

The efficacy of early urotherapy for severe intolerable nocturnal enuresis before the age of 5 years: A prospective randomized trial

Ahmed M. Rammah^{1*}, Mohamed Abdelghani^{1*}, Shrouk M. Abdalla², Ahmed Y. Abdelaziz¹, Ahmed Sharawy¹, Mohamed Kishk¹, Mohamed Salah¹, Ahmed H. Abozamel¹, Hesham Torad¹, Mahmoud S. ElAdawy³, Hossam Skaker³, Hesham Ibrahim¹

¹Department of Urology, Kasr Alainy Hospitals, Faculty of Medicine, Cairo University, Egypt

²Department of Pediatrics, Aboelresh Hospital, Faculty of Medicine, Cairo University, Egypt

³Department of Urology, Faculty of Medicine, Fayoum University, Egypt

*Mohamed Abdelghani shares first authorship and equal contribution with Ahmed M. Rammah.

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Corresponding author

Ahmed M. Rammah
Department of Urology,
Kasr Alainy Hospitals,
Faculty of Medicine,
Giza, Ben Elsarayat, Postal
code: 12624
Cairo University,
Cairo, Egypt,
ahmedrammah2013@
gmail.com

Introduction Assessment of the efficacy of early urotherapy for severe intolerable NE before the age of 5 years was the main objective.

Material and methods A total of 120 children, aged between 4 and 4.5 years, with intolerable NE (bedwetting ≥ 5 nights/ week) were included in our study. They were randomized into group A (early urotherapy regularly until age 5.5 years) and group B (deferred urotherapy started at age 5 years for 6 months). Only 107 (54 in group A, 53 in group B) were interviewed twice, at the age of 5 and 5.5 years, to determine treatment response, categorized as complete response (100% reduction), $\geq 90\%$, 50–89%, or $< 50\%$ reduction in bedwetting during the preceding month. Parental adherence to urotherapy was evaluated using a structured 7-day diary and adherence checklist. In addition, their distress was evaluated and followed up using general health questionnaire-12 (GHQ-12) score.

Results Complete response through the last month was significantly higher in group A than group B at 5-year-old or 5.5-year-old visits (12 vs 6, 25 vs 10 children, respectively, $p < 0.05$). Also, $< 50\%$ reduction of bedwetting was significantly higher in group B than in group A in both visits (32 vs 27 and 23 vs 9 children, respectively, $p < 0.05$). Both groups showed comparable levels of adherence to their protocol. CHQ-12 scores were significantly lower in group A than in B at the first visit, while no difference was observed at the second visit.

Conclusions Early urotherapy in children with intolerable nocturnal enuresis could enhance rapid recovery and reduce psychological distress.

Key Words: intolerable nocturnal enuresis $\leftrightarrow$ early urotherapy $\leftrightarrow$ psychological distress

INTRODUCTION

Nocturnal enuresis (NE) is a common health problem. NE is defined as bedwetting during sleep in a child aged ≥ 5 years in the absence of congenital anomalies of the urinary tract or the central nervous system [1]. Three consecutive months and a minimum frequency of one episode of bedwet-

ting per month are defined as NE. NE is classified as monosymptomatic (MNE) and non-monosymptomatic (NMNE), based on the presence of daytime urinary symptoms. MNE is subclassified into primary and secondary MNE, based on the presence of 6 months of dryness. Enuretic children sleep deeply and are more difficult to rouse than their dry peers [2]. However, these children do not have

abnormalities in sleep architecture, and enuresis occurs at all sleep stages, especially non-REM sleep [3]. Delayed maturation of arousal mechanisms during sleep is the cornerstone in the pathogenesis of NE, as bladder filling provides a powerful arousal stimulus [4, 5]. NE caused by bladder abnormalities such as small capacity is rare in a child >5 years old. Therefore, invasive investigations are primarily not indicated. Thus, most previous studies assessed the different modes of management for primary monosymptomatic nocturnal enuresis (PMNE) at age of 5 years, and there is a lack of research about the PMNE management before that age. However, some children younger than 5 years have a severe form of intolerable NE (bedwetting ≥ 5 nights/week), which causes a psychological and social burden on their parents. In usual cases, the parents are advised to wait until the age of 5 years (because spontaneous physiological resolution can occur) before starting any intervention. We assumed that if the urotherapy started earlier in such cases, it could add benefits in the form of lowering the incidence of PMNE at older ages and making those children more responsive to pharmacological treatment when indicated, as well as reducing the burden on their parents. In the present trial, we try to assess the efficacy and applicability of urotherapy in severe, intolerable NE before the age of 5 years. The aim of study is to assess the success rate of early urotherapy for children with intolerable nocturnal enuresis whose parents could not wait till 5 years of age as the primary outcome and the quality-of-life changes as the secondary outcome.

