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Remote dielectric sensing for detecting pulmonary edema in the emergency department

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ABSTRACT

Background: Dyspnea is a common Emergency Department (ED) complaint of which acute pulmonary edema (APE) is a potentially life-threatening etiology. Remote Dielectric Sensing (ReDS™) is a novel, non-invasive, radar based, rapid, point of care vest testing system used to objectively quantify lung fluid content and may be useful in the early diagnosis of APE.

Objective: To determine the accuracy of ReDS to detect pathologic lung fluid in ED undifferentiated dyspneic patients.

Methods: We performed a prospective convenience sample observation pilot study enrolling adult ED patients with a chief complaint of "shortness of breath." After informed consent, patients were fitted with the ReDS vest and a reading, blinded to the care team, was recorded. A gold standard diagnosis of pulmonary edema, determined by 2 physicians performing a chart review and blinded to ReDs data, was compared to the ReDS reading.

Results: Overall, 123 patients were included; 59% ($n = 73$) were male, mean (SD) age 57.2 (± 12) years, 46.3% ($n = 57$) Hispanic, 34.1%($n = 42$) African American, 13.0% ($n = 16$) Caucasian and 5.7% ($n = 7$) Asian. The gold standard diagnosis showed pulmonary edema in 38 (30.9%) patients, of which 30 were detected by ReDS. At an optimal cutoff (≥ 37%), ReDS had a Sn of 79.5% (CI 63.5% - 90.5%), Sp of 72.6% (CI 61.8% - 81.8%), a PPV of 57.4% and a NPV of 88.4%.

Conclusions: ReDS is moderately sensitive and specific with an accuracy of 74.8% for pulmonary edema.

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1. Introduction

Dyspnea is a common complaint in the Emergency Department, resulting in over 3.9 million visits (2.4%) of the more than 139 million ED visits in 2017 [1]. The differential diagnosis of dyspnea is broad and ranges from an exacerbation of chronic illness to a new acute disorder requiring emergent interventions [2,3]. Patients presenting to the ED complaining of dyspnea are usually evaluated with a combination of history and physical examination, chest radiographs, biomarkers and a multitude of ancillary studies. It is a process that is frequently time intensive and financially burdensome. Accurate early identification of patients suffering from pulmonary edema may shorten this investigative process and allow rapid diagnosis and intervention.

Remote Dielectric Sensing (ReDS™) is a novel point of care testing device used to objectively quantify lung fluid content. It is an FDA-cleared, wearable radar system that transmits low-power electromagnetic signals through the thorax and reports total lung fluid via a bedside console. The transmitter and receiver are placed in a re-usable vest (Fig. 1) and can be worn over the clothing or hospital gown. The system provides a reading within 90 s, representing the percent of lung tissue occupied by fluid. Normal physiologic lung fluid ranges between 20% and 35% [4].

The accuracy of ReDS in detecting lung fluid has been established using serial chest computed tomography in pig models and heart failure patients, where the correlation between ReDS and CT was 0.90 [5]. More recently, ReDS readings were compared with pulmonary capillary wedge pressure (PCWP) measurements, and detected a PCWP≥18 mmHg with a sensitivity of 90.7%, and specificity of 77.1% [6]. Because of its ability to detect pathologic lung fluid, and its predictive capability of estimating elevated PCWP, ReDS has been used as an adjunct test in HF patients in various clinical settings. This includes both home use and skilled nursing facilities, as well as in the acute care and inpatient hospital wards. [7,8]

However, ReDS has not been evaluated for the detection of pulmonary edema in the ED setting. We hypothesized that ReDS can detect

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Fig. 1. ReDS vest positioned to obtain reading.

pathologic lung fluid rapidly and accurately in the ED setting. Our purpose was to determine the accuracy of ReDS to identify acute pulmonary edema in undifferentiated dyspneic ED patients.

