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Heart failure decompensation alerts in a patient's home using an automated, AI-driven, point-of-care device

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Accepted 17 March 2022

To cite: Chausiaux OE, Keyser M, Williams GP, *et al*. *BMJ Case Rep* 2022;**15**:e248682. doi:10.1136/bcr-2021-248682

SUMMARY

Heart failure (HF) is a major challenge worldwide and needs continuous monitoring of patients even after hospital discharge. This case report summarises the data collected and experience gained from the first usage of an automated, point-of-care device (Heartfelt device) in a patient's home in the UK. The device monitors the onset of peripheral oedema and alerts clinicians if an increase in volume outside an expected normal range for the patient is detected. This may provide a reliable method of remotely and automatically monitoring HF patients in the home for those who do not reliably use weighing scales. The device successfully provided data for about 15 months and generated alerts in advance, which supported decisions for the patient's care. The rate of data acquisition was very high and consistent throughout this period. The patient was satisfied with the device and agreed that it helped in her decision to seek medical attention.

BACKGROUND

Heart failure (HF) is a complex condition, which can be explained by the reduced ability of the heart to pump enough blood through the body. It affects more than 26 million people (mostly elderly) across the world[1] and results in higher disability-adjusted life-years (DALYs)—that is, years lost due to ill health—for affected patients. DALYs are high in HF patients due to frequent hospitalisations and decreased quality of life. This leads to an increased burden on hospitals because HF patients are frequently readmitted (1 million bed days per year in the UK alone). DALYs due to ischaemic heart disease, which is a common cause of HF, have steadily increased since 1990 and reached 182 million in 2019 worldwide.[2] Common manifestations of HF include fatigue, dyspnoea, limited exercise tolerance and peripheral/pitting oedema, which is an accumulation of fluid in the body's extremities. HF patients suffer from poor prognoses and there is an urgent need to find reliable monitoring of key indicators of HF in the home.[3]

Peripheral/pitting oedema is a common symptom of HF with a predictable progression (10–14 days) into acute disease.[4] Many strategies have been developed to monitor it and although the estimation of leg and foot volume is done in academic settings,[5] the only practical methods are the evaluation of pitting oedema by a trained medical professional or the daily measurement of full body weight in the home as a proxy.[6 7] This is often too demanding for patients and many struggle to keep up with the medical advice. This leads to patient noncompliance, which is thought to be a major driver of hospital readmissions.[8–10] Clinically, other solutions such as apps reminding patients to take measurements,[11] voice-response systems[12] for daily measurements, or implantable devices such as CardioMems[13] or Heartlogic[14] have been used. However, these methods all suffer from reliability issues,[15] have poor patient compliance, have significant drop-off rates[16] after their installation/setup and/or are very costly.[17]

We aimed to mitigate low patient compliance and offer reliable monitoring (and alert generation) for HF progression by using our automated, point-of-care, artificial intelligence based telemonitoring device (Heartfelt device, Heartfelt Technologies). In this case report, we show the successful operation of the Heartfelt device in a patient's home for the first time and assess its regular, reliable data collection from the HF patient through to the generation of alerts ahead of hospital admissions. In this case, potentially expensive and stressful emergency admissions were avoided, as sufficient notice was given to allow for planned admissions.

CASE PRESENTATION

Patient information

A woman in her 70s diagnosed with HF in 1999, having comorbidities such as chronic obstructive pulmonary disease, asthma, hypertension, diabetes and kidney failure (stage 4). The patient lived with a full-time carer, in one of the most deprived (decile 1 for both the Index of Multiple Deprivation and the Health Deprivation and Disability Domain) areas of England.[18] As per usual practice, the patient was mostly looked after by her general practitioner (GP).

The patient and her son provided informed consent to use her anonymised data for research purposes. The patient's son consented to the access and use of the patient's medical records after she had passed away. The data were collected as part of post-market surveillance activities in the UK.

