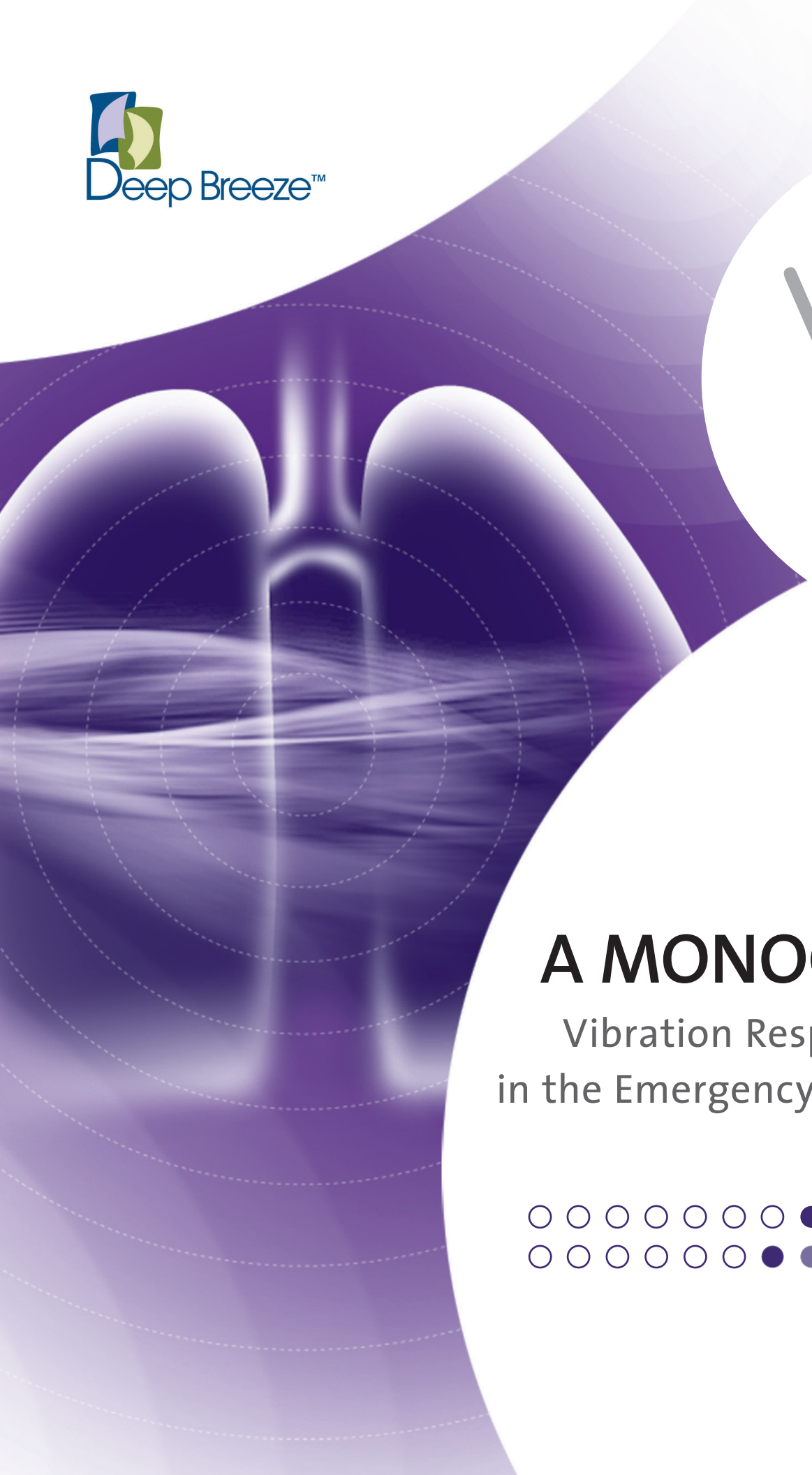
Deep Breeze™

VRI™ XP
Vibration Response Imaging



A MONOGRAPH

Vibration Response Imaging in the Emergency Department

Vibration Response Imaging in the ED

Integration into Clinical Practice

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Objective

The objective of this monograph is to present the practical usage of VRIxp™ in patients being evaluated in the Emergency Department (ED), and to discuss the different applications and the added value perceived and experienced in five leading teaching hospitals throughout the United States.

