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Integrating sleep behavioral modifications into pediatric atopic dermatitis management

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INTEGRATING SLEEP BEHAVIORAL MODIFICATIONS INTO PEDIATRIC ATOPIC DERMATITIS MANAGEMENT

by

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ABSTRACT

Objective: To determine the effects on parental quality of life in managing sleep disturbances associated with their child's atopic dermatitis by integrating sleep behavioral interventions in pediatric atopic dermatitis management.

Design: Randomized Control Trial

Setting: Boston Medical Center Pediatrics and Pediatric Dermatology Program

Participants: 126 pediatricians, dermatologists and pediatric dermatologists**;** 384 parents of children ages less 6 years old with atopic dermatitis; and 384 children ages less than 6 years old with atopic dermatitis

Interventions: This study will provide two webinar modules on sleep behavioral intervention made by experienced psychologists and sleep medicine specialists from existing multidisciplinary care settings for the intervention arm of recruited pediatricians, dermatologists, and pediatric dermatologists.

Main Outcome Measures: The main outcome measured is the score changes in a 26-item parental quality of life questionnaire at the initial first visit and 12-month follow-up appointments. A monthly electronic 5-subscale survey will be sent to all recruited physicians to assess the frequency of addressing and counseling on sleep behavioral interventions to their pediatric AD patients and their parents.

Practice Implications: Primary pediatric physicians and dermatologists, including pediatric dermatologists, should recognize, address, and integrate sleep behavioral counseling and interventions in pediatric atopic dermatitis management. Sleep behavioral interventions should be addressed in anticipation of development of sleep disturbances given the potential impact on children with AD and importance of quality sleep in a growing child. Recognizing and counseling on sleep disturbances can improve parental/caretaker confidence in caring for their child, which may overall improve the quality of life for the parent, child and family.

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LIST OF ABBREVIATIONS

AD..Atopic Dermatitis

ADHD.. Attention Deficit Hyperactivity Disorder

ADQ..Atopic Dermatitis Quickscore

ANOVA..Analysis of Variance

BISQ .... Brief Infant Sleep Questionnaire

BISQ-R ....Brief Infant Sleep Questionnaire-Revised

BMC.. Boston Medical Center

HRQOL...Health Related Quality of Life

QoL ....Quality of Life

PROMIS............................Patient-Reported Outcomes Measurement Information System

SCORAD .... Scoring Atopic Dermatitis Index

SD .... Sleep Disturbance

INTRODUCTION

Background

Atopic dermatitis (AD) is the most common chronic skin condition, affecting 15-30% of children.[1] AD is an inflammatory skin condition that presents as irritated, dry, and pruritic skin that ranges in severity based on degree of irritation, disruption of skin barrier integrity, and body surface involvement.[2] Management of AD typically targets the management of the negative "itch that rashes" cycle that stimulates inflammatory response and worsening pruritus.[3] In addition to topical and systemic treatments, patient education and coping therapies have helped manage the burden of the disease.[4] In the pediatric population, adults act as the primary caretaker for a child with AD. Several studies have highlighted the importance of recognizing, addressing the parental quality of life and need to educate the caretaker role to feel supported, especially in managing sleep disturbances (SD) secondary to AD. [2,5–7]

Approximately 60% of children with atopic dermatitis (AD) report sleep disturbances.[8] Sleep disturbances consist of sleep-wake patterns that decrease sleep efficiency (the ratio of time asleep to time trying to sleep), increase sleep-onset time, and increase frequency of fragmented sleep as a result of night awakening.[9] As a result, negative daytime symptoms such as irritability and tiredness can contribute to a significantly reduced quality of life.[10] Sleep is important for cognitive, behavioral development and linear growth, especially in school-aged children.[8] Multidisciplinary programs incorporating behavioral interventions from pediatricians, dermatologists, psychosomatic specialists and others address symptoms including anxiety, pruritus, environmental triggers, and associated SD and have proven to improve overall AD management.[3] Similarly, multidisciplinary care studies also address parental education and suggest the need to recognize and integrate management of SD as part of standard of care AD management.[6,9,11,12]

Statement of the Problem

Nocturnal symptoms or sleep disturbances may not be reported by parents of children with AD or recognized by pediatric healthcare providers.[13] Further investigation and increased education of managing sleep disturbances, secondary to atopic dermatitis, may be beneficial as part of standard of care management of AD, particularly in the pediatric population. The dependency of the pediatric population on parental/caretaker and pediatric primary care providers should prompt anticipatory guidance and early behavioral implementation to improve quality of life, AD management, and alleviate the burden on families and caretakers.[5,14]

Effective treatment and disease control of AD generally improves sleep as a secondary outcome of controlling pruritus but nocturnal symptoms can persist in remission.[13,15] Incorporating sleep hygiene and behavioral strategies in children have been found to be effective as a specific sleep-directed therapy for sleep disorders in AD multidisciplinary program studies. [11] These sleep-specific interventions and behavioral programs should also be provided and integrated into early and primary AD education especially when multidisciplinary care may not be accessible or yet established.

