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Original Research Article

Impact of mirabegron on nocturnal enuresis in children with overactive bladder

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ABSTRACT

Background: Nocturnal enuresis associated with overactive bladder (OAB) is a common pediatric voiding disorder that can disrupt daily life and psychosocial well-being. Mirabegron, a β3-adrenergic receptor agonist, has emerged as an alternative to antimuscarinic therapy for OAB. This study aimed to evaluate the therapeutic effect of mirabegron on nocturnal enuresis in children with OAB.
Methods: This quasi-experimental study was conducted over 18 months in the Department of Pediatric Nephrology at the National Institute of Kidney Diseases and Urology, Dhaka. Thirty children aged 6–15 years with nocturnal enuresis and OAB were enrolled following informed consent. Clinical, demographic, urodynamic, and laboratory data were recorded. All participants received mirabegron 25 mg at bedtime for 3 months. Bedwetting frequency, urgency, and overall treatment response were assessed at baseline and at monthly follow-up visits.
Results: The mean age of participants was 11.33±2.44 years, and 70% were male. Urodynamic evaluation showed that 60% had small-capacity, reduced-compliance OAB. The mean number of bedwetting episodes decreased significantly from 7.3±3.4 per month at baseline to 4.7±3.6, 0.33±0.66, and 0.1±0.3 at the 1st, 2nd, and 3rd follow-ups, respectively. Urgency also decreased progressively, with 90% of children achieving complete symptom resolution by the end of treatment. No adverse effects were reported.
Conclusions: Mirabegron demonstrated marked effectiveness in reducing nocturnal enuresis among children with OAB, with significant improvement in both bedwetting frequency and urgency. Larger multicenter studies are recommended.

Keywords: Mirabegron, Nocturnal enuresis, Overactive bladder, Pediatric urology, β3-adrenergic agonist

INTRODUCTION

Nocturnal enuresis (NE) is defined as involuntary nocturnal urination occurring in children older than five years at least twice per month, representing one of the most frequent urologic complaints in the pediatric population.[1-5] NE may be classified as primary or secondary, and further distinguished as monosymptomatic or non-monosymptomatic, with non-monosymptomatic cases showing additional daytime

lower urinary tract symptoms such as urgency.[6] Enuretic episodes are considered frequent when they occur four or more times per week.[7] To standardize definitions, the International Children's Continence Society specifies that "enuresis" refers strictly to nighttime wetting, excluding daytime symptoms.[3] Multiple factors contribute to the development of NE, including impaired arousal mechanisms, delay in bladder maturation, detrusor overactivity, reduced bladder capacity, nocturnal polyuria, and disturbances of antidiuretic hormone secretion, all of which can negatively affect a child's psychological health and family dynamics. Comorbidities often include constipation, diabetes, attention disorders, and urinary tract infections.[8]

Overactive bladder (OAB), also termed bladder instability, urge syndrome, hyperactive bladder, persistent infantile bladder, or detrusor hypertonia, is recognized as the most common voiding dysfunction in children.[9] Nocturia represents the most prominent symptom of OAB, and its prevalence increases with age. It may arise from sleep disturbances, psychological factors, nocturnal polyuria, or reduced bladder capacity.[10] The underlying mechanism of OAB is thought to involve delayed maturation of cortical inhibitory pathways that regulate the voiding reflex and detrusor activity.[9]Mirabegron, a selective β3-adrenoceptor agonist, represents a newer therapeutic option for OAB, offering an alternative to conventional antimuscarinic agents.[11]

Initially investigated for metabolic applications, β3-receptors later demonstrated relevance in bladder detrusor relaxation, leading to the development of mirabegron by Astellas Pharma in Japan. Approved in the United States in 2012, mirabegron acts by promoting bladder storage capacity without impairing detrusor contractility. Although generally well tolerated, potential adverse effects include hypertension, nasopharyngitis, dry mouth, constipation, headache, and urinary tract infection.

Considering the limitations of antimuscarinic therapy—such as modest efficacy, low compliance, and bothersome side effects—mirabegron provides a promising alternative. Therefore, this study aimed to evaluate the effectiveness of mirabegron in improving nocturnal enuresis among children with overactive bladder in Bangladesh.

METHODS

Study design

Quasi-Experimental study

Study place

Department of Pediatric Nephrology, National Institute of Kidney Diseases and Urology, Sher-E-Bangla Nagar, Dhaka.

Study period

March, 2022 to August, 2023.

Study population

Outpatients at Pediatric Nephrology Department, National Institute of Kidney Diseases and Urology, Dhaka.