Clinical pearl

"In patients without OAD and in controls, the ratios of peak inspiratory to peak expiratory vibration energy values and the ratios of inspiratory time to expiratory time were remarkably similar. For the OAD patients, the peak I/E vibration ratio and time ratio were significantly lower... VRI was useful in identifying patients whose dyspnea was due to OAD."

Lung Sound Analysis in the Diagnosis of Obstructive Airway Disease, Zhen Wang et al, Respiration 2009; 77:134-138

Target Audience

This document is designed for emergency physicians, as well as other healthcare professionals, involved in the management of patients who present to the ED with respiratory symptoms.

Rationale

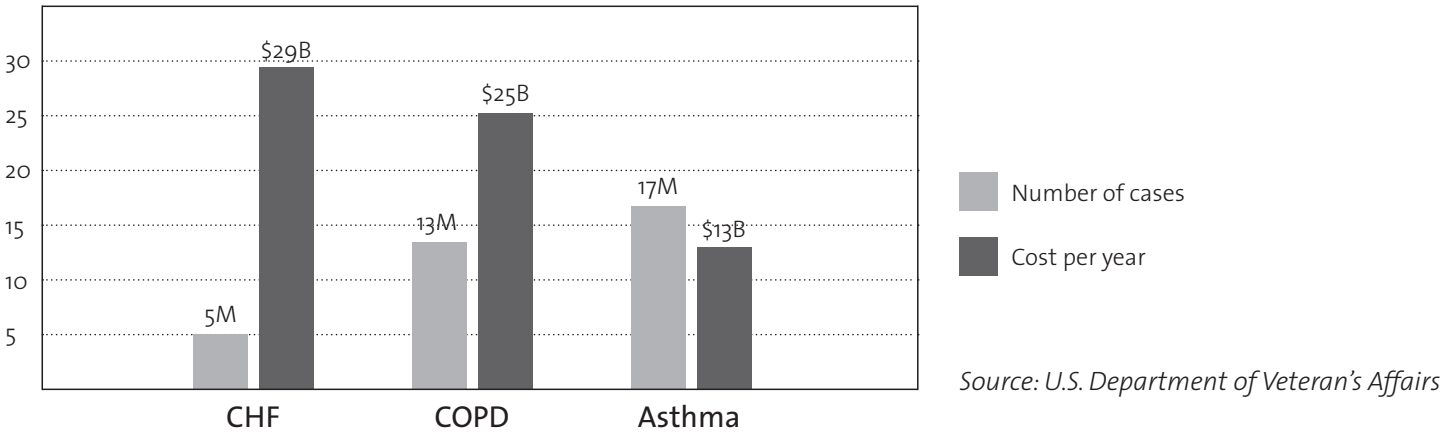
There are about 4800 emergency departments in the U.S. treating 120 million patients per year.[1]

Dyspnea is one of the most common presenting symptoms in the ED, responsible for 5 million ED visits per year in the United States.

Emergency departments see over 1.8 million adult asthma cases per year.[2]

Current methods for determining conclusively the etiology of dyspnea are lacking in the ED. Medical history, physical examination and even chest x-ray (CXR) may not provide a clear diagnosis. BNP, a blood test that measures Brain Natriuretic Peptide levels used to diagnose and grade the severity of heart failure, has been associated with numerous conditions causing false positive and false negative results. As well, a significant share (almost one third) of assays are found to be in the inconclusive range.

U.S. Prevalence and Total Cost



Source: U.S. Department of Veteran's Affairs

The VRIxp has been shown to have added value for aiding in determining cardiac (heart failure) vs. non-cardiac (typically, Chronic Obstructive Pulmonary Disease) sources of dyspnea.

Emergency Departments also see a large volume of adult asthma patients. Existing tools for assessing and monitoring the response to therapy by these patients are mostly subjective and sub-optimal (i.e.; clinical impression, patients' reports, peak flow measurements).

Improvements in monitoring asthmatics in acute exacerbation have the potential to improve accuracy of appropriate disposition and, therefore, improve ED throughput and decrease readmission rates. The ability to perform serial measurements without radiation using the VRIxp plays a significant role in monitoring this population.

