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Diagnostic Technology: Automated lung sound analysis for asthma

Clinical Questions:

In community-based settings, does automated lung sound analysis identify the presence of wheeze compared to routine practice?
In community-based settings, does automated lung sound analysis accurately diagnose new-onset asthma and/or identify changes in asthma severity compared to routine practice?
In community-based settings, can automated lung sound analysis be used for home monitoring of asthma severity compared to routine practice?
In community-based settings, does automated lung sound analysis have an added clinical value when compared to auscultation by a GP?

Devices:
Pulmotrack (Karmelsonix, Haifa, Israel)
Wheezometer (Karmelsonix, Haifa, Israel)
VRI (Deep Breeze, Or-Akiva, Israel)
LSA-2000 (Kenzmedico, Japan)
Multichannel STG (Stethographics, Boston, USA)

Advantages over Current Practice:
The current British Guidelines on the Management of Asthma (1) note that there is no gold standard for the diagnosis of asthma, although most definitions include the presence of symptoms such as wheeze, breathlessness, cough and chest tightness, and variable airway obstruction. A diagnosis of asthma is more likely if there is widespread wheeze on auscultation, and the history of wheeze is an important component in the diagnosis (1). Automated lung sound analysis could provide quantification of the amount and severity of wheeze present, both in the clinic, and via home monitoring.
Definitive diagnosis in children may be assisted by an assessment of response to therapeutic agents, or lung function testing. This may include spirometry or administering substances likely to cause airway hyper-responsiveness (1). In young children, lung function testing may be difficult or impractical, and alternative methods using quantification of wheeze may be preferable.
Monitoring of asthma control is important to optimise treatment, and identify exacerbations early, and can involve symptom questionnaires, peak flow meters or other forms of lung function testing, or monitoring the use of regular and rescue medications. However, compliance with home monitoring of asthma is currently poor, particularly using peak flow meters. Home and clinic monitoring of the presence and severity of wheeze may assist with monitoring changes in severity, and provide more objective answers to symptom questionnaires, which frequently ask about the presence of wheeze or nocturnal asthma. (1).

Details of Technology:
Automated lung sound analysis technology requires the attachment of specialist microphone sensors to the chest wall and/or trachea to monitor lung sounds. The number of sensors and the method of attachment vary between the different technologies, as shown in Table 1. The different technologies also carry out a variety of analyses on the recorded data. The VRI and STG technologies both provide visualisation of the data, and the STG technology also provides counts of detected crackles, wheezes and rhonchi. Pulmotrack provides respiratory rate and inspiratory:expiratory time ratio, although it is likely that these are derived from the additional respiration belt. Both the Pulmotrack and Wheezometer devices calculate %Wz (wheeze rate), the proportion of time that wheezing is present. Pulmotrack also reports separate %Wz values for the inspiratory and expiratory portions of the respiratory cycle. Wheeze rate differs from current clinical assessments of lung sounds, which tend to focus on how widespread sounds are, their type (e.g. wheeze, crackles), and whether they occur in the inspiratory or expiratory portion of the respiratory cycle.

Table 1. Automated lung sound analysis devices.

Technology	Acoustic sensors	Additional sensors	Measurement	Analysis
Pulmotrack	2 sensors attached over trachea and right apex (other locations possible) with adhesive pads	Respiration belt around lower ribcage	Lung sounds	%Wz (inspiratory, expiratory and total) Respiratory rate Inspiratory:expiratory time ratio Cough detection
Wheezometer	1 sensor positioned manually over trachea	None	Lung sounds	Total %Wz
VRI	40 sensors (34 for children) in 2 arrays vacuum coupled to posterior chest wall	None	Vibration energy	Grayscale image of lung vibration energy at various points in respiratory cycle
LSA-2000	1 to 4 sensors attached to chest wall with adhesive pads	None	Lung sounds	Not specified
Multichannel STG	14 sensors embedded in foam pad positioned against posterior chest wall + tracheal and heart sensors	None	Lung sounds	Visualisation of waveforms Counting and visualisation of crackles, wheezes and rhonchi

Two devices are included in the research overview, but were not considered in this report. The ELENS-DSA device appears to have been discontinued, and the Meditron electronic stethoscope does not appear to include any analysis ability; it is designed for recording lung sounds only. However, the addition of an associated software analysis system may allow electronic stethoscopes to be used for clinical lung sound analysis in the future.

