Timer Watch Assisted Urotherapy in Children: A Randomized Controlled Trial

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Abbreviations and Acronyms

AVV = average voided volume
MVV = maximal voided volume
OAB = overactive bladder
stdU = standard urotherapy
UI = urinary incontinence

Submitted for publication January 29, 2010.

Supported by grants from University of Aarhus Research Foundation, Arberg Time and Karen Elise Jensen Foundation.

Study received local ethics committee approval and is registered at ClinicalTrials.gov (NCT00238680).

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Purpose: We evaluated the effect of timer watch treatment in addition to standard urotherapy in children with overactive bladder and daytime urinary incontinence.

Materials and Methods: A total of 60 children with daytime urge incontinence were included in the study. Following a 4-week run-in period of standard urotherapy children were randomized to 12 weeks of standard urotherapy with or without a timer watch. Incontinence episodes were registered and 48-hour bladder diaries were obtained before randomization, and at weeks 1, 11 and 12. Long-term response was evaluated at 7 months.

Results: Two children became continent during the run-in period. Before intervention children in the timer group were slightly more wet than children in the standard urotherapy group (median 7 [IQR 25% to 75% 6 to 7] vs 6 [3 to 7] wet days per week, $p < 0.05$). Following 12 weeks of standard urotherapy children randomized to timer assisted urotherapy had significantly fewer wet days per week (median 2, IQR 25% to 75% 0 to 5) vs those undergoing standard urotherapy alone (5, 2.75 to 6.75, $p < 0.01$). In the timer group 18 children (60%) achieved a greater than 50% decrease in incontinence episodes, compared to only 5 (18%) treated without timer assistance. Nine patients (30%) in the timer group and no child in the standard urotherapy group achieved complete daytime continence. The timer increased compliance with the timed voiding regimen. At 7 months of followup 60% of children in the timer group were still continent in the daytime.

Conclusions: A programmable timer watch significantly improves the effect of standard urotherapy. When using the timer watch as a supplement to standard urotherapy 60% of the children obtained complete and sustainable daytime continence.

Key Words: behavioral therapy; combined modality therapy; urinary bladder, overactive; urinary incontinence; urination

CONSERVATIVE treatment is first line management for nonneuropathic daytime urinary incontinence in children.[1–3] Nonsurgical nonpharmacological treatment for lower urinary tract dysfunction is called urotherapy.[4] In children suffering from daytime urinary incontinence urinary tract infections and defecation disorders must always be ruled out as underlying causes before initiation of urotherapy.[5,6]

Standard urotherapy, the simplest form of urotherapy, encompasses demystification of the disorder, improvement of patient perception of bladder function and structure, teaching proper toilet posture, normalization of fluid intake and toilet habits, support and en-

0022-5347/10/1844-1482/0
THE JOURNAL OF UROLOGY®

Vol. 184, 1482-1488, October 2010
Printed in U.S.A.
DOI:10.1016/j.juro.2010.06.024

couragement by the caretaker, and voiding at regular intervals.[4,7] This behavior modifying training approach is widely accepted, although controlled studies of well characterized pediatric populations with daytime incontinence are scarce. Earlier studies have shown an effect of standard urotherapy in children in the range of 6% to 41% for cure and 44% to 64% for improvement.[2,8,9] However, some of these studies included children with lower urinary tract symptoms other than incontinence. The long-term effect of standard urotherapy was reported by Klijn et al, who observed a 12-month cure rate of 44% in children with dysfunctional voiding.[10]

Although the value of a timed voiding schedule is widely accepted, it is a demanding task for the child and depends heavily on factors such as maturation, motivation, and support from the parents and other adults. In a retrospective analysis from a secondary referral center we recently reported a cure rate for daytime incontinence of up to 55% by isolated stdU.[11] Furthermore, 70% of children without initial response to urotherapy achieved daytime continence when a timer watch was added to the standard urotherapy regimen.