Technology Description

Vibration Response Imaging (Deep Breeze,™ Or-Akiva, Israel) is a non-invasive, dynamic, acoustic-based imaging technique that displays the geographic distribution of vibration energy of respiratory sounds throughout the respiratory cycle. [3,4,5]

For this technique, 36 or 42 sensors (two arrays, one array over each lung) are adhered to the patient's back with a computer-controlled low vacuum and are used to record the vibration energy of transmitted sounds. Subjects are instructed to take deep, comfortable breaths during 15 seconds of recording. A dynamic digital image is created, and acoustic information is presented both in a dynamic two-dimensional gray scale image and in a graphical display. Additionally, regional information about lung sound distribution and automatic detection of crackles and wheezes are presented.

For the graphical representation of vibration transmission, vibration energy in decibels can be plotted over time for each lung. This allows both descriptive and mathematical analysis.

Reproducibility of VRI measurements and ranges for a healthy population has been previously described.[5,6] Moreover, the use of VRI in different disease states and during treatment follow-up has been reported,[7] particularly in patients with pleural effusion,[8] pneumonia,[9] pneumothorax,[10] lung transplant,[11] interventional bronchoscopy,[12,13] foreign body aspiration,[14,15] obstructive lung diseases[16,17,18,19,] and asymmetrical lung disease.[20]

User Tips:

1. Patient compliance and satisfaction are high when they get to see an image of their lungs, and hear their own wheezes.
2. When recording a patient with a fragile, dry or hairy back, it helps to moisturize the skin with a wet wipe.
3. Patients have stated that sensor adherence to their back feels like a massage.

- The VRIxp is a mobile, easy to use, non-invasive, and radiation-free imaging device.
- VRIxp is FDA-approved for monitoring and aid in diagnosis.
- VRIxp offers regional lung assessment not otherwise available at the bedside.
- VRIxp helps follow clinical changes through serial measurements.

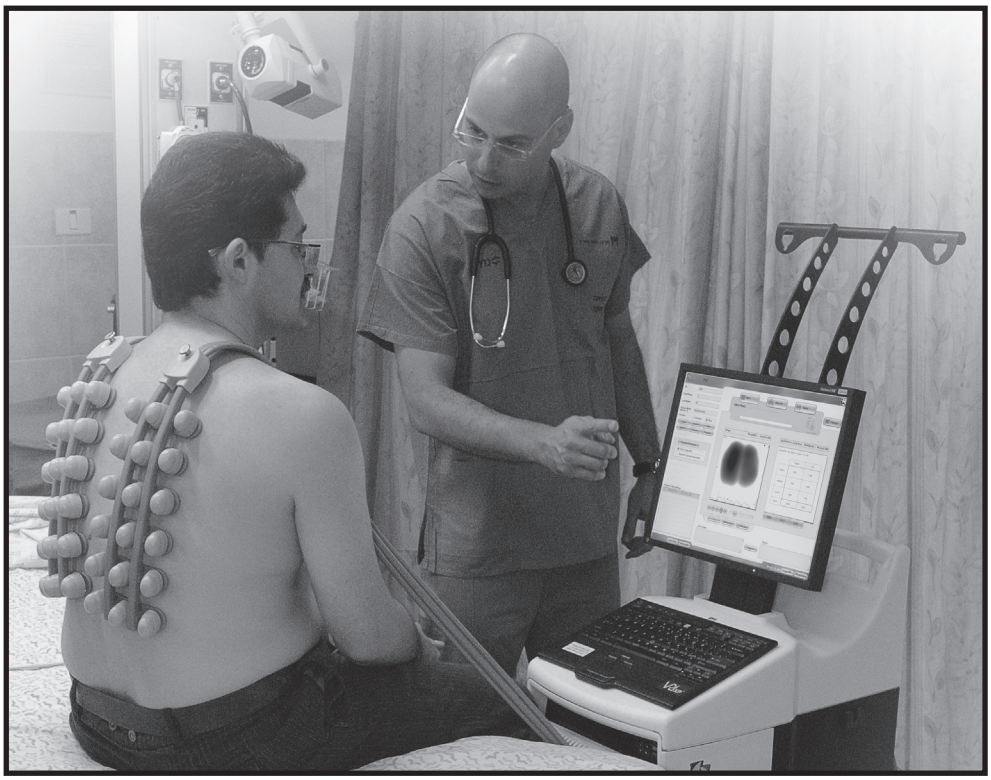
" We were surprised to find out that ambient noise in the ED did not distort the image."

