

Feasibility of actigraphy wristband monitoring of atopic dermatitis in children

C. J. Gustafson¹, J. O'Neill¹, E. Hix¹, D. T. McLaren⁴, O. M. Buxton^{4,5} and S. R. Feldman^{1,2,3}

¹Center for Dermatology Research, Department of Dermatology, Wake Forest University School of Medicine, Winston-Salem, NC, USA,

²Department of Pathology, Wake Forest University School of Medicine, Winston-Salem, NC, USA,

³Department of Public Health Sciences, Wake Forest University School of Medicine, Winston-Salem, NC, USA,

⁴Department of Medicine, Division of Sleep Medicine, Brigham and Women's Hospital, Boston, MA, USA and ⁵Division of Sleep Medicine, Harvard School of Public Health, Boston, MA, USA

Background/purpose: Actigraphy monitors are used to monitor sleep and scratching. Previous studies have implemented these monitors to evaluate behavior in adult patients with atopic dermatitis. However, such monitoring devices have been implemented in a paucity of studies involving pediatric patients with atopic dermatitis. The purpose of this study was to assess the feasibility of actigraphy monitoring in children with mild-to-severe atopic dermatitis.

Methods: A total of six pediatric subjects were recruited. The severity of atopic dermatitis at the wrist area was assessed prior to placement of the wristband monitor. After wearing the wristbands for 7 days, subjects returned to clinic to undergo reassessment of the wrist area to determine if atopic dermatitis was exacerbated by the wrist-worn device. Data on sleep quality and how often patients wore the wristband monitors were also collected. No subjective data from the subjects or parents/caregivers were collected on tolerability of the monitors.

Results: None of the subjects exhibited exacerbation of atopic dermatitis at the wrist area after wearing the actigraphy monitors for 7 days. No adverse events were reported. Pediatric patients with atopic dermatitis exhibited less total sleep time compared with children evaluated in previous actigraphy studies.

Conclusion: Actigraphy wristband monitoring can be used to continuously assess disease severity in children with atopic dermatitis.

Key words: itch – sleep – adolescents – scratch

© 2014 John Wiley & Sons A/S. Published by John Wiley & Sons Ltd

Accepted for publication 5 January 2014

ATOPIC DERMATITIS is the most common skin disease in children, affecting an estimated 15–20% of children in developed countries (1). Atopic dermatitis can be a very distressing disease due to intense pruritus, which results in physical discomfort, emotional distress, and decreased quality of life. Furthermore, approximately 60% of children with atopic dermatitis suffer from disturbed sleep, which is often attributed to nocturnal pruritus and subsequent scratching (2).

Although itch is a subjective sensation, it provokes scratching, which is an observable behavior. Hence, to assess the severity of pruritic skin disease, movements associated with itch, such as scratching and nocturnal restlessness, can be measured. Wrist-worn accelerometers have been implemented as a tool to measure scratching and restlessness in patients with psoriasis and eczema. With regard to pediatric patients

with atopic dermatitis, the relationship between scratching and sleep disruption has been evaluated using actigraphy monitors and infrared video monitoring (3).

While wrist-worn actigraphy monitors may serve as a useful means to assess the severity of pruritic skin disease and its response to treatment, the implementation of such devices may exacerbate skin disease as atopic dermatitis can be aggravated by exposure to various physical and chemical irritants. Hence, wrist-worn monitors may potentially exacerbate atopic dermatitis at the wrist area via frictional irritation and/or chemical irritation. Also, patients may have hypersensitivity/allergy to the wristband material. Patient adherence is another variable that may limit the efficacy of wristband monitoring as pediatric patients might play with and remove the wrist-worn devices, which can be detected by the software used for data collection.

As a pilot to a larger clinical trial, we assessed the feasibility of monitoring atopic dermatitis severity using wristband monitors in children with atopic dermatitis.

