

An open observational trial evaluating the role of individualised homoeopathic medicines in the management of nocturnal enuresis

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Abstract

Context: Nocturnal enuresis is a widespread and distressing condition that can have a deep impact on the subject's behavioural, emotional and social life. **Aim:** We intend to evaluate the role of homoeopathic treatment in nocturnal enuresis. **Materials and Methods:** A prospective, single arm, pre-post comparison, non-randomised, open-label, observational trial on individuals of 5–18 years of age presenting with nocturnal enuresis at the outpatient department of The Calcutta Homoeopathic Medical College and Hospital was carried out. A total of 34 individuals were enrolled. A scoring scale was developed; scores were measured at baseline, after 2nd and 4th month. The intention to treat population was statistically analysed in the end. **Results:** The mean age of the patients was 8.71 ± 2.73 years; gender distribution was 1:1. Compared to baseline, scores reduced significantly over 2 months (11.6 ± 1.9 vs. 9.6 ± 3.5 ; mean difference: 2.0 ± 2.5 [95% confidence interval (CI): 1.2, 2.9]; $t = 4.748$; $P < 0.0001$ two-tailed; Student's *t*-test) and 4 months (11.6 ± 1.9 vs. 7.1 ± 4.8 ; mean difference: 4.5 ± 4.2 [95% CI: 3.1, 6.0]; $t = 6.319$; $P < 0.0001$). A *post hoc* one-way repeated measure ANOVA indicated significant time effect ($F[2,32] = 311.286$, $P < 0.0001$). Effect size was considerably large (Cohen's *d*: 0–2 months = 1.653; 0–4 months = 2.200). The most frequently indicated medicine was *Kreosotum* ($n = 9$; 26.5%). **Conclusion:** Homoeopathic medicines seemed to have a potential treatment effect in nocturnal enuresis. Controlled trials are warranted.

Keywords: Homoeopathy, Nocturnal enuresis, Observational trial

INTRODUCTION

Nocturnal enuresis is a disorder in which episodes of urinary incontinence occurs during sleep in children ≥ 5 years of age.^[1] More than 85% of children attain complete diurnal and nocturnal control of the bladder by 5 years of age. The remaining 15% gain continence at approximately 15% per year, such that by adolescence only 0.5%–1% children have enuresis.^[2] Nocturnal enuresis prevalence rates vary from 3.5% to 56.4% in different geographical regions and countries.^[3,4] DSM-5 criteria for the diagnosis of enuresis are as follows:^[5]

- Repeated voiding of urine into bed or clothes, whether involuntary or intentional.
- The behaviour either (a) occurs at least twice a week for at least 3 consecutive months or (b) results in clinically significant distress or social, functional or academic impairment.
- The behaviour occurs in a child who is at least 5-year-old (or has reached the equivalent developmental level).
- The behaviour cannot be attributed to the physiologic effects of a substance or other medical condition.

Primary enuresis (75%–90%) occurs when a child has never established bladder control. Secondary enuresis (10%–25%) occurs when a person has established bladder control for 6 months, then relapses and begins wetting.^[6] Enuresis can be further divided into the following three subtypes on the basis of the time of occurrence: nocturnal (i.e. during sleep), diurnal (i.e. during waking hours) and nocturnal and diurnal.^[5] Primary nocturnal enuresis is caused by a disparity between bladder capacity and nocturnal urine production and the child's failure to awaken in response to a full bladder.^[7] Factors associated with enuresis include nocturnal polyuria, detrusor instability and an abnormally deep sleep pattern.^[8] A variety of medical and psychological disorders is associated with

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secondary enuresis such as bladder dysfunction, constipation, diabetes mellitus, hyperthyroidism, obstructive sleep apnoea, pinworm infestation and psychological stress.^[8,9] Studies suggest association between sexual abuse and nocturnal enuresis.^[10]

Active treatment should be avoided in children before the age of 6 years. The child should be reassured and no punitive measures to be taken as that can affect the child's psychological development adversely. The first line of treatment is usually non-pharmacological comprising motivational therapy and use of alarm devices. Alarm devices are used to elicit a conditioned response of awakening to the sensation of a full bladder. Pharmacotherapy is to be done if enuresis persists despite institution of alarm and regular voiding habits.^[2,6] Desmopressin acetate (DDAVP) is the preferred contemporary medication for treating children with enuresis.^[6] However, the common side effects include headache, nausea, upset stomach or stomach pain, diarrhoea or flushing of the face (warmth, redness and tingly feeling). DDAVP can infrequently cause low levels of sodium in the blood, which can be serious and possibly life-threatening.^[11]