Hypothesis

Integration of sleep behavioral intervention education in primary AD management education for pediatricians, dermatologists, and pediatric dermatologists will improve the quality of life of parents of children with AD.

Objectives and Specific Aims

The objective of this study is to assess the impact upon parental quality of life in managing sleep disturbances in their child with AD by incorporating sleep hygiene and sleep behavioral management in the continuing education of healthcare providers.

Primary Aim 1: Incorporate sleep hygiene and sleep behavioral management into parent/caretaker atopic dermatitis education.

Primary Aim 2: Provide sleep behavioral intervention education to healthcare providers to counsel and address sleep disturbances.

Secondary Aim 1: Improve parental management of their child's sleep disturbances with newly counseled sleep behavioral interventions.

Primary Outcome Measures

1. Caretaker quality of life will be measured by a 26-item questionnaire that addresses the impact of AD on psychosomatic well-being, emotional coping,

impact on social life, confidence in managing medical treatment, and acceptance of disease.[12]

2. The frequency of sleep behavioral and sleep hygiene intervention counseling by the pediatrician, dermatologist and pediatric dermatologist will be measured by a monthly survey.

Secondary Outcome Measures

1. Improvement of subjective sleep patterns of the children with AD, including difficulty awakening, resettling times, and nocturnal awakening frequency, will be measured by using the 22-item Child Sleep Behavioral Scale at the initial visit of the study and at 12-months.[16]

REVIEW OF THE LITERATURE

Overview

Atopic dermatitis (AD) is an inflammatory cutaneous disorder that is commonly seen in 15-30% of children and 2-10% of adults.[10] It is distinctly characterized as a rash that undergoes a vicious itch cycle that further disrupts the skin barrier integrity and leads to skin inflammation, erythema, and sensitive skin with increased vulnerability to irritants, infection, and autoinoculation.[3] Pruritus is defined as an uncomfortable sensation that leads to an urge to scratch.[4] Pruritus is a hallmark symptom of AD, often described as a constant symptom that varies in intensity and is associated with pain and/or burning that generally worsens at night.[3,10] Poor AD control or chronicity of pruritus leads to the ongoing disruption and compromise of the skin barrier.[3]

The etiology of the pruritic cycle of AD involves a multivariable and complex interplay between an individual's skin barrier deficiency, immune response environmental triggers, and neural mechanisms.[3] Epidermal skin barrier dysfunction leads to transepidermal water loss, which is necessary in maintaining hydration of the stratum corneum.[3] This causes the skin to be vulnerable to irritants and allow the entry of pruritogens or inducing pruritic factors.[3] The pruritic factors then drive the release of cytokines, neuropeptides, and secreted factors to further stimulate an overactive immune response causing this itch cycle to continue.[3] Neural mechanisms involved in AD show an increase in nerve fiber density that contributes to having more sensitive skin.[3] The severity of AD is defined by the active surface area involvement, intensity of pruritus, and associated comorbidities contributing to a reduced the quality of life.[9] These comorbidities include psychosocial development, anxiety, depression, irritability, physical discomfort, and notably sleep disturbances (SD).[9]

Sleep Disturbance and Atopic Dermatitis

The pathophysiology of sleep disturbances (SD) and the relationship with AD are poorly understood.[10] Children with AD may experience decreased sleep efficiency due to pruritus but the pathophysiology is complex.[3] SD are defined as increased wake after sleep onset (WASO), resettling times, difficulty awakening, or daytime tiredness.[1] Objective measures reveal reduced sleep efficiency, increased sleep fragmentation, less REM sleep, and prolonged sleep onset latency in children with AD.[10] These sleep features have been identified as a secondary outcome in establishing the severity of AD and assessing the efficacy of AD treatment.[8] In clinical trials, AD severity can be measured utilizing the Scoring Atopic Dermatitis (SCORAD) index to evaluate improvement with treatment. [17] SCORAD is a validated objective and subjective clinical scoring method.[18] The objective scoring evaluates the extent of area involved and the intensity of lesions.[18] Based on the rule of nines, the body surface area involved is documented and is scored from 0 to 100. [17] The intensity of lesions is defined by the following items on a scale of 0 to 3: erythema, edema, crusting, excoriations, lichenification, and dryness (assessed on uninvolved skin) for a maximum score of 18.[18] The intensity scale scores are as follows: 0 = absent, 1= mild, 2= moderate, 3=severe. [18] SCORAD subjectively assesses for daily pruritus and sleep loss on a scale 0 to 10 for a combined score out of 20. The score is based on the average of the last 3 days or nights.[18] The SCORAD is calculated using the formula A/5 +7B/2 +C with the maximum total of

