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Efficacy of remote dielectric sensing in detecting pulmonary congestion in patients without clinical sign and symptoms for heart failure management

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Abstract

Introduction: Pulmonary congestion is an underlying cause of heart failure progression and exacerbations, leading to hospitalization. Monitoring of lung fluid levels is essential for enhancing prognosis, minimizing hospitalizations, guiding optimal treatment, and improving overall quality of life. Recently, Remote Dielectric Sensing (ReDS) technology has emerged as a noteworthy advancement. This study explored the effectiveness of ReDS in detecting pulmonary congestion in asymptomatic patients for the management of heart failure.

Methods: This study was a single-centric, observational, and retrospective cohort conducted at Department of Cardiology, PBM Hospital, Bikaner, Rajasthan, India. Those patients who visited the cardiology department between July 2023 to August 2023, were enrolled in the study. Data including age, gender, clinical signs and symptoms were systematically collected. Clinical signs and symptoms were assessed based on standard clinical evaluation including dyspnea, fatigue, peripheral edema, jugular venous pressure, leg swelling, low pulse pressure, and third heart sound. A non-invasive ReDS technology was used to measure lung fluid levels and further patients were categorized as non-congested with ReDS score of $\leq 35\%$ and congested with $>35\%$ score. Based on ReDS score, correlation between age and clinical signs and symptoms of congested patients was also assessed.

Results: A total of 300 patients with a mean age of 58.03 ± 13.22 years were enrolled in the study. Of 300 patients, 46.3% exhibited no clinical signs and symptoms. ReDS detected congestion in 180 patients, including 20 patients without clinical signs and symptoms. The mean ReDS score of patients with signs and symptoms was significantly higher as compared to patients without signs and symptoms (42.07 vs. 32.17; $p < 0.0001$). Among patients without signs and symptoms, ReDS identified congestion in 11 patients who were above 60 years of age. Lastly, correlation analysis revealed no significant correlation between age and presence/absence of clinical signs and symptoms in congested patients detected using ReDS device.

Conclusion: Our data suggest that ReDS has the efficacy to identify pulmonary congestion in patients without any clinical signs and symptoms, particularly among elderly patients. Thus, ReDS may be considered as a valuable addition to routine clinical practice for heart failure management.

Keywords: Pulmonary congestion, heart failure management, ReDS, lung fluid

Introduction

Heart failure (HF) continues to be a significant global health concern, affecting an estimated 64.3 million individuals worldwide [1]. According to World Health Organization (WHO), the prevalence of HF tends to increase every year and accounts for more than 10 million hospitalizations. Of these, approximately half of individuals were re-hospitalized within 6 months due to HF exacerbation [2]. In India, the prevalence of HF ranges between 1.3 to 4.6 million individuals [3]. This underlines the need for effective management strategies for HF in diverse healthcare settings for improving prognosis, reducing hospitalization rates, and enhancing the quality of life [4-5].

Pulmonary congestion is the primary cause of acute HF decompensation [3]. Clinical studies in the literature reported that approximately 90% of HF patients hospitalize due to pulmonary congestion [6-8]. The Cardiological Society of India (CSI) position statement on HF management stated "warm" (normal perfusion) and "wet" (presence of congestion) types as

the most commonly admitted cases for acute HF [9]. The Trivandrum Heart Failure registry data reported 94% of admitted HF were treated with diuretics to reduce congestion [7]. Thus, monitoring of pulmonary congestion in HF patients becomes paramount. The American College of Cardiology Foundation/American Heart Association (ACCF/AHA), European Society of Cardiology (ESC), and Indian guidelines provide a comprehensive framework for HF management, highlighting the importance of congestion monitoring in preventing exacerbations and reducing hospital readmissions [9-12]. However, the challenges of congestion monitoring lie with insufficient accuracy of clinical assessment methods, modest accuracy of proposed clinical congestion scores, and early diagnosis before symptoms worsen.