A randomised, double-blind, double-dummy, controlled trial^[12] conducted by Ferrara *et al.* on 151 children suffering from nocturnal enuresis and treated with complex homoeopathic medicines (homotoxicological remedies) were superior to placebo ($P < 0.001$) with regard to the number of children attaining 14 consecutive dry nights during treatment, but less effective than standard treatment with Desmopressin. Naude^[13] in his randomised, double-blind, placebo-controlled trial used homoeopathic complex remedies and evaluated against placebo; but it was under-reported. In a case series^[14] of 27 patients, homoeopathic medicine *Equisetum* was coupled with a visualisation technique and the results were promising after 2 years of treatment. A Cochrane review^[15] in 2011 could not identify any randomised trial of Homoeopathy for nocturnal enuresis in children and hence concluded that efficacy or effectiveness of Homoeopathy was uncertain in this condition. We identified one on-going single arm, open-label observational trial on 50 participants suffering

from nocturnal enuresis evaluating the effects of homoeopathic medicine *Causticum* 200C (ClinicalTrials.gov Identifier: NCT02154152); however, no relevant publication could be identified. Thus, literature on homoeopathic medicines in the treatment of nocturnal enuresis with improvement in the quality of life was insufficient and required more studies for a clinical research decision on enuresis. The objective of this study was to evaluate the role of individualised homoeopathic medicines in the treatment of nocturnal enuresis.

MATERIALS AND METHODS

Setting and design

A prospective, single arm, pre-post comparison, non-randomised, open-label, observational trial on individuals of 5–18 years of age presenting with nocturnal enuresis was conducted on the patients attending the outpatient departments at The Calcutta Homoeopathic Medical College and Hospital (CHMCH), Kolkata. The protocol was approved from the Institutional Ethical Committee of the institution. A total of 34 patients were included in the study. Each patient was provided with a patient information sheet in local vernacular Bengali detailing the objectives, methods, risks and benefits of participating and confidentiality issues. Before enrolment, written informed consent was taken from either of the parents or guardians of the patients.

Inclusion and exclusion criteria

Individuals of both sexes between 5 and 18 years of age with episodes of involuntary urination at least twice a week for 3 consecutive months, having no organic pathology behind enuresis, no anatomical and/or surgical changes leading to enuresis, and who have not used systemic antibiotics in the past 1 month, were enrolled. Patients whose parents did not give consent and had objection in being involved with the study were not included.

Outcome assessment

On account of the absence of any valid scales on nocturnal enuresis, we developed a nocturnal enuresis symptom severity scoring scale [Table 1]; measured at baseline, and after the 2nd and 4th month were completed by one or both of the

Table 1: Nocturnal enuresis scoring scale

Questions	Score		
	2	1	0
Frequency of night wetting	Daily	>2 times/week but not daily	<2 times/week
Wets several times more than once a night	Frequent	Occasional	Never
Any experience of diurnal enuresis	Frequent	Occasional	Never
Experiences urge for urination before voiding	Never	Occasional	Yes
Is conscious about the enuresis after voiding	Never	Occasional	Yes
Any experience of such in stressful times	Frequent	Occasional	Never
Enuresis affects sleep	Frequent	Occasional	Never
Feel embarrassed and shy because of enuresis	Always	Occasional	Never
Enuresis affects academic performance	Always	Occasional	Never
Spend the night away from home	Never	Hesitates	Yes

parents with the help of the child under the guidance of the investigating physician. The assessment form consisted of ten questions with their respective scores ranging from 0 to 2 relating to the frequency of night wetting, experience of diurnal enuresis, urge for micturition, consciousness about enuresis after voiding and effects due to enuresis.