MATERIAL AND METHODS

A prospective randomized clinical trial was conducted at our institution. Boys and girls aged 4.0–4.5 years presenting with intolerable nocturnal enuresis, defined as bedwetting on five or more nights per week despite normal daytime bladder control, were eligible for inclusion. Children were excluded if they were older than 4.5 years, had daytime lower urinary tract symptoms or voiding dysfunction, behavioral disorders such as attention-deficit/hyperactivity disorder (ADHD), or comorbid medical conditions including diabetes mellitus or congenital anomalies. Children whose parents declined to provide written informed consent were also excluded. The restricted age range was intentionally selected to target children younger than 5 years who are typically more cooperative with parental guidance and are often attending kindergarten, an age associated with greater independence and more structured daily routines.

A total of 120 children with primary monosymptomatic nocturnal enuresis were initially enrolled and randomly allocated, using a computer-generated randomization sequence, into two equal groups. Group A (early urotherapy) consisted of 60 children who received urotherapy from enrollment until 5.5 years of age. Group B (deferred urotherapy) included 60 children who received no intervention until the age of 5 years, after which urotherapy was initiated and continued for 6 months. Allocation concealment was ensured using sequentially numbered, sealed, opaque envelopes prepared by an independent investigator not involved in the patient recruitment or outcome assessment. Envelopes were opened only after enrollment to assign participants to the study groups. Due to the nature of the intervention (urotherapy requiring active parental involvement), blinding of participants and caregivers was not feasible. In addition, outcome assessment was based primarily on parental-reported diaries, which precluded blinding of outcome assessment. Parental psychological burden and distress were assessed using the General Health Questionnaire-12 (GHQ-12), with a cutoff score of ≥ 4 indicating distress, at enrollment and at each follow-up visit.

Urotherapy was delivered as a structured behavioral program that included prompted and scheduled daytime voiding every four hours to promote healthy voiding habits and prevent lower urinary tract dysfunction that may exacerbate nocturnal enuresis. Additional measures included maintaining regular sleep schedules, restricting fluid and caffeine intake two to three hours before bedtime, and avoiding electronic devices, such as mobile phones, for at least two hours before sleep. Children with constipation were managed with dietary modification and stool softeners when required. Parents were encouraged to wake the child once nightly, approximately one to two hours after the onset of deep sleep, to allow voiding before resuming sleep. This practice was maintained throughout the study period except during the final month, which was reserved for evaluating spontaneous nocturnal arousal. Parents were counselled on the importance of psychological support, emphasizing avoidance of punishment, blame, or embarrassment, and the use of diapers was discouraged to enhance the child's awareness of nocturnal bladder sensations. Parents were instructed to document the number of wet nights during the preceding month and to adhere to the urotherapy protocol throughout the study, except for night awakening during the final assessment period, even if dryness was achieved.

Parental adherence to urotherapy was evaluated using a structured seven-day diary and adherence checklist. Compliance was calculated as the proportion of recommended urotherapy components – timed voiding, fluid regulation, evening voiding routine, and night awakening – performed each day. Adherence was categorized as high ($\geq 80\%$), moderate (50–79%), or low ($< 50\%$). According to International Children's Continence Society criteria, children were evaluated at 5.0 and 5.5 years of age based on changes in the number of wet nights during the preceding month compared with baseline. Treatment outcomes were classified as complete response (100% dry nights), good partial response ($\geq 90\%$ reduction in wet nights), intermediate response (50–89% reduction), or non-response ($< 50\%$ reduction). Relapse was defined as the recurrence of one or more wet nights per week after achieving complete response. Children in the early urotherapy group continued treatment until 5.5 years of age, marking the end of the study. After study completion, children who achieved complete response were allowed to discontinue or continue urotherapy according to parental preference, while those who failed to achieve complete response were advised to continue urotherapy with the addition of pharmacological treatment using desmopressin.