Patient Group and Use:

- Identification of nocturnal asthma in adults and children with an existing diagnosis of asthma
- Assessing symptom severity in acute asthma exacerbations
- Quantifying level of asthma control and response to trial of therapeutic medication
- Assessment of response to bronchial provocation testing in young children where the diagnosis of asthma is uncertain

Importance:

In 2004, Asthma UK estimated that there were 5.2 million people with asthma in the UK, of whom 1.1 million were children (2). Asthma UK currently estimates that 5.4 million people in the UK are currently receiving treatment, of whom 1.1 million are children (3). Mortality from asthma is low (1,131 people died from asthma in 2009) (3), but 30-80% of these deaths may be preventable if optimal treatment was available (4,5).

Asthma patients utilise a large number of GP appointments (over 4.1million per year), and may also require hospital admission (over 69,000 admissions in 2002), costing the NHS an estimated £889 million (estimate for 2001), in addition to the burden of lost work and school days (2). Improving the control of asthma may reduce the need for acute consultations, in addition to decreasing morbidity and mortality.

Previous Research:

There is a large body of research on automated analysis of lung sounds for a variety of clinical conditions. However, much of this relates to recordings made using research devices, which are not available for routine clinical use. The studies summarised below were identified as using commercially available equipment specifically designed for capture and analysis of lung sounds, and which are appropriate for use in clinical situations. In addition, five clinical trials using the Pulmotrack and Wheezometer devices were identified from a search of current trial registries (6-10).

Accuracy compared to existing technology

Two studies using devices not included in the list of devices above investigated agreement between %Wz measurement and clinician classification of wheeze. These devices were not included as they have either been discontinued (11), or do not currently include an analysis capability (12). One study showed that a cut-off of 3% produced sensitivity and specificity values of around 70% when compared to wheeze detection by a clinician listening to the same audio recordings (11), while the other reported very good agreement at a cut-off of 10%, with a positive predictive value of 100%, and a negative predictive value of 91% when compared to clinical auscultation during bronchial provocation testing (12).

Detection of wheeze using the Pulmotrack device has been shown to be at least as accurate as manual auscultation in intensive and emergency care settings (13,14), with one study showing that the Pulmotrack device had a sensitivity of 75%, and specificity of 76% for detection of wheeze when compared to auditory review of the recorded sound files by a panel of experienced clinical specialists in paediatric respiratory or intensive care (13). A %Wz measurement of 3% has been shown to correspond to the upper limit of normality in children (15), although the cut-off for detection of wheeze is typically set at 5% (16,17). The Pulmotrack cough counter was shown to have a sensitivity of 96% and a specificity of 94% when compared to expert listeners (18). Measurement of %Wz was shown to have significant correlation with physician classification of wheeze severity (r=0.83), with 77% agreement between a four-point score of wheeze s (19). Two studies reported inconsistent correlation with FEV_1 measures and symptom scoring children with asthma (16,17). However, these two studies had relatively small sample sizes of 9 and 15 subjects, and so would have been underpowered to detect significant relationships.

The Wheezometer device is a simplified version of the Pulmotrack technology, and measures of %Wz using this device have been reported to correlate with clinical assessments of wheeze, spirometry, and symptom scores (20). However, there is limited information available on the degree of correlation, or how relevant it might be to clinical practice.