Methods

This was a single-center, open-label, prospective study. A total of six subjects with mild-to-severe atopic dermatitis ages 2–5 were enrolled (Table 1). Subjects with a known allergy or sensitivity to hospital wristband material, or components therein, were excluded from the study. No screened subjects were excluded. Informed consent was obtained from subjects parents/caregivers prior to initiating any study procedures. With the exception of discontinuing oral antihistamines during the 7-day study period, no additional attempts were made to change subjects' treatment regimens during the study period. Subjects were instructed to continue their current atopic dermatitis medication regimens throughout the study period, provided they avoided contact of topical medications with the wristband monitor.

The primary endpoint of the study was severity of atopic dermatitis at the wrist site after wearing the wristband monitor for 7 days. Severity of atopic dermatitis was quantified using Investigator Global Assessment (IGA) scores. IGA is a simple measure commonly used to quantify disease severity for clinical studies, as well as in non-study clinic settings. Scores range from '0' = Clear to '1' = Almost Clear to '2' = Mild Disease to '3' = Moderate Disease to '4' = Severe Disease.

At screening visits (day 1), the diagnosis of atopic dermatitis was confirmed by the investigator. Prior to wristband placement, the severity of atopic dermatitis, specifically at the wrist area, was quantified using IGA scores. At the end of study visit (day 7), IGA was performed

to re-evaluate the severity of atopic dermatitis at the wrist area.

Study participants were asked to wear the Spectrum (Philips/Respironics, Murrysville, PA, USA) on the wrist for 1 week. The wrist-worn devices have a watch face and measure wrist movements with a uni-axial accelerometer in 30-s epochs. Devices were collected on day 7. Data collected by the monitors were processed and analyzed using Respironics Actiware 5 (Philips/Respironics, Murrysville, PA, USA) (Fig. 1). Rest intervals indicated by periods of 30 min or more of very low activity were inserted by a scorer using standard procedures. Actigraphs recorded frequency and volume of upper limb movements throughout the night. These data were interpreted to provide assessments regarding sleep quantity and quality and amount of wrist movements during sleep. Sleep quality was assessed by evaluating the following variables: sleep percentage (percentage of minutes the subject was asleep from sleep onset to sleep end), wake after sleep-onset (WASO) number (frequency of waking bouts lasting >2 min after initial sleep onset), and WASO duration (minutes awake after sleep onset) (4). We were also able to assess compliance, meaning whether the wristbands were worn continuously during the 7-day study period using the Spectrum's on-wrist detection system. Statistical analyses were not performed as this was a small, exploratory pilot study.

Results

Prior to placement of wrist monitors, five of the six subjects had mild atopic dermatitis at the wrist area (IGA score = 2) and one subject had moderate atopic dermatitis (IGA score = 3) (Table 1). Following the 1-week wristband trial, IGA scores for five subjects remained unchanged. A final IGA score was not assessed for one subject as a clinical investigator was not available to access the subject when they returned for the day 7 visit due to scheduling issues.

No adverse events, such as local skin reactions, were noted by the investigator and sub-investigators during subjects' study visits. Actigraphy data were analyzed to provide information regarding quality of sleep (Table 2). No actigraphy data were collected for one subject due to malfunctioning of the monitoring device. Amongst the five subjects with recorded

TABLE 1. Patient demographics

Subject	Age	Gender	IGA Day #1	IGA Day #7
1	5	Female	Mild (2)	Mild (2)
2	4	Female	Mild (2)	Mild (2)
3	5	Female	Mild (2)	Mild (2)
4	3	Female	Mild (2)	Mild (2)
5	4	Female	Moderate (3)	Unknown*
6	5	Male	Mild (2)	Mild (2)

*No IGA score obtained after 7-day wristband monitor trial.

