Enuresis Management in Children: Retrospective Clinical Audit of 2861 Cases Treated with Practitioner-Assisted Bell-and-Pad Alarm

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Objective To establish the treatment efficacy of practitioner-assisted bell-and-pad alarm therapy in children with enuresis between the ages of 5 and 16 years by retrospective medical chart review of 2861 children in multiple clinical settings.

Study design This review was conducted across 7 Australian clinical practices. The primary outcome measure was the time taken for children with either primary, secondary, monosymptomatic, or nonmonosymptomatic enuresis to be dry for 14 consecutive nights. The secondary outcome measure was to determine relapse rates, defined as 1 symptom recurrence per month post interruption of treatment. Data were analyzed by correlation and χ^2 test via IBM SPSS Statistics (version 22).

Results The overall success rate of the bell and pad treatment was 76%, irrespective of age. The mean treatment time to achieve dryness was 62.1 ± 30.8 days, and the relapse rate was 23%. Concurrent bowel dysfunction was associated with a slightly lower success rate (74%). Concurrent lower urinary tract symptoms were associated with a lower success rate (73%) and greater relapse (1.75 times more likely to relapse). Children with secondary enuresis had significantly greater success than those with primary enuresis (82% vs 74%).

Conclusion The type of alarm therapy reported in this study is highly effective. This study will provide the basis for clinical guidelines and practice tools for clinicians, which will help to reduce variation in care pathways for alarm treatment for enuresis. *(J Pediatr 2018;193:211-6).*

Bedwetting (enuresis) is a common and distressing condition that can impact a child/young person's behavior and their emotional and social wellbeing.[1,2] Internationally, first-line treatment for monosymptomatic enuresis predominantly comprises body-worn alarms for enuresis or desmopressin,[3-5] although other therapies have been reported, with minimal information regarding their effectiveness.[6] Desmopressin and enuresis alarms are evidence-based medicine level 1, grade A International Consultation on Incontinence–recommended treatments.[5,7,8] These treatments are aimed at children aged 6 years and older[9-11]; children younger than 5 years old are not treated, as the occurrence of enuresis is developmentally expected.[10]

Although desmopressin is regarded as an effective treatment for enuresis, it is less effective than alarm therapy, and the benefit is not sustained.[12] Relapse rates for desmopressin have been reported to be as high as 91%.[13] In Australia, alarm therapy is the first-line treatment for enuresis, and desmopressin can only be prescribed when alarm therapy has been unsuccessful or deemed unsuitable.[13,14]

Meta-analyses of randomized controlled trials in alarm therapy have shown bell-and-pad alarm therapy efficacy up to 66%[15-17]; however, the quality of many of the trials examined was poor and evidence for many comparisons inadequate.[18] Although guidelines for the diagnosis and management of monosymptomatic enuresis recommend the use of alarm therapy,[4,19,20] no distinction is made regarding the type of alarm that should be used. Body-worn alarms of various types can be purchased directly by families. This is in contrast to practitioner-assisted bell-and-pad alarms which, in Australia, are only provided by a clinician who supports the treatment. In Australia, the bell-and-pad alarm is the preferred treatment used by practitioners for children with enuresis. Anecdotal evidence from Australian practitioners indicates that this bell-and-pad alarm method is their treatment and alarm of choice; it is reported to have the highest efficacy and the lowest relapse rate; however, there are limited published data to support this.[21]

To address this gap, we designed a retrospective, multicenter medical record review to capture information about children between the ages of 5 and 16 years of age treated for enuresis in multiple clinical settings to determine (1) the efficacy of practitioner-assisted bell-and-pad alarm therapy in healthy children with enuresis in Australia; (2) the relapse rate after such treatment, (3) the impact of lower urinary tract symptoms on the success of this treatment method, and (4) the comparative efficacy of bell-and-pad alarm therapy with other reported interventions.

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Methods

This was a retrospective, multicenter medical record audit conducted in 7 settings across Australia: 2 tertiary children's hospital outpatient clinics, 2 community continence clinics, a general medical practice, a private continence nurse practice, and a university psychology teaching clinic. These clinics represent a cross section of Australian practices that treat children with enuresis. A total of 2995 patient records (3671 treatment records) were included in the study. The study protocol was approved by 4 independent Human Research Ethics Committees (HRECs) with the primary ethics committee being Ballarat Health Service St John of God; Study No: HREC/12/BHSSSJOG/111.

