



# Evaluation of remote dielectric sensing (ReDS) technology-guided therapy for decreasing heart failure re-hospitalizations



Offer Amir<sup>a,h,1</sup>, Tuvia Ben-Gal<sup>b,1</sup>, Jean Marc Weinstein<sup>c</sup>, Jorge Schliamser<sup>d</sup>, Daniel Burkhoff<sup>e</sup>, Aharon Abbo<sup>f</sup>, William T Abraham<sup>g,\*</sup>

<sup>a</sup> Cardio-Vascular Institute, Baruch Padeh Medical Center, Poriya, Israel

<sup>b</sup> Department of Cardiology, Rabin Medical Center, Petah Tikva, Israel

<sup>c</sup> Cardiology Department, Soroka Medical Center, Beer-Sheva, Israel

<sup>d</sup> Lady Davis Carmel Medical Center, Haifa, Israel

<sup>e</sup> Columbia University, New York, NY, United States

<sup>f</sup> Sensible Medical Innovations Ltd., Netanya, Israel

<sup>g</sup> Division of Cardiovascular Medicine, The Ohio State University, OH, USA

<sup>h</sup> Faculty of Medicine in the Galilee, Bar Ilan University, Tiberias, Israel

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## ABSTRACT

**Objective:** We tested whether remote dielectric sensing (ReDS)-directed fluid management reduces readmissions in patients recently hospitalized for heart failure (HF).

**Background:** Pulmonary congestion is the most common cause of worsening HF leading to hospitalization. Accurate remote monitoring of lung fluid volume may guide optimal treatment and prevent re-hospitalization. ReDS technology is a quantitative non-invasive method for measuring absolute lung fluid volume.

**Methods:** Patients hospitalized for acute decompensated HF were enrolled during their index admission and followed at home for 90 days post-discharge. Daily ReDS readings were obtained using a wearable vest, and were used as a guide to optimizing HF therapy, with a goal of maintaining normal lung fluid content. Comparisons of the number of HF hospitalizations during ReDS-guided HF therapy were made, both to the 90 days prior to enrollment and to the 90 days following discontinuation of ReDS monitoring.

**Results:** Fifty patients were enrolled, discharged, and followed at home for  $76.9 \pm 26.2$  days. Patients were  $73.8 \pm 10.3$  years old, 40% had LVEF above 40%, and 38% were women. Compared to the pre- and post-ReDS periods, there were 87% and 79% reductions in the rate of HF hospitalizations, respectively, during ReDS-guided HF therapy. The hazard ratio between the ReDS and the pre-ReDS period was 0.07 (95% CI [0.01–0.54]  $p = 0.01$ ), and between the ReDS and the post-ReDS period was 0.11 (95% CI [0.014–0.88]  $p = 0.037$ ).

**Conclusions:** These findings suggest that ReDS-guided management has the potential to reduce HF readmissions in acute decompensated HF patients recently discharged from the hospital.

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## 1. Introduction

There are 5.1 million chronic heart failure (HF) patients in the US [1]. The total annual direct costs associated with HF total approximately \$30 billion, with \$15 to \$25 billion attributable to hospitalizations for worsening HF [1]. Moreover HF is a leading cause of death in adults over 65 years and is associated with the highest 30-day rate of readmissions in the Medicare population [2–3].

Although total rates of HF hospitalizations have decreased by nearly 30% during the past decade, a result of improvements in medical therapy

and management of risk factors [4], there has been no sign of a reduction in rate of readmission after a HF hospitalization. The latest reports indicate that HF readmission rates range between 19% and 31% at 30 days [5] and at around 50% at 6 months [2–3]. High readmission rates after an index HF admission are a global problem [7] that cross racial and ethnic groups [8]. Studies show that 50% to 80% of HF hospitalizations can be prevented when physicians prescribe drugs in accordance with accepted guidelines and when patients comply with prescribed medication regimens [9–10]. In the US, reducing readmission rates has become a national priority to improve health care and to reduce costs. The Centers for Medicare and Medicaid Services (CMS) initiated public reporting of 30-day readmission rates as an indicator of hospital performance at the level. This, however, has so far resulted in only minor improvements in outcomes [11–12] and therefore a variety of tools are being evaluated to aid in early detection of impending HF exacerbation before overt,

\* Corresponding author at: Division of Cardiovascular Medicine, The Ohio State University, 473 West 12th Avenue, Room 110P, Columbus, OH 43210-1252, United States.