The initial step to detect congestion involves examination of signs and symptoms such as jugular vein distention, pulmonary crackles, hepatomegaly, dyspnea at rest, the presence of peripheral edema, and additional cardiac sounds. However, the specificity and sensitivity of the signs and symptoms of pulmonary congestion are often limited and missed during clinical examination [13]. Conventional approaches such as chest radiography and natriuretic peptides measurement demand specialized skills from medical professionals, access to laboratory facilities, and interpretation methods that are not readily available within the confines of patients' homes. Therefore, simple, accurate and timely monitoring tools are required for the identification of pulmonary congestion, implementation of interventions, and prevention of HF exacerbation [14].

In this regard, (ReDS) has been introduced recently. The Remote Dielectric Sensing (ReDS) technology is a non-invasive approach that utilizes low-power electromagnetic signals to quantify thoracic fluid content for the detection of pulmonary congestion [15]. It is approved by Food and Drug Administration (FDA) and Conformance Europeenne (CE) for lung fluid monitoring [16]. ReDS provides real-time data on fluid status, distinguishes minor changes, measures fluid levels during natural breathing, and assesses both intra-vascular and tissue congestion [17]. Clinical studies further established a robust correlation between ReDS measurements and fluid status during diuresis throughout the hospital admission of patients with acute decompensated HF, validating the accuracy of ReDS compared to CCT [17-18]. Other studies also reported that the positive ReDS reading of 37% exhibit high sensitivity of 89%, specificity of 83%, positive predictive value of 74%, and negative predictive value of 93% [16, 19]. However, ReDS data in asymptomatic patients with HF are limited.

To fill this critical gap, the present study aimed to assess the efficacy of ReDS in assessing pulmonary congestion in HF patients without clinical signs and symptoms. By evaluating this, we seek to contribute valuable insights into the potential of ReDS technology as a proactive approach for congestion monitoring, reducing the burden of hospital readmissions, and revolutionizing HF management.

Materials and methods

Study Design

The study employed single-centric, observational, and retrospective cohort research design. The study adhered and followed the regulations and ethical principles stated in the Declaration of Helsinki. Ethical approval for this study was obtained from the Institutional Ethics Committee (IEC).

Selection of Patients

Patients who visited the Department of Cardiology at PBM Hospital, Bikaner, India, during the period from July 2023 to August 2023, were enrolled in the study. The study was conducted as a registry, encompassing a diverse cohort of patients with heart failure. The inclusion criteria comprised those individuals, aged >18 years, who visited the Cardiology department of the hospital and diagnosed with HF.

Data Collection

Baseline characteristics of the enrolled patients, including sex, age, specific diagnosis of heart failure, clinical signs and symptoms, and ReDS readings, were systematically collected. Clinical signs and symptoms were assessed based on standard clinical evaluation. Lung fluid was measured using a qualitative non-invasive method using ReDS technology.

ReDS utility and Cut-off Values

ReDS comprises an inbuilt radar system that transmits electromagnetic radiation via two sensors placed on the right side of the thoracic cavity. The signal processor assesses the electromagnetic signals passing through the thorax to calculate average dielectric coefficient of the lung tissue between the electrodes, reflecting the percentage of lung tissue fluid content. The results are displayed within 90 seconds. The comprehensive spectrum of lung fluid volume extends from 15% to 60%. The standard or normal lung fluid volume typically falls within the range of 20% to 35%. A lung fluid volume exceeding 35% is indicative of a hypervolemic state, while values below 20% suggest dehydration [15]. In the literature survey, several categorizations of ReDS scores were found based on lung fluid percentage such as low, normal, high, and hypervolemic; and dry, congested, and non-congested states [20-21]. These cut-off values served as crucial benchmarks for identifying pulmonary congestion in patients without apparent clinical signs and symptoms.

Statistical Analysis

The statistical analysis of the collected data was performed using GraphPad software version 8.0. Descriptive statistics, including mean with standard deviation for continuous variables and proportions/percentages for categorical variables, were utilized to summarize results of the study cohort. Comparisons between two parameters were conducted and analyzed using t-test. The p-value of <0.05 is considered statistically significant.