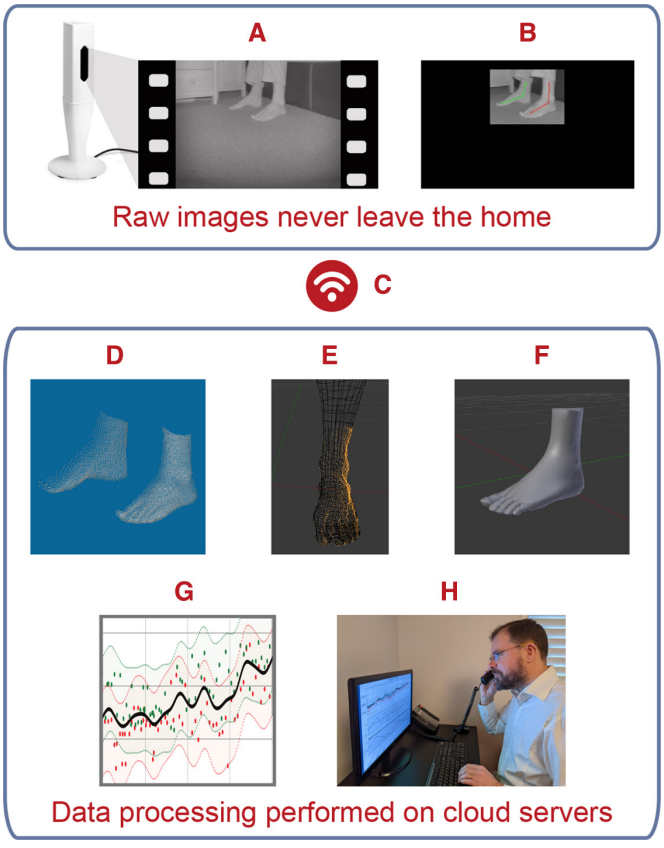

Figure 1 The data processing workflow of Heartfelt device from data acquisition to generation of HF decompensation alert. (A) A convolutional neural network (CNN) monitors each 3D sensor, deciding when to capture a suitable 3D image. (B) The 3D image is censored to show only the foot/lower leg and estimate pose (location and orientation of the feet) using another CNN. (C) The censored 3D image and pose estimation is transmitted via the Internet to our cloud-based server. (D) The 3D data from a set of 3D images is fitted to an anatomical model using non-linear regression. (E) The refined model produces a virtual foot in a standard pose and orientation which is (F) filled with virtual water to a standard height to obtain foot volume and the foot volume trend over time (G) is monitored in exactly the same manner as currently done with patient weight for oedema detection. An increase above preset volume results in an alert to the health-support staff (H).

TREATMENT

Device information

The Heartfelt device (Heartfelt Technologies) and connected weighing scales (Xiaomi Smart Scales, Anhui Huami Information Technologies) were installed in the patient's home and connected via the internet to cloud-based servers for continuous monitoring.

The Heartfelt device is an automated, non-invasive, remote volume-monitoring system that uses 3D sensors to automatically measure the volume of the foot/lower leg and generates alerts when the foot volume increases. In a hospital study, the volumes measured using the Heartfelt device were compared with volumes measured using water displacement (gold standard to measure foot volume) and the Heartfelt device had a SE of measurement of ±12.6 mL.

The 3D sensor captures images (figure 1) at a rate of 30 images per second, which are censored at knee height. Measurements are then processed using artificial intelligence in cloud servers.

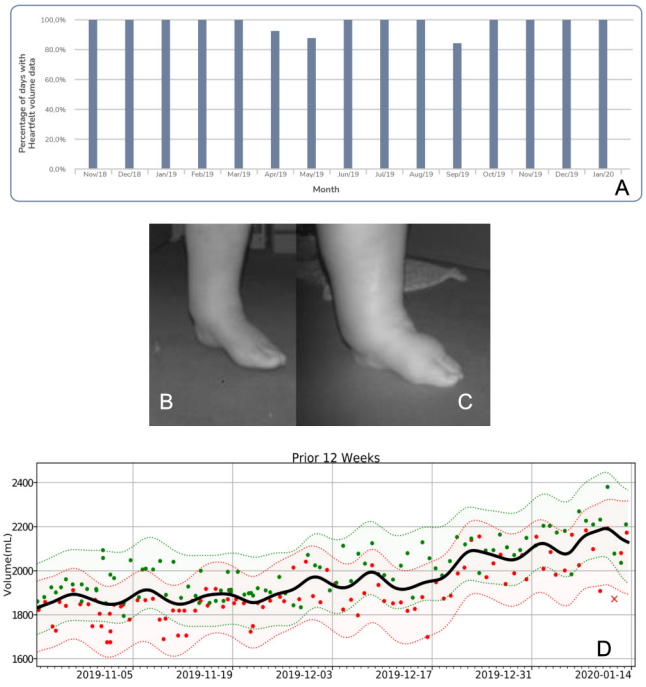

Figure 2 (A) Percentage of days with 'volume data' generated for the patient from November 2018 to January 2020. Representative images collected with the Heartfelt device: (B) on the installation date; (C) on one of the days an alert was generated. (D) Foot volume variation over time. The green dots are the volume of the left foot and the red dots are the volume of the right foot. The solid lines are Kalman estimators of foot volume with 90th percentile CIs for any one measurement falling within the dashed lines. The solid black line is the average of the left foot and right foot Kalman estimators.

