiding disorder can be assessed by detailed history and clinical examination [4,5] along with questionnaire based screening tools or voiding diary. Voiding diary enquires compliance, motivation as well as additional visits [6,7]. A questionnaire-based assessment appears more practical in the out-patient setting. Clinical management tool (CMT) is a validated one-time recall based questionnaire, developed by International Children's Continence Society (ICCS), for evaluation of enuresis in children [2]. Concerns remain about missing markers of bladder dysfunction and mislabelling a bedwetting child as PMNE based on questionnaire filled by patient/parent from recall. There is sparse data comparing CMT and voiding diary [2,8]. We conducted this prospective cohort study to assess the agreement of clinical management tool and voiding diary for classifying children presenting with enuresis as having PMNE or voiding disorder.

METHODS

Between January, 2014 and March, 2015, twice weekly, a systematic random sampling was carried out in the general pediatric outpatient department of a referral armed forces hospital. Twice weekly a random number between 1 and 10 was generated using a web-based random number generator. Every 8th child with general pediatric OPD registration number starting from this generated number, aged 5-12 years with parents with high school education and comprehension of Hindi/English language was enrolled in the study. Children with structural anomalies or preexisting neurological /psychiatric/renal disorders were excluded. Institutional ethics clearance was obtained for the study. After obtaining informed consent, parents were administered a CMT questionnaire [2] and also taught to complete a voiding diary at home.

The children were classified as PMNE or voiding disorder, as per ICCS criteria [2], after assessing CMT and voiding diary. A single lower urinary tract symptom was sufficient to classify as voiding disorder as per CMT. For interpreting voiding diary, standard ICCS parameters were used. Children were subsequently managed and followed up in a weekly pediatric nephrology clinic over the next 18 months. The proportion of children with bedwetting who were diagnosed to have PMNE or voiding disorder was calculated.

Statistical analyses: Data were analyzed using Microsoft Excel. Difference between proportions was analyzed by Chi square test. Cohen's kappa was calculated to assess the agreement of classification as primary mono-symptomatic nocturnal enuresis versus voiding disorder using either clinical management tool or voiding diary as the assessment tools. Sample size was calculated with an assumption of Cohen Kappa 0.9 with 15% precision at 95% confidence level as per a previous study [9]. At an assumed prevalence of 10% of voiding dysfunction and 5% drop out rate, a minimum of 98 children with enuresis had to be enrolled for the agreement study.

RESULTS

A total of 100 children (64 males) were analyzed (**Fig. 1**). Most children (53%) were <7 years of age, family history being positive in 37%. Symptom distribution is shown in **Table I**. No significant male predilection was noted for children diagnosed as voiding disorder by CMT or voiding diary (53% vs 55%, $P=0.89$). Frequency and urgency on voiding diary were not significantly correlated with constipation. Reduced maximum voided volume (MVV) was seen in 66% children on voiding diary.

Using CMT, 65% and 35% of children got classified as voiding disorder and PMNE, respectively; whereas, voiding diary reclassified them as 71% voiding disorder and 29% PMNE. The pattern was independent of the age group. Increased frequency of micturition was recorded significantly more in voiding diary compared to CMT (51% vs 30%, $P=0.004$). Overall agreement for classification

between the two tools was 80% [K (95% CI)=0.54 (0.37-0.72)]. Diagnostic classification discordance was noted in 20% cases with 7 additional cases diagnosed by voiding diary (**Fig. 2**).

The CMT has a sensitivity of 81.7% (95% CI 70.7-89.9) and specificity of 75.9% (95% CI 56.5-89.7) to diagnose voiding dysfunction in comparison to voiding diary (AUC 0.79; 95% CI 0.70 to 0.88). The positive and negative predictive values of CMT is 89.2% (95% CI 79.1 to 95.6) and 62.9% (95% CI 44.9 to 78.5), respectively, to diagnose voiding dysfunction.

DISCUSSION

The frequency of enuresis and its characteristics like male preponderance, family history, higher prevalence between 5-7 years and progressive decline thereafter, noted in our study, is concordant with published literature [10]. We noted a moderate agreement of 80% between CMT and voiding diary for classification as voiding disorder versus PMNE, this aspect not having been studied so far. Significant discrepancies in LUTS were noted between questionnaire-based screening and bladder diary in few previous studies [11,12]. A recall bias with CMT may have led to a lower detection of decreased urinary frequency with CMT than the voiding diary. Using CMT, incontinence was reported in 17% cases.

Akin to published literature, we noted urgency and dysuria more commonly amongst females while leakage and poor stream was commoner in males [2,4]. Also, similar to these studies, urgency was found to be equally distributed across genders between 5-8 years age, progressively declining thereafter.

We chose to simplify the existing tools of CMT and Voiding Diary for a quick administration in the OPD, maintaining the core components whose reliability has been proven [7]. Also, since ICCS guidelines suggest that a 2 day voiding diary suffices to evaluate bladder capacity and fluid intake, we used a simplified 2-day diary, omitting additional parameters [2].