Benjamin Wiederhold, MD

Department of Emergency Medicine

Alameda County Medical Center

Methodology



Between October 2008 and August 2010, over 300 patients who presented to the ED with various respiratory symptoms were studied.

One of the main applications studied was differentiating between cardiac and pulmonary sources for acute dyspnea in the ED.

For this objective, patients who presented to the ED with dyspnea or pedal edema, and had either a history of CHF or COPD, and/or had a BNP test ordered, were studied with VRI. Recordings were then compared to BNP and other diagnostic studies, and the final diagnosis made either at the ED or after hospitalization (if patients were admitted).

A second study enrolled patients with acute asthma exacerbations. Recent data suggest that airway inflammation and obstruction in acute asthma is inhomogeneous.[17] To test this hypothesis, we compared respiratory patterns from VRI recordings in asthmatic patients arriving in the ED for treatment with those of non-smoking patients with no known cardio-respiratory disease ("non-asthmatic"). Data derived from the VRI recordings was compared to that from existing tools, such as peak flow measurements, that were utilized in patients being evaluated in the ED.

Findings

Using VRI Lung Sound Measurements to Differentiate between COPD and CHF in the Emergency Department

30 patients (18 CHF: 13 males, 5 females; age 67.2±15.6 years and 12 COPD: 7 females, 5 males; age 68.1±11.6 years) underwent lung sound recordings with the VRI device. Quantitative data for lung sound distribution was evaluated for both groups: (a) intensity ratios in the upper vs. lower lung regions; (b) number of respiratory cycles per 15-second recording; (c) duration of exhalation phase; (d) amplitudes of inspiration/exhalation waveforms, and; (e) synchrony between left and right inspiration/expiration peaks in respiratory waveforms.

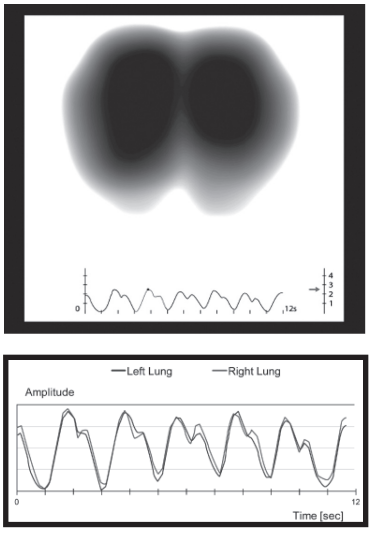
Clinical pearl

"With clinical improvement of acute CHF exacerbations, there was more homogenous distribution of lung vibration energy, as demonstrated by the increased geographical area of the vibration energy image."

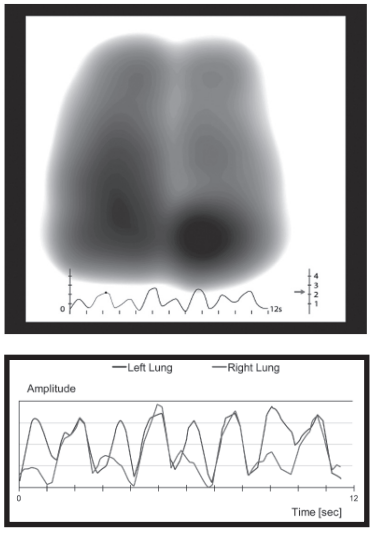
Respiratory sound energy and its distribution patterns following clinical improvement of congestive heart failure: a pilot study by Zhen Wang et al, BMC Emerg Med. 2010 Jan 15;10(1):1.

The accuracy of the VRI data to differentiate between the two groups was assessed by comparison of VRI findings to final physician diagnosis in the ED (based on CXR, BNP levels, medical history, etc.).

By combining the quantitative data parameters, overall VRI accuracy was 80% (75% for COPD, 83% for CHF, per final ED/inpatient diagnosis) for correctly differentiating patients with a confirmed diagnosis of COPD or CHF. These findings show VRI to be superior to published data for clinical judgment (47-73%), additionally helpful to CXR and other combined measures (41.7-85.4%), and comparable to the performance of BNP in the Breathing Not Properly trial.



