Heart & Lung 50 (2021) 59–64

Contents lists available at ScienceDirect

Heart & Lung

journal homepage: www.heartandlung.com

The use of the reds noninvasive lung fluid monitoring system to assess readiness for discharge in patients hospitalized with acute heart failure: A pilot study

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ARTICLE INFO

Article History:
Received 30 December 2019
Revised 28 June 2020
Accepted 2 July 2020
Available online 20 July 2020

Keywords:
Heart failure
Fluid management
Non-invasive lung fluid volume
Remote Dielectric Sensing

ABSTRACT

Background: Inadequate decongestion is common in hospitalized heart failure (HF) patients and may contribute to readmissions. Our purpose was to use remote dielectric sensing (ReDS) technology to measure lung congestion at discharge in patients admitted with acute HF and to see if a device-targeted intervention could reduce HF readmission rates.

Methods: We conducted a prospective pilot study of patients admitted with acute decompensated HF randomized to receive standard therapy or ReDS-guided therapy to determine the timing of hospital discharge based on the amount of lung congestion present after diuresis. ReDS measurement was performed for all patients once they were deemed ready for discharge. Patients in the treatment arm with residual lung congestion defined by ReDS ≥39% had HF consultation and further diuresis.

Results: Of 108 HF patients (50% male, age 73.6 ± 12.6 years, BMI 29.3 ± 4.3 kg/m^2, EF 38.5 ± 15.1%, BNP 1138 ± 987 pg/mL), 32% demonstrated residual lung congestion at the time of proposed hospital discharge. ReDS guided therapy triggered additional diuresis in 30% (18/60) of the patients in the treatment arm (average weight loss 5.6 pounds, $p = 0.02$). 30-day HF readmission rates were similar in the treatment and the control arms (1.7% vs 4.2%; $p = 0.44$). Patients discharged as planned with residual lung congestion with ReDS ≥39% had higher 30-day readmission rate compared to patients who were adequately decongested at discharge with ReDS <39% (11.8% vs. 1.4%, $p = 0.03$).

Conclusion: In our single-center cohort, ReDS testing demonstrated that 32% of HF patients deemed ready for discharge have clinically significant residual lung congestion which was associated with a higher risk of readmission. ReDS-guided management was associated with significant decongestion but not a reduction in HF readmissions in this sample.

Introduction

Heart failure (HF) is the leading cause of hospitalization among patients 65 years and older in the United States and is associated with considerable morbidity, mortality, and cost.[1,2] Nearly one-quarter of all patients admitted with acute HF in the U.S. are readmitted within 30 days.[2] Results from previous studies using indirect measures of decongestion suggest that nearly 50% of patients hospitalized for a heart failure exacerbation are discharged early, with residual volume overload, and that inadequate pre-discharge decongestion is a significant risk factor for heart failure readmissions.[3,4]

Assessment of volume status is a key factor in the management of patients with heart failure, both on an inpatient and outpatient basis. Nevertheless, accurate volume assessment by physical exam is challenging and surrogate measures, such as daily weights or natriuretic peptides, are ineffective in guiding the management of heart failure patients.[5,6] Additionally, recent research has shown only a modest correlation between net fluid loss and overall weight loss during and at admission for acute HF.[7]

The Remote Dielectric Sensing System (ReDS, Sensible Medical Innovations, Israel) is FDA cleared device that measures lung fluid content quickly, non-invasively, in absolute terms, providing objective and reproducible indices of volume status. The technology has been described previously.[8–12] ReDs measures are presented as the

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https://doi.org/10.1016/j.hrtlng.2020.07.003

percentage of fluid compared to lung volume, with the normal value ranging between 20 and 35%.

Initial studies have shown excellent correlations between ReDS measures and Computed Tomography (CT)-measured lung water, as well as invasively determined hemodynamics.[8–10] ReDS measurements also have a good correlation with the clinical course of ADHF, manifesting as pulmonary congestion and with changes in fluid status.[11] In addition, ReDS has been demonstrated to guide HF therapy.[12] Thus, ReDS measurements may be directly actionable, even in the absence of changes in heart failure physical signs or symptoms. The study goal was to identify the rate of residual lung congestion, as determined by ReDS measurement, in patients planned for discharge after hospital treatment for acute decompensated HF, and determine the effect of ReDS-guided management strategy on HF readmission rates and the patient's clinical status.