Intervention and follow-up

Each enrolled patient was enquired about the complaint according to the predesigned questionnaire. A careful history was obtained regarding whether the enuresis is primary or secondary, whether any daytime symptoms are present and whether any voiding difficulty is present. Enuresis-focused history, physical examination and urinalysis were done before initiation of treatment. Information was obtained to know the onset, duration and severity of enuresis; presence of daytime wetting, constipation, genitourinary symptoms and neurologic symptoms; family history of enuresis; patient medical and psychosocial history and details of previous treatment. Medicines were prescribed after analysis and evaluation of symptom of each case. Cases were repertorised as and when required with the help of RADAR software version 10.0.028 (ck), Archibel 2007, Belgium. The selected medicines in appropriate doses were applied as per the directions in the Homoeopathic Philosophy. Medicines were repeated as per the individual requirement of each case and guidelines of Organon of Medicine. Intervention was given to each enrolled patient and follow up was conducted at least once a month (or earlier as required by the patient) for a timeline of 4 months as per the protocol.

Statistical analysis

Intention to treat analysis was conducted. Student's *t*-test and *post hoc* one-way repeated measure ANOVA were used keeping $P < 0.05$ two-tailed as statistically significant. Statistical Package for the Social Sciences, version 20.0 (IBM Corp., IBM SPSS Statistics for Windows, Armonk, NY: USA) was used for analysis.

RESULTS

A total of 34 patients were enrolled in the study; 4 (11.76%) dropped out and 30 completed the study [Figure 1].

Baseline features

The mean age of the participants was 8.71 ± 2.73 years; gender distribution was 1:1. Maximum number of patients spanned the age group of 8–10 years (47.1%). Among the participants, 55.9% children were studying in Class I to Class V, 64.7% belonged to middle economic status and 70.6% residing mostly in urban areas. Dietary habit was mostly non-vegetarian (91.2%). 70.59% of the parents did not have a history of nocturnal enuresis. Further details of the baseline socio-demographic characteristics are given in Table 2.

Symptom profile

The frequency of night wetting was found to be daily in 79.4% patients that were subsequently reduced to 33.3% and 13.3%

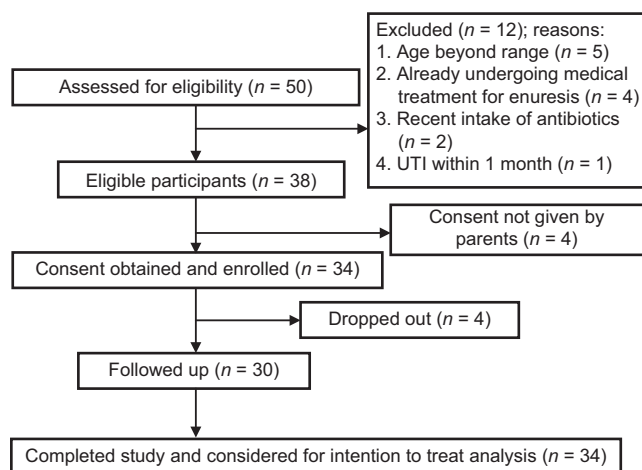


Figure 1: The study flow diagram

Table 2: Baseline features of the patients (n=34)

Features	n (%)
Age groups (years)	
5-7	12 (35.3)
8-10	16 (47.1)
11-13	4 (11.7)
14-16	2 (5.9)
Gender	
Male:female	17:17 (50.0)
Educational status	
Does not go to school	3 (8.8)
Below class I	6 (17.7)
Class I to class V	19 (55.9)
Class VI to class X	5 (14.7)
Class XI and above	1 (2.9)
Economic status	
Lower	10 (29.4)
Middle	22 (64.7)
Upper	2 (5.9)
Habitat	
Urban	24 (70.6)
Semi-urban	6 (17.6)
Rural	4 (11.8)
Diet	
Vegetarian	3 (8.8)
Non-vegetarian	31 (91.2)
History of bed wetting in parents	
None	24 (70.6)
Mother only	2 (5.9)
Father only	8 (23.5)

over 2nd and 4th month of homoeopathic intervention, respectively. The problem regarding bedwetting several times, feeling of embarrassment and shyness, sleep and academic disturbances also improved after treatment. Further details are tabulated in Table 3.