The VRI device operates in a different manner to the other devices considered in this report, and produces an output in the form of a grayscale image, which must be interpreted by a trained assessor. This requirement, combined with the large number of sensors required, may make this device impractical for primary care use. Studies of simulated data have shown inter-rater reliability of 94% (21), and qualitative assessments of the VRI images indicate that different disease processes may lead to identifiable changes in the output (22,23). Use of the device by trained assessors to differentiate between "normal" (healthy) and "abnormal" (pneumonia or pleural effusion) results showed a sensitivity of 82.5%, rising to 90% if additional clinical information was provided (24). Use by a trained assessor also produced 77% accuracy in differentiating patients with COPD and asthma based on images taken before and after bronchodilator therapy (25). Automated detection of wheeze using the device showed 83% agreement with expert opinion (26).

One study reported use of the LSA-2000 to identify interstitial pneumonia in adults. Although a number of automated measures showed significant differences between patients and healthy controls, these were consistently outperformed by identification of crackles using manual auscultation, which resulted in higher areas under the ROC curve (27).

One case-control study assessed an "acoustic pneumonia score", using the frequency of rhonchi and crackles detected using the Multichannel STG. A score of greater than six was shown to have a sensitivity of 78% and a specificity of 88% for radiographic evidence of pneumonia in hospitalised patients (28). However, the size and complexity of this device means that it is unlikely to be more practical or cost-effective than radiography.

Impact compared to existing technology

Use of overnight Pulmotrack measurement of a "nocturnal wheeze index" in asthmatic children showed that it could be used to assess response to treatment with montelukast, and correlated with both FEV_1 and bronchial provocation test results (29). Use of the Wheezometer device in the community has been reported to show a non-linear relationship between %Wz and both FEV_1 and symptom scores, potentially allowing this technology to provide patients with an objective measure of wheeze severity (20).

Guidelines and Recommendations

The current British Guidelines on the Management of Asthma (1) recognise the lack of a gold standard for the diagnosis of asthma. In children, it is recommended that diagnosis focuses on the clinical history and examination, as well as consideration of alternative diagnoses. Where diagnosis is uncertain, testing the response to therapeutic agents, and lung function testing such as spirometry or bronchial provocation testing are recommended. In adults, spirometry is recommended as an initial test to assess the presence and severity of airflow restriction, in addition to the clinical history and examination, followed by a trial of therapeutic agents (1).

Peak flow measurement, spirometry, and symptom reporting are all recognised as methods by which the response to treatment may be assessed (1). In primary care, it is recommended that asthma is monitored using symptom and

exacerbation questionnaires, and lung function testing by spirometry or peak flow measurement (1). It is recommended that asthma patients, particularly those with severe asthma, should have a written action plan and their own peak flow meter to enable them to appropriately adjust medication doses, and seek medical help in the event of an exacerbation (1). Peak flow measurement is also recommended for diagnosis of the onset, severity, and resolution of acute asthma in primary and secondary care settings, and for the diagnosis of occupational asthma in adults (1).

Cost-effectiveness and economic impact:

There is some evidence that lung sound analysis is comparable to manual auscultation by clinicians in detecting wheeze. As stethoscopes are cheap, any benefit of automated wheeze detection is likely to be limited to situations where a trained clinician is not available, such as confirming patient-reported wheezing episodes. However, with the possible exception of the Wheezometer device, which has limited evidence for its use, the existing technology is not suited to these settings, as the equipment is typically large and complex, and is likely to be too expensive for cost-effective use.

Research Questions:

The evidence for the use of lung sound analysis in the diagnosis of asthma is limited, although it may be of assistance in gauging response to treatment or as an alternative to spirometry in bronchial provocation testing, particularly where this is difficult to perform (e.g. young children). Clinical trials to assess the practicality and accuracy of acoustic measures as an alternative to existing diagnostic techniques are required for both paediatric and adult patient groups before this technology could be routinely adopted.

There is currently very little evidence to support the use of automated lung sound analysis in primary care or community settings. Further trials are required to assess the accuracy of automated home monitoring of wheeze, and to identify whether home monitoring of wheeze can be used to improve self-management, or provide early warning of deterioration. In such settings, it may not be appropriate or cost-effective to use some of the more complex multi-sensor devices such as the Multichannel STG or VRI, and so research should concentrate on the more practical devices.