Methods

The study protocol was approved by the local Institutional Review Board and performed at Moses Cone Hospital - a 535-bed tertiary care center in central North Carolina with approximately 125 ADHF admissions per month. Patients admitted to the Hospitalist, Internal Medicine or Family Practice Teaching and General Cardiology services were eligible for screening and enrollment. Patients admitted to or consulted on by the Advanced Heart Failure service were excluded. Per routine practice, the primary care team dictated patient care during the index hospitalization of this study and was responsible for determining eligibility for hospital discharge.

After identification and successful screening, patients were consented for inclusion in this investigation and randomized to a control or a ReDS-guided treatment arm. Patients were eligible for participation if they met all the following criteria: 1) 21 years of age or older; 2) hospitalized for acute heart failure regardless of left ventricular ejection fraction (LVEF; i.e. with reduced [HFrEF] or preserved [HFpEF] LVEF) and requiring treatment with intravenous (IV) diuretics; 3) had a body habitus suitable for ReDS measurement (BMI > 22, < 38); 4) had a b-type natriuretic peptide (BNP) level ≥ 200 pg/ml, 4) if reproductive age female, having a negative pregnancy test; and 5) signed informed consent. Patients were excluded if they were: 1) admitted to or consulted on by the Advanced HF service during the index admission; 2) required inotropic or vasopressor support; 3) had a history of cardiac transplantation or ventricular assist device (VAD) implantation; 4) had cardiac resynchronization therapy (CRT) implantation within 90 days of screening or planned implantation during the study; 5) were diagnosed with pulmonary embolism within past 6 months; 6) had severe pulmonary hypertension; 7) had chronic kidney disease with creatinine clearance < 30 ml/min; 8) had recent acute MI or CABG within 6 months; 9) had end-stage COPD requiring home oxygen; or 10) had a life expectancy < 6 months.

Although patients were randomized in 1:1 ratio, between randomization and planned discharge, there were more dropouts in the control arm versus the treatment arm. Thus, total enrollment was 48 patients in the control arm and 60 patients in the treatment arm (Fig. 1).

On the day the primary care team deemed the patient ready for discharge, based on usual clinical assessments, all patients underwent a ReDS assessment. The care team was blinded to the ReDS readings for patients in the control arm, and once the ReDS reading was obtained these patients were discharged home as planned (Fig. 1). In contrast, measurements from patients in the treatment arm were provided to the care team. Patients with a ReDS <39% were discharged home as planned. Those with readings ≥ 39% were considered inadequately decongested and, per protocol, required an Advanced HF Team consultation to assist with pre-discharge care and received further inpatient treatment with re-initiation of their IV loop diuretics and occasional addition of an oral thiazide diuretic (metolazone). None of the subjects received IV inotropes or IV vasodilators as part this additional treatment. Changes in creatinine, weight and ReDS readings were measured to check the effect of the additional treatment. To avoid excessive volume depletion and related complications like acute kidney injury, daily clinical and laboratory assessments were performed on all study patients including blood pressure, weight, and serum creatinine measurements. These patients were also deemed high risk and were also referred to the