E-mail address: [William.Abraham@osumc.edu](mailto:William.Abraham@osumc.edu) (W.T. Abraham).

<sup>1</sup> Dr. Amir and Dr. Ben-Gal are equal contributors to the manuscript.

acute decompensations occur [6]. Many of these approaches rely on telemonitoring strategies [13–17], but these have been shown to have little impact. The ineffectiveness of these telemonitoring approaches has been partially attributed to the low sensitivity and specificity of the parameters being monitored.

Most recently it has been shown that early detection of impending volume overload by sensing increases in pulmonary artery pressures in patients with heart failure is effective for guiding pharmacological therapy and/or patient behavior (e.g., diet, medication compliance) to avoid re-hospitalizations. This was demonstrated in the COMPASS-HF [18] and CHAMPION [19] studies. These studies however relied on invasive, permanently implanted pressure sensors. A valid, noninvasive approach that provides equivalent information would have many advantages.

We recently described the potential of a novel noninvasive electromagnetic energy-based technology (Remote Dielectric Sensing, ReDS™) that quantifies changes in lung fluid content [20,21] to be used to track fluid status and guide medical management in heart failure patients. As detailed previously, ReDS™ technology (Sensible Medical Innovations Ltd., Netanya, Israel) measures the dielectric properties of tissues which are mainly determined by the lung's fluid content.

The purpose of the current study was to evaluate the feasibility and preliminary efficacy of using ReDS technology to guide post-discharge HF management in acute decompensated HF patients to reduce the rate of re-hospitalization.

## 2. Methods

### 2.1. Study population

Patients > 18 years old with Stage C heart failure, regardless of left ventricular ejection fraction (LVEF), were screened during an index hospital admission for acute decompensated heart failure (ADHF, defined as receiving IV diuretics or vasoactive drugs and having a serum BNP level > 400 pg/ml). Patients had to have the ability to comply with the required daily self-measurements using the ReDS system. The ReDS system's indication for use excludes patients having a height < 155 cm or > 190 cm, BMI < 22 or > 39, chest circumference < 80 cm or > 115 cm, or flail chest. Patients were also excluded if they had focal lung lesions (e.g., a history of pulmonary embolism, active pneumonia), a major cardiac event occurring within two months of index admission and chronic renal failure (eGFR < 30 ml/min).

### 2.2. Study design

This was a prospective, longitudinally-controlled study conducted at 3 sites in Israel. The study protocol was approved by all local ethics committees and written informed consent and authorization to use and disclose health information was obtained from each study participant.

The study was performed in two phases (Fig. 1). The first phase was during the index heart failure hospitalization. ReDS measurements were obtained daily starting on the day of enrollment until the patient was discharged home. ReDS readings were recorded but were not used to guide any treatment decisions; that is, treating physicians were blinded to the measurements during the index hospitalization.

The second phase of the study was a 3 month out-patient phase during which ReDS measurements were obtained once daily, at least 6 days per week. Results were provided to the primary physicians who used this information, in addition to standard clinical assessments such as daily weights and routine clinical follow-up visits, to guide therapy (Fig. 2C). The goal was to maintain pulmonary fluid content within the pre-defined and previously determined normal target range [21] between 20% and 35% as discussed

above. ReDS values were blinded to the patients and were available to the treating physician via a secured website described below (Fig. 2C).

### 2.3. ReDS wearable system description and usage

The ReDS™ Wearable System (Sensible Medical Innovations Ltd., Netanya, Israel) consists of two sensors in a wearable vest that is applied by the patient once daily for an ~90 second long measurement (Fig. 2A).

When applying the vest, the sensors are positioned on the front and back of the patient's thorax with no need for direct skin contact, allowing measurements to be performed through light clothing. The wearable vest is connected via a cable to a bedside monitor console (Fig. 2B). Measurements are transmitted via a cellular data link to a secured server for review by a health care provider using a dedicated web-based electronic data capture and viewing system (Fig. 2C).

