

Alarm Conditioning and Traditional Method for Enuresis Treatment in Thai Children : Randomized Controlled Trial

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Abstract : Compared to traditional methods, Pad and Bell method had more advantages not only for its effectiveness in higher remission rate and less relapse rate, but also for the number of days needed to reach remission. This was not more than the traditional method. Even though Pad and Bell is a new method and unfamiliar to Thai physicians and patients, it has many advantages in both effectiveness and safety, so it should be considered as a new curative method and used more widely in Thailand. If Thai physicians use this new method, enuresis treatment in Thai children can be changed and improved comparably to the western countries.

เรื่องย่อ : การศึกษาเปรียบเทียบแบบสุ่มตัวอย่างในการรักษาปัสสาวะรดที่นอนในเด็กไทยระหว่างวิธีใช้เครื่องมือที่ประกอบด้วยผ้ารองเปื้อนและเครื่องกำเนิดเสียงปลุกกับวิธีที่ใช้กันอยู่ดั้งเดิม

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การรักษาปัสสาวะรดที่นอน ด้วยวิธีใช้เครื่องมือที่ประกอบด้วย ผ้ารองเบื่อนและ เครื่องกำเนิดเสียง ปลุกมีประสิทธิภาพเหนือกว่าวิธีดั้งเดิมมากทั้งในเรื่องอัตราการหายสูงกว่า และอัตราการกลับมาเป็นซ้ำหลังจากหยุดการรักษาต่ำกว่า นอกจากนี้ระยะเวลาที่ใช้ในการรักษาก่อนผู้ป่วยจะหายก็ไม่มี ความแตกต่างกัน ดังนั้น แม้ว่าการรักษาปัสสาวะรดที่นอนด้วยเครื่องมือจะเป็นวิธีใหม่ในประเทศไทยและมีใช้เฉพาะในโรงพยาบาลศิริราชเท่านั้น แต่มี ข้อดีและข้อได้เปรียบทั้งในด้านความ ประหยัด ปลอดภัย และได้ผลดีกว่าวิธีดั้งเดิมที่ใช้กันอยู่มาก จึงควรที่จะได้รับการ สนับสนุนให้มีการรักษาด้วยวิธีใช้เครื่องมือนี้ให้เป็นที่แพร่หลาย เพื่อเป็นการพัฒนาการรักษาปัสสาวะรดที่นอนใน เด็กไทยให้ทัดเทียมกับประเทศตะวันตก

INTRODUCTION

Functional enuresis is defined by DSM IV as "repeated voiding of urine during the day or at night into bed or clothes at least twice per week for at least 3 months or else must cause clinically significant distress or impairment in school, academic or other important areas of functioning." The wetting must not be the result of the direct physiological effects of substance or a general medical condition. There are three subtypes of enuresis : nocturnal, diurnal and mixed. Almost all of enuretic children have nocturnal enuresis which is usually defined as repeated involuntary passage of urine during sleep in the absence of any identified physical abnormality in children aged above 5 years.

DSM IV also cites a spontaneous remission rate at around 10 percent per year after 5 years. The likelihood that a child will be continent spontaneously is reduced sharply after age 4,¹ and associated psychopathology is more commonly found in the child who is still incontinent at age over 4 years.²

There are at least 3 reasons for diagnosing and treating children as enuretics if they still experience bedwetting after the age of 5 years.

1. The developmental perspective : the child should be continent during the daytime at the age about 2-2.5 years and for the nighttime at the age about 3-3.5 years, not over 4 years of age.

2. The likelihood for the child to be continent spontaneously is reduced sharply after age of 4 years.

3. The associated psychopathology is more common in enuretic after the age of 4 years.

Thereby the enuretics after the age of 5 years should be properly treated to prevent further complications such as psychosocial, family and behavior problems. When an enuretic child is treated successfully, his behavior, mood and social adjustment change for the better.³

Eventhough psychotherapy may be helpful for managing the behavioral disorders that accompany enuresis, it appears to have little effect on primary enuresis itself, with recent studies showing a success rate of 20% which may largely be accounted for by spontaneous remission.⁴ Psychotherapy may be more useful for those children with secondary enuresis especially those whose episodes begin after a traumatic event or parental divorce.

Approximately a third of enuretics referred for treatment were not given any a third were prescribed medication and the remainder a miscellany of interventions. Only 3% were prescribed a night alarm system (pad and bell), the only known curative treatment.⁵ These findings are a cause of concern because the same study found that about a third of 5 - 13 year old enuretics were greatly distressed by their symptoms.