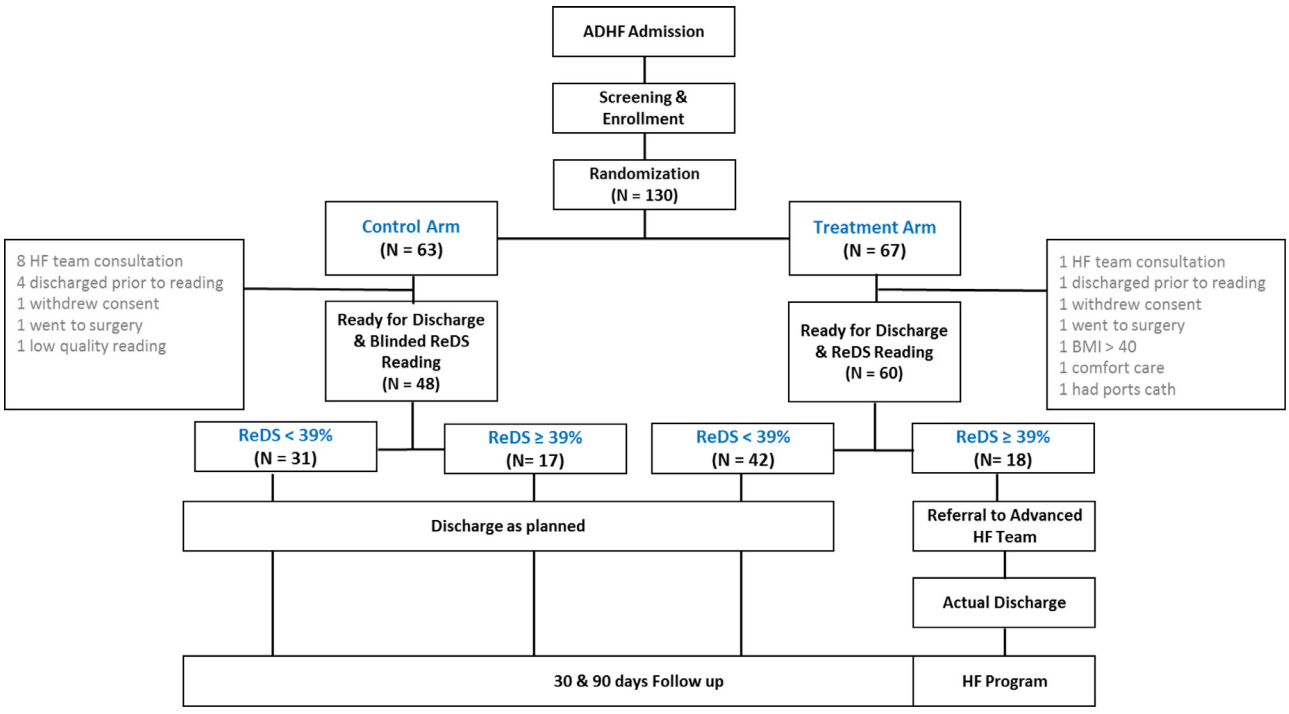

Fig. 1. Study flowchart.

outpatient HF clinic for post-discharge for follow-up. All patients in both groups were followed for 90 days by chart review.

Of note, although the normal range for lung water is considered to be 20–35%,[8,12] in our clinical experience, a ReDS value ≥39% is associated with the development of clinical symptoms including increased dyspnea on exertion and orthopnea. Thus, a ReDS value of ≥39% was chosen as a cutoff for inadequate decongestion in order to provide a conservative approach to decongestion assessment and to balance sufficient decongestion with a desire not to overly prolong hospitalization. ReDS values between 36% and 38% were considered as mild lung congestion.

Study endpoints

The primary outcome for the study was the percentage of patients in each arm who had significant residual lung congestion (ReDS ≥ 39%) at the time of proposed hospital discharge by the primary treatment team.

Pre-specified secondary and exploratory outcomes included: 1) Percent readmitted in 30 and 90 days as stratified by treatment group; 2) Readmission rates in 30 and 90 days stratified by ReDS reading at the time of actual discharge; 3) Change in weight, ReDS measurement and serum creatinine from the day of proposed discharge to actual discharge.

Statistics

Demographic characteristics are presented using descriptive statistics. Chi-squared analysis was used to evaluate dichotomous variables, with a two tailed T test for continuous data. The level of significance was defined as a P-value < 0.05.

Results

One hundred thirty patients were consented for participation. Sixty-seven were randomized to treatment arm and 63 to the control arm. Twenty-one patients were excluded, seven from the treatment arm and 14 from the control, mainly due to being seen in consultation by the Advanced HF team prior to being deemed ready for discharge (Fig. 1). One patient in the control arm had low quality ReDS reading and was excluded from analysis after the study was completed. Therefore, 108 patients were included in the final analysis: 60 in the treatment arm and 48 in the control arm.