2. Methods

This is a prospective convenience sample observational study, performed in a US inner-city academic emergency department in a large metropolitan area. The study was approved by the local institutional review board. Patients were enrolled from July 2017 – March 2020. Inclusion criteria were age ≥ 21 years, presenting with a chief complaint of "shortness of breath", and able to provide informed consent. Patients were excluded if they had sustained chest trauma, if the vest did not fit or caused discomfort, had anatomic abnormalities (e.g. dextrocardia, port-a-cath), had an implanted electronic devices (e.g. pacemaker), or were too ill to participate. Patients were also excluded if pregnant, a prisoner or ward of the state, had a BMI <22 or > 36, or were < 5′1″ or > 6′4″ in height (because of the physical limitations of the vest).

Patients were screened using an Epic (Verona, Wisconsin) track board and enrolled after obtaining informed consent. The ReDS vest was fitted as shown in Fig. 1 and its reading recorded. Demographic and clinical data were collected by study staff. A differential diagnosis from the treating provider was recorded after history and physical exam were completed, but before laboratory and radiographic date were available. Patients were diagnosed and treated per standard of care, and treating physicians were blinded to ReDS data.

To determine gold standard diagnosis of pulmonary edema (i.e., volume overload), the electronic medical record (EMR) was reviewed by two board certified emergency physicians 30 days after

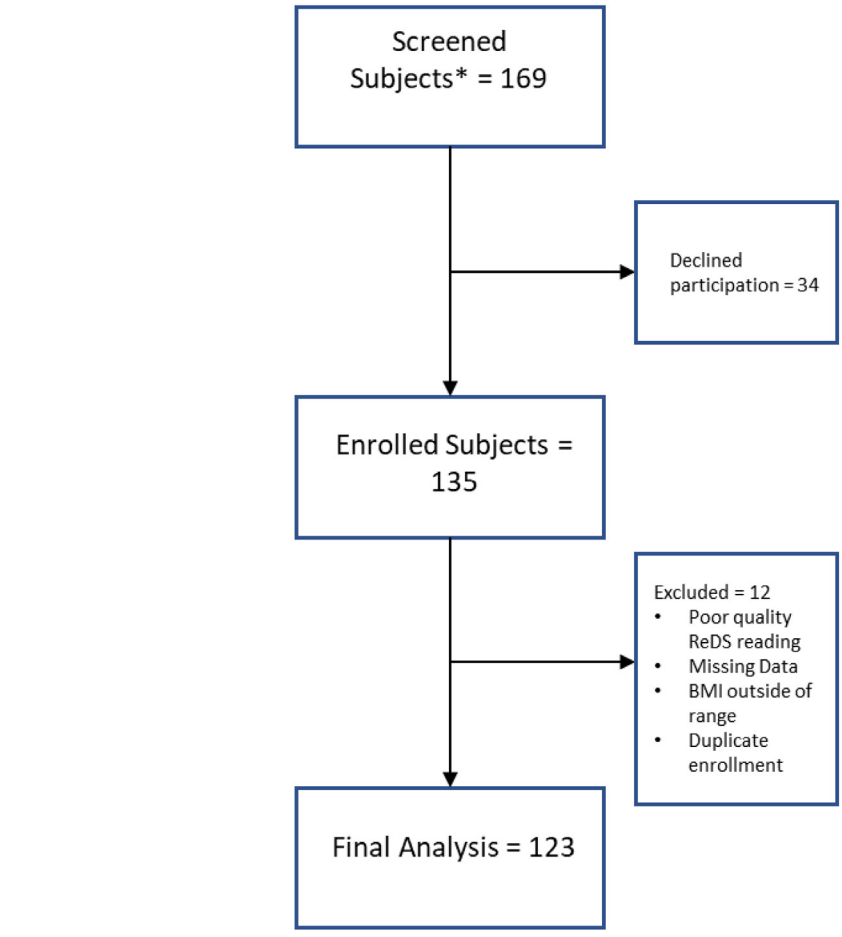

Fig. 2. Patient enrollment flow chart.

enrollment. Since no single laboratory or imaging test is 100% accurate in detecting pulmonary edema, the diagnosis was made after reviewing all available history and physical examination findings, laboratory data, imaging, echocardiograms and consultation notes. Adjudicating physicians were blinded to the ReDS measurements..Diagnostic categories for the etiology of the patient's dyspnea included asthma or COPD, pneumonia, heart failure, pulmonary embolism, pulmonary fibrosis and "other." In cases of adjudicator disagreement, a third board certified emergency physician served as the tie final diagnosis breaker. Interrater reliability was calculated for the gold standard diagnosis of pulmonary edema.