Sample size consideration

Due to the relatively low presentation of children younger than 5 years of age with severe intolerable nocturnal enuresis and the application of strict inclusion criteria, a formal a priori sample size calculation was not performed. The study was therefore designed as an exploratory prospective randomized trial, and the sample size was determined based on recruitment feasibility within the study period. Nevertheless, the number of participants included was comparable to similar exploratory clinical studies, and the study was able to detect statistically significant differences in the primary outcome between groups.

Statistical analysis

Data were analyzed using Statistical Package for the Social Sciences (SPSS) version 28 (IBM Corp., Armonk, NY, USA). Data were summarized using mean and standard deviation for quantitative variables, and frequencies (number of cases) and relative frequencies (percentages) for categorical variables. Comparisons between groups were done using the unpaired t-test (Chan, 2003a). For comparing categorical data, the χ^2 test was performed. The exact test was used instead when the expected frequency

was less than 5 (Chan, 2003b). P-values less than 0.05 were considered statistically significant.

Bioethical standards

The study was approved by the Research Ethics Committee of the Urology Department at Fayoum University in its session (102) on 15-1-2023, with IRB Code: R 408.

RESULTS

A total of 120 children with a mean age of 48.5 ± 2.22 months were enrolled in the study after fulfilling the inclusion criteria and having none of the exclusion criteria. Parents reported that their children suffered from intolerable PMNE, which resulted in marked parental stress and exhaustion, in the absence of daytime lower urinary tract symptoms. Clinical assessment revealed no associated behavioral, cognitive, or developmental disorders in any of the enrolled children. A positive family history of nocturnal enuresis was identified in 63 children (52.5%), with one or more affected siblings. Participants were randomized equally into two groups: group A (early urotherapy) and group B (deferred urotherapy). There were no statistically significant differences between the two groups regarding age, sex, or family history (Table 1).

Table 1. Patient demographics

Parameters	Group A (n = 54)	Group B (n = 53)	P-value
Age	47.89 $\pm$ 2.74	48.60 $\pm$ 2.28	0.147
Sex			
Boy	29 (53.7%)	26 (49.1%)	0.755
Girl	25 (46.3%)	27 (50.9%)	
Positive family history	33 (61.1%)	30 (56.6%)	0.452
Constipation	10 (18.5%)	7 (13.2%)	0.76

Table 2. Outcomes at first and second visits

Outcomes (1 st visit: age 5 years)	Group A (n = 54) n (%)	Group B (n = 53) n (%)	P-value
Complete response:	12 (22.2)	6 (11.3)	0.042
Good response	10 (18.5)	0 (0)	0.000
Moderate response	5 (9.2)	15 (28.3)	0.002
No response	27 (50)	32 (60.3)	0.034
Outcomes (2 nd visit: age 5.5 years)	Group A (n = 54) n (%)	Group B (n = 53) n (%)	P-value
Complete response:	25 (46.3)	10 (18.9)	0.023
Good response	15 (27.7)	12 (22.6)	0.34
Moderate response	5 (9.2)	8 (15.1)	0.21
No response	9 (16.6)	23 (43.3)	0.001

Of the 120 children initially enrolled, 107 completed the study and were included in the final analysis. Eight children were excluded due to poor compliance with the study instructions and inadequate monitoring of bedwetting episodes, while five children withdrew before the second follow-up visit. Consequently, the final study population comprised 54 children in group A and 53 children in group B. Constipation was identified in 17 children, with no significant difference between groups, and was managed effectively with dietary modification and stool softeners (Senna Makki syrup, 2.5–3.75 ml [4.4–6.6 mg sennosides] once daily) (Table 1).

Table 3. Boys vs girls in group A

	Group A (n = 54)	Boys (n = 29)		Girls (n = 25)		P-value
		Count	%	Count	%	
Outcome	Complete response:	14	48.3	11	44	0.055
	Good response	9	31	6	24	0.057
	Moderate response	2	7	3	12	0.643
	No response	4	13.7	5	20	0.83

Table 4. Boys vs girls in group B

	Group B (n = 53)	Boys (n = 26)		Girls (n = 27)		P-value
		Count	%	Count	%	
Outcome	Complete response:	6	23.1	4	14.8	0.052
	Good response	7	26.9	5	18.5	0.082
	Moderate response	3	11.5	5	18.5	0.157
	No response	10	38.5	13	48.2	0.066

Table 5. Parental adherence to urotherapy using the 7-day diary checklist in both groups at end of study

Adherence level	Group A (n = 54) n (%)	Group B (n = 53) n (%)	P-value (χ^2 test)
High ($\geq 80\%$)	27 (50.0)	25 (47.2)	0.79
Moderate (50–79%)	20 (37.0)	21 (39.6)	
Low (<50%)	7 (13.0)	7 (13.2)	

At 5 years of age, 22.2% of children in group A achieved a complete response, defined as the absence of bedwetting episodes during the preceding month, compared with 11.3% in group B. In group A, 18.5% of children demonstrated $\geq 90\%$ improvement, 9.2% showed 50–89% improvement, and 50% experienced <50% improvement. In contrast, in group B, 28.3% of children achieved 50–89% improvement, while 60.3% showed <50% improvement (Table 2).

