**AirSonea**

**An integrated digital system to help in monitoring and treating patients with asthma**

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Asthma is a chronic disease that will require monitoring and treatment throughout the lifetime of a patient. Because of the absence of a singular diagnostic characteristic, asthma is functionally defined as a chronic airway inflammatory disorder leading to airway constriction. This feature of asthma has implications for the diagnosis, management, and potential prevention of the disease1.In affected individuals, inflammation causes recurrent episodes of wheezing, breathlessness, chest tightness, and coughing, particularly at night or in the early morning and in response to both intrinsic and extrinsic triggers. 2 Fortunately asthma can be effectively treated and most patients can achieve good control of their disease.3 The goal of asthma care is to achieve and maintain control and if possible, even prevent the clinical manifestations of the disease for prolonged periods.4

Each well-treated patient should have an Asthma Action Plan designed by his or her doctor and modified as necessary depending on the underlying activity of the disease or the presence of extenuating circumstances. Asthma Action Plans can decrease hospitalisation for and deaths from asthma.5

In addition to routine physician visits and evaluation, the typical action plan recommends ongoing monitoring by patients or their caregivers who can then use the information to help implement their treatment protocol.  As described in the US Centers for Disease Control (CDC) asthma recommendations, this includes monitoring:

* + signs and symptoms of asthma, including history of exacerbations
  + pulmonary function
  + quality of life
  + adherence to and potential side effects of pharmacotherapy
  + patient-provider communication and patient satisfaction

Physicians and patients (or their caregivers) need to integrate all of these in making decisions about ongoing care.

Among the most common physical finds in patients with lung disease are the presence of abnormal breath sounds heard during physical examination. These can be divided into two types-- continuous sounds or wheezes and discontinuous sounds or crackles. Wheezing is a classical physical finding of airways obstruction caused by many diseases. The exact mechanism of sound production is not totally clear, but its relationship to airways obstruction, especially in asthma, is well accepted as an indication of bronchoconstriction. A relationship between the degree of airway obstruction and the presence and characteristics of wheezes in asthma has been demonstrated in several studies6, 7. The best correlation is observed when the degree of obstruction is compared to the proportion of the respiratory cycle occupied by wheeze (*t*w/*t*tot)6 i.e. thewheeze rate. In subjects with induced airflow limitation, the appearance of wheezing detected over the trachea has been found to correlate closely with the concentration of methacholine inducing 20% fall in forced expiratory volume in one second (FEV 1) in children8. Wheezes are common clinical signs during acute episodes of asthma9 .The quality and duration of wheezing depends, among other things, on the size of the affected airways, the degree of obstruction and the rate of airflow.  Thus in any given patient its direct correlation with other measurements of flow may vary and in very severe obstruction, wheeze may be absent as flow rates fall towards zero.  However, in this type of severe obstruction, physiological measurements are not needed as an indication of the severity of the disease.

The iSonea technology uses a contact sensor with excellent acoustical properties in conjunction with computerized acoustic analysis to detect, measure, record, document and quantify the presence of wheezes.  The sensor- microphone (marketed under the name “Air Sonea”) is superior to standard or electronic stethoscopes in "hearing" the frequencies that make up the wheeze sound. Auscultation with a traditional stethoscope has many limitations. It is a subjective process that depends on the listener's own hearing, experience and the ability to differentiate between different sound patterns. It is not easy to produce quantitative measurements or make a permanent record of an examination in documentary form. Long-term monitoring or correlation of respiratory sounds with other physiological signals is also difficult. Moreover, the traditional stethoscope has a frequency response that attenuates frequency components of the lung sound signal above about 120 Hz 10, and the human ear is not very sensitive to the lower frequency band that remains.11

The AirSonea sensor system is placed at the trachea for 30 seconds and the sensor system records the subject’s breath sounds. The transmission of wheezing sound through the airways to the trachea is better than transmission through the lung to the surface of the chest wall. The higher-frequency sounds are more clearly detected over the trachea than at the chest11,12,13.

The ability to successfully record and identify wheezes by the AirSonea sensor and acoustical analysis algorithm has been documented by a comparison study using a series of experts listening to the same acoustical files. iSonea conducted a clinical study designed as a “Multiple Reader Multiple Case Study” that involved 60 sound files collected in the homes of diagnosed asthmatics using the company’s technology. Seven board certified pulmonologists reviewed these recorded breath sounds to determine the presence of wheeze. The overall percent agreement between the physicians and the AirSonea technology for the presence or absence of wheeze was 93.3% with an intra-observer kappa of 0.7114.

The wheeze rate, as measured by the AirSonea technology, has been shown to correlate well with peak flows in patients and is independent of effort. This is particularly important in children where subjective symptom monitoring is often difficult and where peak flow monitoring may be impossible. In a study of 296 children (8 – 16 years of age) they were only able to use a peak flow meter correctly 23.9% of the time15.

Wheeze detection software can be used for long-term monitoring of asthmatic patients, particularly to assess the severity of symptoms and the efficacy of treatments. Wheeze analysis can provide information about the degree of airflow obstruction, e.g. by determining what proportion of each expiration cycle contains wheeze.16 The wheeze rate, as measured by the AirSonea technology, has been shown to correlate with symptom scores better than peak flow.

In the “WheezoMeter Exploratory Field Study” iSonea asked diagnosed asthmatics ranging in age from 11 to 64 years old, to measure and record their symptoms, peak flow and WheezeRATE™ before and after bronchodilator administration in the home for a period of two weeks. Of the twenty one (21) participants who were able to match the 3 parameters we collected 300 matched data points.

**Change in WheezeRATE vs. Change in Symptoms**

|  |  |
| --- | --- |
| R Square = 0.655404791 | Weighted R = 0.809571 |

**Change in FEV1 vs. Change in Symptoms**

|  |  |
| --- | --- |
| R Square = 0.374152765 | Weighted R = 0.61168 |

**Change in Peak Flow vs. Change in Symptoms**

|  |  |
| --- | --- |
| R Square = 0.460614552 | Weighted R = 0.6786859 |

There is a statistically significant and stronger correlation between the Symptoms Scores and WheezeRATE than Symptoms Scores and either Peak Flow or FEV1(14).

In addition to the measurement of wheeze rate, the iSonea system has a robust application (“app”) function for both iPhone and Android operating systems. Presently this app function allows for the monitoring and tracking of Symptoms, Triggers, WheezeRATE and Peak Flow. The app also provides medication and measurement reminders and notifications and alerts when asthma control changes based on the US National Institutes of Health (NIH) and the Global Initiative Against Asthma (GINA) guidelines.

The company is also developing a neural network that will eventually allow for expanded capabilities. Combining the patient’s data and input information with environmental information and data from other patients, this neural network has the potential to provide real-time intelligence to family, caregivers and healthcare professionals about changing risk and improve the ability to adhere to asthma action plans.

The melding of new hardware technology with the power of smart phones to compute, store and transmit is leading to innovative approaches to the treatment of chronic illness. As part of this advance, iSonea seeks to be of help to patients and physicians in the management of asthma, a disease that, when properly treated, can lead to significant improvement in a patient’s functional ability and outcome.

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