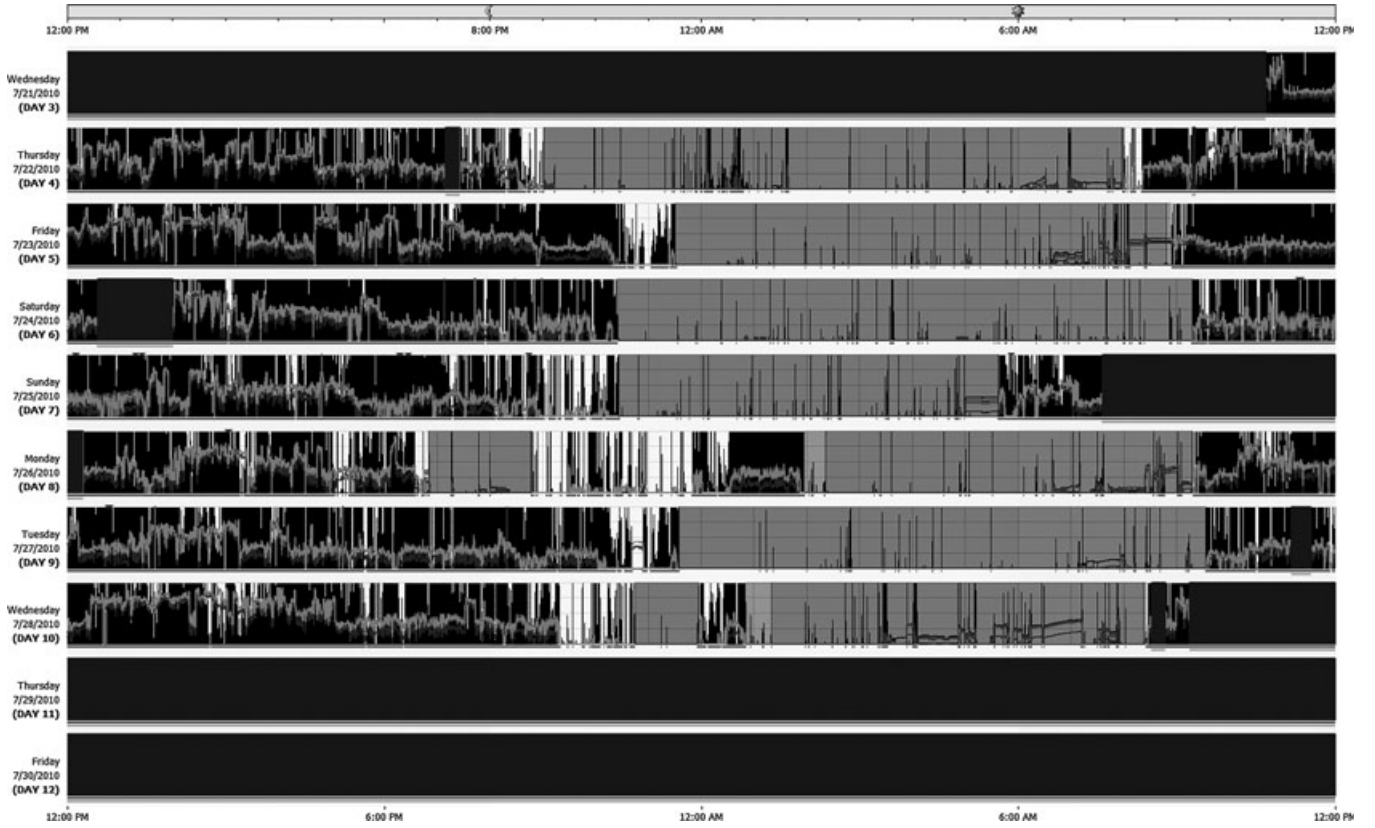


Fig. 1. Example of a 7-day actigraph. Wrist actigraphy measurement of sleep–wake patterns and the light–dark cycle. Multi-modal (activity and light) data were collected using a Spectrum (Respironics/Philips, Murrysville, PA) worn on the wrist during an 8-day period. Each row of data represents one 24-h day during the recording. In general, black represents activity, while infrequent black vertical lines represent periods of mostly sleep. Activity counts are represented by the vertical black lines throughout the recording (raster height spans 0 to a peak of 100 activity counts per 30-s epoch). The solid black sections represent intervals of data excluded from analysis, usually indicative of the subject having the watch off-wrist during that portion of the recording. For example, the watch was set to begin collecting data at noon, but the subject began wearing the watch late morning the next day. The gray rectangular sections represent rest intervals set by research assistants based on a specific set of sleep scoring rules and analyzed using a validated algorithm for determining sleep and wake (4).

actigraphy data, the duration of time asleep ranged 6.6–9.7 h (median = 8.1 h). While asleep, subjects were mobile during 10.3–24.2% (median = 12.7%) of the entire sleep period.

Although subjects were instructed to wear the monitors continuously, the epoch data indicated that none of the patients fully adhered to the instructions. The time excluded from actigraphy

data due to the monitors being off the subjects' wrists ranged from 5.1 h (3.08% of study period) to 80.8 h (48.5% of the study period).

Discussion

Overall, actigraphy wristband monitors appear to be well tolerated by pediatric patients with atopic dermatitis. Wearing such devices does not appear to result in exacerbation of skin disease or symptoms associated with atopic dermatitis. However, subjects were not compliant wearing the wristbands continuously during the study, with one subject wearing the wristband slightly more than half of the study period (51.5%). This adherence issue is not ideal for future research, but may be abated with more permanent wristbands that are not easily removed. It should be also noted that this level

TABLE 2. Actigraph data regarding sleep and mobility

Subject	Sleep duration (h)	Time mobile (min)	% Time mobile (Sleep)
1	8.2	60.1	12.7
2	6.6	69.1	19.8
3	9.7	132.4	24.2
4*			
5	7.5	53.4	12
6	8.1	50.7	10.3

