

Successful outcome of Treatment with Oxybutynin versus Imipramine in Children Presenting with Nocturnal Enuresis at Tertiary Care Hospital, Islamabad

Anoosha Yousaf, Mulazim Hussain

ABSTRACT:

Objective: To compare the efficacy of oxybutynin and imipramine in children presenting with nocturnal enuresis.

Study Design & Settings: Comparative interventional study, Department of Paediatrics, Pakistan Institute of Medical Sciences, Islamabad.

Methodology: A total of 598 children aged 5–14 years with nocturnal enuresis were allocated in equal numbers to oxybutynin or imipramine using sealed opaque envelopes and treated for 12 weeks. Group O received oxybutynin 5–15 mg/day and Group I received imipramine 25–75 mg/day. Participants were reviewed at week 6, and treatment response was defined as achievement of at least 2 consecutive dry weeks during the 12-week treatment period. The primary between-group comparison was supplemented with absolute risk difference, relative risk and odds ratio with 95% confidence intervals, while subgroup analyses were treated as exploratory.

Results: Mean age was 9.16 $\pm$ 2.78 years in the oxybutynin group and 9.32 $\pm$ 2.85 years in the imipramine group. The study-defined dryness outcome occurred in 209/299 (69.9%) children receiving oxybutynin and 185/299 (61.9%) receiving imipramine ($p=0.038$). The absolute difference was 8.0 percentage points (95% CI 0.5-15.6), relative risk 1.13 (95% CI 1.01-1.27), and odds ratio 1.43 (95% CI 1.02-2.01).

Conclusion: Oxybutynin produced a modestly higher short-term study-defined dryness rate than imipramine during the 12-week treatment period.

Keywords: Enuresis; Imipramine; Nocturnal Enuresis; Oxybutynin; Treatment Outcome

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INTRODUCTION:

Nocturnal enuresis is a common childhood condition characterized by involuntary urination during sleep in children aged at least 5 years. It can affect self-esteem, social participation and family well-being.^{1,2} Proposed contributors include delayed maturation of bladder control, nocturnal polyuria, reduced functional bladder capacity and genetic factors.³ Although spontaneous resolution occurs in many children, persistent cases may require structured behavioural and/or pharmacological management. Oxybutynin is an anticholinergic drug that is frequently prescribed to children suffering from nighttime enuresis especially those with low capacity bladders or overactive bladders.⁴ This is accomplished through the relaxation of the detrusor muscles in the urinary bladder which increases bladder capacity and

reduces involuntary bladder contractions at nighttime.⁵ Oxybutynin treatment has been found to be effective in children resulting in fewer incidences of bedwetting. However it is important to note that a number of children taking the drug have suffered side effects such as dryness in the mouth, constipation and facial redness.⁶

Imipramine is a tricyclic antidepressant that has gained popularity in the management of nocturnal enuresis among children.⁷ Although the exact way in which the drug acts has not been entirely clarified, it seems that the medication increases bladder capacity, decreases bladder muscle contraction, and affects sleep arousal.⁸ Various pieces of literature show that positive outcomes have been observed when imipramine was administered, since the frequency of bed-wetting decreased and continence improved.⁹ The administration of the medicine has to be carefully monitored owing to the occurrence of some side effects like alterations in mood, dizziness, problems with sleep, and cardiotoxic effects.¹⁰ Nocturnal enuresis can adversely affect psychological well-being, social functioning and quality of life. Pharmacological options include oxybutynin and imipramine, but comparative evidence is limited and their safety profiles differ. Local comparative data are scarce; therefore, this study aimed to compare the study-defined short-term dryness outcome with oxybutynin versus

Anoosha Yousaf

Post Graduate Resident, Department of Pediatric Medicine
Pakistan Institute of Medical Sciences, Islamabad
Email: anooshayousaf2910@gmail.com

Mulazim Hussain

Assistant Professor, Department of Pediatric Medicine
Pakistan Institute of Medical Sciences, Islamabad
Email: drkhara786@gmail.com

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imipramine in children presenting with nocturnal enuresis.