At the study endpoint (5.5 years of age), further improvement was observed. In group A, 46.3% of children achieved a complete response, 27.7% demonstrated $\geq 90\%$ improvement, 9.2% showed 50–89% improvement, and 16.6% continued to experience <50% improvement, necessitating the addition of desmopressin therapy. In group B, 18.8% achieved a complete response, 22.6% achieved $\geq 90\%$ improvement, 15.1% demonstrated 50–89% improvement, and 43.3% remained with <50% improvement (Table 2). No significant sex-related differences in treatment outcomes were observed in either group at the end of the study (Tables 3 and 4). No relapse was observed in group A during the study period. However, during a post-study follow-up period of approximately 3 months after study completion, two children experienced relapse after achieving complete response. Both cases were advised to continue urotherapy in addition to using desmopressin 120 mg once daily for 3 months.

Parental adherence to urotherapy was assessed using a structured 7-day diary checklist at both the first and second follow-up visits. The χ^2 analysis demonstrated no statistically significant differences in adherence between the two groups at either visit ($p = 0.72$ and $p = 0.79$, respectively), indicating comparable parental compliance with urotherapy protocols (Table 5). Parents in both groups reported varying degrees of psychological distress, as assessed by the General Health Questionnaire-12 (GHQ-12), attributable to their children's intolerable nocturnal enuresis. Parental distress

Table 6. General Health Questionnaire (GHQ-12) score evaluating psychological burden and distress in parents during the study

GHQ-12 score	At enrollment			First visit			Second visit		
	Group A (n = 54) n (%)	Group B (n = 53) n (%)	P	Group A (n = 54) n (%)	Group B (n = 53) n (%)	P	Group A (n = 54) n (%)	Group B (n = 53) n (%)	P
No distress (<4)	10 (18.5)	9 (17.0)	0.84	28 (51.9)	16 (30.2)	0.01	34 (63.0)	32 (60.4)	0.78
Mild distress (4–7)	22 (40.7)	21 (39.6)		18 (33.3)	20 (37.7)		15 (27.8)	16 (30.2)	
Moderate distress (8–10)	14 (25.9)	15 (28.3)		6 (11.1)	12 (22.6)		4 (7.4)	4 (7.5)	
Severe distress (11–12)	8 (14.8)	8 (15.1)		2 (3.7)	5 (9.4)		1 (1.9)	1 (1.9)	

Data are presented as number (percentage). P-values were calculated using the χ^2 test. GHQ-12: General Health Questionnaire-12 score. Bottom of Form.

decreased significantly over the course of the study. This reduction was significantly greater in group A at the first follow-up visit, while distress levels were comparable between the two groups at the second follow-up visit, reflecting overall improvement with continued urotherapy (Table 6).

DISCUSSION

Nocturnal enuresis is a prevalent pediatric condition that can adversely affect both psychological well-being and behavioral development in affected children [8]. Its frequency decreases with advancing age, with an estimated prevalence of approximately 15% at 5 years and 5–10% at 7 years of age [9–11]. The clinical course and prognosis of nocturnal enuresis are influenced by multiple factors, including racial, cultural, socioeconomic, and environmental determinants [12]. PMNE is believed to arise from several interacting pathophysiological mechanisms, most notably nocturnal polyuria, detrusor overactivity, and an increased arousal threshold during sleep [8]. Current international guidelines generally recommend initiating active treatment after the age of 5 years because spontaneous resolution may occur in a large proportion of children. First-line management typically involves conservative approaches, such as behavioral modification and alarm therapy for a period of 2–3 months, followed by pharmacological treatment most commonly desmopressin, with or without anticholinergic agents in children who do not respond adequately [13–15]. Although daytime continence is usually achieved by 3–4 years of age, once children develop awareness of bladder filling and voluntary voiding during waking hours, nocturnal bladder control continues to mature and may not be fully established until 5–6 years of age. In clinical practice, however, a subgroup of children presents with severe and intolerable PMNE that imposes a considerable emotional and psychological burden on their families. In such cases, recommending observation alone until the age of 5 years may be neither practical nor acceptable to caregivers. This provided the rationale for exploring early urotherapy and discussing its potential benefits with parents prior to the traditionally recommended age for intervention. Delaying behavioral management may be unnecessary, particularly in children with recognized risk factors such as a positive family history or disrupted sleep patterns. Irregular or fragmented sleep has been associated with alterations in sleep architecture, including prolonged slow-wave sleep and a higher arousal threshold, which may impair the child's ability to awaken in response to bladder distension.