*No actigraph data obtained for subject 4 due to malfunction of monitor device.

of compliance is typical of research study subjects upon first wearing the devices.

Actigraphy is an established, effective means of detecting sleep in normal, healthy adult populations, and has been used in numerous reports to detect sleep in children and patients of other age groups, who can be difficult to monitor by traditional polysomnography. In prior studies, actigraphy data highly correlated with video-recording measures of sleep, scratching, and restlessness (3). Actigraphy is a useful outcome measure in all patient age groups ranging from children to elderly people, patients with certain medical and psychiatric conditions, and in interventional trials in patients with sleep disorders (5, 6). Actigraphy has been shown as a fair means of measuring sleep fragmentation in children aged 2–18 (7). Additionally, actigraphy is related to parental report of child sleep duration, but has been demonstrated to be a more reliable measure (8).

To date, no prior studies have assessed the specific sleep patterns of pediatric patients with atopic dermatitis. Therefore, we compared the findings in this small pilot study with findings reported in previous actigraphy studies evaluating pediatric sleep patterns. Children with atopic dermatitis appear to have poor sleep quality compared with children of similar age without atopic dermatitis. For instance, the median percent of time mobile while sleeping of the pediatric atopic dermatitis patients evaluated in our small pilot study was 12.7%. In comparison, the control group of typically developing pediatric patients evaluated by Goodlin-Jones et al. exhibited an average percent of time mobile while sleeping of 9% (9). Pediatric patients with atopic dermatitis also exhibited shorter durations of sleep, greater number of wake bouts, and decreased percent sleep compared with other pediatric patients.

To date, the majority of dermatology studies implementing wrist-worn actigraphy monitors have primarily focused on adult patients with pruritic skin disease. As atopic dermatitis is the

most common skin disease affecting pediatric patients, use of wrist-worn monitors in children could be valuable to evaluate the severity of atopic dermatitis in pediatric patients. Wrist-band monitoring permits continuous assessment of atopic dermatitis severity, and such monitoring would be very useful for assessing the rapid response to treatment that is observed with atopic dermatitis treatment.