In addition to its impact on the child, the chronicness of nocturnal enuresis is able to affect family routines, heighten family-caregiving needs, and create anxiety in parents who may misinterpret bedwetting as a behaviour. There is then a need to management through clinical evaluation, reassurance, behavioural interventions, and choice of a medication based on the probable underlying pathophysiology. Anticholinergic therapy can be of particular value to treatment in cases where functional bladder capacity, urgency or detrusor overactivity is felt to be the issue, whilst tricyclic treatment can also alter the bladder storage capacity, as well as the arousal pathways. However, there has been inconsistent comparative evidence, and treatment decision-making is complicated by the safety profile disparities, surveillance needs, adherence, recurrence, and accessibility. It is clinically pertinent to determine which of these medicines offers the most promise of dryness in the short-term in tertiary care, particularly when alarm therapy, or desmopressin, is not at hand, or unaffordable or unwelcomed. The use of a direct comparison can therefore serve to support the decision to prescribe, enhance counselling and inform future locally appropriate therapy protocols towards children and the family.

METHODOLOGY:

This comparative interventional study was conducted in the Department of Paediatrics, Pakistan Institute of Medical Sciences, Islamabad, after approval by the Institutional Ethical Committee (Ref No. F-5-2-2024/ERRC/PIMS, dated 07-10-2024). Recruitment was carried out from 19 February to 18 May 2026. Each enrolled participant received 12 weeks of treatment; consequently, follow-up continued beyond the recruitment period and extended through August 2026 for participants enrolled near the end of recruitment. The sample size was calculated by OpenEpi sample size calculator using 95% confidence level and 80% power taking expected successful outcome with oxybutynin and imipramine as 71% and 61.3% respectively.¹¹ The required sample size was calculated as 598 children with 299 participants in each treatment group. Children of either gender aged 5–14 years presenting with nocturnal enuresis were included in the study. Nocturnal enuresis was considered as involuntary passage of urine during sleep occurring at least twice weekly for a period of 3 or more consecutive months in a child aged 5 years or above. Children whose parents refused consent, those having developmental delay, cerebral palsy, congenital heart disease, rhythm disorders, current use of diuretics, history of urinary tract infection, central nervous system comorbidities, diabetes, chronic or acute renal failure, renal tubular acidosis, diabetes insipidus or genitourinary malformations were excluded from the study.

Written informed consent was obtained from the parents or guardians before enrolment. Baseline variables included

age, sex, weight, duration of complaints, family monthly income, maternal education, family history of enuresis and relevant clinical history. Participants were allocated in equal numbers using sealed opaque envelopes marked O (oxybutynin) or I (imipramine). Group O received oxybutynin 5–15 mg/day and Group I received imipramine 25–75 mg/day. At the first visit, parents received detailed counselling regarding medication use, dosage schedule, possible adverse effects and treatment compliance. Treatment was continued for 12 weeks. All participants were reviewed at the end of week 6, when wet-night frequency was documented. For the primary analysis, treatment response was defined as achievement of at least 2 consecutive dry weeks at any point during the 12-week treatment period. This study-defined dryness endpoint was retained for consistency with the original protocol, while interpretation was limited to short-term treatment response rather than sustained remission after withdrawal. Phenotypic characterization was incomplete. The study protocol does not provide monosymptomatic versus non-monosymptomatic classification, daytime lower-urinary-tract symptoms, constipation/bowel history, bladder-diary or nocturnal-polyuria measures, prior alarm / desmopressin treatment, or standardized sleep/psychosocial assessments. These unmeasured factors may influence treatment response and are acknowledged as limitations.