Using either of the 2 tools, 78% cases could be classified as voiding disorder. Voiding diary led to a label of voiding disorder in additional 7% cases while discounting any abnormality in 13% cases whose initial diagnosis was PMNE based by CMT, implying advantage of voiding diary over CMT. The cut-offs to define frequency on a voiding diary and utility of calculating MVV have been questioned [13,14].

Limitations of our study include a possibility of referral bias, resulting in improper estimation of true community prevalence of enuresis, PMNE or voiding disorder. Being a questionnaire, a recall bias exists in CMT and having been administered to patients presenting with enuresis rather than all cases, a selection bias might be there. Parallel control group would have been preferable. Further, the questionnaire is not adapted to the Indian context. Bladder-bowel habits of our population are vastly different from Western populations and constipation is a common accompaniment of enuresis as well as daytime wetting reporting in Western literature [15]. Agreement of the findings of CMT and voiding

diary with results of invasive urodynamics, ultrasound and uroflowmetry would have been scientifically more valid.

To conclude, we found a moderate agreement between a modified CMT and a simplified 48-hour voiding diary for classification of children with enuresis into primary mono-symptomatic enuresis and voiding disorder. More prospective studies and adaptations are required to ascertain the utility of questionnaire CMT before recommending its universal application as a screening tool in preference to a voiding diary.

Disclaimer: The work reported is those of the individual authors and in no way reflect the official position of the Directorate General Armed Forces Medical Services of India or Ministry of Defence.

Ethics clearance: Institutional ethics committee, Base Hospital Delhi Cantt; No. 139/2013 dated August 17, 2013.

Contributors: MK: conceptualization of study, drafting, finalization and approval of manuscript; SS: case recruitment, initial evaluation, literature review, manuscript drafting and approval; SKP: clinical assessment, analysis, drafting and approval of manuscript. All authors approved the final version of manuscript, and are accountable for all aspects related to the study.

Funding: None; *Competing interest:* None stated.

WHAT THIS STUDY ADDS?

- Voiding diary has additional utility over questionnaire-based tool in pediatric outpatient settings for identification of a voiding disorder and reconfirmation of primary mono-symptomatic nocturnal enuresis identified by clinical management tool questionnaire.

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Table I Symptom Distribution From Clinical Management Tool (N=100)

<i>Symptoms^a</i>	<i>Male</i>	<i>Age distribution</i>		
		<i>5-7 y</i>	<i>8-10 y</i>	<i>>10 y</i>
Increased frequency, <i>n</i> =30	19	23 (76.7)	6 (20)	1 (3.3)
Decreased frequency, <i>n</i> =14	9	3 (21.4)	6 (42.8)	5 (35.7)
Dribbling, <i>n</i> =8	6	3 (37.5)	6 (75)	5 (62.5)
Leakage, <i>n</i> =17	10	10 (58.8)	5 (29.4)	2 (11.7)
Poor stream, <i>n</i> =4	4	1 (25)	1 (25)	2 (50)
Dysuria, <i>n</i> =5	2	4 (80)	1 (20)	0
Urgency, <i>n</i> =30	13	17 (56.6)	13 (43.3)	0
Abdominal pain, <i>n</i> =3	2	2 (66.6)	1 (33.3)	0
Constipation, <i>n</i> =14	11	10 (71.4)	4 (28.5)	0
Family history, <i>n</i> =37	27	19 (51.3)	13 (35.1)	5 (13.5)

Data in no. One child aged 8-10 y each had fever and lethargy.