103. [17] Within the formula, A refers to the objective extent of involvement (0-100).[17] B refers to the intensity score (0-18). C corresponds to the subjective daily pruritus and sleep loss score (0-20).[17] A score of 25 is classified as mild, 25-50 moderate, and greater than 50 will be categorized as severe AD. [17,18]

A SCORAD index of higher than 48.7 out of 103 points has a sensitivity of 83.3% and specificity of 75% in predicting poor sleep efficiency. [10] There is a significant correlation of disease severity with a higher frequency of objectively measured SD and reduced quality of life for the child with AD and their parent(s).[8,19] SD associated with AD can lead to negative effects on the child, parents, and family.[15,20] SD are associated with negative daytime behavior and functioning, including inattention, irritability, and reduced cognitive and academic performance.[21] Sleep problems are a risk factor for the development of mental health problems.[22] Addressing sleep quality should be considered in all ages of children with all severity stages of AD.[23] Sleep quality is negatively affected by AD even in inactive states and mild AD.[23] Comorbidities, including asthma, allergic rhinitis, and increased disease severity, are associated with worse sleep quality outcomes.[23] Therefore, it is clinically suggested that interventions to improve sleep quality are needed, particularly in those with comorbidities of asthma, allergic rhinitis, or severe AD.[23]

Current pharmacologic treatment for SD in AD target sleep hygiene, melatonin dysregulation, AD flares, avoidance of environmental factors, transepidermal water loss, and cytokine dysregulation.[10] There is no current standardized management or algorithm.[2] First generation antihistamines are commonly used but limited in usefulness due to tolerance after 4 to 7 days.[10] Anticholinergics, benzodiazepines, chloral hydrate and clonidine suggestively promote sleep due to their sedative mechanisms but studies lack evidence of efficacy and these medications carry risks with long term use.[10] Melatonin dysregulation in the setting of AD is targeted with exogenous supplementation to promote sleep and utilize its anti-inflammatory properties.[10] Melatonin is a favorable option for children due to its safety profile with no addictive or withdrawal concerns.[10] Further studies will be needed to assess appropriate dosing and duration of treatment pharmacological treatment in children.[10] The increasing prevalence of reported sleep disturbances by parents of children with AD and limited studies of the efficacy of sleeping agents in children directs future research to directly target the secondary outcome of sleep loss as part of AD management.[2]

Sleep Hygiene and Behavioral Strategies

Sleep disturbances, when untreated, can contribute to worsening sleep habits that can become a learned sleeping pattern, which increases the risk of behavioral insomnia. [1] Behavioral insomnia is defined as insomnia that persists with disease control. [1] Behavioral strategies in AD, typically addressed by a psychologist or sleep medicine specialist, aim to promote daytime coping mechanisms of pruritus by habit reversal, cognitive behavioral therapy, and sleep behavioral modifications that involve parents.[1,24] Strategies are individualized depending on the degree of family and parental involvement.[5] In addition to sleep hygiene counseling, behavioral strategies including graduated extinction, scheduled awakening, response cost, habit reversal, progressive relaxation therapy, and decreasing co-sleeping habits should be addressed with caretakers.[1] These strategies have been effective in changing sleep habits that aid in decreasing the frequency of SD.[25]

Graduated extinction ignores a child's crying tantrums for a set timed interval that will gradually increase in duration.[25] Scheduled awakening involves the parent being able to note their child's awakening times during the night.[25] They will then intentionally schedule awakenings 15-30 minutes prior to the noted times and respond as if it were a spontaneous awakening and try to help them sleep.[25] The time between scheduled awakenings will gradually increase, thereby increasing the time the child is asleep.[25] Response cost trains the child to get out of bed when they have difficulty falling asleep, which negatively results in delaying their bedtime.[25] This acts as negative reinforcement to encourage their child to fall asleep more quickly.[25] Habit reversal technique targets the habit of scratching by recognizing and identifying situations that lead to scratching. Then the parent will train their child to form a new or competing response to the urge to scratch.[4] Progressive relaxation therapy is a technique that has been studied in individuals aged 12-40 with AD that showed significant decreases in anxiety, subjective pruritus, and SD.[26] Parents can be trained to target and provide active tension or massage muscle groups for 10 seconds followed by 20 seconds of relaxing muscle groups.[26,27] In addition, decreasing co-sleeping habits also helps reduce parent sleeplessness and independent sleeping habits for the child.[1,5,28]

Parental Quality of Life

As the primary caretakers, parents of children with AD report feeling significantly more distressed, anxious, and helpless.[14] Managing AD can be time-consuming and negatively affect parent-child relationships, marital relationships, home environment, parental psychosocial functioning, and can consequently lead to restrictive diets, sleep deprivation, financial burden, and possibly affect the well-sibling(s).[14] Parents with greater sleep knowledge of their children have reported a more consistent sleep routine for the child.[29] This results in improved sleep and health for the parent.[7,29]