We previously described the ReDS technology [20]. In brief, the system measures the dielectric properties of tissues. Low power electromagnetic signals are emitted through the right mid-thorax and the signals received after passing through the tissue reflect their combined dielectric properties. These, in turn, are mostly affected by the fluid content of the tissue in the path of the signal [20]. We have recently validated the accuracy of the system for quantifying lung fluid content using results provided by chest CT scans as the comparator [21]; chest CT is currently considered to be the most accurate means of quantifying lung fluid content.

### 2.4. ReDS management follow-up period

Outpatient HF management was based on ReDS readings as an adjunct to standard of care (SOC) as defined by American College of Cardiology Foundation/American Heart Association and Heart Failure Society of America treatment guidelines [22–23]. Patients were asked to perform 1 reading per day, at the same time of day, at least 6 days per week. Patients were also asked to weigh themselves around the same time as the ReDS reading. ReDS readings were provided to the treating physicians who used those readings, in addition to standard clinical assessments to guide changes in HF therapies, particularly in diuretic doses. The goal was to keep ReDS readings within a pre-defined normal range by adjusting medication doses, recommending dietary changes, or encouraging compliance with prescribed therapies. The default upper and lower thresholds for lung fluid content were set at 35% and 20%, respectively. Physicians could adjust the thresholds if necessary, based on clinical assessments, indicating that the default values did not apply to a particular patient (such as in patients whose serum creatinine rose to unacceptable levels with attempts to lower ReDS into the target range).

ReDS readings that crossed upper or lower thresholds as well as rates of change of ReDS readings (i.e., an absolute 6 percentage point increase or decrease in ReDS within a 3 day period) resulted in an "alert" notification sent to the investigator. Notifications were in the form of an email and/or text message (per site preference) that was sent to the site primary investigator and/or another designated study investigator. Each alert required acknowledgment by the investigator; at a minimum, the investigator was required to acknowledge receipt and review of the notification within one day of being sent. An example of a report that investigators had access to on the web portal is shown in Fig. 3. The physicians were free to decide on the need for changes in patient management, which could include modifications of medications or diet, assessment of medical compliance, or adjustment of ReDS thresholds.

### 2.5. Statistical analysis

The hazard ratio (HR) for the rates of readmissions between the different study periods was calculated using the Andersen-Gill (A-G) model. The statistical significance level was 0.05 and the confidence interval (CI) was 95%.

### 2.6. Study endpoints

A patient was considered to have reached a protocol-defined endpoint when they had a heart failure-related readmission. Study endpoints were collected during the ReDS-guided management period as well as for the 3 month periods before and after the study period for comparison.