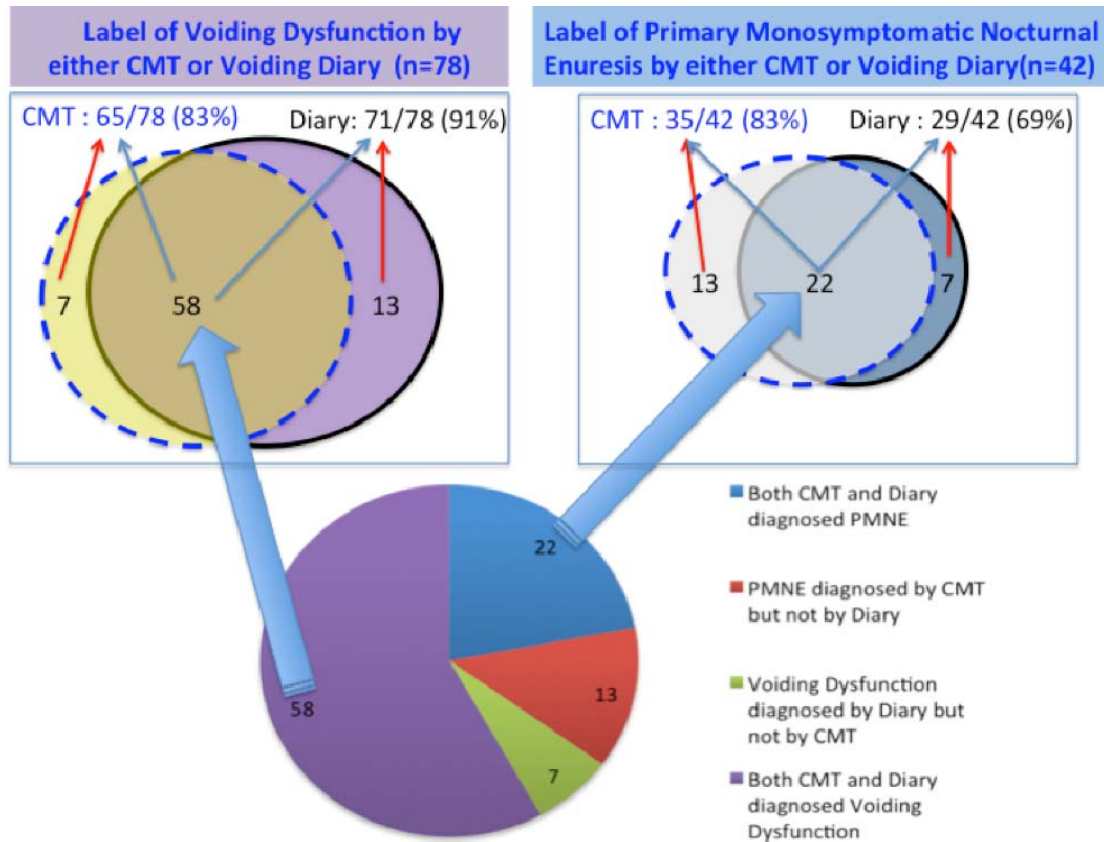


Fig. 2 Schematic depiction of the concordance of diagnosis of primary monosymptomatic nocturnal enuresis (PMNE) and voiding disorder using the Clinical management tool (CMT) questionnaire and the 48-hour voiding diary.

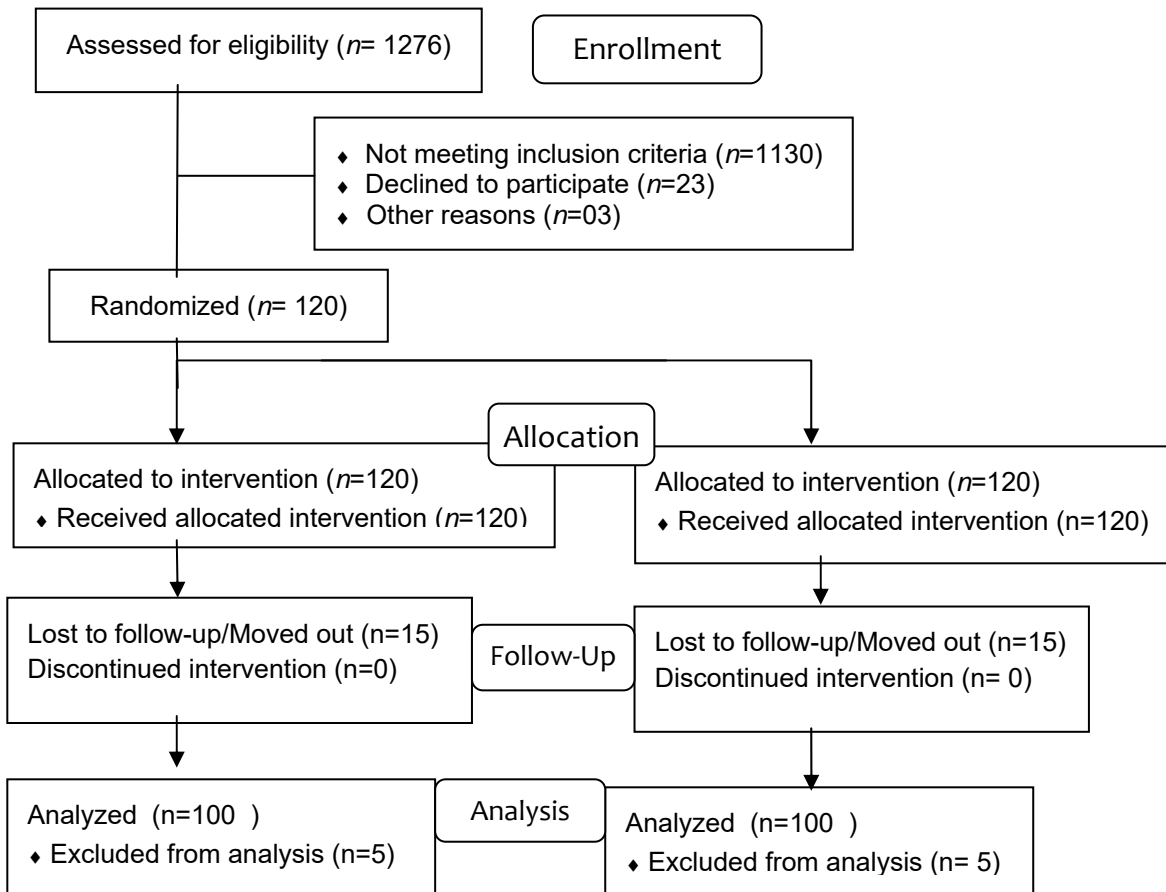


Fig. 1 Flow of subjects in the study.