Traditional treatment methods (night lifting and fluid restriction before bed) are common sense measures frequently adopted by parents. The failure of a parent after trying either one or both methods of traditional treatment may be an indication of a negative or negligent attitude towards the condition of the child. Studies of the treatment efficiency are not well-established, but it is suggested that, although the procedures may lead to a small initial reduction in wetting frequency, the effect is short-lived.⁶ A positive response to one of these techniques may be one of the reasons why professional advice is not sought.

Regarding the night alarm, Pfaundler devised an alarm system to alert maternity nurses to when an infant needed changing. He also tried the apparatus on an enuretic child and noted that the enuresis improved. Despite this early report of a successful treatment of enuresis, the method was only applied irregularly until Mowrer, working from conditioning theory, developed a similar device.⁷ The Mowrer apparatus consisted of an auditory alarm linked to two electrodes, separated in one way or another,

upon which the child slept. When the child was incontinent, the urine established contact between the two electrodes, the alarm sounded to wake the child up.

Although the night alarm (pad and bell) offers the only known cure of enuresis (cure most commonly defined as 14 nights of continual dryness, with the night alarm varies from 50 to 100%, mostly 80%), it is a difficult procedure that tends to be unpopular for clinicians (who are much more likely to prescribe medication). One of the inconveniences of night alarm is that it takes weeks before a cure is obtained. Cure is usually reached during the second month of treatment. In some studies premature termination rates run as high as 48%.⁸

In Thailand, before the last 3 years, there were only 2 available treatment methods for enuresis, i.e., medication and traditional night lifting and fluid restriction, which are not very effective. Pad and bell is the treatment which was used first in the Department of Psychiatry, Siriraj Hospital for 3 years and it was found that the remission rate was about 70-80%.

At Siriraj Hospital, we found quite often that enuretic patients were treated in both the pediatric and psychiatric department. Almost 75-80% of patients have never received any treatment except through the traditional method.⁹ If we can establish the magnitude of difference between these two treatment methods, in terms of remission rate, advantages and disadvantages, Thai physicians will be able to improve their masteries of enuresis treatment techniques.

MATERIALS AND METHODS

The experimental study was an evaluator blind, randomized controlled trial performed on Thai enuretic patients aged above 6 years that were seen in the Psychiatric Department, Siriraj Hospital and in the school's mental health program.

Children over the age of 6 years who have bedwetting at least 2 nights weekly were included in this study. Patients who had any contributing organic causes such as urinary tract infection or diabetes mellitus were excluded. Also excluded were patients with mental disorders which would affect their ability to follow instructions and patients who could not be regularly followed-up.

Sample selection

Inclusion criteria :

- Children over the age of 6 years who have bedwetting at least 2 night weekly.

- Children willing to co-operate in this study.

Exclusion criteria :

- Having any contributing organic causes such as UTI, DM, etc.

Interventions

There are two groups of treatment

- Having any diagnostic mental disorders affecting the child's ability to follow instructions.

- Children could not be regularly followed-up.

Sample size : About 40 patients per group.

Measurement : The outcome variables

1. The proportion of patients who met the remission criterion (absence of bed wetting at least 14 consecutive nights).

2. The proportion of patients who relapsed within 6 months after treatment ended (having at least 2 wetnights in any 7-day period).

3. Number of days taken to reach remission.

4. Number of wetnights before reaching remission.

5. Parent's satisfaction score for the method of treatment by using a visual analogue scale.

	Treatment	Control
Pad and bell	X	
Fluid restriction		X
Night lifting		X
Social approval and disapproval	X	X
Star chart	X	X
Tangible reward	X	X

Method of study

Both parents were asked to accompany the child to the clinic for the first appointment. Each child is first screened by the physician including history, physical examination, blood test for BUN and creatinine, and urinalysis to rule out any contributing organic problems.

Mental status examination and interview were performed by child psychiatrist.

Psychological test (Sentence completion test and Drawing test) were performed by psychologist.

A child psychiatrist and psychologist administered both programs of treatment.

Method was described and demonstrated clearly by child psychiatrist to the family.

The parent and child did a role-play to test whether they understood the instructions or not.

A date was agreed upon for beginning the program.

A follow-up session every 2 weeks both groups.

Weekly phone contact was kept with each family by the child psychiatrist to monitor the child's progress, to reinforce instructions and to ensure that the program is followed properly.

Even after the child reached the dryness criterion of 14 consecutive drynights, the treatment was still continued until 3 months of treatment ended and was then followed up every 2 weeks as well as the weekly phone contact.