Multidisciplinary Atopic Dermatitis Management and Parental Education

Educating parents and implementing multidisciplinary care of AD have beneficial outcomes for both the child and parent.[6,9,11,12,30] Four multidisciplinary care studies and one case-study on sleep patterns of newly diagnosed AD children reveal significant benefits of targeting sleep behavior in the management of AD in children.[6,9,11,12,15] Studies on the impact of AD on parents also highlight the burden and consequences of unmanaged SD.[7]

Staab et. al. investigated the efficacy of an age-related structural education program in educating parents and 823 children, ages three months to eighteen years old, in a multicenter randomized control trial in seven German hospitals. [6] The program stratified participants by ages three months to seven years, eight to twelve years old and thirteen to eighteen years old.[6] The inclusion criteria included a diagnosis of AD by a pediatrician or dermatologist according to the Hanifin and Rajka criteria, a minimum eczema duration of three months and a severity of eczema score of at least 20 points by the atopic dermatitis scale. [6] Exclusion criteria included a current treatment of other acute or chronic illnesses or psychiatric disorders.[6] The objective of this study was to develop an age-targeted standardized intervention for self-management of AD to assess the effects on severity, control of AD, and parental quality of life in a period of 12 months. [6]

The intervention group received the age stratified educational program and the control did not receive the education. [6] If the child was younger than thirteen, parents attended training once a week for a total of six weeks. [6] Children thirteen years old and older attended their own sessions that specifically targeted their concerns. [6] The parents and children were trained by a team of dermatologists, pediatricians, psychologists, nurses, and dieticians. [6] Topics discussed in training sessions included basic medical information about AD, relaxation techniques, stress management, sleep disturbances, recognition and avoidance of triggers, nutrition, self-management, and coping mechanisms. [6] Therapy management of topical or systemic prescriptions was not included in the educational program. [6]

Outcome measurements of the study include the difference or change in severity of eczema and the quality of life of the parent from the start of the study and to 12-month follow-up. [6] Participants were assessed on five quality of life subscales with (1) an objective severity score, (2) subjective severity score, (3-4) two itch questionnaires regarding behavior including coping and catastrophizing (the negative thoughts on pain that are out of control) and (5) a quality of life questionnaire for parents of children less than thirteen years old. [6] The quality of life questionnaire utilized was part of a Berlin public health study and is validated in the analysis of the following 5 subscales: psychosomatic well- being, confidence in knowledge of medical treatment, effects on social life emotional coping, and acceptance of the disease. [6]

The severity of eczema decreased in both groups at 12-month follow-up with a significantly greater decrease in the intervention arm. [6] Subjective severity score similarly decreased significantly more in the intervention group than the control. [6] Itching behavior and catastrophizing was significantly improved among the 8-12 year olds in the intervention group. [6] Among 13-18 year olds, there was a significantly greater improvement in catastrophizing. In the intervention group of children ages 3 months to 7 years, there was significant greater scoring in all five subscales of the questionnaire. [6] In ages 8-12 years, there was significantly improved quality of life in 3 of 5 subscales in the intervention group. [6] The subscales for confidence in medical treatment, emotional coping, and acceptance of disease were significantly improved in the intervention group.[6] Psychomotor well-being and effects on social life questionnaire subscales did not significantly differ between the control and intervention arm. [6] The generalizability is limited as children and families of moderate to severe AD were recruited. [6] This study highlighted the benefits of multidisciplinary educational programs for long term improvements of AD in children and parents in effectively reducing severity of AD and improving quality of life for parents managing treatment with a symptom oriented approach. [6]

Kufper et.al designed a randomized control intervention program consisting of six weekly group session that separated sessions between affected children and their parents to investigate training-specific effects in coping with the disease. [11] One hundred and eight-five children ages 8-12 years and their parents were included in the study and followed for 1 year.[11] The interventional sessions were led by dermatologists or pediatricians, psychologists, and dieticians to address medical, nutritional, and psychological topics. [11] The waiting control group did not attend the treatment programs, while the intervention group attended different sessions depending on their specific needs. [11]

Somatic variables were measured by the objective SCORAD score to assess severity of AD before and at 12 months. [11] Psychological behaviors were completed with five different questionnaires with five-point scale responses for a summative score.[11] Four of the five questionnaires were answered by the child and covered aspects of coping, social anxiety, itch-scratch cycles, cognition related to itching and catastrophizing. [11] The fifth questionnaire was assigned for parents to rate how they felt dealing with their child with AD with the following: aggression against scratching, overprotective behavior control of scratching, and negative treatment experience.[11] The different values or scores were compared between the intervention and control group at the first meeting and at 12-months and analyzed for variance with repeated measures. [11] The SCORAD scores of each respective group was analyzed and compared to a calculated regression equation to compare the predicted scores at the end of the treatment from observed scores of the study. [11] The findings revealed significant improvement of catastrophizing attitude in the training group as compared to the control group.[11] Coping scales for both parents and children were significantly greater in the intervention versus control.[11] In addition, quality of life in parents was significantly improved in the intervention group than the control upon evaluation of their questionnaire in the categories of aggression against scratching, overprotective behavior, and negative treatment experience over the 12 months.[11] The limitation of this study was that it did not evaluate children younger than 8 years old and targeted mainly daytime mechanisms to assess parental quality of life.[11] Overall, the findings highlight the significant effects of multidisciplinary training that enabled the child and parent to effectively improve coping behaviors with pruritus and psychological benefits that are independent of changes in severity of AD.[11] This study suggests reinforcing protective behavioral modifications of managing AD can reduce the helplessness among parents.[11]