Furthermore, disturbed sleep–wake cycles may disrupt the circadian secretion of antidiuretic hormone, leading to nocturnal polyuria. These sleep-related disturbances may also affect autonomic regulation of bladder function, thereby increasing the likelihood and severity of nocturnal enuresis [16]. Early implementation of urotherapy may promote earlier resolution of nocturnal enuresis and foster better cooperation and adherence as children grow older. Additionally, should pharmacological treatment become necessary at a later stage, prior behavioral intervention may enhance therapeutic responsiveness [17]. Severe and persistent enuresis has been associated with negative psychosocial consequences and may coexist with attention difficulties, learning problems, and sleep disturbances. While regular toileting habits can facilitate daytime urinary and bowel control by 2–3 years of age, maturation of nighttime continence typically lags behind and may not occur until around 5 years of age [13]. These considerations collectively supported the evaluation of early urotherapy in children under 5 years old. Early intervention may not only facilitate earlier attainment of dryness but also help establish more regular sleep patterns, thereby mitigating the potential adverse developmental effects of intolerable PMNE.

To the best of our knowledge, this study represents one of the earliest prospective trials evaluating the management of intolerable PMNE in children under 5 years old. Our findings suggest that early urotherapy in this age group may contribute to earlier control of bedwetting and could potentially reduce the persistence of PMNE and improve responsiveness to subsequent medical therapy. Increasing evidence from sleep research supports the concept that nocturnal enuresis may be closely linked to sleep-related abnormalities. Kim et al. reported that irregular bedtimes were associated with poor response to medical treatment and that such children may benefit from structured urotherapy [18]. Similarly, Bani-Hani et al. observed that children with consistent bedtimes tended to experience enuretic episodes at predictable times and were generally younger, whereas those with irregular sleep schedules experienced more frequent and unpredictable bedwetting episodes [19]. Other studies have demonstrated a higher prevalence of sleep disturbances among children with nocturnal enuresis – particularly older boys – compared with unaffected peers [20]. This may be partly explained by greater adherence to parental guidance and sleep routines among younger children, whereas older children may be less compliant. Overall, multiple studies have consistently demonstrated associations

between nocturnal enuresis and sleep characteristics, including sleep depth, bedtime regularity, and sleep patterns [20–22]. Although our findings suggest a potential association between structured behavioral interventions and improved outcomes, no direct assessment of sleep architecture (e.g., polysomnography) was performed. Therefore, interpretations regarding sleep mechanisms remain speculative and are based on previously published literature.

Several limitations of the present study should be acknowledged. These include the relatively short duration of follow-up, the absence of blinding in outcome assessment, and the modest sample size, which may limit the generalizability of the results. The small sample size and the absence of a formal a priori sample size calculation represent limitations of this study. This was primarily due to the restricted number of eligible patients within this specific age group and clinical presentation. Nevertheless, the study demonstrated statistically significant differences in key outcomes, supporting the validity of the findings. The absence of blinding represents an inherent limitation of behavioral intervention studies and may introduce reporting bias. However, objective outcome definitions based on standardized International Children's Continence

Society criteria were used to minimize assessment bias. Future studies with larger cohorts, longer follow-up periods, and blinded assessments are warranted. In addition, comprehensive psychological evaluation by specialists may be beneficial for children with severe or intolerable nocturnal enuresis, and the development of more objective and validated tools to assess adherence and compliance with urotherapy protocols is recommended.

CONCLUSIONS

Early urotherapy can be started early before the age of 5 years, especially in children with severe intolerable PMNE with promising results, to reduce the burden on their parents.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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ETHICS APPROVAL STATEMENT

The Research Ethics Committee of the Urology Department at Fayoum University approved the research in its session (102) on 15-1-2023, with IRB Code: R 408.

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