Clinical assessment focused on the eligibility criteria, duration of nocturnal enuresis, family history and demographic factors specified in the protocol. Parents were counselled regarding possible adverse effects and treatment compliance throughout therapy. Because the principal study objective was comparative short-term efficacy, detailed phenotypic classification, formal adherence quantification, relapse after withdrawal and structured adverse-event comparison were not primary study outcomes. These domains are recommended for prospective assessment in future trials. Participant flow: 598 children were enrolled and allocated equally, with 299 participants in the oxybutynin group and 299 in the imipramine group. The primary outcome analysis included all 598 participants, comprising 209 responders and 90 non-responders in the oxybutynin group and 185 responders and 114 non-responders in the imipramine group.

Data were analysed using SPSS version 26. Quantitative variables were summarized as mean $\pm$ standard deviation and categorical variables as frequencies and percentages. The primary between-group comparison used the chi-square test and is additionally reported with absolute risk difference, relative risk and odds ratio with 95% confidence intervals. Age, sex and duration-of-complaint analyses were considered exploratory. Formal treatment-by-subgroup interaction testing was used to distinguish subgroup differences from true evidence of effect modification.

RESULTS:

The mean age of patients was 9.16 ± 2.78 years in the

oxybutynin group and 9.32 ± 2.85 years in the imipramine group, with weight recorded as 27.83 ± 8.07 kg and 28.31 ± 8.17 kg respectively. Duration of complaints were 3.94 ± 2.09 years and 4.14 ± 2.18 years for oxybutynin and

imipramine groups respectively. Regarding gender, males were 183 (61.2%) and females were 116 (38.8%) in oxybutynin group, while in imipramine group males were 182 (60.9%) and females 117 (39.1%). Family history of enuresis was present in 142 (47.5%) of oxybutynin group and 139 (46.5%) of imipramine group, and absent in 157 (52.5%) and 160 (53.5%) respectively. Regarding maternal education, illiterate mothers were 46 (15.4%) and 55 (18.4%), primary education 76 (25.4%) and 66 (22.1%), secondary education 107 (35.8%) and 112 (37.5%), and higher education 70 (23.4%) and 66 (22.1%) for oxybutynin and imipramine groups respectively. Family monthly income of =75000 was noted in 186 (62.2%) and 197 (65.9%), and >75000 in 113 (37.8%) and 102 (34.1%) of the two groups respectively (Table-1). The study-defined short-term dryness outcome was observed in 209/299 (69.9%) children in the oxybutynin group and 185/299 (61.9%) in the imipramine group; unsuccessful outcome was reported in 90/299 (30.1%) and 114/299 (38.1%), respectively ($p=0.038$). The absolute difference was 8.0 percentage points (95% CI 0.5-15.6), corresponding to a relative risk of 1.13 (95% CI 1.01-1.27) and an odds ratio of 1.43 (95% CI 1.02-2.01). Exploratory subgroup comparisons showed different treatment-response proportions across age and duration strata. In children aged =10 years, response was 63.4% with oxybutynin and 45.2% with imipramine, whereas among those aged >10 years the proportions were 83.5% and 89.4%, respectively. A treatment-by-age interaction test was statistically significant ($p=0.006$), so this finding is presented as exploratory evidence of heterogeneity rather than a definitive age-specific treatment recommendation. For duration =5 years, response was 68.4% versus 59.1%, and for duration >5 years, 74.6% versus 69.0%; the treatment-by-duration interaction was not significant ($p=0.755$). Gender-stratified comparisons were also exploratory.

Table 1: Patients Demographics in both groups

Variables	Oxybutynin n=299	Imipramine n=299
	Mean $\pm$ SD	Mean $\pm$ SD
Age (years)	9.16 ± 2.78	9.32 ± 2.85
Weight (kg)	27.83 ± 8.07	28.31 ± 8.17
Duration of Complaints (years)	3.94 ± 2.09	4.14 ± 2.18
Gender	n (%)	n (%)
Male	183 (61.2%)	182 (60.9%)
Female	116 (38.8%)	117 (39.1%)
Family History of Enuresis		
Yes	142 (47.5%)	139 (46.5%)
No	157 (52.5%)	160 (53.5%)
Maternal Education		
Illiterate	46 (15.4%)	55 (18.4%)
Primary	76 (25.4%)	66 (22.1%)
Secondary	107 (35.8%)	112 (37.5%)
Higher	70 (23.4%)	66 (22.1%)
Family Monthly Income		
=75000	186 (62.2%)	197 (65.9%)
>75000	113 (37.8%)	102 (34.1%)