Meltzer et. al conducted a longitudinal study to measure sleep quality objectively and subjectively in children ages 0.5 to 17.5 years old and their parents as the primary outcome following a two-week full day multidisciplinary care program involving allergists, immunologists, pulmonologists, and behavioral specialists.[9] A total of twenty-nine children and parents (29 mothers, 21 fathers) participated in the intensive treatment program. [9] Exclusion criteria included any other significant chronic illnesses, diagnosed sleep disorder in the child or parent, a professionally diagnosed psychiatric or developmental disorder that is known to disrupt sleep, history of neurologic illness or injury, and parents with night-shift work. [9]

Objective measures of the study included total sleep duration and sleep efficiency. Sleep duration and efficiency were measured using actigraphy and collected one week prior to admission, at end of treatment (day 14), 1 month after discharge and 3 months after discharge. [9] A daily sleep diary completed by parents and children 8 years and older was also collected at the same study points to facilitate accuracy of actigraphy.[9] Subjective sleep outcomes were measured using two scales within the Patient-Reported

Outcomes Measurement Information System (PROMIS) to measure sleep disturbances (PROMIS-SD) and sleep related impairments (PROMIS-SRI). These questionnaires assess for perceived sleep patterns, daytime functioning, sleep continuity, difficulty waking over 7-days of recall. [9] These were completed on admission to the training, at discharge, 1 month and 3 months after discharge. [9] Parents with children less than 4 years or younger with AD were given the Brief Infant Sleep Questionnaire- Revised (BISQ-R) to assess perceived sleep quality and patterns.[9]

The impact of AD on parental and children QoL was assessed using two different questionnaires.[9] Parental QoL was assessed by the 10-item Dermatitis Family Impact questionnaire. .[9] Children would complete the 10-item Children's Dermatology Life Quality Index questionnaire.[9] The Conners 3 ADHD Index screening test was also used and completed at baseline and 3 months after discharge by children 8 years and older to assess for 1-month recall of symptoms of ADHD.[9] Disease severity over the four study points was evaluated by the Atopic Dermatitis Quickscore (ADQ).[9] ADQ was reported by the parents regarding body surface involvement, intensity of involvement, and pruritus over 7 body parts.[9]

The outcomes were analyzed by analysis of variance models (ANOVA) to test for differences and variances between and within participants over the four different study points.[9] A clinically significant decrease in sleep disturbances from baseline in children and an increase in sleep quality in relation to decreased sleep awakenings but non-significant changes in sleep-related impairment was identified.[9] Daytime functioning improved in both children and parents in relation to decreased anxiety and depression.[9] Quality of life in affected children and their parents was also significantly improved.[9]

Given the longitudinal study design, this study is limited in interpreting the outcomes since it did not include a control group. In addition, the duration of the study and length of follow-up only followed patients for about 4 months. [9] Generalizability is limited due to the small sample size and inability to assess for differences among other variables including race, ethnicity, and sex.[9] Meltzer et.al's study highlights the importance of assessing the AD treatment outcomes of both the child and parent and the maintained benefits of improved sleep and daytime functioning with successful AD management. [9]

Wenninger et. al conducted a one year longitudinal study of the effects of an education program for parents of children with AD to aid in incorporating self-behavioral changes, encourage active coping and problem-solving skills in managing their child's AD.[12] Parental feelings of anxiety, loneliness, helplessness or lack of confidence in treatment may lead to suboptimal management of the chronic disease**.** [12] The objective of the study was to address parental education and response to their child's environmental triggers, skin condition, scratching, sleeping, and symptom exacerbation.[12] A team of pediatricians, psychologists, and dieticians provided six groups sessions of medical, nutritional, and psychological training with skills training, modeling and positive reinforcement, and skills to monitor behavior and environmental triggers that may affect their child.[12] Sixty-three families participated in the intervention and sixty-six were part of the control group.[12] The children with AD were between the ages of 5 months to 9 years.[12] Inclusion criteria required a diagnosis of AD for at least 3 months with minimum SCORAD of 20. [12] The intervention and control group did not significantly differ in demographics or SCORAD scores in children.[12]