We consider a patient's remission if continence can be maintained until 3 months of treatment has ended.

After treatment ends, the 2 week-follow up is maintained to ensure regular contact for 6 months. If the child has at least 2 wetnights in any 7-day period, we count this as relapse and if the child is still continent for 6 months follow, we count the patient as cured because it is very rare to relapse after 6 months.

Both groups received the pads for nightly use (marked with the date and number in order) to see whether the child has been bed-wetting or not.

Home visits were done by a child psychiatrist and or a social worker if there was any loss of regular contact with the patients.

During the treatment program, the child had to sleep with his parent so as to ensure that they can follow the instructions properly, record the result on the star chart and record the waking time by a time-recorder correctly.

The parent and child have to be stated clearly about what contamination and co-intervention should be avoided.

Data collection

The child himself recorded the results under the surveillance of his parent, and the record forms were brought to the other physician who was the blind evaluator (the evaluator never saw or had contact with the patient) checking the contaminated pads and time-recorder device to see whether they were corresponding to the record-forms.

The physician who gave treatment to the patients was not informed about the results and she always had a psychiatric nurse to join her during the treatment to ensure that no bias was taken for any treatment method.

Statistical method

The Z-test was used to analyse the differences between the two groups on remission rate and relapse rate.

The unpaired t-test was used to analyse the differences between the groups on the number of days taken to reach remission, number of wetnights before reaching remission and the

satisfaction score.

Co-variate analysis by Mantel-Haenszel method.

Uni-variate and multi-variate analysis.

RESULTS

Baseline data (characters and distribution of sample population)

Table 1. Distribution of sample population compared between two treatment groups of sex

Sex	Pad and bell	Traditional	Total
Male	15 (37.5%)	15 (37.5%)	30
Female	25 (62.5%)	25 (62.5%)	50
Total	40	40	80

P-value = 1

Both treatment groups were equally distributed by gender.

Table 2. Distribution of sample population compared between two treatment groups by type of wakening

Type of wakening	Pad and bell	Traditional	Total
Consciously waken	19 (47.5%)	19 (47.5%)	38
Not consciously waken	21 (52.5%)	21 (52.5%)	42
Total	40	40	80

P-value = 1

Both treatment groups were equally distributed by type of wakening and other baseline variables i.e., education of mother, parental conflict, compliance, number of urinations per wetnight before study, number of wetnights per week before study.

The two baseline variables i.e., age and education of father were statistically different between two groups (P-value < 0.05).

Tables 3. Results of treatment

	Pad and bell				Traditional			
	Male		Female		Male		Female	
	W*	W	W*	W	W*	W	W*	W
Remission	6	4	8	11	1	1	4	-
Much improved	2	2	3	-	1	-	-	-
Improved	-	1	-	2	4	5	3	9
Not improved	-	-	-	-	1	1	4	5
Drop out	-	-	-	1	1	-	-	-
Total remission	72.5% (29/40)				15% (6/40)			

W* = Consciously waken

W = Not consciously waken

Table 4. Remission rate compared between two treatment groups

	Pad and bell	Traditional
Remission	72.5% (29/40)	15% (6/40)
95% CI	(58.66 , 86.34)	(3.93 , 26.07)

P-value by Z-test (with α error = 0.05, magnitude of difference = 0.3 one-tailed hypothesis) was 0.007 (P-value < 0.05).

Table 5. Relapse rate compared between two treatment groups

	Pad and bell		Traditional	
	Male	Female	Male	Female
Relapse	3	5	2	2
During F/U	-	1	-	1
Still remission	7	13	-	1
Total relapse	28.57% (8/28)		80% (4/5)	

There was a statistical difference between two groups in relapse rate, P-value was 0.0139 (P < 0.05 by Z-test).

Table 6. Comparison between two groups of treatment by number of days taken to reach remission and number of wetnights before reaching remission

	Pad and bell	Traditional	P-value
Days taken			
N	29	6	
Mean \pm SD	50.86 \pm 15.36	42.67 \pm 26.33	0.493
95% CI	(44.05, 57.67)	(15.03, 70.30)	
Wetnights			
N	29	6	
Mean \pm SD	17.36 \pm 10.33	7.50 \pm 5.96	0.035
95% CI	(12.79, 21.94)	(1.25, 13.75)	

By unpaired t-test, there was a statistical difference in number of wetnights before reaching remission compared between the two groups of treatment (P-value < 0.05).