As shown in Table 1, baseline characteristics were similar between groups. ReDS readings on the proposed day of discharge are summarized in Table 2 for the entire cohort and for each study arm separately. The primary study endpoint, the ReDS measurements made on the day of proposed discharge, revealed that despite planned discharge, 32% of patients (30% in the treatment arm and 35% in the control arm, $p = 0.55$), had evidence of significant persistent fluid overload (Fig. 2). Another 12% of patients had mild lung congestion (ReDS 36–38%) at proposed discharge. There were no significant demographic differences between arms.

Secondary and exploratory endpoints

Overall, 18 (30%) patients in the treatment arm were deemed ready for discharge by the primary team, but remained volume overloaded by ReDS measurement, and so were seen by the Advanced HF team. However, 2 of these patients did not stay for additional treatment. This ReDS defined, unblinded volume overloaded group underwent additional diuretic therapy which extended the hospital stay by an average of 2.6 ± 1.6 days and brought 7 (44%) patients to ReDS value $< 39\%$. Over that time, patients experienced a mean additional weight loss of 5.6 ± 4.8 pounds. The mean decrease in the absolute ReDS measurements for this group over the extra days of diuresis was $7.1 \pm 5.1\%$ (Fig. 3 & Table 3). Creatinine changes were similar between the arms (Table 4). One patient experienced a rise in SCr ≥ 0.5 mg/dl with additional diuretic therapy which corrected quickly after holding IV diuretics for one day.

Table 1
Baseline characteristics.

	Control Arm ($N = 48$)	Treatment Arm($N = 60$)	P-value
Male	44% (21/48)	55% (33/60)	0.25
Age	73.6	73.6	0.99
EF (mean)	40% ± 15	37% ± 15	0.302
%HFrEF (LVEF ≤ 40%)	26/48 (54%)	38/60 (63%)	0.335
%HFpEF (LVEF >40%)	21/48 (44%)	22/60 (37%)	0.455
BMI	29.1 ± 4.32	29.4 ± 4.33	0.696
BNP (pg/ml)	1162	1200	0.47
SCr (mg/dl)	1.3	1.4	0.34
ACE-I/ARB/ARNI	22 (46%)	336 (60%)	0.142
Beta-blocker	39 (81%)	49 (82%)	0.956
MRA	5 (10%)	5 (8%)	0.711
Hydralazine/Nitrate	3 (6%)	6 (10%)	0.484
Loop diuretic	30 (63%)	43 (72%)	0.312

EF= Ejection Fraction, HFrEF=Heart Failure with Reduced Ejection Fraction, LVEF= Left Ventricular Ejection Fraction, HFpEF= Heart Failure with Preserved Ejection Fraction, BMI=Body Mass Index, BNP= Brain Natriuretic Peptide, SCr= Serum Creatinine, ACE-I= Angiotensin-Converting-Enzyme Inhibitors, ARB= Angiotensin II Receptor Blockers, ARNI= Angiotensin Receptor-Neprilysin Inhibitors, MRA= Mineralocorticoid Receptor Antagonists.

Although the current study was underpowered to look at the effect of residual lung congestion (as measured by ReDS ≥ 39%) at the time of actual discharge on 30-day and 90-day readmission rates, notable trends were observed between the control and treatment arms and between volume-overloaded and non-volume-overloaded subgroups.

The percentage of patients readmitted for recurrent HF in 30 days was 4.2% in the control arm and 1.7% ($p = 0.44$) in the treatment arm. The 90-day readmission percentages were 12.5% in the control arm and 16.7% ($p = 0.54$) in the treatment arm (Tables 5 and 6). We also investigated HF readmission rates by ReDS-measured volume status at the time of actual hospital discharge by comparing readmissions of patients who were adequately decongested to those with residual volume overload at time of actual discharge (Tables 5 and 6). For those who were adequately decongested prior to discharge 1.25% were readmitted for recurrent HF in 30 days compared to 7.1% in those with residual congestion ($p = 0.1$). At 90 days, the percentages were 13.75% and 17.9% ($p = 0.6$), respectively.

