Effect of the Remote Dielectric Sensing Vest on Reducing Heart Failure Admissions

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ABSTRACT

Introduction: Congestive heart failure (CHF) remains a major cause of hospital admissions in the United States despite advances guideline-directed medical therapy and cutting-edge technology. Few interventions have reliably demonstrated a sustained reduction in hospital admission. The Remote Dielectric Sensing (ReDS) vest, known as the Sensivest, is a non-invasive approach to assist in optimizing volemic status in patients with heart failure.

Hypothesis: In this study, we hypothesize that utilizing the ReDS vest in the outpatient setting prevented hospitalization for acute CHF exacerbation in patients with known CHF.

Methods: A retrospective chart review was performed to identify patients over the age of 18 with symptomatic CHF who received an outpatient ReDS vest reading in 2018. A total of 96 patients were entered in the study, and data related to demographics, heart failure variables, and use of guideline-directed medical therapy were collected. Following each ReDS vest reading, subsequent trends were tracked including CHF-related medication changes, ED visits, and hospitalizations. Results were compared to the general system population or to historical control.

Results: Three months after a ReDS vest reading, patients were significantly less likely to be hospitalized for CHF exacerbation compared to the interval prior to ReDS vest utilization (20.8% vs 43.8%, p < 0.001, CI 0.303-0.748). The overall number of CHF admissions was significantly decreased at 3 months (59 vs 25, p < 0.001). Interestingly, of the 22 patients who had been discharged from an inpatient stay and optimized with the ReDS vest outpatient within 30 days, the readmission rate was only 13.6%.

Conclusions: The ReDS vest offers a non-invasive, user-friendly approach to optimize management of heart failure that could offer the significant benefit of reducing hospital admission rate of these patients. Based on this study, further investigation including prospective randomized trials is warranted to identify how best to maximize the utility of this novel technology.

INTRODUCTION

Heart failure (HF) is one of the most costly and deadly disease states in the United States, being responsible for 1 in 9 deaths in 2009[1], an estimated $30.7 billion in health care expenses annually, and projected direct medical expenses of $57.5 billion by 2025.[2]

Remote telemonitoring holds potential as a method for reducing re-hospitalizations through the ability to gain objective fluid status data before the patient experiences symptoms that require hospitalization. One such monitoring device is the ReDS (Remote Dielectric Signaling) device, commonly referred to as the Sensivest. Although there is not currently an abundance of literature on outcomes of Sensivest use in the ambulatory setting, its initial outcomes study showed that HF admissions were reduced by 87% when used daily for fluid status monitoring.[3] Another study including use of a nurse-driven diuretic protocol resulted in a reduction in overall hospital HF readmission rate from 25% to 15%.[4]

This study aims to determine if the use of the Sensivest in the ambulatory setting and subsequent treatment decisions prevented hospitalizations.

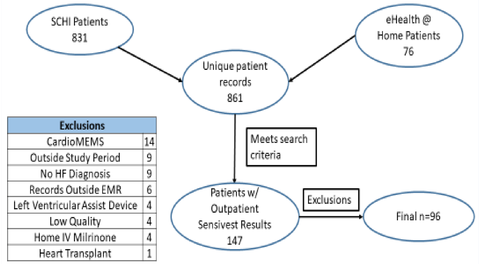
METHODS

Study Patients

All patients who received an outpatient Sensivest reading during the study period of January 2018-December 2018 were screened. The electronic medical record was used to create a list of all patients who had had a provider of nurse visit with the heart failure clinic, or office or home visits with the eHealth at Home team during calendar year 2018. The lists were combined for a total of 861 unique patient charts. Institutional Review Board approval was obtained to complete the study.

Patient charts were eligible for this study if the patient was 18 years of age or older, carried a diagnosis of symptomatic heart failure, and a documented use of a Sensivest device with a successful result.

Patient Chart Screening



Exclusions	
CardioMEMS	14
Outside Study Period	9
No HF Diagnosis	9
Records Outside EMR	6
Left Ventricular Assist Device	4
Low Quality	4
Home IV Milrinone	4
Heart Transplant	1

Figure 1
Describes the patient chart screening process.

Study Outcomes

The primary outcome of this study was to assess the efficacy of Sensivest-driven diuretic changes in reducing frequency of hospital admissions.

Multiple secondary outcomes include:
- Reduction in 30-day readmissions
- Reduction in ED visits
- Type of treatment change
- Percentage of patients with treatment changes without an office visit

Statistical Analysis

A convenience sample was used which included all eligible patients. As such, power calculations were not performed prior to study initiation. A two-sided alpha of 0.05 was pre-specified as significant.

McNemar's contingency tables were used to yield Chi-squared values for comparing an individual patient's admission status before and after a Sensivest reading. Chi-squared values were then converted to P-values to test for significance.

Wilcoxin-ranked sign test was used to compare number of admissions before and after Sensivest readings.

Descriptive statistics were used for the operational secondary outcomes.