A selection of 4–8 3D images are used to calculate the volume, these images may have been captured over a period of a few minutes or hours depending on the patient's routine in the room where the device is located. When an increase in volume is detected beyond baseline level (oedema), an alert is generated. The alert can be sent to the patient, their carer or their clinical team. The innovation of the Heartfelt device is that it requires no specific action from the patient unlike other telemonitoring technologies that require patients to interact or comply with instructions for use. Even weighing scales, which are used as part of standard care for the management of HF,[19] require a level of compliance from patients.

OUTCOME AND FOLLOW-UP

Timeline

The Heartfelt device was installed in the patient's house at a location and height to allow for optimal data collection and it successfully collected and transmitted data for fifteen months (November 2018 to January 2020; figure 2A) until the patient's first hospital admission. A few more days of data were collected between discharge and the second admission. 3D images of feet/lower legs of the patient were automatically captured, censored, encrypted and transmitted securely over the internet to cloud-based servers for final processing to generate daily foot/lower leg volumes. These daily data points were monitored by trained operators and our setup ensured that no change was required in the patient's lifestyle or standard care and she could be monitored safely in her home.

First alert

Following an increase in lower limb volume starting in late December 2019 (figure 2B–D), an alert was raised on third Jan 2020 and the patient and her carer were informed as per the agreed contact method with the patient and her family at the time of installation. A follow-up alert was generated on 11 January 2020 and the patient was visited by a GP on 12 January 2020 on patient's request, at which point peripheral oedema was confirmed up to the knee. Given that the patient had kidney failure and was on the maximal tolerated dose of oral diuretic (120 mg furosemide/day and 50 mg/day spironolactone), the ongoing medications were kept the same.

First hospitalisation

For the next few days, the patient's condition did not improve and the GP was called for a home visit again. Peripheral oedema was noted as thigh-high and ascites, and the patient also suffered severe shortness of breath after five steps. The GP and patient agreed that the best course of action would be to get IV diuretic to help reduce congestion. In the patient's area, this can only be done through an admission. Therefore the GP planned for the patient to be admitted on 16 January 2020. The patient was admitted as a non-urgent admission to a cardiology ward and HF decompensation was subsequently confirmed. The patient remained hospitalised and was discharged on 7 February 2020 with further treatment of high-dose diuretics.

Second alert

The system logged measurements following discharge, which indicated the patient was not euvolaemic and her feet were still swollen. The patient was then bedbound for several days, and on 12 February 2020 a further measurement with >300 mL increase was made, and the patient was informed.

Second hospitalisation

After the second alert, the condition of the patient deteriorated rapidly. New diuretics were prescribed by her GP, 5 mg amiloride and 2.5 mg metolazone and furosemide was reduced to 160 mg/day. She was then admitted to hospital again on 15 February 2020 as a non-urgent admission. The patient remained in hospital until the 23 February 2020 and began to receive palliative care from 24 February 2020 onwards. The patient subsequently died on 8 March 2020.

Follow-up and outcomes

The volume trends and alerts generated throughout the 15 months for the patient are shown in figure 2D. Alerts were generated both times in a timely fashion to prevent the need for an emergency hospital admission. The device has successfully provided volume data on 97.7% of days (over fifteen months) and the volume capture did not drop off over time (figure 2A).

DISCUSSION

The monitoring of a patient's symptoms such as peripheral oedema, weight gain, breathlessness and tiredness can indicate the progression into acute HF. A number of existing solutions for monitoring symptoms are available to HF patients; however, they all require some level of long-term adherence, which can be challenging for some patients. Despite the fact that daily weighing is the standard recommendation in the UK,[6] this patient did not weigh herself once during this period. She did not measure blood pressure on a regular basis either, or use any other monitoring devices which require protocol adherence. By comparison, given the Heartfelt device's automatic mode of operation, its rate of data acquisition can be very high provided that the device is strategically positioned in the patient's home to face an area where the patient is likely to be barefoot at some point each day. In this case study, the device collected and transmitted at least one foot volume measurement for 97.7% of days (416 days out of 426 possible), with the volume of both feet being measured on 414 days. No drop-off in acquisition rate was observed over the 15 months. This rate of data acquisition is both superior to and more consistent over time than published rates for other telemonitoring technologies.[15–17 19]

For telemonitoring solutions to be effective, alerts need to be actionable by clinical teams. This means that they need to receive easy to interpret alerts, in a timely fashion and with a reasonable false positive rate to avoid alert fatigue. The volumes measured by our device are easy to interpret by clinicians as they are provided in a well-known international standard unit (mL). The proprietary algorithm used to trigger an alert is likely to be optimised over time as more data is collected with this technology.