Above: 86 year old female with CHF. VRI image shows reduced breath sounds in lower regions; and amplitude over time curve shows well synchronized right and left lungs.

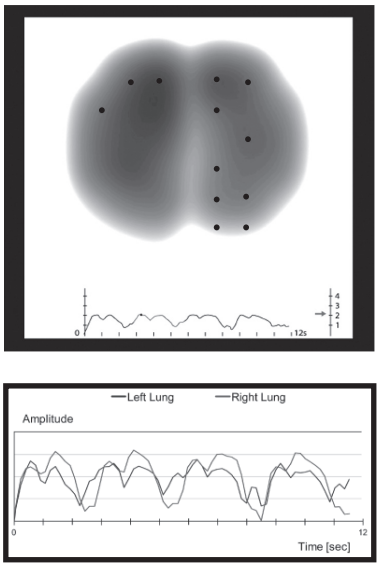


Above: 43 year old female with COPD. VRI image shows abnormal distribution of breath sounds in both lungs, with increased energy in left lower lung; amplitude over time curve presents asynchrony in peaks of inspiration and expiration, typical in obstructive airway diseases.

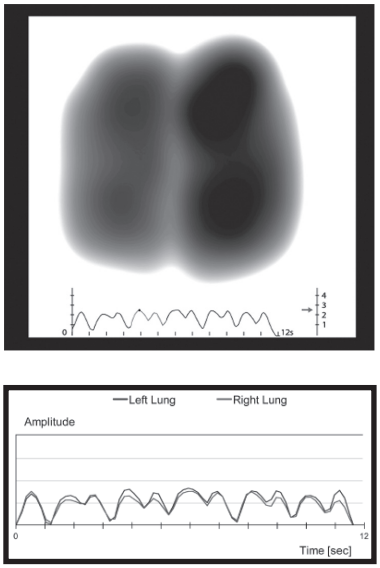
Comparison of VRI Patterns in Acute Asthmatic Patients and Non-asthmatic Patients in the ED

27 asthmatic patients (15 males; age 46±16years) and 22 non-asthmatic subjects (12 males; age 41±14years) underwent imaging with the VRI device. Synchrony of inspiratory and expiratory peaks was evaluated for left and right lungs separately. The presence of abnormal breath sounds was also identified using the device algorithm.

A significantly higher level of inspiratory and expiratory asynchrony was noted between right and left lungs in the asthmatic compared to non-asthmatic patients (7.5±6.6msec vs. 2.4±2.8 msec; 95% CI: 4.9-10 msec vs. 1.2-3.7msec; (p=0.002)). The VRI device algorithm detected abnormal breath sounds in 63% of the asthmatic patients and 14% of non-asthmatic subjects (p<0.05).



Above: 44 year old female with asthma. VRI image shows bilateral wheezes during mid-inspiration (dots); amplitude over time curve demonstrates asynchrony between right and left waveforms.



Above: 54 year old healthy male. VRI image with normal lung sound distribution; amplitude over time curve demonstrate perfect synchrony between right and left waveforms.

Conclusions

- Vibration response imaging is associated with dynamic clinical status and provides an additional bedside, prompt, and radiation-free imaging tool to differentiate between exacerbations of COPD and CHF in the ED setting.
- Early differentiation between cardiac and non-cardiac causes of dyspnea in patients arriving at the ED is essential for proper patient management. Triaging patients quickly and accurately has a beneficial impact upon outcome, disposition, stratification, and length of stay in the ED and duration of hospital admission. It may also lead to more cost effective treatment and outcomes.
- An additional and significant benefit in the use of VRI is the reduction of unnecessary or inappropriate treatments. By enabling earlier diagnosis, the VRI is expected to reduce administration of combined (and perhaps indiscriminate) treatment for both COPD and CHF, which commonly occurs in contemporary practice.
- Respiratory patterns from VRI recordings are significantly different in acutely obstructed asthmatics and in non-asthmatic subjects. VRI provides a quantitative objective measure to assist the emergency physician in deciding whether to discharge or hospitalize an asthma patient. Monitoring acoustic parameters (such as wheezes and reduced vibration energy in lower regions) before and after treatment may help physicians determine if additional therapy is needed prior to discharge, which could avoid subsequent ED visits and/or hospital admissions.

