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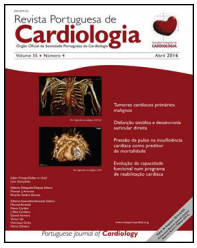

EDITORIAL COMMENT

Wearable remote monitoring in heart failure care – where do we stand?

Monitorização remota da insuficiência cardíaca com *wearables* – onde nos encontramos?

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Heart failure (HF) is a highly prevalent and increasingly present condition with a huge impact on several global healthcare dimensions. HF hospitalizations are particularly burdensome and are among the leading concerns of HF health providers, both related to the economic impact and the association with adverse outcomes. In Europe, the (re)admission rate at 12 months varies from 25.9% to 44%[1,2] and in the ESC Heart Failure Long Term Registry a medium 5.5% in-hospital mortality rate was observed(ranging from 1.8% to 36.1% according to presenting clinical phenotype),[2] highlighting the insufficiency of current approaches to disease management. According to Gouveia et al., in Portugal, HF hospitalizations portended 39% of direct HF-related costs in 2014, corroborating the economic burden of HF hospitalization among us.[3] Telehealth has been embraced as a practice to mitigate HF effects by allowing upstream detection of worsening clinical status. This home-rendered medical care strategy encompasses a range of methods, from structured self-monitoring telephone-based programs to sophisticated device remote monitoring. A promising methodology that might be conceptually superior to standalone clinical appointments, albeit with inherent limitations not easy to circumvent. The difficult journey to where we are now illustrates this clearly.

Developing technologies using surrogate biomarkers for earlier detection of HF exacerbation may enable prompt adoption of stabilizing measures prior to overt clinical deterioration and avert the need for hospitalization. This concept has triggered multiple approaches in recent years. One of the first attempts explored technical breakthroughs affording automatic monitoring of physiological (heart sounds, respiration, thoracic impedance, heart rate, patient activity) and technical data (arrhythmic burden, pacing percentage, inappropriate shocks, lead sensing properties) in implanted cardiac electronic devices (CRT pacemakers, defibrillators), using single or multisensory based diagnostic algorithms. This device-guided telemonitoring proved to be feasible and potentially incrementally beneficial.[4,5] Yet, clinical trials using implanted devices have not consistently shown clinical benefit in HF settings.[6] At the heart of the problem might be finding the right biomarker or set of biomarkers to track rather than the specific idea of remote management. Since filling pressures play a pivotal role in decompensating HF's pathophysiology, it did not come as a surprise that monitoring some of their surrogate markers has been revealed as one of the most sound for that purpose. Recent data show that remote hemodynamic-guided care,

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tracking left atrial pressure, pulmonary artery pressure or right ventricular pressures as estimates of filling pressures is undoubtedly beneficial in preventing HF hospitalizations,[7] validating the robustness and apparent superiority of the predictive value of these parameters.[8] Of these, sensing pulmonary artery pressure by CardioMEMS HF System (Abbott, Sylmar, California) seems to outperform other options having one of the most solid pieces of evidence in reducing HF hospitalizations, with a remarkable more than 50% drop, regardless of HF phenotype (either with a reduced or a preserved ejection fraction).[9] Wearable devices, defined as externally applied gadgets capable of sensing functional and physiological signals, are newcomers to the HF arena as non-invasive alternatives to such technologies.

In this issue of the *Journal*, Martins et al. present the rationale behind a proposed prototype of a wearable vest with an inbuilt multisensory system.[10] In brief, the authors integrate this device in a broader project of remote HF monitoring they intend to implement – the GENICA project. Is this unprecedented? Despite being an emerging approach, they are not pioneers in this field. As others have done previously, they hypothesized that ambulatory non-invasive device-based capture, collection, transference, and processing of biodata might be of value in HF care. The efficacy of this non-invasive biodata streaming has not yet been entirely determined, and the evidence in this setting is scarce. Preliminary strategies using single-channel monitoring, based on transthoracic bioimpedance obtained via a wearable vest, have shown encouraging results. The SENTINEL-HF trial reported 87% sensitivity and 70% specificity for identifying recurrent HF events, the downside being significant data loss and patient withdrawal.[11] Estimation of lung fluid content by dielectric sensing is another alternative under investigation. Amir et al., using remote dielectric sensing technology (ReDS), reported, in an observational, multicenter, prospective study of 50 patients, an 87% reduction and a 79% increase in hospitalization with ReDS-guided medical titration when compared, respectively, to the 90 days prior and the 90 days post-use of the vest.[12] A prospective randomized clinical trial using this device in acute HF hospitalized patients is underway (NCT03586336). An analogous device, targeting lung-fluid evaluation, albeit with additional functionalities, is being tested in a larger-scale clinical trial (NCT03476187) and will, hopefully, shed further light on this topic. Furthermore, novel metrics to assess cardiovascular hemodynamics and impending HF decompensation are emerging, such as evaluation of seismocardiogram signals that rely on chest vibrations and leg bioimpedance measurements.[13,14] Nevertheless, despite the heightened interest in these wearable vests, there are no data on their real-world impact on HF hospitalizations.