Medical records were interrogated at each of the clinics, and the following clinical variables were collected via a custom-made questionnaire: demographics (date of birth, sex, postcode), enuresis and constipation history (constipation [previous and current]), day wetting (previous and current), current frequency, current urgency, current urinary tract infection, comorbidities (attention deficit disorder, autism spectrum disorder, intellectual disability, and conduct disorder), family history, previous and current use of desmopressin, duration of treatment (period of alarm use), age of child at treatment, success, and relapse. Where information was missing, the data point was entered as unknown. Treatment success was defined as ≥14 dry nights with no reported relapse within 6-24 months of treatment. Relapse was defined as 1 symptom recurrence per month postinterruption of treatment, as defined by the International Children's Continence Society definitions.[11,19,22] The enuresis and constipation history of each patient was determined through the medical history. Comorbidities were recorded only where there was a clinical diagnosis present in the medical history.

Otherwise-well children without physical disability (male and female) between the ages of 5 and 16 years old at the beginning of treatment who, when presented to a clinic, were diagnosed with enuresis and were treated with the Ramsey Coote bell and pad conditioning alarm (Compliance AS/NZS 2394; Ramsey Coote Instruments, Mordialloc, Victoria, Australia) were included. This bell-and-pad conditioning alarm is a bed-based rubber pad (455 mm × 605 mm [1.5 ft × 2 ft]) connected to an alarm box producing a high-frequency and high-pitched 80- to 90-dB ring. Clinics purchase the bell-and-pad alarm and, in most cases, charge families a fee for alarm use. The alarm and bed pad are provided by clinicians to families immediately following their consultation, and on completion of treatment, alarms are returned to the clinic and bed pads cleaned and prepared for reuse.

Patients whose medical history indicated any of the following comorbidities were excluded: malformation of the renal tract, previous bladder or renal surgery, spinal cord malformation, trauma or tumor, cerebral palsy, and any brain injury or neurodegenerative disorder. Previous use of any alarm or medication did not exclude patients from the study.

Statistical Analyses

Deidentified data were collected and managed via a secure custom-built Microsoft Access database (Microsoft, Redmond, Washington), which enabled an audit trail and export procedures for downloading to common statistical analysis software. The deidentified dataset was exported and analyzed with SPSS Statistics for Windows, Version 22.0 (IBM Corp, Armonk, New York). Because of the nature of the data records, it was necessary to maintain the data in 2 file formats. The first format was structured with the patient as the case for analysis; however, 676 patients had more than 1 treatment record, with some variables changing among treatment records for an individual. Hence, a second data file was maintained with treatment as the case for analysis.

Results

This study interrogated 3064 patient records. A total of 2995 patients with enuresis met the inclusion criteria, with 1918 (64%) boys and 1077 (36%) girls; 69 patients (2.2%) were excluded from the analyses. Of the 2995 patients who met the inclusion criteria, outcome data were available from 2861 patients. An intention-to-treat approach to the analysis was considered; however, several features of the data led to a decision to analyze the data as available. First, for those patients for whom outcome was unknown, an assumption of failure could not be made, given the nature of the methodology. Second, the level of missing data varied widely across variables, and for some variables assumptions for the use of data imputation were not met. Finally, our initial analysis revealed no systematic significant differences between those patients for whom outcome was known and those for whom it was unknown.

At first treatment, 2718 (91%) children presented with primary enuresis, and only 141 (5%) presented with secondary enuresis, with 136 (4%) unknown. Patients with secondary enuresis were significantly older (mean age = 8.96 years) than patients with primary enuresis (mean age = 8.18 years), $P < .001$. This pattern of findings did not vary across multiple treatments (**Table I**).

Monosymptomatic enuresis was reported in 71% of children at time of first treatment (67% boys and 33% girls). Nonmonosymptomatic enuresis was reported in 29% of children (57% boys and 43% girls); these children reported at least 1 of the following lower urinary tract symptoms—day wetting, urgency, or frequency. These figures did not vary across multiple treatments, even though it was possible for a patient's enuresis type to change from treatment to treatment. A description of the patient sample is presented in **Table I**.

The age distribution of the sample across all treatments is shown in the **Figure**. The median age of the sample was 8 years with the mean treatment age being 8.48 years. The sex distribution varied across age; for example, for patients at or below the median age of 8 years, 62% of patients were male and 38% female, but for patients above the median, 72% of patients were male and 28% female.

