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EDITED AND REVIEWED BY
Elisabetta Salvioni,
Monzino Cardiology Center
(IRCCS), Italy

*CORRESPONDENCE
Leor Perl
leorperl@gmail.com;
leorper@clalit.org.il
Domenico D'Amario
domenico.damario@
policlinicogemelli.it

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Editorial: Advances and challenges in remote monitoring of patients with heart failure

Leor Perl^{1,2*}, Sebastian Feickert³ and Domenico D'Amario^{4*}

¹Cardiovascular Department, Rabin Medical Center, Beilinson Hospital, Petah Tikva, Israel, ²The Faculty of Medicine, Tel-Aviv University, Tel Aviv, Israel, ³Department of Cardiology, Vivantes Klinikum Am Urban, Berlin and Rostock University Medical Center, Rostock, Germany, ⁴Department of Cardiovascular Sciences, Fondazione Policlinico Universitario Agostino Gemelli Istituto di Ricovero e Cura a Carattere Scientifico (IRCCS), Rome, Italy

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Editorial on the Research Topic

Advances and challenges in remote monitoring of patients with heart failure

Heart failure (HF) is a global pandemic affecting millions worldwide, contributing to high rates of mortality and morbidity, as well as increasing health expenditures, despite significant advances in therapies and prevention and rates are expected to significantly rise in the next years (1, 2).

Remote monitoring of physiological parameters was shown to reduce rates of hospital readmissions for decompensated HF by either invasive hemodynamic sensing systems or structured remote patient management interventions in some trials (3–8), and possibly mortality as well (6, 9, 10). In case of invasive monitoring, it has also proven to be cost-effective in selected patients with HF (11, 12). However, the literature remains equivocal in the evidence of efficacy and safety of these methods. Several trials assessing non-invasive methods to remotely monitor HF patients have failed to show clinical benefit (13–15). Regarding pulmonary artery pressure sensing, the recent GUIDE-HF trial failed to confirm efficacy when it was extended to a wider, real-world setting, including NYHA Class II and IV HF patients (16). A previous clinical trial assessing a right ventricular outlet-based sensing system named Chronicle (Medtronic Inc., Minneapolis, Minnesota) had also failed to reduce the rates of HF-related events (17).

Pressures measured in the right heart do not always adequately correlate with left-sided pressures, leading to inaccurate left-sided filling pressure estimation (18). This is especially true in clinical contexts, such as in patients with non-cardiac-related pulmonary hypertension. A trial assessing left atrial-pressure (LAP) using a sensor lead that is attached to a subcutaneous module, implanted in the atrium through a trans-septal approach was halted prematurely by the safety monitoring board due to a perceived high rate of procedure related complications. However, an analysis made on existing data showed a 41% reduction in HF admissions at 12 months (19, 20).

Monitoring of patients with HF is mostly focused on preventing hospital readmissions. This is reasonable, since HF is the leading cause of hospitalizations among the elderly (21). In fact, the rates of readmissions have even arisen lately, despite readmission reduction programs in the United States (22) and the United Kingdom, especially in lower socio-economic statuses (23). Nevertheless, remote monitoring holds the potential of improving HF patient care by improving the prognosis during admission or enhancing their quality of life in the ambulatory setting.

Chang et al. assessed the ability of models based on machine learning to anticipate the occurrence of cardiogenic shock in a cohort of hospitalized patients who are at increased risk for its development. These models were trained on data spanning 8 years (from 2010 to 2017), from a large regional healthcare system, consisting of 30 hospitals in the United States. The model was designed to predict the need of first cardiogenic shock intervention 2 h ahead, and achieved an overall area under curve (AUC) of 0.87. Interestingly, the authors demonstrated that it can be refined based on specific parameters defining patient subpopulations, such as the presence of HF, which further increases its precision (Chang et al.). Several studies have been published on the value of artificial intelligence in the diagnosis, assessment and prediction of patients with HF (24–28). In the near future, the field of remote monitoring is expected to include these models, as stand-alone or in addition to hardware-based remote-monitoring devices.

One such device is HeartLogic™, a multisensory cardiac implantable electronic device (CIED) based algorithm. It was assessed in the study by Feijen et al. They studied 107 HF patients in a real-world setting, and estimated the accuracy of the system in the prediction of fluid retention, as validated by dedicated HF nurses. For a follow up of 14 months (IQR 8–23), they showed sensitivity of 79%, specificity of 88%, positive predictive value of 71% negative predictive value of 91%. There was a false negative rate of 0.17 alerts/patient year. Importantly, the system could predict which patients required more intense treatment and hospitalization.