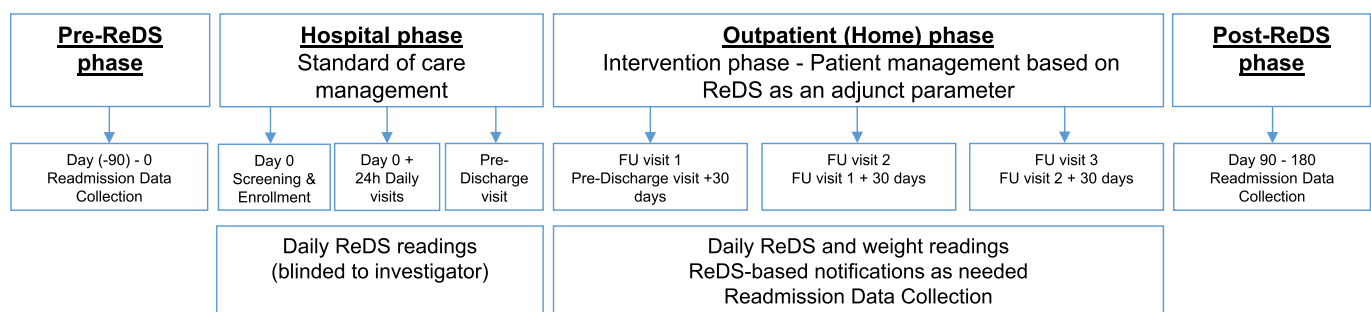
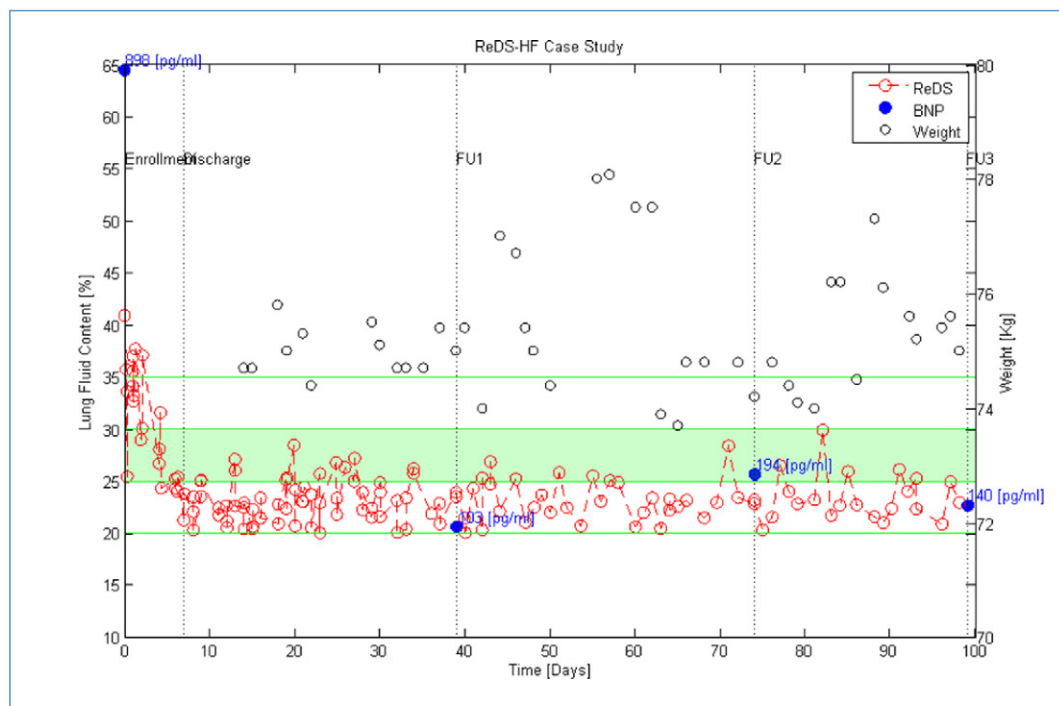


Fig. 1. Overview of study design.



**Fig. 2.** A. Picture of ReDS wearable vest. B. The console interfaces with the vest and transmits information to a secured database via a cellular data link. C. Web based portal for HF patients' management.



**Fig. 3.** An example of ReDS graph used for HF management including weight and BNP parameter.

Safety of the ReDS system was evaluated through assessment of the incidence and severity of ReDS device and measurement-related adverse events.

### 3. Results

Between October 2012 and February 2015, 59 patients were enrolled. Six consented patients failed to meet study entry criteria, 1 withdrew consent, and 2 were withdrawn due to non-compliance prior to hospital discharge. Consequently, the results presented herein are from the remaining 50 patients who were discharged from the hospital with a ReDS device.

Patient demographics are summarized in Table 1. Sixty two percent of patients were men. The average age was 73.8 years, the average BMI was 28.6 Kg/M<sup>2</sup>, and the patients were predominantly in NYHA functional class III. Forty percent of patients had an ejection fraction >40%. Patients were well medicated with therapies for heart failure.

#### 3.1. In-hospital study phase

At enrollment, the ReDS reading averaged  $35.3\% \pm 7.5\%$  (range 25%–65%), serum BNP averaged  $1231 \pm 941$  pg/ml and weight averaged  $80 \pm 16.4$  kg. Upon discharge, the ReDS readings decreased to an average of  $30.6\% \pm 7.2\%$  ( $p = 0.006$ ) (range 16%–49%). Lower reductions of BNP ( $918 \pm 934$  pg/ml) and weight ( $77.7$  kg  $\pm 13.8$ ) did not reach statistical significance (Fig. 4). The median hospital stay after enrollment was 3.5 days.