When doing the same analysis for patients who were discharged home as planned (i.e. without the patients who received further inpatient treatment) the readmission rates were 11.8% and 1.4% ($p = 0.03$) for the adequately decongested patients (ReDS < 39%) vs the patients discharged with residual congestion (ReDS ≥ 39%).

Baseline characteristics per ReDS at proposed discharge were similar except for increased age and female sex which were associated with lower ReDS readings (Table 7).

In addition to receiving further inpatient treatment by the Advanced HF Team at the time of proposed discharge, patients in the

Table 2
Number and percentage of patients with normal (≤35%), mildly elevated (36–38%) or elevated (≥39%) ReDS reading on the day of intended hospital discharge. Values provided for all patients and divided by study arm.

Congestion Level at Proposed Discharge as measured by ReDS per treatment arm				
Study Arm	Total	ReDS ≤ 35%	ReDS 36–38%	ReDS ≥ 39%
Treatment	60 (100%)	36 (60%)	6 (10%)	18 (30%)
Control	48 (100%)	25 (52%)	6 (13%)	17 (35%)
Total	108 (100%)	61 (57%)	12 (11%)	35 (32%)
				P-value= 0.55

ReDS = Remote Dielectric Sensing.

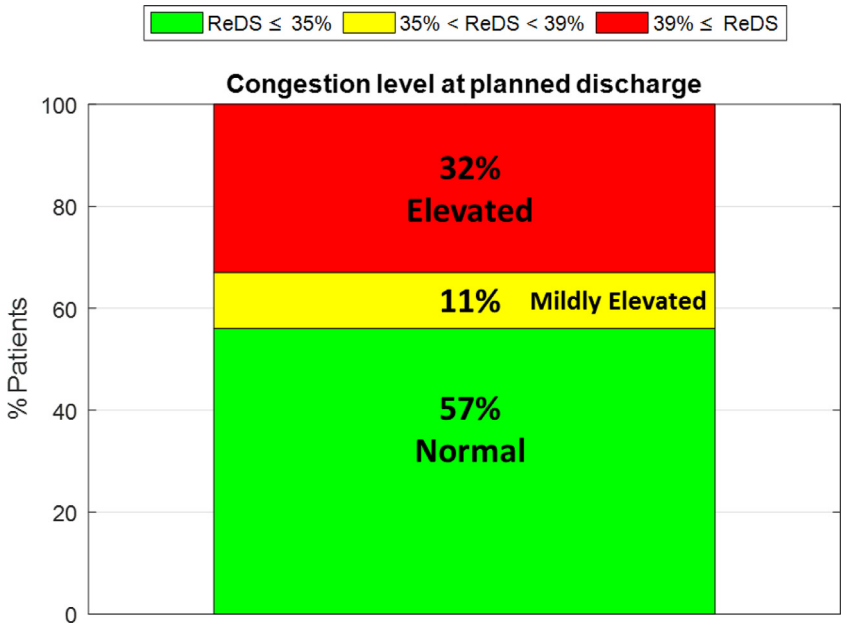

Fig. 2. Congestion level by ReDS at time of planned discharge for all patients.

