

## **A Novel Monitoring Device for Predicting Asthma Exacerbation in Children**

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**Introduction:** Early detection and treatment of asthma exacerbations may decrease their severity and improve outcomes. Night time symptoms are common in asthmatics. The EarlySense device (ES) is designed for continuous, contact-free, nocturnal monitoring of breathing patterns, breathing rate, heart rate, and sleep quality in order to characterize early warning signs of impending asthma attacks, and enable early intervention.

**Objective:** To evaluate the effectiveness of the ES device in predicting asthma exacerbations without requiring patient compliance.

**Methods:** An open labelled, prospective study. Patients with history of at least 3 episodes of asthma were enrolled. The ES was placed under the mattress and contact-free, continuous, prolonged nightly measurements were conducted for 3-6 months. Through the study period we also obtained: Daily symptom diary, daily FEV<sub>1</sub>, and technician weekly home visit that included complete spirometry and assessment of clinical changes. Asthma exacerbations were divided into 3 categories: 1. Possible event: defined as 3 days either preceding or following any outright exacerbation; 2. Minor event: parent-reported event; 3. Severe event: physician or technician-confirmed event. Statistical modelling procedures, based on logistic regression and Receiver Operating Characteristic (ROC) analysis, were applied in order to obtain an asthma score based on the measured parameters.

**Results:** 15 asthmatic children (8 male; age 9.8±2.8 years), who had more than one exacerbation, were enrolled. Recordings from the ES were available for 15 physician-confirmed events, 33 parent reported events, and 90 possible events, and 886 non-event days, and constituted the basis for the statistical modelling. The optimum combined accuracy of the statistical model in predicting the physician-confirmed events was 87% (13/15), with specificity of 97%. ES-score was significantly higher 1 night before the severe events compared to normal or unstable days.

**Summary:** ES may predict most asthma exacerbations earlier than parents, thus allowing early intervention and likely improved outcome. ES can be used for continuous asthma monitoring and can potentially objectify the effect of interventions. Since ES monitoring is contact-free and automatic, it is minimally dependent on patient compliance.

*Presented at ERS (European Respiratory Society), September 2<sup>nd</sup>-6<sup>th</sup> 2006, Munich, Germany.*