Table I. Characteristics of patient sample

Characteristics	n	%
Total patients who met the inclusion criteria	2995	100
Boys	1918	64
Girls	1077	36
Primary enuresis	2718	91
Secondary enuresis	141	5
Missing or unknown enuresis type	136	4
Monosymptomatic enuresis	2139	71
Nonmonosymptomatic enuresis	856	29
Missing or unknown	0	0
Patients with		
Attention deficit disorder	68	2
Autism spectrum disorder	86	2
Intellectual disability	95	3
Conduct disorder	12	≤1
Excluded patients*		
Malformation of renal tract	10	0.3
Previous bladder or renal surgery	11	0.4
Spinal cord malformation	4	0.1
Spinal cord tumor	1	0.0
Neurologic disability - cerebral palsy	11	0.0
Brain injury	5	0.4
Neurodegenerative disorder	4	0.2
Older than 16 y	23	0.8
Total excluded patients	69	2.2

*No information was collected on these patients except for their exclusion status.

In the nonmonosymptomatic enuresis group, current daytime wetting was reported in 507 (15%) children (11% of males and 21% of females) across all treatments; 617 (19%) children had a current recorded symptom of urgency, and 288 (9%) children had a current recorded symptom of frequency. The proportion of children that presented with all 3 lower urinary tract symptoms was 4%.

Across all treatments, constipation was reported in 577 (16%) of children (15% of male patients and 20% of female patients), with 11% reporting current constipation and 14% reporting a history of constipation. A total of 8% of the sample reported missing data for these questions. A total of 213 (6%) medical records had a recorded diagnosis of 1 or more of the inclusion comorbidities (Table I).

Previous use of desmopressin also was interrogated: 408 (11%) records indicated previous use of desmopressin for the treatment of enuresis. The frequency and length of treatment with desmopressin before bell-and-pad therapy could not be determined from the medical history.

In 6 of the 7 clinical settings, family history of enuresis routinely was asked. Positive family history was defined as any sibling, parent, maternal or paternal grandparent, aunt, uncle, or cousin who were bed wetters as children. Of the 2995 patient records interrogated, family history was available for 1639 (57%) of patients. A positive family history of enuresis was identified in 72% of these cases.

The mean treatment time (defined as the alarm use period) was 62.1 ± 30.8 days. There was a significant difference ($P < .001$) between sites, with mean times ranging from 50.3 to 73.5 days. There was no significant difference between the treatment time for boys vs girls at any age.

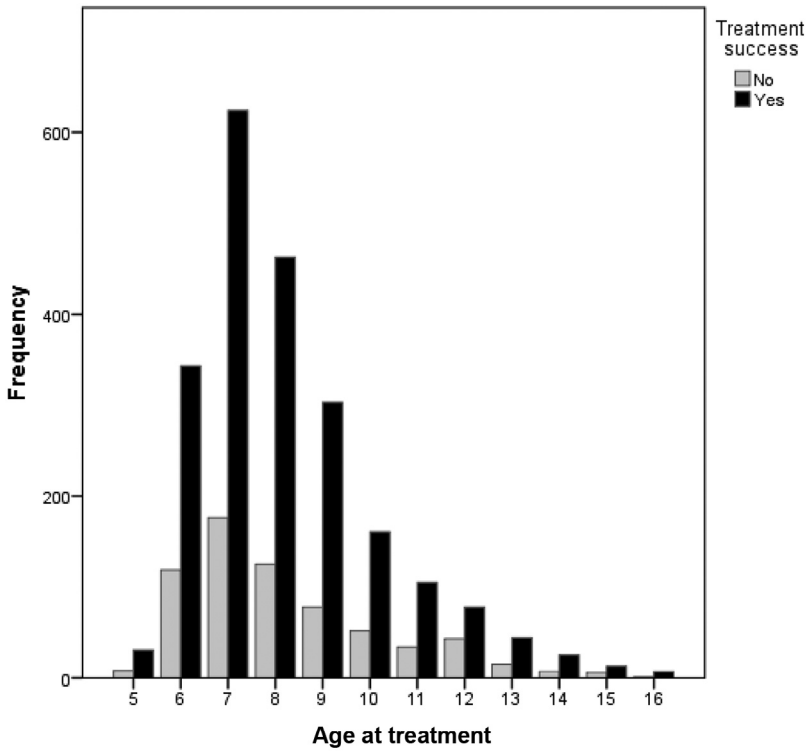

Figure. Age distribution and success after first treatment across age groups.