Results

Baseline characteristics and ReDS score of recruited patients

A total of 300 patients with a mean age of 58.03 ± 13.22 years were enrolled in the study. Male predominance was observed, constituting 83% of the study population. When the clinical signs and symptoms of patients were assessed, 161 patients (53.7%) with a mean age of 57.11 ± 13.12 years reported presence of clinical signs and symptoms. In contrast, 139 patients (46.3%) did not exhibit clinical signs and symptoms. Further, patients were characterized as congested and non-congested with the ReDS score of >35% and ≤35%, respectively. The baseline characteristics of

congested, non-congested, and total patients are summarized in Table 1.

Table 1: Baseline characteristics of the recruited patients

Parameters	Non-congested patients(n=120)	Congested patients(n=180)	Total patients (n=300)	p-value
Age, years	58.84 ± 13.08	57.49 ± 13.32	58.03 ± 13.22	0.388
Gender				
Male	83	165	248 (82.7)	
Mean age, years	60.53 ± 11.29	57.53 ± 13.13	58.57 ± 12.62	0.078
Female	37	15	52 (17.3)	
Mean age, years	55.05 ± 15.92	56.93 ± 15.77	56.19 ± 14.9	0.412
Clinical signs and symptoms				
Yes	01	160	161 (53.7)	
Mean age, years	69	57.03 ± 13.13	57.11 ± 13.12	-
No	119	20	139 (46.3)	-
Mean age, years	58.75 ± 13.10	61.1 ± 14.61	59.09 ± 13.3	0.466

n= number of patients

ReDS Scores

Based on percentage characterizations of ReDS score, three patients had ReDS score in the range of 21-24%, 117

patients in 25-35%, 100 patients in 36-41%, 70 patients in 42-50%, and 10 patients had score of above 50, as shown in Fig. 1.

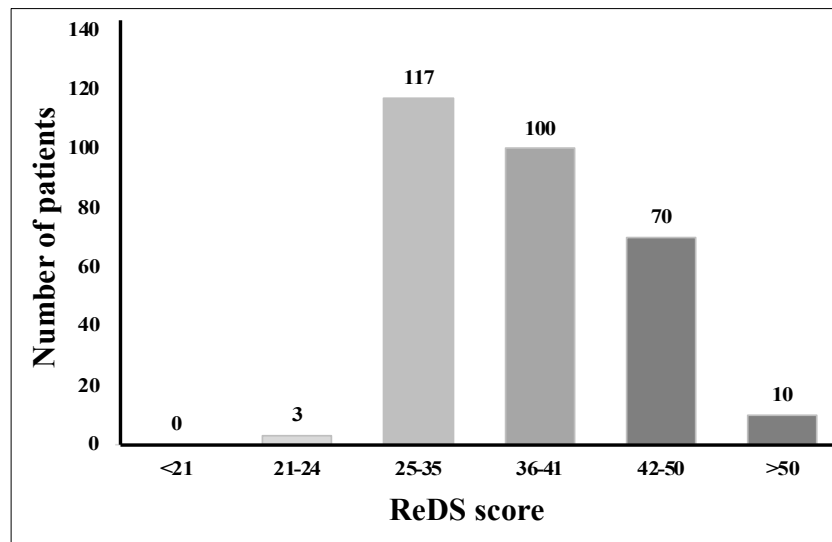


Fig 1: ReDS scores of recruited patients

Efficacy of ReDS

Based on traditional assessment, clinical congestion was identified in 161 patients. However, ReDS device detected congestion in 180 patients, suggesting the efficacy of ReDS in identifying pulmonary congestion particularly in patients without clinically evident signs and symptoms. Notably, the mean ReDS score was significantly higher in patients with clinical signs and symptoms (>35%) as compared to patient

without signs and symptoms (≤ 35%) (42.07 ± 4.5 vs. 32.17 ± 3.9; *p* < 0.0001). ReDS data in HF patients is summarized in Table 2.

Based on ReDS score, correlation between age and presence/absence of clinical signs and symptoms in congested patients was assessed and we found no significant correlation between these variables (*r* = -0.096; *p* = 0.2).