Table-2: Comparison of efficacy between the two groups n=598

Efficacy	Group O (Oxybutynin) n=299 n (%)	Group I (Imipramine) n=299 n (%)
Yes	209 (69.9%)	185 (61.9%)
No	90 (30.1%)	114 (38.1%)
Total	299 (100%)	299 (100%)

*Chi-Square Test

Primary effect estimates: absolute risk difference 8.0 percentage points (95% CI 0.5-15.6); relative risk 1.13 (95% CI 1.01-1.27); odds ratio 1.43 (95% CI 1.02-2.01).

Table-3: Association of Efficacy with Demographic Variables

Demographics variables	Group	Subgroup Group	Efficacy		P-value*
			Yes (n, %)	No (n, %)	
Age (years)	O	=10	128 (63.4%)	74 (36.6%)	<0.001
	I		84 (45.2%)	102 (54.8%)	
	O	>10	81 (83.5%)	16 (16.5%)	0.212
	I		101 (89.4%)	12 (10.6%)	
Gender	O	Male	128 (69.9%)	55 (30.1%)	0.171
	I		115 (63.2%)	67 (36.8%)	
	O	Female	81 (69.8%)	35 (30.2%)	0.110
	I		70 (59.8%)	47 (40.2%)	
Duration of Complaints (years)	O	=5	156 (68.4%)	72 (31.6%)	0.041
	I		127 (59.1%)	88 (40.9%)	
	O	>5	53 (74.6%)	18 (25.4%)	0.441
	I		58 (69.0%)	26 (31.0%)	

DISCUSSION:

The present study compared a short-term study-defined dryness endpoint between oxybutynin and imipramine in children with nocturnal enuresis. Response occurred in 69.9% of the oxybutynin group and 61.9% of the imipramine group, corresponding to an absolute difference of 8.0 percentage points (95% CI 0.5–15.6), a relative risk of 1.13 (95% CI 1.01–1.27), and an odds ratio of 1.43 (95% CI 1.02–2.01). The magnitude of benefit was modest, so the result is best interpreted as a short-term difference in the study-defined dryness outcome rather than broad therapeutic superiority. Present study found successful outcome with oxybutynin in 209 (69.9%) and with imipramine in 185 (61.9%), showing oxybutynin to be more effective option, which is comparable with finding of Seyfhashemi *et al.*¹¹ where oxybutynin show highest response rate (71.0%) and lowest relapse compare with imipramine and desmopressin, though difference was not statistically significant in their study. Similarly, Esmaeili *et al.*¹² also reported higher cure rate with oxybutynin (23%) than imipramine (13.7%), supporting present finding that oxybutynin is superior agent for management of nocturnal enuresis. This better response with oxybutynin in present study and in above mention studies may be due to its direct anticholinergic effect on detrusor muscle, which reduce involuntary contraction and increase functional bladder capacity, a mechanism more directly target the pathophysiology of enuresis in many children. However, finding of present study contrast with Das Gupta *et al.*¹³ who reported imipramine give slightly better cure (46.7%) than oxybutynin (40%), and also with Haque *et al.*¹⁴ where tolterodine showed marginally better efficacy than imipramine but neither drug was statistically superior. These differences may be due to variation in sample size, duration of treatment, and dosing protocol used across studies, as small differences in anticholinergic dose and duration of follow-up can alter clinical response significantly. Also, Ng¹⁵ in narrative review noted that imipramine carry potential toxicity and is usually kept as second-line, which may explain why some studies favour anticholinergic over tricyclic agent, in agreement with present result. Subgroup findings require cautious interpretation. Formal interaction testing suggested heterogeneity by age ($p=0.006$); however, this analysis was exploratory and should be considered hypothesis-generating. The duration-specific comparisons did not show evidence of treatment-effect modification because the treatment-by-duration interaction was not significant ($p=0.755$). Accordingly, mechanistic explanations for the subgroup patterns have been removed and the results are presented as exploratory observations. Regarding combination therapy, Bra *et al.*¹⁸ and Esmaeili *et al.*¹² both showed that imipramine plus oxybutynin combination achieve much higher response (84.8% and 41% respectively) than either drug alone, which is in line with present study showing oxybutynin alone giving better result