Pre-post comparison

- Over 2 months: Compared to baseline, scores reduced significantly over 2 months (11.59 ± 1.99 vs. 9.56 ± 3.45 ;

Table 3: Symptom profile at different time points

Features	Baseline (n=34), n (%)	After 2 nd month (n=30), n (%)	After 4 th month (n=30), n (%)
Frequency of night wetting			
Daily	27 (79.4)	10 (33.3)	4 (13.3)
More than twice/week, but not daily	7 (20.6)	16 (53.3)	11 (36.7)
Less than twice/week	0	4 (13.3)	15 (50.0)
Wets several times more than once a night			
Frequent	12 (35.3)	9 (30.0)	3 (10.0)
Occasional	19 (55.9)	11 (36.7)	11 (36.7)
Never	3 (8.8)	10 (33.3)	16 (53.3)
Any experience of diurnal enuresis			
Frequent	0	0	0
Occasional	5 (14.7)	1 (3.3)	1 (3.3)
Never	29 (85.3)	29 (96.7)	29 (96.7)
Experiences urge for urination before voiding			
Frequent	16 (47.1)	12 (40.0)	6 (20.0)
Occasional	14 (41.2)	9 (30.0)	7 (23.3)
Never	4 (11.7)	9 (30.0)	17 (56.7)
Is conscious about the enuresis after voiding			
Frequent	16 (47.1)	8 (26.7)	3 (10.0)
Occasional	18 (52.9)	17 (56.7)	14 (46.7)
Never	0	5 (16.7)	13 (43.3)
Any experience of such in stressful times			
Frequent	4 (11.8)	2 (6.7)	3 (10.0)
Occasional	10 (29.4)	10 (33.3)	7 (23.3)
Never	20 (58.8)	18 (60.0)	20 (66.7)
Enuresis affects sleep			
Frequent	8 (23.5)	6 (20.0)	3 (10.0)
Occasional	18 (52.9)	14 (46.7)	10 (33.3)
Never	8 (23.5)	10 (33.3)	17 (56.7)
Feel embarrassed and shy			
Always	28 (82.4)	25 (83.3)	21 (70.0)
Occasional	3 (8.8)	2 (6.7)	4 (13.3)
Never	3 (8.8)	3 (10.0)	5 (16.7)
Enuresis affects academic performance			
Always	12 (35.3)	7 (23.3)	4 (13.3)
Occasional	18 (52.9)	16 (53.3)	13 (43.3)
Never	4 (11.8)	7 (23.3)	13 (43.3)
Spend the night away from home			
Never	12 (35.3)	4 (13.3)	4 (13.3)
Hesitates	13 (38.2)	16 (53.3)	11 (36.7)
Yes	9 (26.5)	10 (33.3)	15 (50.0)

mean difference: 2.03 ± 2.49 [95% confidence interval (CI): 1.16, 2.89]; $t = 4.748$; $P < 0.0001$ two-tailed; Student's *t*-test [Figure 2]

- Over 4 months: Compared to baseline, scores reduced significantly over 4 months (11.59 ± 1.99 vs. 7.06 ± 4.79 ; mean difference: 4.53 ± 4.18 [95% CI: 3.07, 5.99]; $t = 6.319$; $P < 0.0001$) [Figure 2]
- Repeated measures over 2 and 4 months: A *post hoc* one-way repeated measure ANOVA indicated significant time effect ($F[2,32] = 311.286$, $P < 0.0001$). Effect size was considerably large (Cohen's *d*: 0–2 months = 1.653; 0–4 months 2.200) [Figure 2].

Medicines used

Kreosotum was the most frequently used medicine ($n = 9$; 26.5%), followed by *Calcarea phosphorica* ($n = 6$; 17.6%), *Calcarea carbonica* ($n = 4$; 11.7%), *Cina* and *Acidum nitricum* ($n = 3$; 8.8%) and *Natrum muriaticum* ($n = 2$; 5.9%). Rest of the medicines, namely *Abrotanum*, *Aloe socotrina*, *Calcarea iodata*, *Chamomilla*, *Equisetum*, *Rhus toxicodendron* and *Tuberculinum* were used once ($n = 1$; 2.9%) [Table 4 and Figure 3]. Indication for *Kreosotum* was nocturnal enuresis specially in first sleep; the child was difficult to wake up even after bedwetting and dreams of urination as if urinating in the toilet during sleep was noted in one case. *Calcarea phosphorica* was prescribed for tall