A major difficulty in assessing the accuracy of devices for diagnosis and monitoring of asthma is the lack of a gold standard method. A comparison of the performance of both the device and clinicians, compared to spirometry or bronchial provocation testing may be an acceptable compromise for the assessment of diagnostic accuracy, whereas the ability to predict the need for rescue therapy may be a useful marker for accuracy in monitoring asthma.

Suggested next step:

The most promising technology for primary care use is likely to be a portable device such as the Wheezometer, which could be used by patients or carers to assess the severity of wheezing at home. The ability of this type of device to assist in self-management of asthma should be investigated. The technology should be compared with current home-monitoring techniques such as symptom scoring and peak flow measurement. As these are cheap and easy to administer, the acoustic monitoring would have to demonstrate significant improvements to be economically viable.

Expected outcomes:

Home monitoring of wheeze severity may be a useful adjunct to an asthma action plan, particularly for patients with limited communication ability such as young children or those with learning difficulties, where symptom scoring and peak flow measurement may be impractical. For use in this environment, the device should allow for storage of a number of readings. This is currently possible with the Wheezometer, which can store up to 10 readings, although this may not be sufficient for regular monitoring (e.g. when titrating a new treatment or to identify exacerbations), when multiple reading are likely to be required each day for a period of time.

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Comments:
The Acoustic Severe Asthma Monitor (ASAM), developed by the same company as the Pulmotrack and Wheezometer devices, is being assessed in an on-going clinical trial (29), but does not yet have any published evidence for its use.

Table 2. Overview of published research

Published Research				
Device	**Condition**	**Study Design**	**Results**	**Ref**
ELENS-DSA	Nocturnal asthmatic wheeze	Measurement of %Wz in 7 asthmatic adults in a sleep laboratory. Compared with expert classification of presence of wheeze in audio recordings. Measurements made in sound-proofed room.	For automated wheeze detection defined as %Wz > 3%, both Se and Sp were reported to be 70%	(11)
Meditron electronic stethoscope	Asthmatic wheeze	Use of wheeze as endpoint for 51 children undergoing AMP bronchial provocation challenge in hospital clinic. Cut-off of 10% of %Wz compared to manual auscultation for wheeze.	%Wz used as gold standard, resulting in 100% Se and 91% Sp for detection of wheeze.	(12)
Pulmotrack	Wheeze	Measurement of %Wz in 11 PICU patients with wheeze (8 asthmatic). Compared to auscultation by clinicians (physician, nurse, therapist) and expert panel classification of audio.	75% sensitivity and 76% specificity for wheeze detection compared to expert panel. More sensitive than clinicians, with similar specificity.	(13)
	Wheeze and crackles in RSV bronchiolitis	Detection of wheeze and crackles in 27 infants attending ED with RSV bronchiolitis. Compared to clinician scoring of presence of wheeze and crackles.	Complete agreement between automated and clinician detection of wheeze and crackles.	(14)
	Wheeze	Measurement of %Wz in 7 healthy children. No setting specified.	Upper limit for %Wz in normal children of 3%.	(15)
	Nocturnal asthmatic wheeze	Measurement of time with %Wz greater than 5% in 9 asthmatic children in a residential clinic. Compared to FEV1, PEF, and weekly symptom score.	Small but significant correlation of length of wheezing time with symptom score and average PEV. No significant correlation with morning FEV_1	(16)
	Nocturnal asthmatic wheeze	Detection of wheeze (%Wz > 5%) in 12 asthmatic children at home. Compared to FEV1, symptom reporting, and GINA scores.	Wheeze correlated with reduced morning FEV1 and increased overnight different in FEV1. No correlation between wheeze and GINA scores or symptom reporting.	(17)
	Voluntary cough	Detection of voluntary cough in 12 healthy adults carrying out various activities in a community setting. Compared to detection by 2 expert listeners.	96% Se, 94% Sp for detection of cough. PPV=0.9	(18)
	Wheeze	Measurement of %Wz and automated wheeze score in 31 children attending walk-in ED with symptomatic wheeze. Compared to doctor's wheeze score and severity of illness score. Measurements made in quiet room.	77% agreement between wheeze scores. Correlation between both automated measures (%Wz and wheeze score) and both doctor's wheeze and severity of illness scores.	(19)
	Nocturnal asthmatic wheeze	Measurement of "nocturnal wheeze index" (NWI, based on overnight %Wz) in 12 newly-diagnosed asthmatic children before and after trial of Montelukast. Compared to FEV1 and PC20 of AMP in bronchial provocation test. NWI also measured in 7 healthy children. No setting specified.	NWI decreased with Montelukast treatment, and correlated with baseline FEV1 and PC20 of AMP. NWI was significantly higher in asthmatic children compared to healthy children.	(29)
VRI	Simulated data	Assessment of accuracy of 8 expert readers at identifying and locating reductions in acoustic intensity on VRI image.	Error rates of 0-12.5%, with 94% inter-rater reliability. Se 95% and Sp 95% for detecting reductions of intensity.	(21)
	Respiratory illness	Observational assessment of VRI images obtained in clinical settings from 13 adults and 1 child with a variety of respiratory illnesses, and 5 healthy controls.	Description of findings for each condition from 3 expert readers. No quantitative analysis.	(22)
	Asthma	Observational assessment of VRI images from 22 asthmatic adults presenting to ED with acute exacerbations, and 15 healthy controls.	Images from untreated asthmatics showed lung asynchrony and peak energy during expiration. Controls and asthmatics after treatment showed greater synchrony and peak energy during inspiration. The degree of asynchrony correlated to PEFR.	(23)
	Pneumonia and pleural effusion	Case-control study of 40 patients with either pneumonia or pleural effusion, and 60 healthy subjects in clinical settings. Two expert readers labelled VRI images as either "normal" or "abnormal".	Without any other clinical information, consensus was 81% between experts, with Se 82.5% and Sp 80%. With clinical information (excluding radiography) on patients, consensus was 94%, Se	(24)

