## 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  $\chi^2$  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  $62.1 \pm 30.8$  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 2017*;

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

Although desmopressin is regarded as an effective treatment for enuresis, it is less effective than alarm therapy, and the benefit is not sustained.<sup>12</sup> Relapse rates for desmopressin have been reported to be as high as 91%.<sup>13</sup> 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.<sup>13,14</sup>

Meta-analyses of randomized controlled trials in alarm therapy have shown bell-and-pad alarm therapy efficacy up to 66% <sup>15-17</sup>; however, the quality of many of the trials examined was poor and evidence for many comparisons inadequate. <sup>18</sup> 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.<sup>21</sup>

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 custommade 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 bedbased rubber pad (455 mm  $\times$  605 mm [1.5 ft  $\times$  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.

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