#### 3.2. Follow up period and compliance during outpatient study phase

Patients were followed with ReDS for an average of  $83.0 \pm 25.4$  days. Forty (40) of the 50 patients completed over 80 days of follow up. Ten patients exited the study earlier; 4 due to either cognitive or physical condition that prevented them from performing ReDS measurement, 4 after reaching a study endpoint and 2 withdrew consent.

Accordingly, there were a total of 3575 days of expected ReDS readings. The actual number of recordings was 3390, amounting to a 95% rate of compliance.

**Table 1**  
Baseline patient characteristics.

<i>Demographics</i>	
Gender (male)	31 (62%)
Age (years)	73.8 $\pm$ 10.3
BMI (kg/m <sup>2</sup> )	28.6 $\pm$ 4.7
NYHA grade (2, 3, 4)	(5, 37, 8)
LVEF (%) > 40	40%
<i>Medical history</i>	
Coronary artery disease	30 (60%)
Diabetes mellitus	29 (58%)
<i>Laboratory and physical findings</i>	
Creatinine (mg/dl)	1.4 $\pm$ 0.6
BNP (pg/ml) – admission	1231 $\pm$ 941
BNP (pg/ml) – hospital discharge	918 $\pm$ 934
$\Delta$ BNP (pg/ml) – admission-discharge	–254 $\pm$ 655
BNP (pg/ml) – last study visit	469 $\pm$ 377
Systolic blood pressure (mmHg)	128 $\pm$ 23
<i>Baseline medications</i>	
ARB/ACE inhibitors	40 (80%)
Beta blockers	43 (86%)
Thiazide	5 (10%)
Loop diuretics	46 (92%)
Statins	42 (84%)
MRA	13 (26%)
<i>Days in hospital and in the study</i>	
Days in hospital	6.1 $\pm$ 6.4
Days at home	76.9 $\pm$ 26.2
Total days in study	83.0 $\pm$ 25.4

#### 3.3. Rate and responses to ReDS reading notifications

A typical report from a patient managed using the ReDS system over the study period is shown in Fig. 3; this also shows daily weights and available BNP data. As seen in this example, and as revealed by average values shown in Fig. 4, changes in daily weight did not correspond closely with the ReDS readings. In such cases, by protocol, heart failure management was mainly guided by the ReDS readings.

From among all readings received, 255 readings in 41 patients (82% of study participants) were “out of range” and resulted in notifications to the investigators. The average rate of notifications was 2 per patient per month. All but 16 of those notifications were for ReDS readings above the upper threshold. In 73% of the notifications ( $n = 187$ ) the physicians chose to change patient management, mainly by changing medications ( $n = 137$ ). Those changes included increasing diuretic dose ( $n = 122$ , 89%), decreasing diuretic dose ( $n = 11$ , 8%) and a change in dose of ACE-inhibitor, ARB, or beta-blocker ( $n = 4$ , 3%). Other interventions included counseling the patient to encourage dietary compliance ( $n = 6$ ), reinforcing compliance with prescribed medications ( $n = 41$ ) and adjustment of thresholds for persistent out of range readings despite optimization of other therapies ( $n = 3$ ). 78% of these actions resulted in improvement of ReDS readings back towards the target zone within one week. Following 82% of those actions, the ReDS readings actually returned fully to within the target zone. As in the typical example of Fig. 3, ReDS values and BNP levels decreased from hospital discharge to the end of the 3-month follow-up period as summarized in Fig. 4 and also summarized in Table 1. However, patient weight did not vary significantly during the study period.

#### 3.4. Protocol-specified heart failure events

During the 3 months preceding enrollment, there were 15 hospitalizations in 11 of the 50 study patients. During the 3-month ReDS-guided management period there were 2 heart failure hospital readmissions in 2 patients and 2 patient deaths. In the 3 months following ReDS-guided management, there were 9 heart failure readmissions in 4 patients and 2 deaths out of the surviving 48 patients.

The readmission rate during the ReDS-guided management period was 0.04 events/patient/3 months. This readmission rate was compared to the pre-ReDS guided management and the post-ReDS guided management periods for which readmission rates were 0.30 and 0.19 events/patient/3 months, respectively. Comparison of these rates corresponded to an 87% reduction in admissions during the ReDS-guided period compared to the pre-ReDS period and a 79% reduction compared to the post-ReDS period (Fig. 5).