Table 7. Parent's satisfaction score for method of treatment compared between two groups of treatment by a visual analogue scale

VAS	Pad and bell	Traditional	P-value	95% CI of mean dif
Mean \pm SD	8.74 \pm 1.46	7.72 \pm 1.94	0.031	(-1.94, -0.09)
95% CI	(8.17, 9.30)	(6.97, 8.84)		

By unpaired t-test, the pad and bell was associated with higher score of parent's satisfaction compared to the traditional method with statistical significance (P < 0.05).

Analysis of the correlation between the results of treatment and other factors such as age, education of father, education of mother, parental conflict, compliance, number of urination per wetnights and number of wetnights per week before treatment.

1. By univariate analysis

There were not any correlations among these factors and the results of treatment or there

were not any factors that could affect the outcome of treatment.

2. By multi-variate analysis (Stepwise logistic regression)

There was only one factor correlated with the result of treatment, i.e., type of treatment with statistical significance (P-value < 0.001).

Co-variate analysis

Stratified analysis for the two prognostic factors, i.e., gender and type of wakening by Mantel-Haenszel method and the results of treatment (remission or not) are not different or were not affected by these two prognostic factors (P -value = 0.375).

DISCUSSION

Remission rate

This was a randomized controlled study evaluating the effectiveness of the pad and bell which is a new method used first at Siriraj Hospital for the first time in Thailand, as compared to the traditional method which is the home-spun technique still used by most physicians. The efficiency of the traditional method is still unknown.

There have been two major modalities for enuresis treatment, i.e., medication and behavior therapeutic method in which both pad and bell and traditional are classified. One of the major disadvantages of medication is the side effects. Physicians are aware of and this and thus to choose the behavior method first.

The traditional method (fluid restriction and night lifting) is a common sense technique that if it is not really effective enough, it may cause the negligence attitude of parent towards the treatment which could magnify the other problems further for the child.

As reported in this study, the remission rate of the traditional method was only about 15 percent (Table 4) which is not much different from the spontaneous remission rate (10-15% per year by DSM IV) that might be an effect from the nature of this study. Because this study was hospital

based, tertiary care and most patients had previously used one or both techniques of traditional method (night lifting and fluid restriction) at some point before enrolling in this study. This might be the reason why treatment by traditional method was not effective.

On the other hand, since both treatment methods in this study mostly relied on the patient and his parent, and we tried very hard to prevent dropping and to improve compliance by keeping weekly regular contact to ensure, encourage and monitor whether the patients could follow the instructions properly (that was unusual in clinical practice) which could improve the results of both treatment methods especially for pad and bell because from the other studies we had found frequent drop-outs and premature termination of treatment due to difficult and time consuming procedure, particularly for Thai patients to whom the method seemed new and unfamiliar.

The remission rate of pad and bell was about 72.5% (Table 4), nearly the same as most other studies which reported the remission rate around 75-80%.^{7-8,10-18} The difference of this result may arise from the difference in the duration of treatment, the sample population studied, the definition of remission or the research methodology.

However, we could state that the pad and bell was one of the effective and curative treatment for enuresis and should be considered for all patients who had failed when using the traditional method, especially in the well-compliant patients.

Relapse rate

In this study, the relapse rate of pad and bell was 28.57% (Table 5), the traditional method

had a relapse rate of 80%. The result was statistically significant (P -value = 0.0139). The relapse rate in this study was little different from some of the other studies which reported the relapse rate of pad and bell at about 10-30%.^{20,21,24} The difference might be due to the difference in the duration of the follow-up period, the definition of relapse, the research methodology or the number of patients studied.

Even though the pad and bell treatment method had a much lower relapse rate than the traditional method, its relapse rate was still rather high. So the attempts to identify the predictors of relapse and to find the techniques to reduce this problems should be important and interesting issues for further studies.

Number of wetnights before reaching remission

The traditional method had a mean of wetnights of 7.50 ± 5.96 , while the pad and bell had a mean of wetnights of 17.36 ± 10.33 (Table 6). The traditional treatment was statistically different in fewer wetnights than the pad and bell (P -value = 0.035). This may be caused by the conditions of method in traditional treatment itself which required both fluid restriction and night lifting (waking the child up to urinate before he wet the bed). These ways reduce the amount of urine and have an advantage over the pad and bell technique.

Even though the traditional method was associated with fewer wetnights, it could not cure the enuresis.

Number of days taken to reach remission

The duration from the start of treatment and remission were 42.67 ± 26.33 and $50.86 \pm$

15.36 for the traditional and the pad and bell methods respectively (Table 6). There was no statistical difference between the two groups of treatment (P -value = 0.345). This may be due to the fact that the difference between the two groups was not big enough and the number of subjects was too small (number of patients who reached remission in traditional method was only 6).

