

Desmopressin versus solifenacin as a treatment of primary nocturnal enuresis in children more than 6 years old (comparative study)

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ABSTRACT

Background :Nocturnal enuresis is a common condition that affects children with greater impact on self-esteem and psychiatric status of an individual.

Aim of the study :To compare between the outcomes and side effects of desmopressin and solifenacin in children with primary nocturnal enuresis.

Patients and methods :Between March 2025 and March 2026 a prospective study was performed in al hussain teaching hospital (al muthana governorate) The study included 100 children patients were between 6 and 14 years and had been diagnosed as primary nocturnal enuresis. The patients were randomized into two groups of equal numbers. One of the group was given desmopressin and another was treated with solifenacin. Response rates and adverse events were recorded and compared between the two groups.

Results :Overall response to desmopressin was significantly higher than that to solifenacin during follow-up period of treatment (40% at 1 month, 76% at 3 months and

82% at 6 months versus

22% at 1 month, 42% at 3 months and 46% at 6 months, p-value less than 0.001). At 6 months of treatment complete response was achieved in 31(62%) and 10(20%) in desmopressin and solifenacin groups respectively, while 10(20%) of desmopressin group and 13(26%) of solifenacin group showed partial response. No response to treatment was recorded in 9(18%) & 27(54%) out of desmopressin and solifenacin groups respectively. Three months post treatment withdrawal 25(60.9%) of patient taking desmopressin and 16(69.5%) of children on solifenacin relapsed. Twelfth percent of children in solifenacin group developed treatment related adverse effects in comparison to only 4% of desmopressin-treated patients with none of those effects were severe enough to discontinue the treatment.

Univariable and multivariable analysis of factors predicting patient' response to treatment have shown that increased frequency of enuritic episodes was negatively correlated with response.

Conclusion :Desmopressin was more effective and safer drug for treatment of nocturnal enuresis in children more than 6 years old but with statistical non significant high withdrawal relapse rate in comparison with solifenacin

Keyword:- N/A

INTRODUCTION

Nocturnal enuresis (NE), commonly known as bed wetting, is one of the most frequent pediatric disorder. According to the International Children's Continence Society, NE is defined as intermittent urinary incontinence while asleep, at least once a week and during a period of minimum three months, in children >5 years.(1) NE is considered mono-symptomatic (MNE) if it occurs without any other lower urinary tract symptoms (LUTS) and without a history of bladder dysfunction. NE in children with any other LUTS and with a history of bladder dysfunction is diagnosed as non-MNE NE (N-MNE). When MNE is diagnosed in children who have never achieved nocturnal urinary continence and have never been dry at night, it is defined as primary MNE (PMNE). Otherwise, secondary MNE (SMNE) describes children who experienced a previous dry period of at least 6 months and it is usually secondary to

psychological stress or organic causes such as urinary tract infections, obstructive sleep hypoventilation, diabetes mellitus/insipidus, and neurogenic bladder. NE is a multifactorial disorder caused by three related mechanisms: nocturnal polyuria, bladder overactivity, and sleep disorder, which could be of urological, neurological, genetic, or psychological origin.(2)(3) Several studies have demonstrated the association between NE and specific comorbidities such as sleep disorders, encopresis, headache, and psychiatric and behavioral disorders.(4)(5) It has been reported that the incidence rate of NE is 10% for children under 7 years old, 3.1% for children aged 11–12 years and 0.5%–1.7% for children aged 16–17 years.(6)

The prevalence of enuresis is similar across cultures. The prevalence varies with age, with 15% of 7-years old (7), 10% of 10-years old (8), 2% of adolescents (10), and 0.5 to 1% of adults being affected by the condition.(11) (12)

Enuresis is more common in boys when compared to girls, with a ratio of 3 to 1, but this difference tends to decrease after age 10.(8) (11) Additionally, 20 to 30% of patients with nocturnal enuresis also suffer from at least one psychological, behavioral, or psychiatric disorder, a rate twice as high as that of the general population. The most common of these comorbidities is attention deficit and hyperactivity disorder, (9) and the postulate is that a common sleep disturbance could link both conditions.(12) Other comorbid conditions in this category include autism spectrum disorder, oppositional defiant disorder, and mood disorders.