The HR for hospital readmission rates between the pre-ReDS period and the ReDS-guided management period was 0.07 (95% confidence interval [0.01–0.54],  $p = 0.01$ ). This represents a 14-fold greater risk for readmission in the pre-ReDS period than during the ReDS-guided management period. The HR for hospital readmission rates between the ReDS-guided management period and the post-ReDS period was 0.11 (95% confidence interval [0.014–0.88],  $p = 0.037$ ). This represents a 9-fold greater risk for readmission in the post-ReDS period than during the ReDS-guided management period.

Also of note, there was only 1 readmission in the study period within 30 days of the initial hospital discharge. This is in comparison to 3 readmissions in the first 30 days of the pre-ReDS period and 2 readmissions in the post-ReDS phase.

#### 3.5. Safety

There were no device-related adverse events experienced by any patient.



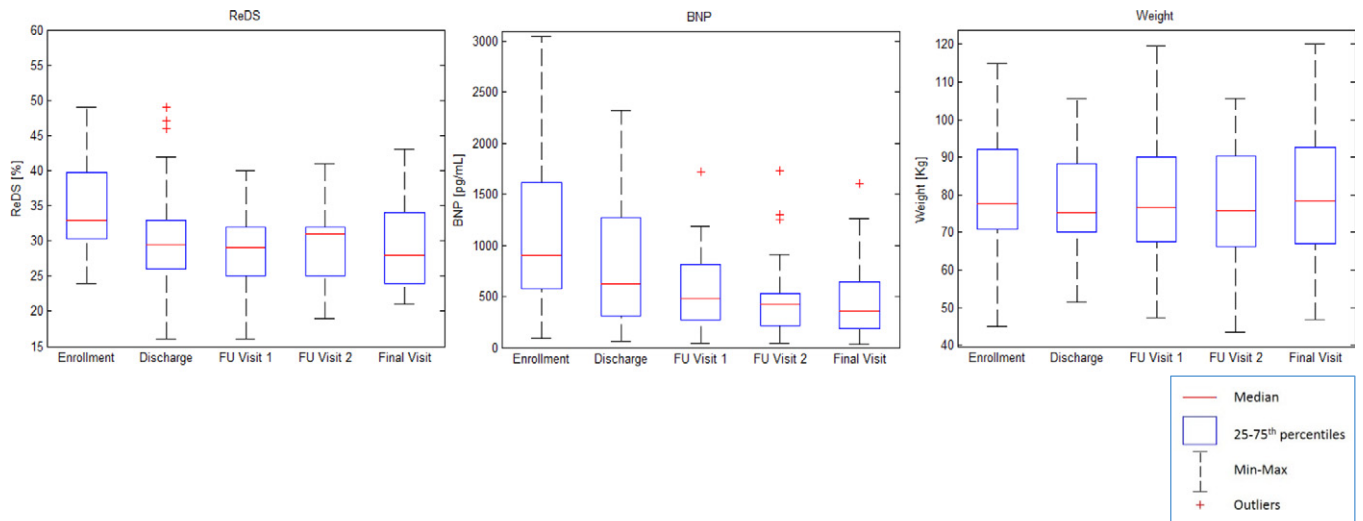


Fig. 4. ReDS, BNP and weight values during the study.

#### 4. Discussion

The results of this study show that use of the ReDS system is safe and provides important clinical information that can be useful in optimizing fluid status in the outpatient setting resulting in a reduction in HF rehospitalizations. Specifically, ReDS-guided HF therapy was associated with a decrease in HF readmission rates in comparison to pre- and post-study periods where ReDS measurements were not available. In comparison to the ReDS-guided management period, there was a significant 87% decrease in HF readmission rates compared to an identical duration of time prior to ReDS management, and an increase of 79% in the HF readmission rates after ReDS system usage was withdrawn. Since the ReDS system management was evaluated during the most vulnerable period for readmission (i.e., the first 90 days post-discharge) [24], the decrease in HF readmission is particularly noteworthy.