Statistical analyses were done using Microsoft Excel (Microsoft Corporation. Redmond, Washington) and Stata v17.0 (StataCorp. College Station, TX), with sensitivity, specificity, positive and negative predictive values for the detection of pulmonary edema were calculated. A test characteristic of ReDS≥35%, as recommended by the manufacturer, was used to define pulmonary edema. Additionally, a receiver operator curve was constructed to determine the optimal cutoff for sensitivity and specificity. No missing data were identified for reference or index standard.

As this was the first study in the undifferentiated dyspneic patient, no reliable baseline data was available regarding correlation of ReDS measurements to final diagnosis of pulmonary edema (volume overload) and hence no power analysis was performed. Data was obtained with an initial plan for enrollment of up to 150 patients to allow appropriate power calculations for a follow-up multicenter study.

3. Results

Overall, 135 patients were consented and enrolled. Of these, 12 were excluded: poor ReDs signal 4 (2.9%), missing data 5(3.7%), extreme BMI 2(1.5%), and duplicate enrollment 1 (0.7%). Of the 123 included in the final analysis (Fig. 2), 59% ($n = 73$) were male, 46.3% ($n = 57$) Hispanic,

Table 1
Demographics and baseline characteristics

Variable	Results
Demographics	
n	123
Age (mean)	57.2 (±12) years
Males	59% ($n = 73$)
Females	41% ($n = 50$)
Ethnicity:	
• African American	• 34.1%(n = 42)
• Asian	• 5.7% (n = 7)
• Hispanic	• 46.3% (n = 57)
• White	• 13.0% (n = 16)
• Middle Eastern	• 0.8% ($n = 1$)
Baseline clinical characteristics	
Vital Signs	
Systolic BP (SD)	136 (±25) mmHg
Diastolic BP (SD)	82 (±15) mmHg
Oxygen saturation (SD)	98.3 (±1.8)%
Oxygen support	
Yes (%)	13 (10.6%)
No (%)	110 (89.4%)
Respiratory Distress	
No distress (%)	43 (34.9)
Mild (%)	58 (47.2)
Moderate (%)	16 (13)
Severe (%)	6 (4.9)
Comorbid Conditions	
• CHF	• 35 (28.5%)
• CKD	• 12 (9.8%)
• Cirrhosis	• 6 (4.9%)
• COPD/Asthma	• 23 (18.7%)
• DM	• 31 (25.2%)
• HTN	• 59 (48.0%)

CHF- congestive heart failure; CKD – chronic kidney disease; COPD – chronic obstructive lung disease; DM – diabetes mellitus; HTN – hypertension.

Table 2
Differential and final diagnoses as per treating provider

Differential Diagnosis[a]	
COPD/Asthma	12 (9.8%)
Pneumonia	11 (8.9%)
Heart Failure	19 (15.4%)
Pulmonary Embolism	8 (6.5%)
Interstitial Lung Disease	1 (0.8%)
ACS	18 (14.6%)
Cirrhosis	3 (2.4%)
Other	51 (41.5%)
Final Diagnosis	
COPD/Asthma	9 (7.3%)
Pneumonia	1 (0.8%)
Heart Failure	19 (15.4%)
Pulmonary Embolism	1 (0.8%)
Interstitial Lung Disease	0
ACS	36 (29.3%)
Cirrhosis	6 (4.9%)
Other	51 (41.5%)

[a] First diagnosis in the differential is listed here; COPD – chronic obstructive lung disease; ACS – acute coronary syndrome;