(8) Also, there is an association between sleep-disordered breathing and enuresis.(7)(13) These patients have high levels of atrial natriuretic peptide leading to inhibition of the renin-angiotensin-aldosterone pathway and increased diuresis,(7) but other proposed links between both entities are an inadequate arousal response secondary from sleep fragmentation due to disordered breathing and bladder stimulation from elevated abdominal pressure resulting from an increased respiratory effort to compensate for an obstructed airway. Enuresis tends to be cured, or its frequency drastically diminished, after tonsillectomy and adenoidectomy in these patients.(7)(14) Patients with sickle cell disease also show a higher incidence of enuresis.(14)

Genetic predisposition to enuresis studies show a 44% chance of enuresis in children with one affected parent and 77% in those with two affected parents.(15) Identical twins have the highest concordance rate (68%). However, we are currently unable to identify the specific gene.

Approximately 50-70% of enuretic children have a large volume of relatively diluted urine during sleep compared to age-matched peers.(16) ((17) The cause of nocturnal polyuria may be associated with vasopressin deficiency or alterations in its circadian release. In addition, there may be a small subgroup of enuretic children with impaired renal sensitivity to vasopressin.(18)

Bladder capacity tends to be decreased in children with enuresis compared with age-matched children without enuresis. The reduced bladder capacity appears to be functional rather than anatomic. The reflects differences in function bladder capacity with contractions occurring earlier in filling.(19)

32% of children with nocturnal enuresis had involuntary detrusor contractions that resulted in enuresis. This can be related to increased bladder irritability, usually due to a urinary tract infection and constipation.(20)(21)

Enuresis is classified as a sleep disorder by the American Psychiatric Association in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders. Enuresis is correlated with the quality of sleep and the arousability of the child. Poor sleep quality, periodic movement during sleep, and inadequate sleep are factors associated with enuresis and night-time diuresis.(22) Obstructive sleep apnea (OSA) can be associated with nocturnal enuresis.(23)

Some researchers suggest that chronic over-stimulation in the child with OSA leads to downregulation of the voiding center, which precedes to decrease in the child's sense of full bladder and subsequent bedwetting.(24)

PATIENTS AND METHOD

Between March 2025 and March 2026 a prospective cohort study including 100 children was performed. The cases were seen as they visited urology out-patient clinic in Alhussain teaching hospital. The included patients were between 6 and 14 years and had been diagnosed as primary nocturnal enuresis. Children; who were not within preset age range, with history of DM or neurological diseases, history of urological procedures or congenital anomalies affecting genitalia and lower urinary tract, those who were lost to follow up, and whom their families refused to participate in the study,

were excluded from the study.

After full explanation of the aim of study and obtaining the consent from the families of enrolled patients, all children were evaluated by full history including voiding diary for 3 days and complete physical examination. All demographic and clinical parameters were recorded separately for each child. We sent all children for urinalysis, random blood sugar, and abdominopelvic ultrasound. Post void urine volume was measured using ultrasound in initial visit.

Our patients were randomly allocated into two groups with each group had equal numbers of 50 children. Children were given desmopressin and solifenacin in the first and second groups respectively. Desmopressin was given 0.2mg up to 0.6mg orally once daily at bedtime while 0.2mg/kg/day up to 5mg of solifenacin was given orally once a day.

Treatment in both groups was continued for 6 months and then gradual stopped. Patients were seen for follow up visits at 3 months and 6 months for assessment of response rate and adverse effects and at 3 months after treatment withdrawal for evaluation of relapse rate in those who responded to treatment. Voiding diary and Post void urine volume were assessed again at the end of treatment.

Statistical analysis

Shapiro-Wilk test was used to test the normality of distribution. As the age and enuresis episode per month were not normally distributed, they were compared using Mann-Whitney test. Categorical variables were analyzed by chi-square test. Predictors of successful treatment were analyzed using models of logistic regression. *P*-value was considered significant when less than 0.05.