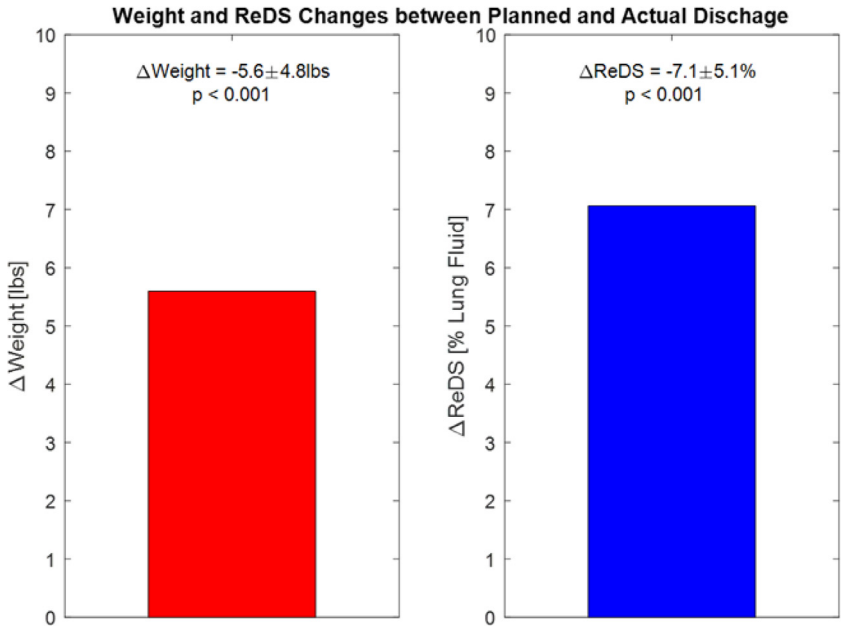

Fig. 3. Weight and ReDS readings in treatment arm patients with initial ReDS ≥39% at planned discharge and at actual discharge after referral to HF program.

Table 3
Change in clinical status for patients in the treatment arm deemed congested patients based on ReDS ≥39% between proposed discharge day and actual discharge day.

Study Parameter	
Number of patients in Treatment arm with ReDS ≥39%	18 (30%)
Mean weight loss from proposed to actual d/c	5.6 ± 4.8 lbs
Mean added length of stay	2.6 ± 1.6 days
% patients with rise SCr ≥ 0.5 g/dl after additional ReDS-guided diuresis	6.25% (1/16)
Mean change in ReDS reading from proposed to actual d/c	7.1 ± 5.1%

ReDS = Remote Dielectric Sensing, SCr= Serum Creatinine.

Table 4
Creatinine Change > 0.3 by treatment arm and by ReDS reading at actual discharge.

Arm	Total	ReDS < 39	ReDS ≥ 39
Treatment	13.3%	13.6%	12.5%
Control	10.4%	9.7%	11.8%
P-value	0.65	0.6	0.95

HF= Heart Failure, ReDS = Remote Dielectric Sensing.

Table 5
Number and proportion of patients readmitted within 30 days of index hospital discharge by treatment arm and by ReDS reading at actual discharge.

% Patients readmitted for HF – 30 days				P-value
Arm	Total	ReDS < 39	ReDS ≥ 39	
Treatment	1.7% (1/60)	2% (1/49)	0% (0/11)	0.63
Control	4.2% (2/48)	0% (0/31)	11.8% (2/17)	0.05
Total	2.8% (3/108)	1.25% (1/80)	7.1% (2/28)	0.1
P-value	0.44	0.42	0.24	

HF= Heart Failure, ReDS = Remote Dielectric Sensing.

Table 6
Number and proportion of patients readmitted within 90 days of index hospital discharge by treatment arm and by ReDS reading at actual discharge.

% Patients readmitted for HF – 90 days				P-value
Arm	Total	ReDS < 39	ReDS ≥ 39	
Treatment	16.7% (10/60)	18.3% (9/49)	9.1% (1/11)	0.45
Control	12.5% (6/48)	6.5% (2/31)	23.5% (4/17)	0.09
Total	14.8% (16/108)	13.75% (11/80)	17.9% (5/28)	0.6
P-value	0.54	0.13	0.33	

HF= Heart Failure, ReDS = Remote Dielectric Sensing.

Table 7
Baseline characteristics per ReDS at proposed discharge.

	ReDS < 39% (*N* = 73)	ReDS ≥ 39% (*N* = 35)	P-value
ReDS [%]	28.9 ± 4.3	46.3 ± 5.3	<<0.001
Age [year]	76.5 ± 12.0	67.5 ± 11.8	<0.001
Sex (Male)	29 (40%)	25 (71%)	<0.001
EF* [%]	39.7 ± 15.9	36.3 ± 13.2	0.28
BMI* [kg/m^2]	28.9 ± 4.3	30.1 ± 4.2	0.17
BNP* [pg/ml]	1162 ± 1079	1089 ± 772	0.72
SCr [mg/dl]	1.4 ± 0.6	1.5 ± 0.5	0.73
SBP [mmHg]	127.0 ± 19.1	126.7 ± 17.9	0.95
DBP [mmHg]	65.9 ± 14.0	69.3 ± 14.6	0.25

