

A Novel Monitoring Device for Predicting Asthma Exacerbation in Children



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Introduction

- ✓ Asthma is the most prevalent chronic disease in childhood, affecting approximately 10% of children.
- ✓ Morbidity and mortality are often associated with failure to predict critical worsening of airflow obstruction.
- ✓ Asthma exacerbation includes breathlessness, wheezing and increased heart and respiration rates and is frequently worse at night.
- ✓ Current asthma monitoring strategies require active compliance.

Aims

To evaluate the effectiveness of the EarlySense (ES) device in predicting asthma exacerbations without requiring patient compliance.

Methods

Inclusion criteria: Asthma patients, age 3 to 18 years, able to perform spirometry with 3 or more asthma exacerbations during the previous year.

Exclusion criteria: Previous admission to intensive care unit due to a severe asthma exacerbation that required ventilatory assistance, any pre-existing medical pathology of a serious nature, tendency to recurring infectious diseases, or sleep apnea.

No clinical decisions were based on information obtained from the ES study device.

Monitoring

The ES device logs physiological parameters, such as respiration rate, heart rate, and sleep quality, in a contact-less manner without patient intervention.

Measurement is conducted by a piezoelectric sensor placed under the mattress connected to a digitizing box and a laptop.



EarlySense home monitoring system

Study design

Parents filled out a daily diary including: symptoms, FEV1 and Peak Flow measurement (PIKO-1).

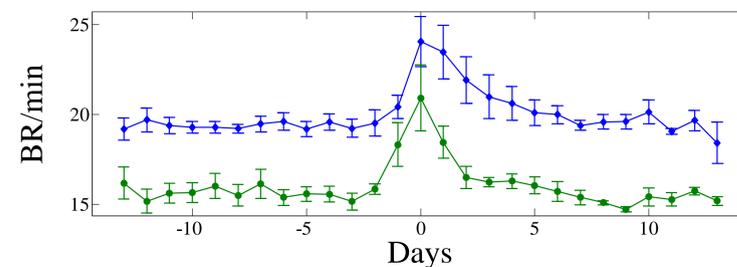
A trained respiratory technician visited the patients weekly to perform spirometry (Koko), to assess and report patients' clinical status, changes in medications and asthma exacerbations.

Asthma exacerbations (3 categories):

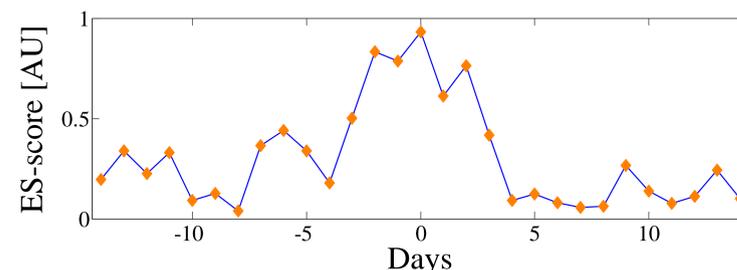
1. Possible Event: 3 days either preceding or following exacerbation
2. Minor Event: parent-reported event
3. Severe Event: physician or technician - confirmed event

Statistical Analysis

Asthma score was calculated based on the measured parameters. Analyses were based on multivariate logistic regression and ROC models to discriminate between event and non-event states.



Average breathing rate around asthma events of 2 patients.



ES score progression around 15 asthma events providing an early alert of ~36 hours.

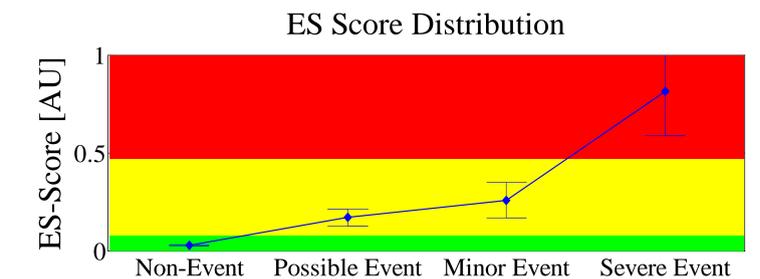
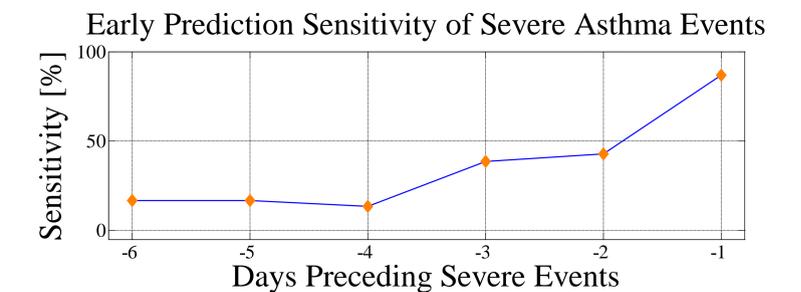
Results

Accumulated Data

Data from 15 patients (8 male;7 female, age 9.8 ± 2.8 years) who had more than one exacerbation were analyzed.

Overall 15 physician-confirmed events, 33 parent reported events, and 90 possible events, as well as 886 non-event days.

The statistical model for ES-score had a sensitivity of 87% (13/15) for the physician events, with specificity of 97%. ES-score was significantly higher 1 night before the severe events compared to normal or unstable days.



ES-score for normal days (green) unstable days (yellow) and severe events (red). Significant differences between the 3 classes ($p < 0.0001$).

Conclusions

- 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.