This program enabled participants to openly share their experiences and make their own decisions and outline behavioral steps to implement at home.[12] Discussions of psychological issues, such as stress management, sleep disturbances, and the itch-scratch cycle, along with relaxation training and development of an age- appropriate sleep training were provided.[12] The program's promotion of the self-management skills resulted in a reduction of cognitive avoidance or rumination, which is suggestive of a motivated and active role in managing their child's condition and could positively impact the family's overall quality of life.[12] The impact of the educational program was measured with a health-related quality of life questionnaire (HRQOL) that is specific to AD.[12] HRQOL addresses the parent's psychosomatic well-being, confidence in medical management, coping strategies, acceptance of disease, and effects of daily life.[12] The results revealed a trend of increased confidence and knowledge of medical treatment, emotional coping, and self-management within the intervention group as influenced by the program.[12] There was a decrease in disease severity over the study period of 1 year in both groups but the difference in SCORAD scores in both groups was not significant.[12] The limitation of this study is that it cannot conclude that the impact of the program solely decreased the disease severity since a decrease was seen in both groups.[12] This study implies benefits of integrating parental education of self-management in addition to AD interventions to the primary caretaker of a child with AD.[12]

Onset of Sleep Disturbances

Dogan et.al conducted a controlled case study to investigate the sleep patterns of children newly diagnosed with AD and healthy children using the Brief Infant Sleep Questionnaire (BISQ).[15] Forty-six children with AD and sixty healthy children were recruited in this study between the ages of 3-36 months.[15] AD patients were classified by SCORAD scores.[15] BISQ, a validated questionnaire on parent- reported sleep measures, was completed by the mothers and was used as a screening tool to assess sleep patterns.[15] The newly diagnosed patients included children that had not started drug therapy and excluded children with a history of allergies.[15] The control group also excluded children with a history of allergies.[15] The study reported statistically significant differences in average nighttime and daytime sleep duration between the control and AD group.[15] AD infants had more reported awakenings and longer resettling time.[15] In addition, infants with AD had greater wakefulness time upon awakening.[15] The limitations of this study include a small sample size, selection criteria of children 3-36 months old with admissions to the hospital, and sleep behaviors were not compared within the different severity SCORAD scores. [15] Given the small sample size and age criteria between 3-36 months old, the results may not be generalizable to older children. This study highlights notable sleep disturbances at the early onset of diagnosis.[15] This suggests opportunity for early intervention of sleep behaviors in infants with AD.[15] The quality of life and burden may be improved if parents and/or professionals are able to screen and assess sleep problems earlier. [15]

Parental Sleep Loss

Angelhoff et. al investigated the perception of sleep in Swedish-speaking parents and their coping strategies for sleep loss.[7] The twelve parents (11 mothers, 1 father) included in the study were from three outpatient pediatric clinics in southeast Sweden with children aged 0-2 who had an objective SCORAD index greater than 15, also defined as mild eczema.[7] The parents were interviewed with 10 questions to describe their perception of sleep and daily schedule.[7] The data was analyzed by a seven-step phenomenographic analysis to ensure that the researchers and authors would avoid interpreting the data with their own perceptions, given their prior nursing experiences in educating families with children with AD.[7] The data was categorized into the following: acceptance and normalization of sleep loss; changed routine and behavior to compensate for sleep loss; and support is needed to gain sleep and manage the daily life.[7] The main findings of the study revealed that parents perceived their sleep loss caused by their child's condition was normal and negatively led to changes in both behavior and routine.[7] It was expressed that their sleep loss was ignored by the healthcare professionals as normal for parents of young children.[7] Due to the loss of sleep, parents would compensate by sleeping earlier, co-sleeping with the child, taking naps, or sleeping during the daytime.[7] The coping strategies highlighted in the interview responses were having practical support, supportive understanding from healthcare professionals, and me-time for the parent to recover and rest.[7] The small sample size of twelve parents and subjective responses allowed the data to include some variability while remaining manageable for phenomenographic analysis, though it may not be generalizable.[7] There were no exclusion criteria for the parents recruited which inherently provided the variance in responses.[7] In addition, the researchers of this study consisted of pediatric nurses who have clinical experience in educating families which could have led to a bias in analyzing the responses as compared to researchers of a different discipline.[7]

Overall, the findings from these studies suggest the need to address sleep disturbances as it relates to the general management of AD and the beneficial impact on the child, as well as the quality of life of the family, specifically parents or caretakers. Sleep disturbances in children and their effect on quality of life of the family should be addressed and counseled upon diagnosis and early management.

METHODS

Study Design

The study will be a randomized controlled trial designed to primarily assess the impact on parental quality of life as a result of providing SD education to pediatricians, dermatologists, and pediatric dermatologists. This study will follow the physicians, their recruited pediatric patients and parents longitudinally for 1 year. Outcomes will be measured by surveys to assess the impact of sleep medicine education on physicians and counseling effects to parents of the children with AD.