ReDS=Remote Dielectric Sensing, EF=Ejection Fraction, BMI=Body Mass Index, BNP= B-type natriuretic peptide, SCr = Serum Creatinine, SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure. Data is presented as mean ± standard deviation or number (percentage of patients). *At admission.

treatment arm who had an initial ReDS reading > 39% were deemed high-risk and thus received referral to the outpatient HF clinic for post-discharge follow-up. In comparing patients in the treatment arm whose initial ReDS were ≥39% to patients in the control arm who also had initial readings ≥39%, the ReDS guided intervention resulted in a reduction in HF readmissions from 11.8% to 0% at 30 days ($p = 0.13$) and from 23.5% to 9.1% at 90 days ($p = 0.33$). Patients with ReDS < 39% had readmission rate higher than the treatment arm with ReDS > 39% and lower than the control arm with ReDS > 39%, 1.25% in 30 days 13.75% in 90 days (Fig. 4).

Discussion

Previous observational studies have suggested that nearly 50% of patients admitted with acute HF are discharged with residual congestion based on changes in pre- and post-discharge weights. To our knowledge, this pilot study, is the first trial to objectively confirm this finding by directly measuring lung fluid with the ReDS technology. We found that in our sample of 108 patients, 32% percent of patients were deemed ready for discharge despite the presence of clinically significant residual lung congestion with a ReDS measurement of > 39% (normal 20–35%). Furthermore, 11% of patients deemed ready for discharge had mild residual lung congestion, (ReDS measurement 36–38%) supporting the findings from ADHERE that nearly half of all hospitalized heart failure patients are sub-optimally diuresed prior to discharge and this may be a risk factor for short-term HF readmissions.

Among patients who were inadequately decongested at the time of proposed discharge (as defined by a ReDS ≥39%), inpatient consultation with the Advanced HF team led to improved pre-hospital decongestion, as indicated by an average weight loss of 5.6 pounds over an additional 2.6 days of hospitalization without significant safety concerns (i.e. worsening renal function or hypotension). We noted that with diuresis ReDS readings decrease rapidly, dropping 7.1% from planned to actual discharge for patients in the treatment arm, and supporting the physiologic validity of ReDS measurements reflecting accurate volume assessment and the presence of diuretics responsiveness – an important finding when trying to assess patients for the presence of cardiorenal syndrome. In addition, to assisting

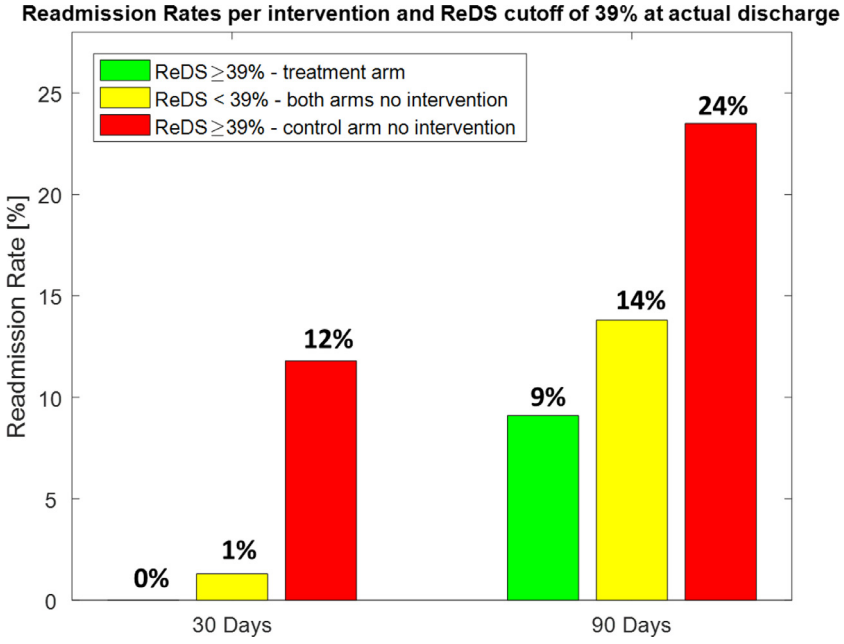

Fig. 4. Readmission Rates at 30 and 90 days per intervention and ReDS cutoff of 39% at actual discharge.

with the timing of discharge, ReDS readings may have utility in the timing of when to switch from intravenous to oral diuretics or to proceed with an invasive evaluation.