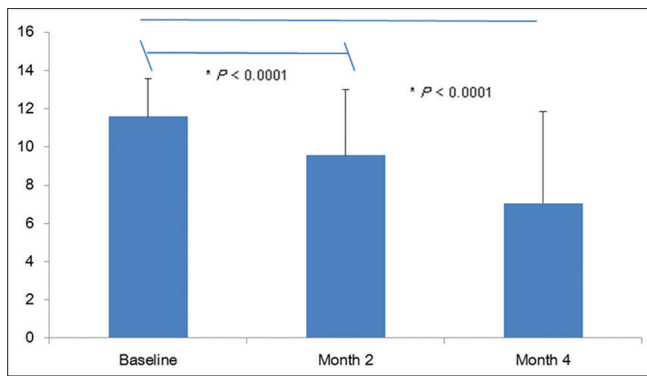


Figure 2: Changes in outcomes over different time-points

Table 4: Medicines in first prescription (n=34)

Medicines	Potency	n (%)
1. <i>Abrotanum</i>	30c	1 (2.9)
2. <i>Aloe socotrina</i>	30c	1 (2.9)
3. <i>Calcarea carbonica</i>	30c, 0/2LM, 0/3LM	4 (11.7)
4. <i>Calcarea iodata</i>	30c	1 (2.9)
5. <i>Calcarea phosphorica</i>	30c, 200c, 1000c	6 (17.6)
6. <i>Chamomilla</i>	30c	1 (2.9)
7. <i>Cina</i>	30c, 200c	3 (8.8)
8. <i>Equisetum</i>	30c	1 (2.9)
9. <i>Kreosotum</i>	30c, 200c, 1000c	9 (26.5)
10. <i>Natrum muriaticum</i>	30c	2 (5.9)
11. <i>Nitricum acidum</i>	30c	3 (8.8)
12. <i>Rhus toxicodendron</i>	30c	1 (2.9)
13. <i>Tuberculinum</i>	200	1 (2.9)

slender children with profuse perspiration, pain and stiffness in legs along with enuresis. Obese children with a tendency to easily catch cold, profuse perspiration and constipation reacted well with *Calcarea carbonica*. *Cina* was prescribed for children with worm infestation and nocturnal enuresis, especially at first sleep. Very strong offensive urine was a strong indicator for *Acidum nitricum*.

DISCUSSION

A prospective, single arm, pre-post comparison, non-randomised, open, observational trial was carried out on 34 individuals of 5–18 years of age presenting with nocturnal enuresis. As no such work on individualised homoeopathic treatment was available on search, the studies available were with complex homoeopathic medicines or with *Equisetum* or *Causticum* 200, hence a scoring scale was developed; scores were measured at baseline, after 2nd and 4th month. Compared to baseline, scores reduced significantly over 2 and 4 months. Effect size was considerably large. Totally 13 different homoeopathic medicines were used; *Kreosotum* being the most common. Homoeopathic medicines seemed to have a promising treatment effect in nocturnal enuresis.

This prospective observational study was aimed to reflect the contemporary homoeopathic health care in real practice

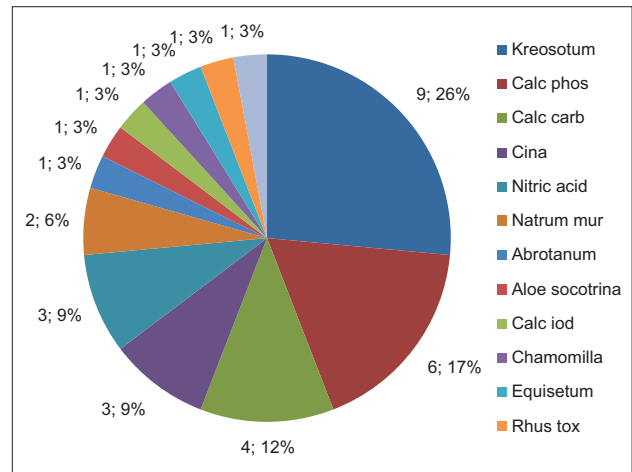


Figure 3: Medicines used

settings and its outcome in 34 patients suffering from nocturnal enuresis. The methodological strengths of our study include its prospective design, the participation of qualified and experienced homoeopathic physicians schooled in and practicing ‘classical’ Homoeopathy, and dealing with a challenging condition like nocturnal enuresis.