than imipramine, and suggesting that addition of anticholinergic to tricyclic may further enhance efficacy through their complementary mechanism on bladder capacity and arousal threshold. Kazi *et al.*¹⁹ also found that combination of desmopressin with oxybutynin significantly improve urgency and incontinence compare to desmopressin alone, again pointing toward added benefit of anticholinergic component, consistent with overall direction of present finding favouring oxybutynin.

Few studies, such as Ezodin *et al.*²⁰ found no significant difference between oxybutynin and tolterodine (another anticholinergic) when combine with desmopressin, which is not directly comparable with present study but still support idea that anticholinergic class as whole tend to perform reasonably in resistant or difficult cases. Likewise, Macedo *et al.*²¹ in their cohort of refractory overactive bladder reported complete response in 33% with oxybutynin and 50% with imipramine, slightly differ from present result, possibly because their population was already resistant to other modality like pTENS, representing more difficult subgroup than general enuretic children studied here. The observed between-group difference represents a difference in the study-defined short-term dryness outcome rather than a complete assessment of clinical benefit. Nocturnal enuresis is heterogeneous, and clinically important response may also depend on nocturnal urine production, bladder capacity, daytime urinary symptoms, constipation, sleep characteristics, psychosocial factors and treatment adherence. Future comparative trials should incorporate these characteristics prospectively alongside standardized response categories. The age-stratified result is presented as exploratory despite the interaction signal. Future studies should prespecify age-based interaction analyses and include bladder diaries, daytime urgency/frequency, voided volumes, bowel history, sleep characteristics, previous treatment exposure and adherence so that any age-related difference can be interpreted clinically rather than attributed to unmeasured mechanisms. Duration-of-complaint subgroup findings do not support a differential treatment effect because the formal interaction test was not significant ($p=0.755$). These results are therefore presented descriptively. Future studies should prospectively assess previous therapy, family motivation, adherence, nocturnal polyuria, psychosocial factors and clinical phenotype when evaluating duration-related treatment response.

Safety remains important when comparing these medicines. Oxybutynin may cause anticholinergic adverse effects, while imipramine has clinically important toxicity concerns, particularly in overdose. Parents in this study received counselling regarding possible adverse effects and medication compliance. Future comparative trials should add structured adverse-event reporting, treatment discontinuation, dose reduction, objective adherence measures and standardized cardiac-safety assessment for imipramine to permit a balanced

benefit-risk comparison. The study-defined endpoint of at least 2 consecutive dry weeks was assessed during the 12-week treatment period and represents short-term dryness. To improve clinical interpretability, future studies should additionally report baseline wet-night frequency, percentage reduction from baseline, standardized ICCS complete/partial response categories, time to response and relapse after medication withdrawal. The clinical implications of the results are that oxybutynin should be considered in selected children especially where the reduced bladder capacity or detrusor overactivity suspects. Medication is supposed to be a component of a planned programme such as education, daytime voiding, voiding prior to sleep, reasonable fluid intake in the evenings, constipation therapy, positive reinforcement and avoiding punishment. Standardized diagnostic classification, safety monitoring, longer follow-up and advanced in the relapse should be compared in multicentre studies to direct an individualized treatment of the affected family.