Sampling method

Nonrandom purposive sampling.

Sample size

Sample size was calculated using the following formula

$$n = \frac{\left\{Z_\alpha \sqrt{\left[p_0(100-p_0)\right]} + Z_\beta \sqrt{\left[p(100-p)\right]}\right\}^2}{(p-p_0)^2}$$

Here, n= sample size

p0=89.6% (Improved 89.6% (Blais et al 2016)

P=72.0% (Assumed)

Zα=1.96 at a 95% confidence interval

Zβ=0.85 at an 80% power

Putting the values in the above equation the sample size n was estimated as

$$n = \frac{\left\{1.96\sqrt{[89.6(100-89.6)]} + 0.85\sqrt{[72.0(100-72.0)]}\right\}^2}{(89.6-72.0)^2} = 30$$

Sample size = 30.

Selection criteria

Inclusion criteria

Nocturnal enuresis (NE) associated with an overactive bladder occurs in both male and female children, typically within the age group of 6 to 15 years.

Exclusion criteria

Monosymptomatic NE refers to bedwetting without any associated lower urinary tract symptoms and occurs in children younger than 6 years as well as in individuals older than 15 years. It includes cases of nocturnal enuresis that are not related to an overactive bladder.

Data collection procedure

All patients with NE due to OAB (age ranged from 6 to 15 years) were approached for this study. Suspected

patients were 65 in number having NE with urgency, frequency and urge incontinence. Diagnosis was done by history and clinical examination initially, then complete blood count, urine analysis (by routine microscope), urine for culture sensitivity (bimanual or vitek 2 system), serum creatinine level (by modified jaffe method), USG of KUB region with MCC with PVR (Chison machine) and 3 days bladder diary was done. Among 65 patients, 35 patients with normal findings were included in this study, 5 patients had raised serum creatinine, 10 had positive urine culture sensitivity, 15 had plenty pus cell on urine R/M/E and were excluded from the study. On USG of KUB region with MCC with PVR, 35 patients were normal and included in the study. Among the remaining patients 10 had hydronephrosis, cystitis in 15 and cystitis with significant PVR in 5 patients and they were excluded from this study. OAB was diagnosed clinically and by imaging study like uroflowmetry and urodynamic study. On uroflowmetry the curve showed sharp peak with a short duration and high amplitude, with the peak flow lasting for only a short period during urgency sensation, then slowly decreasing (Tower shape). Tower shape curve indicated OAB. The 5 patients who did not show tower shape curve were excluded from this study. Then urodynamic study (Menfic biomedical) was done in these 30 patients at BSMMU.

After describing the aim, purpose and procedure of the study, a total of 30 patients were enrolled finally. Informed written consent was taken from the parents or their legal guardians. A semi-structured questionnaire was developed for admiting the data. Data were collected from the participants and their caregiver through face-to-face interviews by researcher herself. A detailed history of socio-demographic profile, clinical presentations, physical examinations along with relevant investigations were also collected before treatment. Mirabegron 25mg tablet orally single dose at bed time was prescribed for 3 months. Patients were followed up for three times at one-month interval. They were observed urgency, bed wetting and side effects of drugs from baseline to three follow-up.

Data collection tools

A checklist was prepared for each child to ensure systematic data collection. Additionally, an interview schedule was developed in Bengali, which included questions related to the objectives of the study.

Data processing and analysis

After collection of all the required data, data were checked, verified for consistency and tabulated using the SPSS 26 software. Exploratory data analysis was carried out to describe the study population. Statistical significance was set as 95% confidence level. Socio-demographic characteristics, clinical and investigation findings, and post-treatment outcomes were reported.

Continuous data were expressed as mean and standard deviation and categorical data were expressed as frequency and percentage and comparisons were assessed by repeated measured ANOVA for continuous variables and McNemar's test for categorical variables, respectively. All test results were two-tailed, and statistical significance was defined as $p<0.05$.

Ethical consideration

The protocol was submitted to the ethical review committee and research review committee of NIKDU. Patients who met the inclusion criteria were thoroughly evaluated by the researcher. The details of the study and related information were read out and explained in the local language using a printed handout. After providing all the necessary information, signed written informed consent was obtained from the caregiver. It was clearly communicated to both the patient and the caregiver that confidentiality would be maintained, that there would be no monetary benefit for participating in the study, and that they had the right to refuse participation at any time without affecting the patient's treatment.

RESULTS

Half of the patients were in 12-15 years age group and majority from middle income family. Table 1.