The corroborating decrease in serum BNP levels during the ReDS study period supports the stability of the HF state achieved using the device and reflects the fluid status optimization in these patients. The stable average ReDS values (at follow-up visits) from discharge to the end of the follow up period also signifies the stability of the patients (Fig. 4). Additionally, our study also identified weights as being insensitive to physiological changes in fluid status in comparison to ReDS and BNP measurements.

The data summarizing investigator responses to ReDS out-of-range alerts show that for the majority of alerts (73%) the investigators chose immediate action and in 81% of those actions, the ReDS value returned to within the normal range within a week. This suggests that the ReDS parameter is a sensitive and actionable parameter when managing heart failure patients.

Early detection of systemic fluid overload and/or pulmonary congestion is considered to be a fundamental means of preventing acute HF deteriorations, especially in high-risk patients. Accordingly, several strategies have been applied to anticipate lung water accumulation in HF patients. Remote telemonitoring using weight or detecting changes in bioimpedance, including internally implanted devices and wireless pressure sensors have been tried with variable success [19,25–28]. In the modern era of wireless transmission of patient data from personal hand-held devices, other technologies are also being investigated to detect changes in fluid status in heart failure patients such as changes in QRS amplitude [29–31]. The results of the present study contrasting changes in ReDS readings to changes in weight over the observation period provide insight into why weight-based strategies have been unsuccessful.

#### 5. Study limitations

Several study limitations should be noted. First, we compared ADHF observed hospitalization rates during the study period to those prior to and after the ReDS management period. Medication utilization was not tracked during those two periods but, by definition, it was based on standard of care. The study did not have a concurrent randomized control arm. Factors other than ReDS home monitoring may have contributed to the reduction in ADHF readmission rates during the study period. However, the increase in HF hospitalizations following withdrawal of ReDS monitoring supports a true treatment effect of ReDS-guided HF management. Second, the present feasibility study included a relative small number of patients. A larger randomized controlled study is currently recruiting patients and will more rigorously test the hypothesis that ReDS-based lung fluid content monitoring reduces the rate of heart failure readmissions (SMILE™, NCT02448342). That same study will explore the overall health economic benefits of the ReDS management system.

#### 6. Conclusions

The ReDS™ non-invasive technology provides sensitive and actionable alerts that serve as an early detection system of decompensation

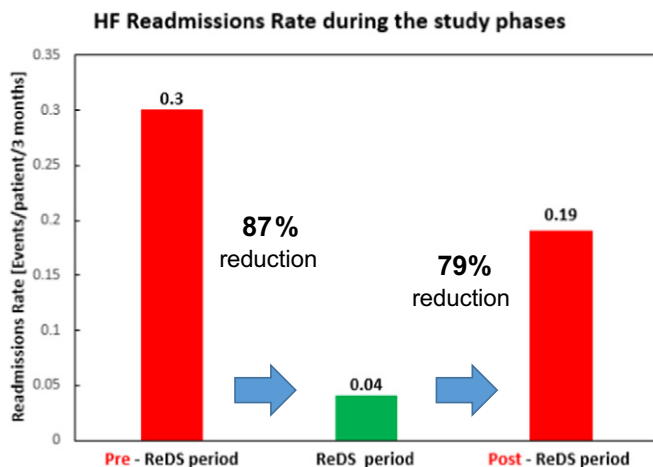


Fig. 5. Hospitalization rate in the 3 month pre-ReDS period, the 3-month ReDS monitoring period and the 3-month post-ReDS period.

with relatively low burden to patients and the health care system. Maintaining normal lung fluid content based on ReDS in these patients results in reductions of BNP levels and reduced hospitalizations compared to the pre- and post-study periods. Thus, the ReDS technology appears useful for remote, home management of patients who are at risk for HF rehospitalizations. A prospective, randomized controlled study is currently underway to prove that ReDS-based lung fluid content monitoring reduces the rate of heart failure readmissions.

## Industry disclosures

The study was sponsored by Sensible Medical Innovations Ltd. (SMI).

Dr. Abraham is an SMI consultant.

Dr. Amir was an SMI consultant at the time of study enrollment.

Dr. Ben-Gal was an SMI consultant at the time of study enrollment.

Dr. Burkhoff is an SMI consultant.

Dr. Abbo is an SMI employee.

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