Title

Mixed Method Analyses to Document Content Validity of Sleep Disturbance Measurements in Adult and Adolescent Populations with moderate-to-severe Atopic Dermatitis

Authors

Jorge Puelles – Galderma
Anna Ryzhkova – Galderma
Sylvie Gabriel - Galderma
Danielle Rodriguez – Evidera
Fatoumata Fofana – Evidera
Carla Dias-Barbosa – Evidera

Disclosures: Jorge Puelles, Anna Ryzhkova and Sylvie Gabriel are employees of Galderma.
Danielle Rodriguez is an employee of Evidera Seattle WA, USA, Fatoumata Fofana an employee of Evidera Bennekenorn the Netherlands, and Carla Dias Barbosa an employee of Evidera, Ivy-sur-Seine, France, working on these analyses on behalf of Galderma.

Abstract

INTRODUCTION & OBJECTIVES: Itch associated with atopic dermatitis (AD) often causes patients to experience sleep disturbance (SD). The combination of a single-item Sleep Disturbance Numerical Rating Scale (SD NRS) and a Consensus Sleep Diary for AD (CSD-AD) was explored for a holistic assessment of the multidimensional nature of SD related to itch/AD symptoms. A qualitative study provided strong support for the importance and relevance of SD in adults and adolescents with AD and demonstrated understanding and ease-of-use of the SD NRS and CSD-AD measures in these populations. The objective of this research was to further investigate the relationship between SD NRS and CSD-AD.

MATERIALS & METHODS: Data from a qualitative research study that involved one-on-one semi-structured telephone interviews with adult (n=20) and adolescent (n=10) patients with AD, recruited from six clinical sites in the United States was used for this analysis. Participants had to be aged ≥12 years; have a clinical diagnosis of moderate-to-severe AD, as defined by an Eczema Area and Severity Index (EASI) ≥12; and have a score ≥4 on the SCORing Atopic Dermatitis (SCORAD) sleep loss visual analog scale (VAS). Interviews were audio recorded, transcribed, coded using qualitative data analysis software (ATLAS.ti Scientific Software Development, Berlin, Germany) and analysed following a qualitative content analysis approach. Additionally, the following quantitative analyses were conducted: (1) analysis of the SD NRS score by sub-populations (adults vs. adolescents); (2) CSD-AD item description by subpopulations (adults vs. adolescents); and (3) correlations between SD NRS and items 10 (quality of sleep) and 11 (level of
RESULTS: The SD NRS average weekly score was 4.8 (standard deviation: 2.7) for adolescents and 6.1 (standard deviation: 2.2) for adults, suggesting that sleep disturbance was more severe in adults than in adolescents. These findings are corroborated by patient reports collected during the original qualitative study. Overall, adult participants reported more night-time awakenings (adults: 90%, adolescents: 80%), trouble falling asleep (adults: 80%, adolescents: 60%) and feeling unrested (adults: 60%, adolescents: 40%). In addition, most adults stated that their sleep was disturbed daily (adults: 70%, adolescents: 30%), whereas most adolescent participants experienced sleep disturbance less often than weekly (adults: 30%, adolescents: 70%). The number of awakenings also slightly varied across groups with a large majority of adults (80%) reporting two or more awakenings per night compared to 60% of adolescents.

Correlations between the SD NRS and item 10 (quality of sleep) of the CSD-AD were large overall (r=-0.66) and across both subpopulations (adults r=-0.68; adolescents r=-0.59). For item 11 (level of freshness and rest in the morning), correlations were moderate to large overall (r=-0.46) and across both subpopulations (adults r=-0.44; adolescents r=-0.57). Additional analyses by subgroup and correlations between SD NRS and CSD-AD items supported that SD was more severe in the adult population and correlations between these two measures were large to moderate.

CONCLUSIONS: SD is more severe in adults than adolescents based on qualitative and quantitative findings. Moderate to large correlations between SD NRS and CSD-AD items suggest that both measures are complementary but do not overlap. These results complement previous content validity findings and confirm the appropriateness of the combined SD NRS and CSD-AD measurement approach for the assessment of the multidimensional nature of SD in AD.