In this case study, the Heartfelt device detected an increase in the patient's foot/lower leg volume 13 days prior to first hospital admission and generated alerts which gave enough time for providing medical attention to the patient. This appears to be in line with other remote monitoring methods used for HF patients and is expected to provide enough time for medical interventions aiming to prevent urgent hospital admission. For example, Heartlogic typically provides 38 days[14] of warning before admission, CardioMEMS over 20 days[20] and weight monitoring 11 days.[20]

Although implantable devices may provide an earlier response time, which might allow the titration of ACE inhibitors, for example, many patients are not suitable for this type of surgery, or lack the required level of compliance to transmit data on a daily basis. Many healthcare systems also take into consideration likely benefits for each patient before approving the use of implantable devices, which are generally more expensive. This is why the standard care uses weighing scales as these are very cheap, even if only a minority of high-risk patients are able to use them reliably to effectively manage their HF.[21 22]

Some HF home monitoring solutions measure a range of markers to provide alerts,[23–26] whereas the Heartfelt device focuses solely on peripheral oedema. However, in both cases, the response to alerts is similar. Alerts always require validation by a doctor cross-examining the patient's history before any clinical decision to change to the patient's treatment plan is made. The Heartfelt device is designed to raise reliable alerts to clinicians, patients and their carers in order to prompt and inform an assessment of the patient, not to be used as a closed loop system recommending the change in medication. A change in volume may be caused by other medical conditions, which may be comorbidities. It is therefore important to review these prior to recommending the device. In this case study, the fact that the alerts for the patient were relevant despite her having stage four kidney disease, known to also affect the fluid state of the body, is encouraging.

The Heartfelt device is not currently commercialised, and is used exclusively in pilots and trials. Further trials are needed to establish the cost effectiveness of the device and allow the manufacturer and healthcare systems to agree on a price structure that would reflect this value. The device is manufactured from electronic components which are more expensive than those found in connected weighing scales, but vastly cheaper than those found in implantable devices. So it is expected that the cost will

Patient's perspective

Having the device in the home was a Godsend. We felt that the calls made to us when the volume readings increased made us aware of the problem and helped us communicate the situation to our doctor. This ultimately ensured that we received a prompt visit from the doctor. The alerts prompted us to seek help as otherwise we might have waited another few days before deciding to seek medical help. Before the calls we hadn't noticed the worsening of heart failure symptoms.

Learning points

- This is the first example of how a new automated, point-of-care device for monitoring foot volume has been used in the UK with a patient with heart failure (HF). This technology promptly and accurately generated alerts for worsening HF in the patient's home. It monitored the patient for a long period of time without the rate of data acquisition drop-off that has been observed with other telemonitoring methods.
- The patient had a good experience with the installed device and it improved her and her carer's ability to decide whether to seek medical help when needed. The data produced from the patient is very promising, in particular for patients who are casually compliant with monitoring recommendations.
- If these findings are confirmed in larger studies, with a wide range of patient groups and geographies, the Heartfelt device may provide a non-invasive solution for clinicians to reliably monitor patients remotely who are living alone or with minimum assistance in the comfort of their home.

be significantly less than implanted devices (typically £10 000+) but more than conventional weighing scales (<£100).

Acknowledgements OEC and SLGH are founder-directors of Heartfelt Technologies and hold stock in the company, GPW is a director of Heartfelt Technologies and holds stock options in the company, and all three are employed by the company and are inventors on granted patent GB2576770B. SLGH is the inventor on granted patent GB2542114B. PJD and MK are employees and option holders in the company. MN is a consultant and an option holder in the company. RB and REG were both student interns with the company when they contributed to the work.

Contributors OEC drafted the manuscript and did some of the analysis. MK collected some of the data and contributed to the critical review of the manuscript. GPW did some of the analysis and contributed to the critical review of the manuscript. MN contributed to the critical review of the manuscript. RB contributed to the critical review of the manuscript. REG contributed to the critical review of the manuscript. PJD contributed to the data analysis and critical review of the manuscript. SH did most of the analysis and contributed to the critical review of the manuscript.

Funding This study was funded by Heartfelt Technologies, UK.

Competing interests None declared.

Patient consent for publication Consent obtained directly from patient(s)

Provenance and peer review Not commissioned; externally peer reviewed.

Case reports provide a valuable learning resource for the scientific community and can indicate areas of interest for future research. They should not be used in isolation to guide treatment choices or public health policy.

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