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The FOOT study: observational retrospective multi-center clinical trial evaluating alerts from the Heartfelt device



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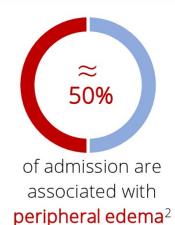
<u>Introduction</u>



Standard care recommendations include the monitoring of symptoms and daily weighing at home



of patients do not weigh themselves or monitor symptoms in the 2 weeks prior to admission¹





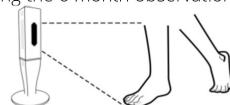
Is there a missed opportunity for clinicians to respond rapidly to early changes in congestion?

Hypothesis

Our hypothesis is that the Heartfelt device can directly detect the increase in peripheral edema associated with heart failure decompensation and that, on average, the number of days with missing data collected by the Heartfelt device will be lower than that of the weighing scales.

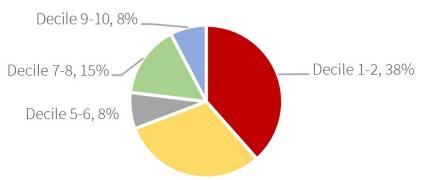
Methods

31 patients were recruited to the study and 26 provided with connected weighing scales and the Heartfelt device (+4G internet dongle if required) from 5 hospital trusts in the UK. Many patients lived in areas with high deprivation levels. We looked at the acceptability, usage of the devices and correlation between alerts and HF events (hospitalisations and death) during the 6 month observational study.



Inclusion criteria: Patients age 18 years or older; Patient with any heart failure diagnosis; Patient with one prolonged inpatient stay; Patient with significant peripheral edema at admission; Patient with significant weight loss following admission (at least 5kg weight loss); Patient has been discharged on at least Furosemide 80mg or Bumetanide 2mg/d.

$Health\ Deprivation\ and\ Disability\ Index$



Decile 3-4, 31%

Distribution of the locations of study participants: from 10% most deprived areas (Decile 1) to the least deprived areas (Decile 10) in the UK.

Exclusion criteria: Patient has bandages every day; Patient has an amputation of the foot; Patient lacks capacity to consent; Patient is of no fixed abode; Patient has plans for intervention (CRT, Valves); Patient taking part in another study.

CONSORT Diagram

31 patients recruited

1 died before installation

1 could not have device in

1 died before discharge

1 could not have device installed due to prolonged use of large leg bandage

1 withdrew: "patient feeling depressed, not wanting commitment of a trial"

patients with device installed

Results

| | All Patients N=26 | Patients with Events <mark>N=8</mark> | |
|---------------|-------------------------|---|--|
| Median Age | 76.8 (70.4-83.8) | 82.3 (76.3-84.7) | |
| Gender | 35% female | 38% female | |
| LVEF >50% | 30% | 25% | |

| | # of Events | # Alerted | |
|--|----------------|--------------|--|
| Outpatients | 2 | 0 | |
| Hospitalizations | 6 | 5 | |
| Deaths | 1 | 1 | |
| #Alerted is number of events for which the alert was raised in the prior 2 weeks | | | |

1 end of life: relative against trial participation



1.1 day/week of data [0.3-4.1]
Median patient has
5.9 day/week of data [4.9-6.6]

Median patient has



Baseline Patient hospitalized Scan next day

Data leading up to hospitalization for one of the trial participants





13 days advance warning on hospitalization/worsening [6.5-20]

Conclusion

The Heartfelt device can directly detect the increase in peripheral edema associated with heart failure decompensation and provides significantly more days with data than weighing scales, thus predicting more HF events.