In the absence of control arm, there is always chance of overestimation of treatment effect sizes. This is attributable to placebo effect, regression effect to the mean and undisclosed use of concurrent therapeutic modalities. This issue could not be addressed in our study. Another limitation was the absence of prevalidated scale to measure the construct. We developed a scoring scale; however, its validity and reliability remained untested.

All the 34 patients were treated with homoeopathic medicines in different outpatient departments of the institution by different visiting physicians. After proper case taking medicines were selected on the basis of individualisation and totality of symptoms. The potency and dose selection for indicated medicine depended on the patient’s susceptibilities, seat, nature and intensity and stage and duration of disease, previous treatment of patient and as per directions in Organon of Medicine and Homoeopathic Philosophy. Changes in the medicines, potencies and repetitions were made according to the homoeopathic principles after observing the prognosis of the case, assessment of remedy reaction and changes in the presenting symptoms over 4 months of follow-up. Medicines were dispensed by the pharmacists of CHMCH at Hospital dispensary as per as direction of the physician according to individualised case.

CONCLUSION

Nocturnal enuresis is a widespread and distressing condition that has a deep impact on the child or young person’s behaviour and on their emotional and social life. This prospective observational trial, though preliminary, revealed promising treatment effect of homoeopathic medicines in nocturnal enuresis. The study

findings need to be interpreted with caution and further be experimented in randomised placebo-controlled design with enhanced methodological rigor and longer follow-up.

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Conflicts of interest

Non declared.

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रात्रि शय्या मूत्रण के प्रबंधन में विशिष्ट होम्योपैथिक औषधियों की भूमिका का मूल्यांकन एक खुला अवलोकन परीक्षण

सार:

संदर्भ: रात्रि शय्या मूत्रण एक व्यापक और परेशानी की स्थिति है जो रोगी के व्यवहार, भावनात्मक और सामाजिक जीवन पर गहरा प्रभाव डाल सकती है।

उद्देश्य: रात्रि शय्या मूत्रण में होम्योपैथिक उपचार की भूमिका का मूल्यांकन करना।

सामग्री और विधि: कलकत्ता होम्योपैथिक मेडिकल महाविद्यालय एवं अस्पताल (सीएचएमसीएच) के बाह्य रोगी विभाग में आने वाली 5-8 वर्ष की आयु के रात्रि शय्या मूत्रण से ग्रस्त रोगियों पर एक संभावित, सिंगल आर्म, प्री-पोस्ट तुलना गैर-यादृच्छिक, ओपन लेबल, अवलोकन परीक्षण किया गया। कुल 34 रोगियों को नामांकित किया गया। एक गणन पैमाना विकसित किया गया व बेसलाइन पर, दूसरे और चौथे महीने के बाद मापा गया। इंटेशन टू ट्रीट सिद्धांत द्वारा अंत में सांख्यिकीय विश्लेषण किया गया।

परिणाम: रोगियों की औसत आयु 8.71[°] 2.73 वर्ष थी; लिंग वितरण 1:1 था। बेसलाइन की तुलना में, स्कोर 2 महीने में (11.6[°] 1.9 बनाम 9.6[°] 3.5; औसत अंतर: 2.0[°] 2.5 (95 प्रतिशत सीआई: 1.2, 2.9); टी=4.748; पी 0.0001 टू-टेल्ड; स्टूडेंट्स टी टेस्ट) और 4 महीने में (11.6[°] 1.9 बनाम 7.1[°] 4.8; औसत अंतर: 4.5[°] 4.2 (95 प्रतिशत सीआई: 3.16.0); टी=6.319; पी 0.0001) काफी कम हो गया। एनोवा ने महत्वपूर्ण समय प्रभाव (एफ (2,32)=311.286, पी 0.0001) का संकेत दिया है। प्रभाव का आकार काफी बड़ा था (कोहेन्स डी: 0-2 महीने=1.653; 0-4 महीने=2.200)। सबसे अधिक बार संकेतित औषधि क्रियोसोट (एन= 9,26.5 प्रतिशत) थी।

निष्कर्ष: होम्योपैथिक औषधियाँ रात्रि शय्या मूत्रण के उपचार में प्रभावी हो सकती है। नियंत्रित परीक्षणों की आवश्यकता है।

Une étude observationnelle ouverte évaluant le rôle des médicaments homéopathiques personnalisés dans la gestion de l'énurésie nocturne

RÉSUMÉ

Contexte: L'énurésie nocturne est un trouble généralisé et gênant qui peut avoir un impact profond sur le comportement, la vie affective et la vie sociale du patient.