Table 1: Distribution of socio-demographic features of participants (n=30).

Variable	FNrequency (N)/mean±SD	Percentage (%)
Age of participants (year)		
6-8	5	16.7
9-11	10	33.3
12-15	15	50
Mean age (year)	11.33±2.44	
Monthly family income		
<10000 Tk	4	13.3
10000-25000 Tk	14	46
>25000 Tk	12	40

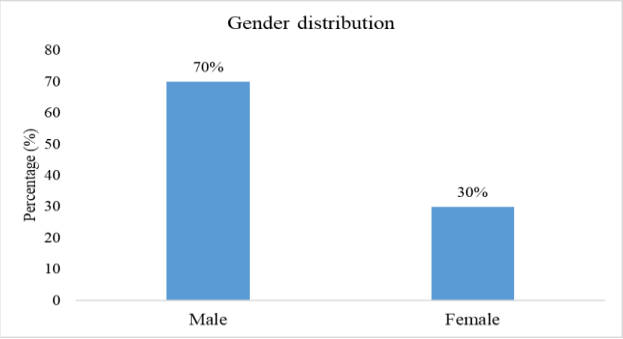

Figure 1: Gender distribution (n=30).

Table 2: Clinical examination findings (n=30).

Variable	Mean±SD
Height (cm)	140.03±5.21
Weight (kg)	36.57±9.74
Pulse rate (beat/min)	71.9±2.41
Systolic BP (mmhg)	100.33±1.82
Diastolic BP (mmhg)	74.33±5.04

Most of the respondents were male (n=21) Figure 1. There was significant difference between baseline number of bed wet per month with 1st, 2nd and 3rd follow up Table 2. Table 3 summarizes the clinical examination findings of the study participants (n=30), showing a mean height of 140.03±5.21 cm and mean body weight of 36.57±9.74 kg. p value between 1st vs. 2nd f/u=0.002, between 2nd vs. 3rd f/u>0.999, between 1st vs. 3rd f/u<0.001. Figure 3 *McNemar test was done, values were expressed as frequency with percentage in parenthesis over column.

Table 3 summarizes the clinical examination findings of the study participants (n = 30), showing a mean height of 140.03±5.21 cm and mean body weight of 36.57±9.74 kg.

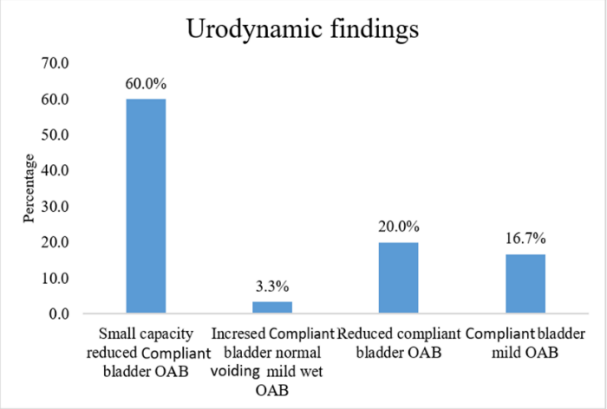

Figure 2: Urodynamic findings of participants (n=30).

Table 3: Association of number of bed wet per month with baseline data of 1st, 2nd and 3rd follow up (n=30).

	Baseline	1st follow up	2nd follow up	3rd follow up
Number of bed wet per month				
Mean (SD)	7.3±3.4	4.7±3.6	0.33±0.66	0.1±0.3
Median (IQR)	7(4-10)	5(0-8)	0(0-0.25)	0(0-0)
	Baseline vs. 1st,2nd, 3rd	1st vs. 2nd f/u	2nd vs. 3rd f/u	1st vs. 3rd f/u
P value*	<0.001	<0.001	<0.001	<0.001

*Repeated measure ANOVA was done.

Table 4: Frequency of side effects of mirabegron between 1st, 2nd and 3rd follow- up (n=30).