Although the ability of this pilot study to correlate ReDS readings with the risk for HF readmission was limited by a small sample size and an unusually low 30-day readmission rate in the control arm (4.2% vs our hospital's baseline 30-day readmission rate of 17%) some important trends arose. Irrespective of arm assignment, only 1.25% (1/80) of patients who had a ReDS reading $< 39\%$ at the time of actual discharge were readmitted for HF at 30 days while 7.1% patients with ReDS $\geq$ 39% at actual discharge were readmitted in 30 days. When looking at ReDS as the only factor to assess 30-day readmission rate risk, meaning without including patients who received further inpatient treatment and were referred to HF program, we see that patients with ReDS $\geq$ 39% are at higher risk to get readmitted vs. patients with ReDS $<$39% (11.8% vs. 1.4%, $p = 0.03$). As expected, a single volume measurement at the time of the index admission had no effect on 90-day readmissions (13.75% for patients with ReDS $<$ 39% vs. 17.9% for patients with ReDS $\geq$ 39%).

Unlike other clinical (weight, JVP, peripheral edema) and laboratory (BNP) measures of congestion, the ReDS technology provides an objective, absolute and actionable measure of lung congestion in HF patients which may allow cardiologists and general practitioners to provide inpatient HF patients with more effective, and safe, HF care over our current standard.

Previous work by Amir et al.[12] has shown that daily ReDS monitoring at home can be a useful tool to reduce the rate of HF readmissions. Our study provided a novel approach to utilize ReDS as an in-hospital assessment for triaging patients prior to discharge to help ensure adequate decongestion and identify high-risk patient who would likely benefit from post-discharge follow-up in the HF Clinic.

As alluded to previously, this pilot study has several major limitations including: single-center enrollment, a small sample size (108 enrolled with only 18 vol-overloaded patients in the treatment arm), and an extremely low baseline event rate in the control arm. The choice of a 39% cutoff point may be criticized due to a lack of prospective validation. We chose to use this cutoff based on prior published works of Amir, et al.[8] which suggest that normal lung water content is 20–35%. Further, our previously unpublished clinical experience suggests that patients rarely became symptomatic with lung water below 40%. Therefore, in an effort to bridge the gap between full inpatient decongestion and the desire not to overly prolong hospitalization, we selected the 39% cutoff empirically. Further validation of the 39% cutoff point as a decision aid is warranted. Unfortunately, we did not require natriuretic peptide levels at discharge, so we cannot comment on this measure of systemic congestion. However, in prior studies, NP guided HF management has not consistently demonstrated improved outcomes[13] and thus would be unlikely to have altered our findings.

In addition to BNP values, other clinical signs and symptoms of congestion at discharge were not collected and could have contributed to our results; however all patients were felt stable for discharge by the primary team prior to undergoing ReDS reading at the time of proposed discharge. Finally, the readmission numbers were also confounded by the fact that patients in the treatment arm who had a ReDS measurement exceeding 39% at the time of proposed discharge were deemed high risk and in addition to receiving inpatient consultation from the Advanced HF team prior to discharge, were also referred to the outpatient HF Clinic for ongoing care. All of these issues will need to be addressed in larger follow-up studies.

In conclusion, in this single-center pilot study we objectively confirmed that nearly half of acute HF patients discharged from our hospital are sent home with residual lung congestion and this congestion may be a modifiable risk factor to reduce HF readmissions using the ReDS technology to directly measure lung congestion. Larger, multicenter studies are needed to confirm these findings and to determine if the refined use of ReDS-based protocols can improve the care of patients hospitalized with acute HF.

Funding

This work was supported by Sensible Medical Innovation, Netanya, Israel.

Declaration of Competing Interest

None.

Acknowledgments

The authors would like to thank Dr. Daniel Burkhoff for his review, feedback and support.

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