Table 2: Efficacy of ReDS in the detection of pulmonary congestion

Parameters n (%)	Clinical Signs & Symptoms		Total
	Present	Absent	
ReDS Score >35% (Congested)	160 (53.3)	20 (6.7)	180 (60)
ReDS Score ≤ 35% (Not Congested)	1 (0.3)	119 (39.7)	120 (40)
Total	161 (53.6)	139 (46.4)	300 (100)
Mean ReDS score (± SD)	42.07 ± 4.5	32.17 ± 3.9	<0.0001

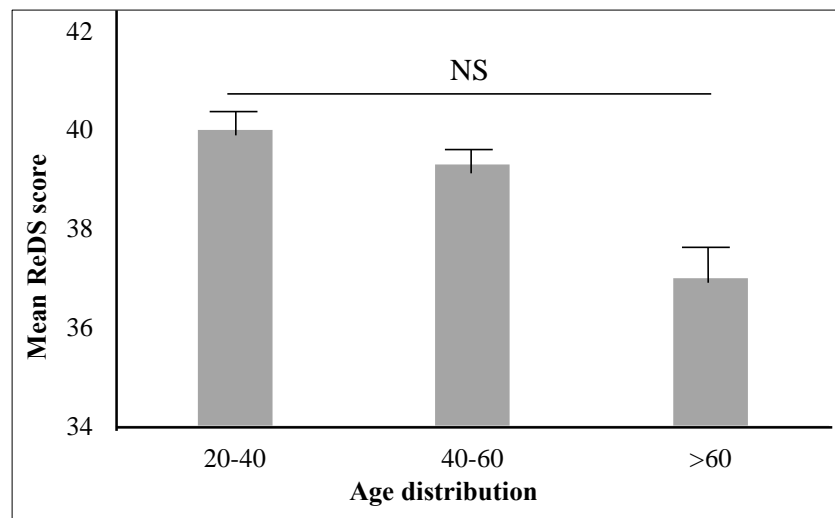
Baseline characteristics of patients without clinical signs and symptoms

The baseline characteristics of the patients without clinical signs and symptoms are given in Table 3. Out of 300 recruited patients, 180 patients exhibited ReDS score of >35%. Among them, 20 patients (6.7%) with mean ReDS score of 38.1 ± 2.91, did not report any clinical sign and symptom. Of 20 patients, 85% were males (n=17) and three patients were female. As shown in Fig. 2, we compared mean ReDS score of age-distributed patients however, no significant difference was observed (*p* > 0.05).

Table 3: Characteristics of patients without clinical signs and symptoms but have the ReDS score of >35%

Parameters (Mean \pm SD)	Patients (n=20)
Total patients without clinical signs and symptoms but have the ReDS score of >35%	20
Gender, n (%)	
Male	17 (85)
Females	03 (15)
Age	
Mean age	61.1 \pm 14.61
Mean age of males	60.06 \pm 15.43
Mean age of females	67 \pm 7.81
Age distribution, n (%)	
20-40	02 (10)
40-60	07 (35)
>60	11 (55)
Mean ReDS score	38.1 \pm 2.91

ReDS= Remote Dielectric Sensing; n=number of patients; %=percentage

**Fig 2:** Mean ReDS score as per gender distribution in congested patients without clinical signs and symptoms. (NS= Non-significant)

Discussion

The present study revealed that ReDS detected pulmonary congestion in 20 patients who did not report clinical signs and symptoms in addition to 160 patients with clinical signs and symptoms. This highlights the potential of ReDS as a sensitive tool for identification of congestion in asymptomatic HF patients. Early detection is crucial for implementing timely interventions, ultimately contributing to improved patient outcomes and a reduction in hospital readmissions, aligning with the goals of contemporary HF management [10]. Thus, ReDS technology plays a vital role in measuring lung congestion at discharge in admitted patients with acute HF to follow device-targeted intervention and reduce the rate of re-admissions [22].

Our study reported the mean age of 58.03 \pm 13.22 years and a male predominance of 83% which are consistent with existing literature on heart failure demographics. The baseline characteristics of our study population align with the demographics typically associated with HF in Indian population [23-35]. The Trivandrum Heart Failure Registry (THFR) reported the mean age of recruited HF patients as 61.8 \pm 13.4 years, 59.1 \pm 11.8 years in the Medanta Registry, and 56 \pm 15 years in the International Congestive Heart Failure INTER-CHF [Indian population subset] study [23-25]. Further, the demographic features of Indian patients with HF differ from the Western countries. For instance, Indian patients exhibit a younger age of onset of HF disease.