Table II. Treatment success after 1 treatment and any treatment success after 2 or more treatments

	Dry ≥14 days after					
	1 treatment		2-3 treatments		>3 treatments	
Patient groups	n	%	n	%	n	%
Total patients	2197	77	360	81	19	91
Boys	1387	76	232	73	13	93
Girls	810	78	128	87	6	86
Monosymptomatic enuresis	1595	78	233	80	11	92
Nonmonosymptomatic enuresis	603	73	127	83	8	89
Primary enuresis	1996	77	324	79	16	89
Secondary enuresis	104	77	24	89	3	100

Percentages represent percentages within each group in the total sample; eg, 77% of all male participants reported treatment success after their first treatment.

From 2861 patients for whom treatment outcome was reported, 76.8% of children showed a complete response to the bell-and-pad alarm treatment after only 1 treatment period (complete response defined as 100% reduction in enuretic episodes as measured by ≥14 consecutive dry nights) with no significant association between age and treatment response. The age distribution of patients relative to response is shown in the **Figure**.

Further evaluation of complete response within the enuresis subtypes, primary enuresis vs secondary enuresis and monosymptomatic enuresis vs nonmonosymptomatic enuresis, is summarized in **Table II**. There was no significant association between age and success, $r = -.02$, $P = .21$, nor between primary enuresis and secondary enuresis and success, but there was a significant association between monosymptomatic enuresis and nonmonosymptomatic enuresis and success, $P = .007$, with monosymptomatic enuresis recording a greater success rate. It is important to note that these results are based on response after first treatment.

After all treatments, this pattern changed slightly. The significant result for monosymptomatic enuresis vs nonmonosymptomatic enuresis was maintained, with success rates of 76% and 72%, respectively, $P = .02$. However, there was a significant association between primary enuresis vs secondary enuresis and success after all treatments, with secondary enuresis showing a greater success rate of 82% compared with 74% for primary enuresis, $P = .002$.

From the complete responder group after 1 successful treatment, 23% relapsed (relapse defined as more than 1 symptom recurrence per month[22]), although it should be noted that there was 35% missing data for relapse (ie, relapse status was unknown). There was a weak, but significant, association between relapse and age, with older patients tending to record greater relapse rates, $r_t = .08$, $P < .001$. There was a significant association when we used χ^2 between the presence of lower urinary tract symptoms and relapse rate after the first (21% vs 12%, $P < .001$), second (6% vs 3%, $P < .001$), and third (2% vs 1%, $P = .001$) treatments, although it should be noted that the percentage of cases for whom relapse status was unknown was 35% after first treatment, 43% after second treatment, and 36% after third treatment.

From 444 children who relapsed after the first treatment, 60% were monosymptomatic and 40% nonmonosymptomatic, indicating that the percentage of relapsing patients in the nonmonosymptomatic group was greater than across the complete sample (29%). From these children, data were available for 278 children who received a second treatment. Of that 278, 79.5% achieved success; 77% of patients with monosymptomatic enuresis recorded success vs 83% of the patients with nonmonosymptomatic enuresis. From this group of 278 children, 30.2% relapsed. Of those patients who relapsed after a second treatment (n = 113), 56% were monosymptomatic and 44% were nonmonosymptomatic, indicating a slight increase in the number of relapsing nonmonosymptomatic patients. Of those 113 children, data for a third treatment are available from 62 children; 77.4% of whom recorded a successful treatment with 38.7% relapsing after the third treatment. The success rate for patients with monosymptomatic enuresis in this group was 74% vs 82% for the patients with nonmonosymptomatic enuresis. Sample numbers beyond the third treatment are too small to be meaningful.

There was no significant association between sex and number of treatments. A significant association at $P = .004$ was found between lower urinary tract symptoms and multiple treatments, with 27% of children receiving 1 treatment reporting lower urinary tract symptoms vs 34.5% of children who received 2 or 3 treatments and 42.9% of children who received more than 3 treatments. No significant association was found between number of treatments and constipation.

Discussion

Although many randomized controlled studies of treatment with alarms have been conducted, the lack of baseline information, small sample sizes (average 57 participants per trial), high drop-out rates, and lack of uniform outcome measures make it difficult to evaluate and compare them.[18,23-25] Families that participate in such studies also are motivated to commit to the rigid clinical trial criteria. As such, these participants are not representative.