RESULTS

Demographics weren't statistically significantly different between desmopressin and solifenacin groups (table.1). Overall response to desmopressin was significantly higher than that to solifenacin during follow-up period of treatment (40% at 1 month, 76% at 3 months and 82% at 6 months versus 22% at 1 month, 42% at 3months and 46% at 6 months, *p*-value less than 0.001) (table.2). At 6 months of treatment complete response was achieved in 31(62%) and 10(20%) in desmopressin and solifenacin groups respectively, while 10(20%) of desmopressin group and 13(26%) of solifenacin group showed partial response. No response to treatment was recorded in 9(18%) & 27(54%) out of desmopressin and solifenacin groups respectively (table.3). three months post treatment withdrawal 25(60.9%) of patient taking desmopressin and 16(69.5%) of children on solifenacin relapsed (table.4). Twelfth percent of children in solifenacin group developed treatment related adverse effects in comparison to only 4% of desmopressin-treated patients with none of those effects were severe enough to discontinue the treatment (table.5).

There was a significant increase in maximum and mean bladder capacity in solifenacin group with no effects on post void urine volume (table.6). Desmopressin group did not show any significant differences in maximum and mean bladder capacity and post void volume before the and after commencing the treatment.

Univariable and multivariable analysis of factors predicting patient' response to treatment have shown that increased frequency of enuritic episodes was negatively correlated with response (table.7, table.8, figure.1).

TABLE.1. COMPARISON OF DEMOGRAPHICS BETWEEN 2 GROUPS;

VARIABLE	DESMOPRESSIN n=50	SOLIFENACIN n=50	p- value
Age (y) Mean ± SD Range	9.38 ± 2.633 (14-6)	8.96 ± 2.523 (14-6)	0.43
Sex	F= 19 M= 31	F= 23 M= 27	0.41

EE per month Mean $\pm$ SD Range	23.686 $\pm$ 3.635 (16-29)	24.45 $\pm$ 3.596 (17-29)	0.15
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SD; standard deviation, EE; enuresis episodes, *P*- value less than 0.05 is considered significant.

TABLE.2. COMPARISON OF OVERALL RESPONSE BETWEEN 2 GROUPS;

TIME	Desmopressin n=50(%)	Solifenacin n=50(%)	<i>P</i> -value
Overall response at 1 month	20(40%)	11(22%)	0.051
Overall response at 3 month	38(76%)	21(42%)	Less than 0.001
Overall response at 6 month	41(82%)	23(46%)	Less than 0.001

P- Value less than 0.05 is considered significant.

TABLE.3.3 COMPARISON OF COMPLETE RESPONSE BETWEEN 2 GROUPS;

TIME	Desmopressin n=50(%)	Solifenacin n=50(%)	<i>P</i> -value
Complete response at 1 month	13(26%)	5(10%)	0.29
Complete response at	27(54%)	7(14%)	0.004

3 month			
Complete response at 6 month	31(62%)	10(20%)	0.01

P-value less than 0.05 is considered significant.

TABLE.3.4 COMPARISON OF CR, PR, NR, AND RR

GRO UPS	CR n (%)	PR n (%)	NR n (%)	RR n (%)
Desmopressin At 6 month	31(62%)	10(20%)	9(18%)	25(60.9%)
Solifenacin At 6 month	10(20%)	13(26%)	27(54%)	16(69.5%)

CR; complete response, PR; partial response, NR; no response, RR; relapse rate.

Overall response: complete + partial response .

Complete response: 100% reduce frequency of symptoms (nocturnal attacks). **Partial response:** 50-99% reduce frequency of symptoms (nocturnal attacks). **No response:** 0-49% reduce frequency of symptoms (nocturnal attacks).

TABLE.3.5 COMPRISON OF TREATMENT-REALTED ADVERSE EFFECTS BETWEEN 2 GROUPS;

ADVERSE EFFECT	Desmopressin n=50(%)	Solifenacin n=50(%)	Pvalue
Constipation	0(0%)	3(6%)	0.26
Dry mouth	1(2%)	2(4%)	
Headache	1(2%)	0(0%)	

Dizziness	0(0%)	1(2%)
TOTAL	2(4%)	6(12%)

P-value less than 0.05 is considered significant.

DISCUSSION

Our sample included 100 primary nocturnal enuresis-affected children divided into 2 equal groups. The sample size was comparable with several nocturnal enuresis-evaluating trials. (25) 26) But smaller than studies conducted (25) and Caixi et al (160).(27,28) and (25)(49) performed studies with size smaller than ours.