As this was a small pilot study, one of the main limitations was the small number of subjects enrolled. Another limitation was the short duration of the study period. Nevertheless, we found that the wrist-worn monitors were well tolerated. Future studies will need to take into account that subjects often do not wear wrist-band monitors continuously.

Actigraphy is an objective and unobtrusive method to measure itch and sleep quality in pediatric patients with atopic dermatitis. Additionally, actigraphy may have the potential to provide useful information regarding the clinical response of pruritic skin disease to various treatment modalities.

Acknowledgements

The Center for Dermatology Research is supported by an unrestricted educational grant from Galderma Laboratories, L.P. SF is a consultant and speaker for Galderma, Stiefel/GlaxoSmithKline, Abbott Labs, Warner Chilcott, Janssen, Amgen, Photomedex, Genentech, BiogenIdec, and Bristol Myers Squibb. SF has received grants from Galderma, Astellas, Abbott Labs, Warner Chilcott, Janssen, Amgen, Photomedex, Genentech, BiogenIdec, Coria/Valeant, Pharmaderm, Ortho Pharmaceuticals, Aventis Pharmaceuticals, Roche Dermatology, 3M, Bristol Myers Squibb, Stiefel/GlaxoSmithKline, Novartis, Medicis, Leo, HanAll Pharmaceuticals, Celgene, Basilea, and Anacor and has received stock options from Photomedex. SF is the founder and holds stock in Causa Research. CG, JO, EH, DM, and OB have no conflicts to disclose.

References

1. Odhiambo JA, Williams HC, Clayton TO, Robertson CF, Asher MI. Global variations in prevalence of eczema symptoms in children from ISAAC phase three. *J Allergy Clin Immunol* 2009; 124: 1251–1258.
2. Camfferman D, Kennedy JD, Gold M, Martin AJ, Lushington K. Eczema and sleep and its relationship to daytime functioning in children. *Sleep Med Rev* 2010; 14: 359–369.
3. Brighurst C, Waterston K, Schofield O, Benjamin K, Rees JL. Measurement of itch using actigraphy in pediatric and adult populations. *J*

- Am Acad Dermatol 2004; 51: 893–898.
4. Marino M, Li Y, Rueschman M, Winkelman J, Ellenbogen J, Solet J, Dulin H, Berkman L, Buxton O. Measuring sleep: accuracy, sensitivity, and specificity of wrist actigraphy compared to polysomnography. Sleep 2013; 36: 1747–1755.
5. Littner M, Kushida CA, Anderson WM et al. Practice parameters for the role of actigraphy in the study of sleep and circadian rhythms: an update for 2002. Sleep 2003; 26: 337–341.
6. Morgenthaler T, Alessi C, Friedman L et al. Practice parameters for the use of actigraphy in the assessment of sleep and sleep disorders: an update for 2007. Sleep 2007; 30: 519–529.
7. O’Driscoll DM, Foster AM, Davey MJ, Nixon GM, Horne RS. Can actigraphy measure sleep fragmentation in children? Arch Dis Child 2010; 95: 1031–1033.
8. Chang A, Rondon L, Taveras E, Buxton O. Validation of a parental report of child sleep versus direct actigraphic assessment of sleep. Sleep 2011; 34(Suppl): A268.
9. Goodlin-Jones BL, Tang K, Liu J, Anders TF. Sleep patterns in pre-school-age children with autism, developmental delay, and typical development. J Am Acad Child Adolesc Psychiatry 2008; 47: 930–938.

Address:
S. R. Feldman
Department of Dermatology
Wake Forest University School of Medicine
Medical Center Boulevard, Winston-Salem
NC 27157-1071, USA
Tel: +1 336-716-7740
Fax: +1 336-716-7732
e-mail: sfeldman@wakehealth.edu