Published management protocols do not usually specify alarm type. Our results reflected a greater response rate, lower relapse rate, and a shorter treatment time than that in many published series. Overall treatment success was 76.8% after the first treatment with a relapse rate of 23% with no association with outcome, age, and sex. This finding is in contrast to published randomized controlled studies that show alarm therapy success to be approximately 66%, with greater than 50% of children failing or relapsing following treatment, irrespective of alarm.[18,26] One publication from a single community pediatric practice, reviewing the management of monosymptomatic enuresis using body-worn enuresis alarms,[27] showed a similar success rate to that found in this study, but the time to achieve dryness was longer (mean of 10.4 weeks vs mean of 8.8 weeks). In addition they only included children with monosymptomatic enuresis, and the patient population may have been biased toward a greater socioeconomic group, so it is not directly comparable.[27] Given that this study is a

retrospective review with a very large sample across various socioeconomic groups, the results are unlikely to have been a reflection of better supervision or education. It is possible that the difference is related to the alarm type used in these clinical settings. The pad-and-bell alarm used is robust and reliable, and this may have led to better adherence to treatment. Alarms that are less reliable may lead to loss of confidence in the treatment, early cessation of the trial, or even to poor response related to inconsistent conditioning due to false alarms or failure of triggering despite wetting.

Although the management of enuresis using alarm therapy is well established, repeated treatments are not. We have not identified any studies reporting multiple treatments using the same alarm and repeated treatment efficacy. Repeated treatment of children with this type of bell-and-pad alarm is commonly practiced in Australia. For children who had relapsed following their initial treatment, when alarm treatment was repeated, we noted that 79.5% of these children became dry again, with only 30.2% of these children relapsing a second time. We identified 48 children who were treated at least 3 times using this bell-and-pad alarm. Although success rates either increased or were maintained across repeated treatments, relapse rates also increased; despite this, there is evidence that repeated treatments with the bell and pad can be beneficial.

Of the 664 children who failed to achieve dryness following initial treatment, 166 (25%) children were retreated a second time, with 46% of these achieving dryness. Subsequent treatments were associated with a reduction in success rates for this cohort (38% success after 3 treatments and 29% success after 4 treatments). Where there is a lack of response to initial alarm treatment, published guidelines recommend combination treatments of alarm and desmopressin or to treat with desmopressin alone.[23,28] Repeated treatment with alarm is not prescribed in current guidelines, and we believe that as long as families and children are motivated, up to 3 alarm treatments could be considered before pharmacologic interventions are used.

It is important, however, to consider that when alarm treatment is successful initially but then relapse occurs repeatedly, that bladder dysfunction may be present, and evidence for this should be actively sought. In this study, the incidence of concomitant lower urinary tract symptoms was progressively greater in each cohort of children retreated with alarm therapy. Children who were treated 2 or 3 times with alarm therapy, whether successful or not, were more likely to have had nonmonosymptomatic enuresis than those who received 1 alarm trial only (35% compared with 29%). Of children who received >3 treatments, 43% had nonmonosymptomatic enuresis.

The results reported in this study are only for treatment with bell and pad alarms, and we could not directly compare these with body-worn alarm treatments. It also should be noted that the service providers were not selected randomly, and the impact of this is unknown. The retrospective nature of this study relied on the completeness of the medical records. Across the various Australian clinical settings, the medical histories varied; however, the data collection form managed the variation with unknown data fields. Number of wet nights before treatment was not systematically recorded by all the clinics interrogated, so these data were not recorded. The degree and patterns of missing data varied. For some demographic variables, none was missing, and for key variables such as treatment success after the first treatment, only 4.5% were missing; however, for other variables, such as relapse, a greater level of missing data was evident. Despite this, the large overall sample meant that cell sizes remained viable for all meaningful analyses.

The reporting of previous or current constipation in these children was 11%. We believe this figure for constipation to be lower than the real level because of underreporting. Constipation is a common problem among children with enuresis, and clinical evaluation, management, and treatment can in some cases resolve enuresis.[20]

Overlearning plays an important role in reducing the incidence of relapse.[21,29-32] The inclusion of overlearning following 14 successful dry night was not commonly documented (except for 1 clinic), and this study cannot comment on whether overlearning had an impact on success; this requires further investigation. Further research is necessary to examine possible reasons for failure, attrition, and variations across practices. ■

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