Mean age in recent study is 9.13 year which is comparable with what reported by (8.7 year) and higher than average age mentioned by Ahmed et al (8.1year,7.9 year) (30) and lower than that applied (10.6 year).(31) 62% of enrolled children were under 10 years old reflecting high incidence of bedwetting in younger children with a gradual decrease with age.(31)

Recent study included 58 boys and 42 girls with a ratio of 1.38 male to 1 female which contrasts with a ratio of 3 to 1 reported by (32). This difference can be explained by small sample and selection bias. However, (30), witnessed a comparable ratio. Nonetheless a ratio of almost 1 to 1 was proposed by (31)

In our work it has been found that 46% of children had family history of bedwetting which was in accordance with findings of (32) (33) strengthened role of genetics in disease process underlying nocturnal enuresis through his work.

We intended to directly compare between desmopressin and solifenacin in this study. Desmopressin demonstrated significant superiority in context of efficacy with nonsignificant differences with respect to drug-related adverse effects and relapse rate. No wonder high response rates of desmopressin in treatment of bedwetting have been declared and confirmed by several previous trails.

At 6 months of treatment desmopressin achieved an overall response of 82% which was comparable with (34), and (35) Complete response to desmopressin in our study

(62%) was higher than that in work of shim et al (22%)(48) but comparable with (33)

three months post desmopressin cessation we found that 60.9% of children with complete and partial response had relapsed. This relapse rate was in line with (36) but higher than that reported by (27.3%)(38) and lower than that found by (up to 90%)(37)

This wide range in relapse rate can originate from the variable definitions of relapse suggested by different trails. Other possible explanations involved the age, severity, and the duration of the treatment. Also, due to the retrospective aspect of the recent study, there may be differences in demographics, other than the age, sex, and severity that affected the response and relapse rates.

Four percent of children in desmopressin group developed side effects which was lower than that reported by (39) and (0%)(41)

6 months. Relapse rate was found to be (21.4%). No reported adverse events necessitated cessation of treatment.

(34) explored desmopressin treatment in nocturnal enuresis by a study upon 322 children. The trail showed that desmopressin achieved overall success in 70% with 32.3% responded completely. (38) didn't report any serious side effects.

In 2020 and 2021 2 studies were performed by (35)(36) to determine desmopressin effectiveness in relation with urine osmolality and nocturnal polyuria. Response to desmopressin was comparable across the studies without significant difference. The response rates to desmopressin treatment were 64.3% and 59.2% in low urine osmolality and high urine osmolality groups respectively (P=0.99). 54% and 67% response rates was recorded for polyuria and non-polyuria children respectively (P = 0.2).

Solifenacin is selective antimuscarinic with long half-life.(42) In this trail solifenacin exhibited an

overall response of 23(46%) with 10(20%) had complete response. Response to solifenacin ranges from 10% to 65 %.(42) Results of recent study were higher than what mentioned by Caixi et al (30%)(42). But lower than that found by Fujinaga et al (62%).(37) Even in combinations solifenacin can exert comparable response rate. Additive effect of solifenacin to desmopressin had been investigated in 2 previous trails. First study by Ghanavanti et al(43) included 62 patients who were randomly divided into 3 groups; desmopressin plus solifenacin, desmopressin plus tolteridine, and desmopressin alone. Complete Responses were 95% and 63.3% in desmopressin plus solifenacin and desmopressin alone groups respectively.

Similarly.(38) Performed a study upon 88 children divided equally between two groups; desmopressin alone group and desmopressin plus solifenacin group. In group of desmopressin plus solifenacin complete response was achieved in 84% in contrast with 61.3% in desmopressin alone group. Both of these trails demonstrated an additive effect of solifenacin of about 30%. Relapse rate in solifenacin group was found to be

69.5% which was lower in contrast with (more than 90%) relapse rate reported by Caixi et al.(42)

Solifenacin group in our study recorded adverse effects in 6 patients (12%) which was comparable with (38) findings(10.3%) but lower than that declared by (35%)(39) and (22%)(40). These differences may be brought by several factors namely; demographics, drug's regimen and dosage, and under or over reporting..

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