Study Population and Sampling

The physicians (n=126) will be recruited among pediatricians, dermatologists and pediatric dermatologist in Boston Medical Center (BMC). Of the 126 physicians recruited, 63 (q_1= 0.5) will be randomly selected to be in the intervention group which will receive additional sleep behavioral intervention training. The sample size is a sample of convenience given the limited number of physicians within BMC. Given this sample size, this study has 80.0% power to detect an effect size of 0.503.

Diagnosis of Recruited Patients

Patients will initially be evaluated by the recruited pediatrician, dermatologists, or pediatric dermatologists at BMC and diagnosed based on clinical characteristics and categorized by severity using the SCORAD index. SCORAD index ranging from 0 to 103, consists of morphology evaluation and subjective parameters of sleep disturbances and itching. A score of 25 is classified as mild, 25-50 moderate, and greater than 50 will be categorized as severe AD. [17,18]

Inclusion Criteria

Patient inclusion criteria includes children 3 month to 6 years old with a diagnosis of AD.

Exclusion Criteria

Exclusion criteria include currently receiving multidisciplinary care for AD.

Intervention

The control arm will continue to provide standard of care for the pediatric AD population. The intervention arm will be provided access to two online sleep behavioral intervention modules made by experienced psychologists and sleep medicine physicians in multidisciplinary care settings. These modules will introduce the sleep behavioral methods of graduated extinction, scheduled awakening, habit reversal therapy, response cost, progressive muscle training and a pharmacological primer on sleep aids. A summary or table of techniques may be provided for the recruited physicians and caretakers.

Study Variables and Measures

The main study variable is the change in scoring of the parental QoL questionnaire. All recruited parents will be consented and asked to fill a 26-item QoL questionnaire at the initial visit and at the 12-month follow-up. This questionnaire is adapted from the Staab et al. study, which utilized a validated German questionnaire that has been used to evaluate the impact of educational programs for parents with AD.[6] The questionnaire has 5-subscale of which 1 is equal to “does not apply at all” and 5 is equal to “really the way it is” that address the following categories: psychosomatic state, confidence with medical treatment, effects on social life, and level of acceptance of the disease.[6]

The second variable is the frequency of addressing and integrating sleep disturbance interventions by all of the physicians in the study. This will be measured by a monthly emailed survey form in which the physicians will indicate their frequency of addressing and counseling on sleep disturbances with the following 5 choices: 4= all visits, 3=most visits, 2= at least half of visits, 1=a few visits, 0=none. The third variable of this study is the sleep behavioral changes of the child at the initial and 12-month visit. This will be measured with the 22-item Child Sleep Behavioral Scale.[16] This behavioral scale will be answered by the parents to assess sleep-related behaviors and habits that include willingness to go to bed, ease in falling asleep, night awakenings, and ease of awakening in the morning.

Recruitment

All pediatricians, dermatologists, and pediatric dermatologists at BMC will be emailed and asked to participate in the study. Patients and parents of the child will be approached during their visit and invited to participate. They will be given a consent form in the clinic at the start of their enrollment.

Data Collection

Physicians in both arms will be sent a monthly survey via email upon completion of each webinar course for a total of 12 surveys. All recruited parents will be given a physical copy of the QoL questionnaire to be filled out after each encounter with the physician starting at the first visit until the 12-month follow-up. The questionnaires will then be scanned, uploaded into the study database, compiled and paired by the patient’s randomly generated study identification number with the respective provider study identifier, and initial SCORAD severity. The data will be transferred to a spreadsheet and stratified by age and based on the SCORAD severity in the control and intervention group by the study staff.

Usage of personal health information and identifiers will be protected for all recruited physicians, parents, and children participating in the study. Upon enrollment of the study, physicians, parents, and children identifying information including their initials, age, and the physician's specialty will be entered into a separate encrypted document. This document will be saved in a password protected and encrypted hard drive that is only accessible to study staff. Each participant will be assigned a randomly generated participant identification number. Study data utilized or recorded outside of the master document will only correlate with the assigned identification number.

Data Analysis

The 26-item parent QoL questionnaire scores and the 22-item Child Sleep Behavioral Scale will be analyzed by a paired t-test to compare the mean change of scores at the initial visit and 12-month visit in the control and intervention group.[16] The monthly survey scores from the physicians will be grouped by physician specialty within the control and intervention group and analyzed by ANOVA test to assess for variances among specialties, as well as the intervention and control group over the study period.

Timeline

This proposal will require no less than 2 years for the study. The recruitment phase will take 4 months. Clerical assistants and student workers will be required to contact, recruit and follow-up with BMC pediatricians and pediatric dermatologists to ensure timely monthly data collection. Patients and their parents recruited will be required to schedule a 6-month and 12-month follow-up appointment to complete the study. The study itself will be given two years plus 6 months of overlap for potential scheduling conflicts. A statistician and analyst will be hired to organize and analyze the data.