Lastly, the results indicate the need to promote further multicentre studies with specified diagnostic categories and standard dosing schemes. Sufficient follow-up, safety, adherence, and constipation adjustment, comparative studies ought to have constipation adjustment, assessment of family history, socioeconomic factors, previous therapy, and baseline wet-night frequency. These enhancements would enhance the strength of causal interpretation, increase the level of generalizability and enable the development of treatment regimens with children that are characterized by various patterns of nocturnal enuresis. Another factor should be taken into consideration the psychosocial impacts of therapy. The treatment of bedwetting can also lead to satisfied control of the problem, better sleep habits and attendance of school trips, and familial relationships. On the other hand, the frustration and stigmatization can be enhanced by the lack of treatment or inconvenient side effects. The inclusion of tested quality-of-life, child-rated distress, parental and school involvement would reveal whether the statistical difference observed translates into actual meaningful daily change. This is especially so as the absolute difference in success between the groups was relatively minor though it was statistically significant.

Sustainability of response is another clinical issue of interest. The current definition of success was that found children who scored two dry weeks of treatment although it failed to determine whether the dryness was maintained on ceasing medication treatment. It is also not uncommon to observe relapse in nocturnal enuresis; notably when pharmacological therapy alleviates symptoms without altering the underlying maturational process. Adequate follow-up of gradual drug withdrawal would give subsequent evidence on sustained remission, thus being pivotal. Instead of a binary outcome, reporting complete response, partial response, relapse, time to first dry week and decrease wet night per week would

result in a more detailed evaluation. These measurements would also assist the families to realize that even without achieving complete dryness, improvement might be of clinical value. It is also necessary to consider the higher success rate with oxybutynin along with the treatment adherence. The compliance can be lowered due to anticholinergic adverse effects (eg dry mouth and constipation) and the acceptability of imipramine can be affected by fear of cardiac toxicity and need to ensure careful storage. Parents can also change doses, can give up treatment with an initial response, or underreport missed medication. Since adherence had not been objectively measured, it might have added to the results due to actual drug exposure differentiations. Medication diaries, pill counts, planned telephone follow-up, and standardized counselling should be used in future studies to differentiate pharmacological with adherence-related effects. The systematic documentation of adverse events would facilitate the comparison of benefit, tolerability and termination of treatment in a balanced way as well.

Another fact that comes up in the current findings is the significance of suitability of treatment according to the probable clinical form of nocturnal enuresis. Oxybutynin might have a better likelihood of success in small functional bladder capacity and urgency and frequent daytime voiding children, or those who are suspected of detrusor overactivity, as it has its main effect on bladder capacity. In comparison, those children with symptoms that are largely linked with nocturnal polyuria, impaired arousal, or psychosocial stress may have to employ alternative or combined measures. Participants in the current study were not stratified by these mechanisms and thus this could have created variation in each of the treatment groups. Comparative studies ought to incorporate bladder diaries, lower urinary tract symptoms during the day, bowel, and sleep patterns, and past response to treatment so that it can establish which clinical variables are most predictive of the most significant benefit with any drug. Limitations: This was a single-center study using a study-specific short-term dryness endpoint rather than standardized ICCS response categories. Detailed nocturnal-enuresis phenotyping, structured adverse-event comparison, objective adherence measurement and relapse assessment after treatment withdrawal were outside the primary study outcomes. Subgroup analyses were exploratory, and only the age interaction showed evidence of heterogeneity. Despite the large overall sample of 598 participants, longer follow-up and standardized safety and response assessment would strengthen future comparative trials.

CONCLUSION:

In this single-center comparative study, oxybutynin was associated with a modestly higher rate of the study-defined short-term dryness outcome than imipramine (69.9% vs 61.9%; absolute difference 8.0 percentage points, 95% CI

0.5–15.6; RR 1.13, 95% CI 1.01–1.27). The finding supports a short-term efficacy difference under the study protocol, while treatment choice should also consider tolerability, adherence, clinical phenotype and safety. The exploratory age interaction warrants confirmation in prospective studies using standardized response categories and longer follow-up.

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Authors Contribution:

Anoosha Yousaf: Conception and design, acquisition of data analysis and interpretation of data, drafting and critical revision, final approval of the version to be published.

Mulazim Hussain: drafting and critical revision, final approval of the version to be published

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