Galinier et al. assessed the impact of interventional specialized telemonitoring (ITM), as compared to standard telemonitoring and standard of care in reducing all-cause mortality, cardiovascular mortality and unplanned HF hospitalizations. Four hundred fourteen HF patients from two cohorts in France (OSICAT and ETAPES) were included in this study. The ITM group included patients who were regularly contacted by nurses for therapeutic decisions and guidance. In an event of an alert, cardiologists intervened, adjusted medications and decided on hospitalizations as needed. In the study which lasted a year, there was a lower rate of primary endpoint events in the ITM-group, including all-cause mortality (4.5 vs. 20.2 vs. 16.8%, $p < 0.05$), cardiovascular mortality (3.2 vs. 15.2 vs. 8.4%, $p < 0.05$) and unplanned hospitalizations (13.6 vs. 34.3 vs. 36.8%, $p < 0.05$). This trend remained following

multivariable logistic regression ($p < 0.05$ for all endpoints) (Galinier et al.).

Finally, Restivo et al. reported of their 3-year single center experience with the V-LAP™ system, a latest-generation LAP-based device, capable of monitoring pressure wirelessly, via an intracardiac lead-less sensor which transmits information to an external device (29). The system is being examined in the V-LAP™ Left Atrium Monitoring system for Patients with Chronic systolic and Diastolic Congestive Heart Failure (VECTOR-HF) trial, which has shown promising initial results (30). In the current study, 5 patients with advanced HF were enrolled, and followed-up for a mean period of 18 months. LAP-based therapy management reduced LAP over time and no hospital readmissions occurred. This result was also accompanied by an improvement in the functional capacity (6-min walking distance 352.5 ± 86.2 meters at baseline to 441.2 ± 125.2 meters at last follow-up) and measures of quality of life (KCCQ overall score 63.82 ± 16.36 vs. 81.92 ± 9.63) (Restivo et al.). This publication joins others showing potential benefit from LAP-based monitoring systems (31–33), but future randomized controlled trials are needed to corroborate this assumption.

In short, the articles published in this Research Topic offer important insights into recent advances in the field of remote monitoring of patients with HF. The rapid development of remote sensing, communication, machine learning, non-invasive methods and the experience gained from clinical trials will surely enable better assessment of patients with HF, improving their wellbeing and reducing their risk of admissions and subsequent adverse events.

Author contributions

All authors made substantial contribution to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work and the drafting the work or revising it critically for important intellectual content, provided approval for publication of the content and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated, and resolved.

Conflict of interest

Author LP has received consulting fees from Vectorious Medical Technologies and owns stock options in the company.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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References