The current trend on the toolbox of wearables in HF focuses on multiparameter systems. The authors' proposal is part of this recent trend and has the potential to bring additional insights into this field. The precursor MUSIC study comprised an external, adherent, multisensor system that had, in the validation cohort, 63% sensitivity and 92% specificity for detection of HF events.[15] Recently, Stehlik et al. described the results of a wearable device similar to the authors, also integrating a variety of sensors (ECG, heart rate, respiratory rate, body temperature, activity level, and body position), tested in the LINK-HF study (Multisensor Non-invasive Remote Monitoring for Prediction of Heart Failure Exacerbation).[16] Using a machine learning algorithm, the analytical platform tested demonstrated 76% to 88% sensitivity and an 85% specificity to detect precursors of HF hospitalizations with median anticipation (time from alert to readmission) of 6.5 days. These results compare closely to those of implantable devices. Likewise, just a few months ago, another analogous cloth-based diagnostic monitoring platform (Wearable Congestive Heart Failure Management System - SimpleSENSE) received FDA approval. Its application in HF care is being tested in the validation NanoSENSE trial (*NCT03719079*). The device designed by the authors integrates a sizable number of biosensors targeting vital, electrophysiological, hemodynamic, and chemical biosignals: transthoracic impedance, electrocardiographic data (heart rate and heart rate variability, T wave amplitude variability, electric conduction abnormalities, atrial and ventricular arrhythmias, myocardial ischemia), right atrial and left atrial pressures, systemic arterial blood pressure, pre-ejection period, cardiac output, peripheral oxygen saturation, respiratory rate, and skin sodium content, along with patient's physical activity levels.

In this paper, the investigators explore the theoretical foundations for selecting these specific bioparameters. Most of them are self-evident options, whereas others are of questionable interest. The complex interplay of pre-ejection period determinants alongside the redundant information it provides compared to other signals impairs its incremental diagnostic value with the disadvantage of adding intricacy to the analytical system. The skin has increasingly been recognized to participate in the regulatory system of body sodium (Na) homeostasis. Skin Na-storage role, better studied in other conditions such as hypertension and chronic renal disease, has little evidence in HF, as acknowledged by the authors. Hence, the inclusion of a Na-sensor has the single merit of functioning as a research tool rather than an intervention-guiding parameter.

One of the main difficulties that this prototype may encounter is feasibility. Technical operability, although challenging considering the number of sensors required, is probably the easiest to circumvent. The assembling of the enormous dataflow volume that such a system will generate is the ultimate challenge the authors face, along with mapping out well-defined downstream healthcare delivery models to attain this approach's full potential.

This device, similar to others, offers the possibility of reshaping the monitoring paradigm of HF ambulatory care. However, some caution is wise before becoming overenthusiastic. Several obstacles, beyond the technological ones, must be overcome. We are at a point in engineering informatics where remote collection and processing of data pose little difficulties, and the level of precision is high. Data overload is a concern, but several upfront technical solutions integrating artificial intelligence-driven algorithms are already in place or on the horizon. Contrarily, most of the medical infrastructures and healthcare modus operandi face some inertia and are now surpassed by these technological innovations. So, converting those data into better clinical decision-making impacting HF outcomes is the actual task that the medical community has to handle. Successful implementation of these interventions is dependent not only on appropriate patient selection and widespread availability,

but also on the effectiveness of the network of logistics and operationality set. The inconsistent application of cardiac implantable electronic devices monitoring capabilities in HF care, tracking almost the same biosignals as wearables, clearly demonstrates this. Lastly, there are legal and ethical issues related to regulation and data security that have to be addressed. In Europe, strict regulatory systems require conformity with the CE marking (EU Regulations 2017/745 and 2020/561) and General Data Processing Regulation (GDPR - EU Regulation 2016/679).