Side effects	1st follow- up	2nd follow- up	3rd follow- up
Dry mouth	0	0	0
Nasopharyngitis	0	0	0
Constipation	0	0	0
Elevated BP	0	0	0
Tachycardia	0	0	0
Blurred vision	0	0	0

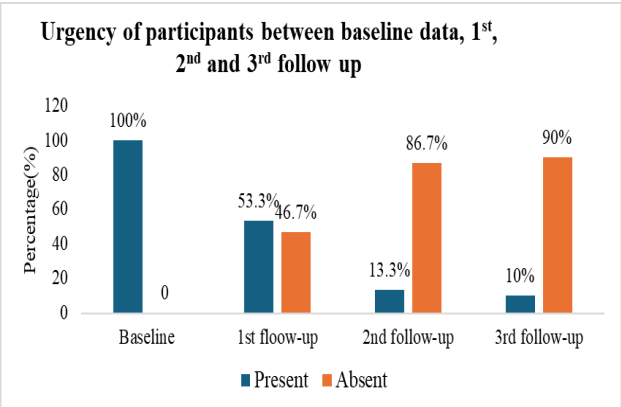

Figure 3: Association of urgency of participants between baseline data of 1st, 2nd and 3rd follow-up (n=30).

The mean pulse rate was 71.9±2.41 beats/min, while the average systolic and diastolic blood pressures were 100.33±1.82 mmHg and 74.33±5.04 mmHg, respectively, indicating overall stable vital parameters in the study group. Table 3. No side effects were found among respondents having mirabegron treatment for nocturnal enuresis in 1st, 2nd and 3rd follow-up. Table 4. Majority of the participants had small capacity reduced compliant OAB followed by reduced compliant OAB, compliant and mild OAB and increased compliant normal voiding mild wet OAB Figure 2.

DISCUSSION

From this study, it is evident that mirabegron significantly decreases the mean number of bedwetting episodes per month and urgency from baseline to final

follow-up. Mirabegron, a selective β3-adrenoreceptor agonist, is a novel drug for controlling OAB symptoms and has been used as an alternative to antimuscarinics because it increases bladder capacity without impairing detrusor contractility.[12] Most of the patients were aged 12-15 years (mean 11.33±2.44 years). In international studies, the mean age of children with nocturnal enuresis ranged from 8.5±2.3 years (Salem Algethami and Ahmed Albarq, 2022), and in some Middle Eastern studies, most children presented between 5-10 years.[13] Males predominated in this study, whereas other studies reported higher prevalence in females. This discrepancy may reflect delayed presentation or late diagnosis in Bangladesh. Most patients belonged to middle-income families, whereas a study from Pakistan reported that most children with NE/OAB came from low-income households.[14]

NE with OAB was significantly associated with family history, consanguineous marriage, and bullying in this study. Sixty-three percent of children had parental consanguinity, and around 10% had a positive family history of similar urinary problems.[14] Genetic influences, such as variations in connexin, have been implicated in bladder capacity regulation. All patients showed tower-shaped uroflowmetry curves, with abnormal patterns observed in 42% of children. Concordance uroflowmetry categorization of bladder capacity was present in 74% of subjects.[15] Urodynamic findings indicated that 60% had small capacity reduced compliant OAB, 20% had reduced compliant OAB, 16.7% had mild compliant OAB, and 3.3% had increased compliant mild wet OAB. There was a significant reduction in mean bedwetting episodes from baseline (7.3±3.4/month) to the 3rd follow-up (0.1±0.3/month). Median (IQR) decreased from 7 (4–10) to 0 (0–0). These results are consistent with previous studies showing a significant decrease in bedwetting episodes after mirabegron therapy.[16]

Urgency also improved significantly, with 53.3% reduction after the first follow-up, and continued improvement in subsequent follow-ups, indicating that daytime urinary symptoms often resolve faster than nocturnal enuresis.[16] Overall response increased progressively across follow-ups. Adult studies also demonstrated improved nocturia within 1 month of treatment (Lee, Ong and Kuo, 2020). Complete response, partial response, and no response rates at 3 months in other studies were 21.7%, 43.5%, and 34.8%, respectively.[17] No adverse effects were observed in this study, likely due to the low 25 mg dose and small sample size. Previous studies reported side effects like headache (2%) and constipation (1.6%) at 50 mg doses.[18]

CONCLUSION

This study demonstrates that mirabegron is an effective therapeutic option for managing NE in children with overactive bladder, offering significant improvement in bedwetting frequency and urgency. The progressive reduction in enuretic episodes across follow-ups indicates enhanced bladder capacity and stabilization, consistent with the drug's β3-adrenergic mechanism of action. Baseline clinical characteristics—including high rates of consanguinity, family history, and psychosocial stressors—highlight the multifactorial nature of enuresis in Bangladeshi children. The excellent safety profile observed, with no reported adverse effects, further supports mirabegron as a well-tolerated alternative to antimuscarinic therapy. Larger, multicenter studies with longer follow-up are recommended to validate these findings and establish standardized pediatric treatment guidelines.

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