Institutional Review Board

This proposal will be submitted to the IRB for an expedited review as it follows consideration Category 1 of inclusion of children in research with minimal risk. The research conducted will be performed in the established and accepted setting of an outpatient clinical office. The additional clinical training provided by the sleep medicine and psychologist directed seminars will not adversely impact the practicing physicians, who will then be responsible to counsel parents of children with AD. The parents and their children, a special population, will continue receiving standard of care treatment of AD with or without addition of existing sleep behavioral interventions. Therefore, the impact of these existing interventions is unlikely to adversely affect this special population.

CONCLUSION

Discussion

This study is specifically emphasizing the importance of counseling on SDs associated with AD in the primary provider setting. The strength of this study is the simple study design of the seminars, use of surveys, and low risk strategies for caretakers. The intervention is made in collaboration with specialists, such as experienced sleep medicine physicians and psychologists. This provides expert expertise and partnership in educating primary providers. The surveys and questionnaires are validated and easy to manage by email and paper form during each patient visit.

Confounding variables within this study include provider experience, provider motivated counseling, and improving AD severity due to other mainstay treatments. Prior to the study, providers in the control group may already implement sleep behavioral management to their patients prior to the study. Sending monthly emails with the survey assessing their frequency of counseling may motivate physicians to integrate sleep behavior counseling more frequently since they have to report it, despite not receiving the formal seminar training. On the other hand, physicians who did not receive the training would be less motivated to follow-up with the surveys. Improvement of AD severity due to complimentary standard of care treatment may also affect the parental questionnaire results.

The study results on the impact of parental QoL may be useful for providers and families with resources for patient education in AD management. BMC, an urban safety net hospital, serves a community often with multifactorial social determinants of health.

The results may be generalizable and applied to providers who work with a similar population. The results in the change in frequency of sleep behavioral education counseling is generalizable as applies to recruited physicians whose scope of practice will involve managing and counseling pediatric patients with AD. The outcome of improvement in sleep disturbances in the children with AD may be difficult to accurately assess or interpret as the study does not directly study the impacts on each severity and is dependent on variables that are not controlled or measured in this study such as efficacy of parental implementation and changes in AD treatment during study period.

The weaknesses and limitations of this study include variability among provider counseling, parental implementation, self-reported data, child's baseline symptoms profile, short-term study period, and subjective questionnaires. Similarly, parents may or may not be effective in implementing the interventions, which may contribute to variability of treatment that cannot be identified in this design. As mentioned above, the patients and families treated at BMC may have social determinants of health including environmental, educational, financial issues that are not addressed in this study. Therefore, this can impact the outcomes of quality of life independent of AD education.

This study design is unable to directly correlate improvement of AD severity as a result of counseling. In addition, early sleep behavioral interventions have not been proven to prevent sleep disturbances but may establish long term habits earlier.[15] This design targets the pediatric population in order to address parental quality of life, but future applications of this study may include a multi-center study with a larger sample size and longer study duration.

Summary

This proposal promotes continual education for pediatricians and pediatric dermatologist to be more familiar with sleep interventions as part of standard of care counseling and treatment of AD. Sleep disturbances are often overlooked or undermanaged. By integrating sleep education into primary counseling for AD, this introduces interventions to aim in the prevention of worsening SD. This study addresses the gap of early intervention of sleep education and emphasizes the positive effects on parental quality of life and sleep deprivation in families with children with chronic dermatologic diseases.

Clinical and Public Health Significance

Providing sleep-related education can empower families who feel burdened or helpless about a child's skin condition. Insufficient parental confidence or knowledge about AD management, insufficient healthcare provider support, or any causes of lower quality of life can lead to suboptimal AD management and increased utilization of healthcare resources.[11] Given the evidence supporting multidisciplinary care that includes attention to health sleep behavioral strategies, it should be helpful to directly educate providers without access to multispecialty collaborators.

LIST OF JOURNAL ABBREVIATIONS

Acta Derm Venereol	Acta Dermato-Venereologica
Allergol Immunopathol	Allergologia et Immunopathologia
Ann Dermatol	Annals of Dermatology
Arch Pediatr Adolesc Med	Archives of Pediatrics and Adolescent Medicine
BMJ	BMJ: British Medical Journal
Curr Probl Dermatol	Current Problems in Dermatology
DRM	Dermatology
Int J Mol Sci	International Journal of Molecular Sciences
Ital J Pediatr	Italian Journal of Pediatrics
J Paediatr Child Health	Journal of Paediatrics and Child Health
JAMA Pediatr	JAMA Pediatrics
Pediatr Dermatol	Pediatric Dermatology
Postepy Dermatol Alergol	Postępy Dermatologii i Alergologii
Semin Cutan Med Surg	Seminars in Cutaneous Medicine and Surgery

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