DATA

Demographics		#	%
Sex	Male	57	59.4
Ethnicity	Caucasian	63	65.6
	African American	18	18.8
	Asian	1	1.0
	Hispanic	13	13.5
	Native American	1	1.0
Average Age		68.0	
Body Mass Index (kg/m^2)	Average	30.7	
	>35	23	24.0
	30-34.9	28	29.2
	25-29.9	28	29.2
	17.5-24.9	17	17.7
	<17.5	0	0.0
eHealth @ Home		28	29.2

Clinical Measures			
Average Ejection Fraction		38.6	
HF Type	Reduced	49	51.0
	Preserved	35	36.5
	Midrange	12	12.5
NYHA Functional Class	I	0	0.0
	II	25	26.0
	III	42	43.8
	IV	2	2.1
BNP/Pro-BNP*	Unknown*	26	27.1
	BNP	29	30.2
	NT-Pro BNP	40	41.7
Average	BNP	818	
	NT-Pro BNP	3895	
Serum Creatinine (mg/dL)	Average	1.4	
eGFR (mL/min/1.73m^2)	>60	37	38.5
	45-59	25	26.0
	30-44	24	25.0
	15-29	8	8.3
	<15	0	0.0
Event within 30 days prior		36	37.5
	Admission*	22	22.9
	ED/OBS	6	6.3

Medications			
Beta-Blocker		75	78.1
ACE		27	28.1
ARB		8	8.3
ARNI		27	28.1
Spironolactone		46	47.9
Hydralazine/Isosorbide		7	7.3
Ivabradine		1	1.0
SGLT-2		1	1.0
Diuretics	Furosemide	40	41.7
	Torsemide	47	49.0
	Bumetanide	1	1.0
	Metolazone	8	8.3
	None	7	7.3

Figure 2
Background characteristics of the study population.

3 Months

		Sensivest		
		Admission	No Admission	Sum
No Sensivest	Admission	13	**29**	42
	No Admission	**7**	47	54
	Sum	20	76	***96***

- McNemar's Chi-squared: 13.4

Figure 3
When used as their own controls, patients were less likely to be admitted for HF after a Sensivest reading. This effect was significant (P<0.001) at 3 months, and nominal (P=0.099) at 1 month after Sensivest reading. In the 3 month period, 42 (43.8%) patients were admitted before reading, while 20 (20.8%) were admitted after (RR: 0.476 (95% CI: 0.303-0.748). The total number of HF admissions was also significantly decreased from 59 prior to reading to 25 after (P=0.0007) at 3 months. Of 22 patients who had been discharged from a heart failure admission within 30 days prior to reading, 3 (13.6%) were readmitted

N= 203 Readings	#	%
Change	141	69.5
No Change	62	30.5

Change Type	#	%
Acute	68	48.2
Chronic	39	27.7
Both	34	24.1

Acute Change	#	% (Of all changes)
IV Furosemide	85	60.3
Temporary PO Increase	20	14.2

Chronic Change	#	% (Of all changes)
Increase Maintenance Diuretic	24.0	17.0
Decrease Maintenance Diuretic	5.0	3.5
Change to GDMT	36.0	25.5
Change to Both	10.0	7.1

Figure 4
Describes the summary of treatment decisions based on 203 total Sensivest readings. Average Sensivest reading result was 38.7%; 153 readings (75.4%) indicated fluid overload. In addition, 85 readings (41.9%) were performed without a provider visit.

CONCLUSION

- In a small sample size outpatient clinical practice we demonstrated significant reduction in unexpected hospitalizations for heart failure (23% ARR)
- Despite a low number of patients, the overall 30 day readmission rate with the use of the vest was 13.6% which is comparable to what other trials have found with use of the vest (4)
- Approximately 70% of patients managed with the vest had a change made in medical management for heart failure based purely on an elevated vest reading
- 41.9% of vest reading and management decisions were made via protocol with nursing interactions, no provider was present

DISCUSSION

- There are very few clinical trials exploring the use of external monitoring devices to manage heart failure in the outpatient setting
- This is only the 2nd reported use to our knowledge of the Sensible Medical Vest in an outpatient/nursing visit protocol to manage heart failure
- This data demonstrates both the feasibility and benefits of incorporating an algorithm based approach with nursing visits to drive down admissions to the hospital environment
- Limitations of this trial include the retrospective nature of the data, using patients as their own controls and the small sample size and single center experience
- Certainly a randomized blinded trial should be done to validate this

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REFERENCES

1. Mozaffarian D, Benjamin EJ, Go AS et al. Circulation 2016; 133: e38-360.
2. Heidenreich PA, Trogdon JG, Khavjou OA et al. Circulation. 2011; 123 (8): 933–44.
3. Abraham WT, Amir O, Weinstein JM et al. Jour of Card Failure. 2015. 21 (8): S77.
4. Curran L, Peck, K, Carter K et.al. Jour of Card Failure. 2018. 24(8): S48.

DISCLOSURES

Sumon Roy: *none*. Scott Feitell: *Consultant, Sensible Medical Technologies; Consultant, Abbott*. Remaining authors do not have relevant disclosures.