Objectif: Nous avons comme objectif d'évaluer le rôle du traitement homéopathique dans l'énurésie nocturne.

Matériels et méthodes: Une étude observationnelle, prospective, non randomisée, ouverte, sur un seul groupe et avec comparaison avant et après le traitement, a été effectuée sur des patients âgés de 5 à 18 ans souffrant d'énurésie nocturne et qui fréquentaient le département des consultations externes du Calcutta Homoeopathic Medical College and Hospital (CHMCH). 34 patients ont participé à l'étude. Une échelle de scores a été élaborée et les scores ont été mesurés au début de l'étude et à la fin des 2e et 4e mois. L'intention de traiter la population a été statistiquement analysée à la fin de l'étude.

Résultats: Les scores ont baissé de manière significative après 2 mois par rapport au score au départ [$11,6 \pm 1,9$ contre $9,6 \pm 3,5$; une différence moyenne de $2,0 \pm 2,5$ (95% CI: 1,2, 2,9); $t = 4,748$; $P < 0,0001$ bilatéral; le test t de Student] et après 4 mois [$11,6 \pm 1,9$ contre $7,1 \pm 4,8$; une différence moyenne de $4,5 \pm 4,2$ (95% CI: 3,1, 6,0); $t = 6,319$; $P < 0,0001$]. Une analyse de la variance (ANOVA) simple après l'étude a indiqué un effet significatif du temps [$F(2, 32) = 311,286$, $P < 0,0001$]. L'ampleur de l'effet était considérable [d de Cohen: 0-2 mois = 1,653; 0-4 mois = 2,200]. Le médicament le plus fréquemment prescrit a été le *Kreosotum* ($n=9$; 26,5%).

Conclusion: Les médicaments homéopathiques semblent avoir un effet positif dans le traitement de l'énurésie nocturne. Des essais contrôlés sont souhaitables.

Ensayo observacional abierto de evaluación del papel de los medicamentos homeopáticos individualizados en el tratamiento de la enuresis nocturna

RESUMEN

Contexto: La enuresis nocturna es una patología muy extendida y angustiante que puede tener un impacto profundo en el comportamiento y en la vida emocional y social del afectado.

Objetivo: Evaluación del papel del tratamiento homeopático en la enuresis nocturna.

Materiales y métodos: Se efectuó un ensayo observacional, prospectivo, de diseño abierto, un solo brazo, comparación pre-post, no aleatorizado en individuos de 5 a 18 años que padecían enuresis nocturna y que eran tratados en el ambulatorio del CHMCH (*Calcutta Homoeopathic Medical College and Hospital*). Se incluyó un total de 34 individuos. Se desarrolló una escala de puntuación; las puntuaciones se midieron al principio, así como tras 2 y 4 meses. Al final, se efectuó un análisis estadístico de la población de intención-de-tratar.

Resultados: La edad media de los pacientes fue de $8,71 \pm 2,73$ años; la distribución de sexo fue de 1:1. En comparación con el inicio, se produjo una reducción significativa de las puntuaciones durante 2 meses [$11,6 \pm 1,9$ frente a $9,6 \pm 3,5$; diferencia media: $2,0 \pm 2,5$ (IC del 95%: 1,2, 2,9); $t = 4,748$; $P < 0,0001$ bilateral; test t de Student] y 4 meses [$11,6 \pm 1,9$ frente a $7,1 \pm 4,8$; diferencia media: $4,5 \pm 4,2$ (IC del 95%: 3,1, 6,0); $t = 6,319$; $P < 0,0001$]. El análisis ANOVA *post hoc* unilateral de medidas repetidas indicó un efecto de tiempo significativo [$F(2, 32) = 311,286$, $P < 0,0001$]. El tamaño del efecto fue considerablemente grande [d de Cohen: 0-2 meses = 1,653; 0-4 meses = 2,200]. El medicamento más frecuentemente indicado fue *Kreosotum* ($n=9$; 26,5%).