All things considered, given modern HF care needs, once proven valid and reliable, it is foreseeable that these innovative wearable solutions will assuredly be well-received. It is expected that their application will be efficacious, provided they do not jeopardize intangibles variables such as quality-of-life and well-being.

For the time being, we are at the outset of this new frontier in HF management.

Conflicts of interest

The author has no conflicts of interest to declare.

References

1. Maggioni AP, Dahlström U, Filippatos G, et al. EURObservational Research Programme: regional differences and 1-year follow-up results of the Heart Failure Pilot Survey (ESC-HF Pilot). Eur J Heart Fail. 2013;15:808–17.
2. Chioncel O, Mebazaa A, Harjola VP, et al. Clinical phenotypes and outcome of patients hospitalized for acute heart failure: the ESC Heart Failure Long-Term Registry. Eur J Heart Fail. 2017;19:1242–54.
3. Gouveia MRA, Ascenção R, Fiorentino F, et al. Current costs of heart failure in Portugal and expected increases due to population aging. Rev Port Cardiol. 2020;39:3–11.
4. Hindricks G, Taborsky M, Glikson M, et al. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. Lancet. 2014;384:583–90.
5. Boehmer JP, Hariharan R, Devecchi FG, et al. A multisensor algorithm predicts heart failure events in patients with implanted devices: results from the MultiSENSE study. JACC Heart Fail. 2017;5:216–25.
6. Morgan JM, Kitt S, Gill J, et al. Remote management of heart failure using implantable electronic devices. Eur Heart J. 2017;38:2352–60.
7. Adamson PB, Ginn G, Anker SD, et al. Remote haemodynamic-guided care for patients with chronic heart failure: a meta-analysis of completed trials. Eur J Heart Fail. 2017;19:426–33.
8. Halawa A, Enezate T, Flaker G. Device monitoring in heart failure management: outcomes based on a systematic review and meta-analysis. Cardiovasc Diagn Ther. 2019;9:386–93.
9. Shavelle DM, Desai AS, Abraham WT, et al. Lower rates of heart failure and all-cause hospitalizations during pulmonary artery pressure-guided therapy for ambulatory heart failure: one-year outcomes from the CardioMEMS post-approval study. Circ Heart Fail. 2020;13:e006863.
10. Martins C, Machado da Silva J, Guimarães D, et al. MONITORIA: starting a new era of ambulatory heart failure monitoring? Part I – theoretical rationale. Rev Port Cardiol. 2021.
11. Darling CE, Dovancescu S, Saczynski JS, et al. Bioimpedance-based heart failure deterioration prediction using a prototype fluid accumulation vest-mobile phone dyad: an observational study. JMIR Cardio. 2017;1:e1.
12. Amir O, Ben-Gal T, Weinstein JM, et al. Evaluation of remote dielectric sensing (ReDS) technology-guided therapy for decreasing heart failure re-hospitalizations. Int J Cardiol. 2017;240:279–84.
13. Inan OT, Baran Pouyan M, Javaid AQ, et al. Novel wearable seismocardiography and machine learning algorithms can assess clinical status of heart failure patients. Circ Heart Fail. 2018;11:e004313.
14. Lindholm D, Fukaya E, Leeper NJ, et al. Bioimpedance and new-onset heart failure: a longitudinal study of >500 000 individuals from the general population. J Am Heart Assoc. 2018;7.
15. Anand IS, Tang WH, Greenberg BH, et al. Design and performance of a multisensor heart failure monitoring algorithm: results from the multisensor monitoring in congestive heart failure (MUSIC) study. J Card Fail. 2012;18:289–95.
16. Stehlik J, Schmalfuss C, Bozkurt B, et al. Continuous wearable monitoring analytics predict heart failure hospitalization: the LINK-HF multicenter study. Circ Heart Fail. 2020;13:e006513.