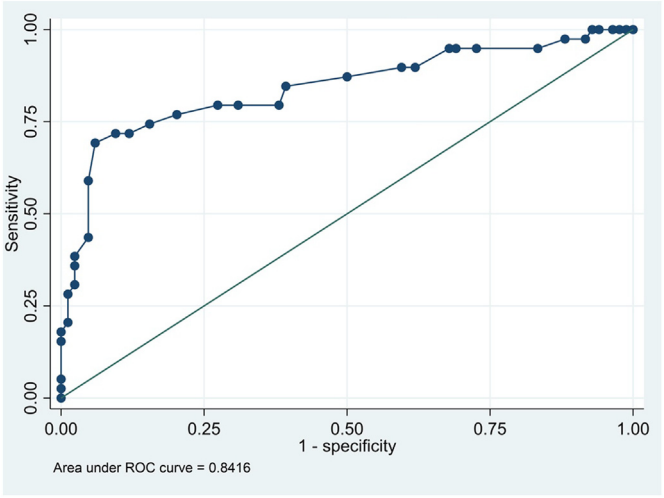

Fig. 3. ROC of ReDS detecting pulmonary edema.

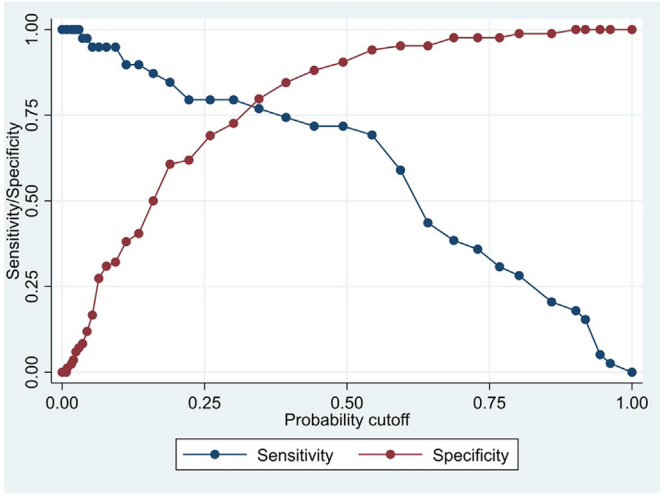

Fig. 4. Comparison of sensitivity and specificity of ReDS cutoffs.

Table 3
ReDS test characteristics for detection of pulmonary edema at various cutoff values

Cutoff point	SN	SP	PPV	NPV	+LR	-LR	Accuracy
ReDS ≥35%	79.49% (63.53%–90%)	61.79% (61.79%–81.78%	49.2	86.76	2.08	0.33	67.48%
ReDS ≥37%	79.49% (63.53%–90%)	72.6% (61.8%–81.78%	57.4	88.41	2.9	0.3	74.8%
ReDS ≥41%	71.74% (55.12–84.94%)	90.48% (82.04–95.79%)	77.77	87.36	7.53	0.31	84.55%

34.1%($n = 42$) African American, 13.0% ($n = 16$) Caucasian and 5.7% (n = 7) Asian. The mean (SD) age of the cohort was 57.2(±12) years. Patient reported respiratory distress, categorized as mild, moderate, and severe, was noted in 47.2% ($n = 58$), 13% (n = 16) and 4.9% ($n = 6$), respectively, with 10.6% requiring supplemental oxygen at presentation. The most common comorbid condition was hypertension, present in 48%. Demographics and baseline clinical characteristics are shown in Table 1.

Differential diagnoses at initial evaluation (prior to diagnostic testing) and final diagnoses of treating physicians are presented in Table 2. Heart failure, as the cause of dyspnea, was diagnosed in 19 (15.4%) at the initial evaluation and at discharge by the treatment team.

Dyspnea was adjudicated to be secondary to pulmonary edema in 38 (30.9%) patients with an adjudicator interrater reliability of 0.84. Using the manufacturer recommended cutoff of 35%, ReDS detected pulmonary edema in 30 out of 38 patients with a Sn of 79.5% (CI 63.5% - 90.5%), Sp of 61.8% (CI 61.8% - 81.8%), a PPV of 49.2% and a NPV of 86.8%.

A receiver operator curve (ROC) to assess test performance along a range of cutoff values had an AUC of 0.84 (CI 0.76–0.93; $p = 0.00$) (Fig. 3). Using the ROC a ReDS reading of 37% was determined to be optimal in detecting pathologic lung fluid, and provided a Sn of 79.5% (CI 63.5% - 90.5%), Sp of 72.6% (CI 61.8% - 81.8%), a PPV of 57.4% and a NPV of 88.4%. Fig. 4 shows the Sn and Sp interaction of the ReDS device.