Conclusiones: Los medicamentos homeopáticos parecen tener un efecto terapéutico en la enuresis nocturna. Se requieren ensayos controlados.

Eine offene Beobachtungsstudie, die die Rolle individualisierter homöopathischer Arzneimittel bei der Behandlung von nächtlicher Enuresis untersucht

ABSTRAKT

Kontext: Die nächtliche Enuresis ist eine weit verbreitete und belastende Erkrankung, die das Verhalten, das emotionale und soziale Leben des Probanden stark beeinflussen kann

Ziel: Wir beabsichtigen, die Rolle der homöopathischen Behandlung bei nächtlicher Enuresis zu bewerten.

Materialien und Methoden: Eine prospektive, einarmige, vor-post-Vergleich, nicht-randomisierte, Open-Label-Beobachtungsstudie an Personen im Alter von 5-18 Jahren mit nächtlichen Enuresis in der ambulanten Abteilung der Kalkutta Homöopathische Medical College und Das Krankenhaus (CHMCH) wurde durchgeführt. Insgesamt wurden 34 Probanden aufgenommen. Eine Scoring-Skala wurde entwickelt; Scores wurden zu Beginn, nach dem 2. und 4. Monat gemessen. Die Absicht, die Bevölkerung zu behandeln, wurde am Ende statistisch analysiert.

Ergebnisse: Im Vergleich zum Ausgangswert reduzierten sich die Scores über 2 Monate signifikant [$11,6 \pm 1,9$ vs. $9,6 \pm 3,5$; mittlerer Unterschied: $2,0 \pm 2,5$ (95% CI: 1,2, 2,9); $t = 4,748$; $P < 0,0001$ zweiseitig; Student's *t*-Test] und 4 Monate [$11,6 \pm 1,9$ vs. $7,1 \pm 4,8$; mittlerer Unterschied: $4,5 \pm 4,2$ (95% CI: 3,1, 6,0); $t = 6,319$; $P < 0,0001$]. Eine post hoc einmalige Einweg-ANOVA zeigt einen signifikanten Zeiteffekt [$F(2, 32) = 311,286$, $P < 0,0001$]. Effektgröße war beträchtlich groß [Cohens *d*: 0-2 Monate = 1.653; 0-4 Monate = 2.200]. Das am häufigsten angegebene Arzneimittel war Kreosotum ($n = 9$; 26,5%).

Schlussfolgerung: Homöopathische Arzneimittel schienen einen Behandlungseffekt bei nächtlicher Enuresis zu haben. Kontrollierte Studien sind gerechtfertigt.

非盲的觀察性研究以評估個人化順勢療法藥物在夜間遺尿症治療上的作用

摘要

背景: 夜間遺尿症是一種常見和令人煩惱的疾病，可能對患者的行為、情緒和社交生活產生深遠的影響。

目的: 我們打算評估順勢療法治療在夜間遺尿症中的作用。

材料和方法: 對加爾各答順勢療法醫學院和醫院(CHMCH)門診的5~18歲夜間遺尿患者進行前瞻性、單組、前後對照、非隨機、非盲、觀察性試驗。共納入了34名受試者。已編制了評分表；在基線、第二個月和第四個月後進行測量。最後以治療意向分析法進行統計分析。

結果: 患者平均年齡是 8.71 ± 2.73 歲，性別分佈1:1。與基線相比，分數在2個月後 [11.6 ± 1.9 v.s. 9.6 ± 3.5 ；平均差值： 2.0 ± 2.5 (95%CI：1.2, 2.9)； $t=4.748$ ； $P<0.0001$ ；雙尾；學生*t*檢驗] 和4個月後 [11.6 ± 1.9 v.s. 7.1 ± 4.8 ；平均差值： 4.5 ± 4.2 (95%CI：3.1, 6.0)； $t=6.319$ ； $P<0.0001$] 得分顯著下降。以事後比較單向重複測量方差分析(ANOVA) 表示有顯著的時間效應 [$F(2, 32)=311.286$, $P<0.0001$]。效應值相當大 [Cohen's *d*: 0~2個月=1.653；0~4個月=2.200]。最常使用的藥物是山毛櫸木焦油($n=9$, 26.5%)。

結論: 順勢療法藥物似乎對夜間遺尿症有治療作用。有必要進行對照試驗。