Although the positive effect of a timer watch in increasing compliance with a timed voiding regimen seems rational, its exact efficacy has yet to be proved in a randomized controlled fashion. The primary aim of this randomized controlled study was to elucidate the efficacy of a timer watch as a supplement to standard urotherapy for daytime incontinence in children with overactive bladder. We also sought to identify potential prognostic factors for timer response.

MATERIALS AND METHODS

Study Subjects

The study was approved by the local ethics committee and registered at ClinicalTrials.gov (NCT00238680). Children referred for daytime incontinence to the outpatient clinics of the Center for Child Incontinence at our university hospital were considered for participation. Inclusion criteria were age 5 to 14 years, at least 1 episode of daytime incontinence weekly, voiding frequency of 6 or more times daily, overactive bladder (urgency), normal urinalysis, unremarkable kidney and urinary tract ultrasonography, normal clinical examination, no indication of bladder underactivity or lower urinary tract obstruction as assessed by uroflowmetry and no present fecal problems according to Rome III criteria.[4,12] Exclusion criteria were previous treatment with timer assisted urotherapy and/or a history or present use of anticholinergics or alpha-blockers. A total of 61 children were initially included and 7 patients declined participation. These subjects did not differ from the included children with regard to demographics or severity of incontinence. Of the participants 57 (95%) had previously tried stdU without timer watch assistance.

Study Design

The study design is illustrated in figure 1. Children received standard urotherapy, as described previously,[4] including instructions regarding daily fluid intake of at least 1,200 ml equally distributed throughout the day and timed voiding with 2-hour intervals until bedtime. The children were allowed to void at any time in the interim if they had the urge to do so. During the run-in period (4 weeks) children were requested to complete 48-hour bladder diaries and report the number of wet days during week 4.

At the second visit children who continued to experience incontinence episodes once or more weekly were randomly allocated to either timer assisted (timer group) or standard urotherapy (stdU group). Children were provided with a watch with 7 alarms (Triax 35, Nike Inc., Beaverton, Oregon). Registrations of wet days and 48-hour bladder diaries were obtained during weeks 1, 11 and 12. MVV was identified and corrected for age (expected MVV = 30 × age + 30).[4] AVV was calculated and data on voiding frequency, total daily fluid intake and fluid intake before 4 p.m. were obtained.

Compliance with timed voiding was determined from review of the bladder diaries. If 1 voiding interval exceeded 3 hours during at least 3 registered days, children were characterized as noncompliant.

The primary end point was response to treatment appraised by comparing pre-intervention registrations of wet days with mean number of wet days weekly during weeks 11 and 12 of the intervention period. Response to treatment was reported in accordance with International Children's Continence Society standards.[4] Thus, a 0% to 49% reduction in wet days was defined as no response, 50% to 89% as partial response and 90% or greater as response, and complete daytime continence was defined as full response. Secondary end points included age corrected MVV and AVV, total daily fluid intake, fluid intake before 4 p.m. and compliance. For selected parameters change scores were used for comparisons. At visit 3 all children and/or parents were asked to report their subjective opinion of the effect of intervention by multiple choice of "improved," "unchanged" or "worse."

Posttreatment Evaluation

Children randomized to stdU who did not achieve dryness were at the third visit provided with a timer watch for another 12 weeks. All children were offered 2 followup visits within 12 months after the intervention period. At followup visits the number of wet days weekly and usage of the timer watch system were noted.

Statistical Analysis

Based on retrospective studies,[11] the sample size for adequate statistical power of 27 children per group was calculated. Results are reported as mean ± standard deviation or, for parameters that were not normally distributed, as median (IQR 25% to 75%). Student's t test was used for group comparisons. Mann-Whitney rank sum test was used for nonparametric analysis and Fisher's exact test or Pearson's chi-square test was used for distribution comparisons for categorical values. A p value of less than 0.05 was considered statistically significant.