A cutoff of 41% was determined to optimize for specificity, resulting in an accuracy of 84.5% for pulmonary edema with sensitivity of 71.7% (CI 55.1% - 84.9%) and specificity of 90.5% (CI 82.0% - 95.8%), PPV of 77.8% and a NPV of 87.4%. Table 3 shows the performance of ReDS at various cut-off points. No adverse events were attributed to be a result of using the ReDS device during the study.

4. Discussion

This is the first study evaluating ReDS for detection of pulmonary edema in undifferentiated ED dyspneic patients. We found that ReDS, with an optimized cutoff of 37%, is moderately sensitive and specific for pulmonary edema, with an accuracy of 74.8% and NPV 88.4%. When optimized for specificity, ReDS achieved a specificity of 90.5% and an accuracy of 84.6%.

The implications of an easy-to-use point-of-care pulmonary edema detector are myriad. First, ReDS could determine pulmonary edema in 90 s, and thus shorten the total time to intervention in some patients (e.g. pulmonary edema) as well as reduce the ED length-of-stay. The ability to shorten ED length stay is critical, and several studies have demonstrated a strong relationship between ED length-of-stay and mortality [9-11]. Second, the use of ReDs could minimize the number of adjunct radiographic and laboratory tests and decrease per patient cost. Third, the early use of the ReDs device could potentially shorten time to treatment in heart failure patients by providing an earlier diagnosis. Time to intervention in acute heart failure has been shown to be associated with decreased mortality and morbidity [12-14]. Interventions as short as 60 min earlier may provide improved mortality rates in patients presenting with acute heart failure [15-17]. Fourth, its easy-to-use design and user-friendly interface make it amenable for use by nurses and physicians alike and hence can assist in decision making from time of triage to discharge from ED. However, the accuracy needs to be optimized and more studies are needed to evaluate the utility of ReDS to assess its impact on diagnosis, time to therapy, resource utilization and patient throughput. Future studies should also include head-to-head comparative evaluations of other point-of-care devices used to detect pulmonary edema.

Our study is a real-world evaluation of ReDS in dyspneic patients in the ED and is unique in its application. Prior studies focused on correlation of ReDS reading with CT detection of lung fluid [4,5] or monitored clinical improvement in patients with Covid-19 [18]. The bulk of ReDS studies evaluated its utility in managing heart failure where repeated measures were performed and the delta ReDs reading was used to infer clinical status [7,19]. Our study enrolled patients with dyspnea of unknown etiology and used a single reading to determine lung fluid status. Moreover, we correlated ReDS reading with a clinical diagnosis determined by blinded board-certified physicians after reviewing all available medical data, including biomarkers (e.g. BNP), radiography, echocardiography, and consultation and discharge notes. This method of diagnosing pulmonary edema was more rigorous than any one laboratory or imaging study. Thus, our study provides the strongest evidence supporting ReDS as a detector of pulmonary edema.

The study has several limitations. Most notably this was a single center pilot study with a relatively small sample size and a predominance of Hispanic patients, and thus may not be generalizable to the broader population. Second, enrollment was on a convenience basis and patients with severe respiratory distress, needing ventilatory support were excluded. It is plausible that the inclusion of critically ill patients would affect the performance of ReDS. Third, the physical limitations of the device (requires alignment of transmitter and receiver) excluded the extremes in BMI and height, which may have influenced the test performance. The next generation device, ReDS Pro, has attempted to address the BMI limitation but needs testing in a similar trial. A larger, multi-center study would make these results more generalizable.

5. Conclusion

In this pilot study, ReDS is moderately sensitive and specific for pulmonary edema in the undifferentiated ED dyspneic patient. Our results are encouraging and support the need for larger, multicenter studies to establish the utility of ReDS in the diagnosis and treatment of dyspnea in the ED.

Declaration of Competing Interest

ReDS devices used in this study were borrowed from Sensible Medical, makers of ReDS.

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