We can conclude from this study that even though the traditional method has the advantage of fewer wetnights before reaching remission than the pad and bell, it did not have any other advantages and could not really cure more enuresis.

Co-variate analysis

In this study, we planned to evaluate two important prognostic factors which might affect the main outcome (remission), i.e., gender and type of waking by using Mantel-Haenszel method because both factors were discrete variables. The analysis showed no statistical differences by both strata of genders and types of waking (P -value = 0.375). This might be related to the small number of subjects in each arm of stratum. We can state from this study that the results of treatment were not different or affected by genders or type of waking.

Parent's satisfaction for the method of treatment received

The pad and bell method was associated with higher parent satisfaction score than the traditional method with statistical significance (Table 7).

Even though the pad and bell method was more complicated and had more difficult instructions, the parent still had higher satisfaction scores than the traditional method. This might be due to the fact that the parents were more interested in the new method and felt more successful with the pad and bell method.

In this study, for both treatment methods, the mother most often was the person who had to wake her child up.

But in the real practice, the alarm (pad and bell) itself wakes the child while the traditional method still has the mother to wake the child.

So the parents might be more satisfied for not being the one who had to wake the child as well as the child might be happier for not being forced by his/her parents.

We did not plan to evaluate the satisfaction score of the child since we thought that the child might be unable to understand and answer correctly the questions and explanations about the visual analogue scale.

It is possible that the parent's satisfaction score might be different from the satisfaction score of the child.

Factors correlated to the results

We tried to evaluate and find the factors which correlated to the main outcome (remission). Those factors we evaluated were gender, age, education of father, education of mother, type of wakening, compliance, parental conflict, number of urinations per night before treatment and number of wetnights per week before treatment.

We used univariate analysis to evaluate each of those factors to see whether it had any

significant correlations with the main outcome. As reported, there weren't any factors which had a significant correlation with the main outcome (P -value > 0.05).

By stepwise logistical regression, the factor which had the highest correlation order with the main outcome was type of treatment and it also had a statistical significance (P -value < 0.001). The next order of correlation with the main outcome was compliance, but it did not achieve a statistical significance (P -value > 0.05). This might be due to the too small number of patients (there were only 4 cases of non-compliant patients in this study).

CONCLUSION

Nocturnal enuresis is a chronic condition which we can find quite commonly not only in daily life but also in clinical practice, though few patients receive adequate and appropriate treatment. Even though enuresis itself is not a serious illness, it causes many direct and indirect complications and can cause distress to the child and his or her family.

Until now, there have been two major modalities for enuresis treatment, i.e., medication and behavior therapeutic method in which both the pad and bell and the traditional one are classified. The major disadvantage of medication are the side effects and possible recurrence after discontinuation. Most parents don't prefer to use medication for their children and always refuse to prolong medication. It is the reason that almost all parents had already tried home-spun technique of behavior method (traditional method). So if the traditional method is not really

effective enough, it may cause a negligent attitude on the part of the parents towards the treatment, which in turn could magnify further problems for the child and his family.

On the other hand, most physicians themselves prefer to use medication and traditional method because they are easy and familiar. However both methods have low efficiency rates effective and high relapse rates. If both methods don't work, it seems helpless for both physicians and patients.

We can conclude from this study that the pad and bell treatment was associated with a high remission rate of about 72.5% and low relapse rate of 28.57% while the traditional method was associated with about 15% and 80% for remission rate and relapse rate respectively.

The traditional method had only one advantage of having fewer wetnights, however, the number of days consuming of two methods were the same.

Since most patients who come to see a physician had previously used a traditional method for some period of time, and medications can cause many side effects for the child, pad and bell may be an other appropriate treatment of choice especially in the compliant child because it is effective and safe.

In Thailand, pad and bell is a new method used first at Siriraj Hospital. It isn't familiar to Thai physicians or patients, but from this study we also reported its efficacy for enuresis treatment as in other studies. The pad and bell method should provide us with other helpful curative treatments of choice for enuresis for Thai patients. It can give a new effective technique for Thai physicians and improve for enuresis treatment in Thailand comparable to the western countries.

SUGGESTION

Since the traditional method is not effective and most of patients have previously tried of before coming to see a physician. The disadvantages of medication are side effects and high relapse rate.

Pad and bell, on the other hand, is effective and safe. It should be recommended as the first choice of treatment especially in complaint patients or patients who failed with other treatments.

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