"The VRIxp is a unique, non-invasive tool that enables physicians to triage and manage patients rapidly and accurately, and potentially decrease length of stay in the ED, stratify patients, and improve patient outcomes."

Rita Cydulka, MD

Department of Emergency Medicine

MetroHealth Medical Center

"Establishing an accurate diagnosis early on has a significant clinical and financial impact. The sooner the patient receives the right treatment, the better the outcomes potentially get."

Charles V. Pollack, Jr., MD

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References

1. http://www.gao.gov/new.items/d09347.pdf
2. http://www.cdc.gov/Features/dsAsthma/
3. Dellinger RP, Parrillo JE, Kushnir A, et al. Dynamic visualization of lung sounds with a vibration response device: A case series. Respiration 2008:75(1):60-72,
4. Mehta AC, Gat M, Mann S, Madison JM. Accuracy of gray-scale coding in lung sound mapping. Comput Med Imaging Graph. 2010 Feb 18.
5. Maher TM, Gat M, Allen D, Devaraj A, Wells AU, Geddes DM. Reproducibility of dynamically represented acoustic lung images from healthy individuals. Thorax. 2008 Jun;63(6):542-8
6. Yigla M, Gat M, Meyer JJ, Friedman PJ, Maher TM, Madison JM. Vibration response imaging technology in healthy subjects. AJR Am J Roentgenol. 2008 Sep;191(3):845-52.
7. Dellinger PR, Parrillo JE, Kushnir A, Rossi M, Kushnir I: Dynamic visualization of lung sounds with a vibration response device: a case series. Respiration 2008; 75:60-72.
8. Anantham D, Herth F, Majid A, Michaud G, Ernst A: Vibration Response Imaging in the diagnostic evaluation of pleural effusions: a feasibility study. Respiration 2009; 77:166-72.
9. Mor R, Kushnir I, Meyer JJ, Ekstein J, Ben-Dov I: Breath sound distribution images of patients with pneumonia and pleural effusion. Respir Care 2007; 52:1753-1760.
10. Blanco M, Mor R, Fraticelli A, Breen DP, Dutau H. Breath Sound Distribution Images of Patients with Pneumothorax and of Healthy Subjects: Diagnostic yield of vibration response imaging technology. Respiration. 2009;77(2):173-8.
11. Kramer MR, Raviv Y, Hardoff R, Shteinmatz A, Amital A, Shitrit D: Regional breath sound distribution analysis in single-lung transplant recipients. J Heart Lung Transplant 2007; 26:1149-1154.
12. Becker HD, Slawik M, Miyazawa T, Gat M: Vibration Response Imaging (VRI) as a New Tool for Outcome Assessment of Interventional Bronchoscopy: A Prospective Pilot Study. Respiration. 2009;77(2):179-94.
13. Becker HD: Vibration Response Imaging - Finally a Real Stethoscope. Respiration 2009; 77:236-9.
14. Bentur L, Livnat G, Husein D, Pollack S, Rotschild M. Dynamic visualization of breath sound distribution in suspected foreign body aspiration: A pediatric case series. Journal of Bronchology 2007; 14:156-161.
15. Kramer MR: Dynamic Visualization of Breath Sound Distribution: Can We See the Voices? Journal of Bronchology 2007; 14:142-143.
16. Wang Z, Jean S, Bartter T: Lung Sound Analysis in the Diagnosis of Obstructive Airway Disease. Respiration 2009; 77:134-8.
17. Wang Z, Bartter T, Baumman BM, Abouzgheib W, Chansky ME, Jean S: Asynchrony between left and right lungs in acute asthma. J Asthma 2008; 45:575-8.
18. Guntupalli KK, Alapat PM, Bandi VD, Kushnir I. Validation of Automatic Wheeze Detection in Patients with Obstructed Airways and in Healthy Subjects. J Asthma 2008;45(10):923-30.
19. Guntupalli KK, Reddy RM, Loutfi RH, Alapat PM, Bandi VD, Hanania NA. Evaluation of Obstructive Lung Disease with Vibration Response Imaging. J Asthma 2008; 45:903-7.
20. Jean S, Cinel I, Tay C, Parrillo JE, Dellinger RP. Assessment of Asymmetric Lung Disease in Intensive Care Unit Patients Using Vibration Response Imaging. Anesth. Analg. 2008; 107:1243-1247.

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