			90% and Sp 88%	
	COPD and asthma	Assessment of synchrony and intensity in VRI images from 76 adults with COPD or asthma before and after bronchodilator therapy in hospital clinic. Flow chart used by trained assessor to identify condition.	Overall accuracy 77%, with 81% Se for asthma, and 74% Se for COPD	(25)
	Wheeze in COPD and asthma	Wheeze detection in 7 patients with asthma or COPD, and 7 healthy controls in pulmonology clinic. Automated detection compared to expert panel.	Using individual sensors to detect wheeze, agreement was 83%, Se 70%, and Sp 92%. Combining data from groups of sensors showed 84% agreement, 83% Se, and 85% Sp.	(26)
LSA-2000	Interstitial pneumonia (IP)	Case-control study of 21 patients with IP, and 10 healthy controls. Various automated measures for identifying IP compared with detection of crackles by manual auscultation. Measurements made in sound-proofed room in hospital clinic.	Although a number of automated measures showed significant differences between the two populations, these were consistently outperformed by identification of crackles using manual auscultation.	(27)
Multichannel STG	Pneumonia	Case-control study of 100 patients with pneumonia, and 100 healthy controls in community hospital. "Acoustic pneumonia score" calculated from frequency of detected rhonchi and crackles.	Acoustic pneumonia score of >6 had Se 78%, Sp 88% and PPV 87%.	(28)
Unpublished abstracts				
Device	Condition	Study Design	Results	Ref
Wheezometer	Asthma with wheeze or stridor	Measurement of %Wz in 118 children. Compared to physician detection of wheeze or stridor. No setting specified.	%Wz > 3% correlated with wheeze or stridor during tidal breathing.	(20 Abstract 2)
	Asthma with paroxysmal vocal cord dysfunction	Single case report of %Wz measurement in a child. Compared to spirometry. No setting specified.	%Wz correlated with exercise-induced reduction in lung function	(20 Abstract 3)
	Asthma	Single case report of community %Wz measurement in a child. Compared to symptom scoring and FEV1.	A threshold non-linear relationship was observed between %Wz and both FEV1 and symptom scores.	(20 Abstract 4)

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