In contrast to THFR, Medanta Registry, and INTER-CHF study, Acute Decompensated Heart Failure National Registry (ADHERE) reported mean age as 69.8 \pm 14.4 years in the United States population [26]. Additionally, the male-to-female ratio is 70:30/80:20 in India compared to 50:50 ratio observed in the West [26-27]. These findings reaffirm the generalizability of our study population to broader HF populations in India [23-25]. Considering potential differences in disease etiology, risk factors, and treatment responses, it is imperative to focus on the development of personalized strategies and tailored approaches for optimizing outcomes in the management of HF within younger demographic in India [12].

Pulmonary congestion is characterized by interstitial and alveolar edema in patients with acute decompensated HF. Some patients may develop silent decompensation without the occurrence of symptoms or may precede with the clinical signs and observable manifestations of congestion. Despite treating patients with diuretics, pulmonary congestion may persist for long that require re-hospitalization [13, 28]. Therefore, an accurate evaluation of pulmonary congestion is a dependable approach.

Traditionally, chest radiography, a rapid and cost-effective diagnostic imaging method is commonly employed in the emergency department as the primary tool for assessing patients with acute dyspnea. In a serial assessment of the population presenting with dyspnea, 18% exhibited negative

radiography results. Surprisingly, nearly one in five patients diagnosed with acute HF did not show signs of chest congestion. Consequently, the use of chest radiography is discouraged for evaluating pulmonary congestion in congestive HF [29]. Nearly 90% of HF cases are due to pulmonary congestion therefore, patients are at high risk of HF hospitalization and mortality [12]. To provide real-time data on pulmonary congestion for the management of HF, ReDS technology was considered.

ReDS system is a portable, non-invasive, and user-friendly technology that requires minimal patient collaboration. It utilizes a focused electromagnetic beam to directly measure lung fluid content through the chest cavity. Previous animal model studies demonstrated the sensitivity of both chest CT and ReDS technology in detecting changes in lung fluid content with high interclass and Pearson correlation coefficients of 0.95 [17-18].

In our study, 180 patients of 300 patients exhibited pulmonary congestion with and without signs and symptoms using ReDS technology. On comparing ReDS values in our study, the mean ReDS score was significantly higher in patients with evident signs and symptoms compared to those without clinical signs and symptoms (42.07 ± 4.5 vs. 32.17 ± 3.9 ; $p < 0.0001$). In our study, 11 out of 20 patients without clinical signs and symptoms but with ReDS-identified congestion were above the age of 60 ($p > 0.05$). This observation aligns with the challenges outlined in the Indian consensus statement, emphasizing the commonality of missing signs and symptoms in elderly heart failure patients [9]. Elderly patients often exhibit atypical or less pronounced symptoms of HF during routine evaluations. This commonality of missing signs and symptoms in elderly HF patients reflects insufficient efficacy of traditional diagnostic approaches. Thus, incorporating advanced tools, such as ReDS, becomes particularly relevant in addressing this challenge of identifying congestion in patients without clinical signs. This also aligns with the growing acknowledgment of the need for tailored and sophisticated diagnostic methods to improve the accuracy of HF management [30].

Limitations

The study has a few limitations: It was a single-centre study with the small sample size. Future multi-center studies are warranted to validate and further generalize the efficacy of ReDS in assessing pulmonary congestion, especially in patients without clinical signs and symptoms. Considering the observational design of the present study, we did not assess the impact of treatment modification based on ReDS scores in the management of patients with HF which is another major limitation.

Conclusion

In conclusion, our study provides evidence supporting the utility of ReDS in identifying pulmonary congestion in HF patients. The study highlighted that ReDS can identify congested HF patients without clinical signs and symptoms which could be useful particularly in elderly patients. ReDS technology has the potential to monitor and detect congestion due to decompensation, particularly in elderly populations prone to asymptomatic phase. Consequently, ReDS technology proves valuable for the remote and home management of patients with HF. Further research with larger cohorts is required to comprehensively study the

positive effects of ReDS scores on treatment modification and clinical outcomes in the management of HF patients.

Conflict of interest: None declared.

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