- Mohebi R, Chen C, Ibrahim NE, McCarthy CP, Gaggin HK, Singer DE, et al. Cardiovascular disease projections in the United States based on the 2020 census estimates. *J Am Coll Cardiol.* (2022) 80:565–78. doi: 10.1016/j.jacc.2022.05.033
- Savarese G, Lund LH. Global public health burden of heart failure. *Card Fail Rev.* (2017) 3:7–11. doi: 10.15420/cfr.2016:25:2
- Koehler F, Koehler K, Deckwart O, Prescher S, Wegscheider K, Kirwan B-A, et al. Efficacy of telemedical interventional management in patients with heart failure (TIM-HF2): a randomised, controlled, parallel-group, unmasked trial. *Lancet.* (2018) 392:1047–57. doi: 10.1016/S0140-6736(18)31880-4
- Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. *Lancet.* (2011) 377:658–66. doi: 10.1016/S0140-6736(11)60101-3
- Adamson PB, Abraham WT, Stevenson LW, Desai AS, Lindenfeld J, Bourge RC, et al. Pulmonary artery pressure-guided heart failure management reduces 30-day readmissions. *Circ Heart Fail.* (2016) 9:e002600. doi: 10.1161/CIRCHEARTFAILURE.115.002600
- Zhu Y, Gu X, Xu C. Effectiveness of telemedicine systems for adults with heart failure: a meta-analysis of randomized controlled trials. *Heart Fail Rev.* (2020) 25:231–243. doi: 10.1007/s10741-019-09801-5
- Sharif F, Rosenkranz S, Bartunek J, Kempf T, Assmus B, Mahon NG, et al. Safety and efficacy of a wireless pulmonary artery pressure sensor: primary endpoint results of the SIRONA 2 clinical trial. *ESC Heart Fail.* (2022) doi: 10.1002/ehf2.14006
- Mullens W, Sharif F, Dupont M, Rothman AMK, Wijns W. Digital health care solution for proactive heart failure management with the Cordella Heart Failure System: results of the SIRONA first-in-human study. *Eur J Heart Fail.* (2020) 22:1912–9. doi: 10.1002/ehf.1870
- Mazimba S, Ginn G, Mwansa H, Laja O, Jeukeng C, Elumogo C, et al. Pulmonary artery proportional pulse pressure (PAPP) index identifies patients with improved survival from the CardioMEMS implantable pulmonary artery pressure monitor. *Heart Lung Circ.* (2021) 30:1389–96. doi: 10.1016/j.hlc.2021.03.004
- Naik MG, Budde K, Koehler K, Vettorazzi E, Pigorsch M, Arkossy O, et al. Remote patient management may reduce all-cause mortality in patients with heart-failure and renal impairment. *Front Med.* (2022) 9:917466. doi: 10.3389/fmed.2022.917466
- Schmier JK, Ong KL, Fonarow GC. Cost-effectiveness of remote cardiac monitoring with the CardioMEMS heart failure system. *Clin Cardiol.* (2017) 40:430–436. doi: 10.1002/clc.22696
- Cowie MR, Simon M, Klein L, Thokala P. The cost-effectiveness of real-time pulmonary artery pressure monitoring in heart failure patients: a European perspective. *Eur J Heart Fail.* (2017) 19:661–9. doi: 10.1002/ehf.747
- Chaudhry SI, Mattera JA, Curtis JB, Spertus JA, Herrin J, Lin Z, et al. Telemonitoring in Patients with Heart Failure. *N Engl J Med.* (2010) 363:2301–9. doi: 10.1056/NEJMoa1010209
- Ong MK, Romano PS, Edgington S, Aronow HU, Auerbach AD, Black JT, et al. Effectiveness of remote patient monitoring after discharge of hospitalized patients with heart failure: the better effectiveness after transition–heart failure (BEAT-HF) randomized clinical trial. *JAMA Internal Med.* (2016) 176:310–8. doi: 10.1001/jamainternmed.2015.7712
- Koehler F, Winkler S, Schieber M, Sechtem U, Stangl K, Böhm M, et al. Impact of remote telemedical management on mortality and hospitalizations in ambulatory patients with chronic heart failure. *Circulation.* (2011) 123:1873–80. doi: 10.1161/CIRCULATIONAHA.111.018473
- Lindenfeld J, Zile MR, Desai AS, Bhatt K, Ducharme A, Horstmanshof D, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomised controlled trial. *Lancet.* (2021) 398:991–1001. doi: 10.1016/S0140-6736(21)01754-2
- Bourge RC, Abraham WT, Adamson PB, Aaron MF, Aranda JM, Magalski A, et al. Randomized controlled trial of an implantable continuous hemodynamic monitor in patients with advanced heart failure: the COMPASS-HF study. *J Am Coll Cardiol.* (2008) 51:1073–9. doi: 10.1016/j.jacc.2007.10.061
- Campbell P, Drazner MH, Kato M, Lakdawala N, Palardy M, Nohria A, et al. Mismatch of right- and left-sided filling pressures in chronic heart failure. *J Card Fail.* (2011) 17:561–8. doi: 10.1016/j.cardfail.2011.02.013
- Abraham WT, Adamson PB, Costanzo MR, Eigler N, Gold M, Klapsholz M, et al. Hemodynamic monitoring in advanced heart failure: results from the LAPTOP-HF trial. *J Cardiac Fail.* (2016) 22:940. doi: 10.1016/j.cardfail.2016.09.012
- Maurer MS, Adamson PB, Costanzo MR, Eigler N, Gilbert J, Gold MR, et al. Rationale and design of the left atrial pressure monitoring to optimize heart failure therapy study (LAPTOP-HF). *J Card Fail.* (2015) 21:479–88. doi: 10.1016/j.cardfail.2015.04.012
- Jackson SL, Tong X, King RJ, Loustalot F, Hong Y, Ritchey MD. National burden of heart failure events in the United States, 2006 to 2014. *Circ Heart Fail.* (2018) 11:e004873. doi: 10.1161/CIRCHEARTFAILURE.117.004873
- Khan MS, Sreenivasan J, Lateef N, Abougergi MS, Greene SJ, Ahmad T, et al. Trends in 30- and 90-day readmission rates for heart failure. *Circ Heart Fail.* (2021) 14:e008335. doi: 10.1161/CIRCHEARTFAILURE.121.008335
- Lawson C, Crothers H, Remsing S, Squire I, Zaccardi F, Md D, et al. Trends in 30-day readmissions following hospitalisation for heart failure by sex, socioeconomic status and ethnicity. *EclinicalMedicine.* (2021) 38:101008. doi: 10.1016/j.eclinm.2021.101008
- Wang Q, Li B, Chen K, Yu F, Su H, Hu K, et al. Machine learning-based risk prediction of malignant arrhythmia in hospitalized patients with heart failure. *ESC Heart Fail.* (2021) 8:5363–5371. doi: 10.1002/ehf2.13627
- Desai RJ, Wang SV, Vaduganathan M, Evers T, Schneeweiss S. Comparison of machine learning methods with traditional models for use of administrative claims with electronic medical records to predict heart failure outcomes. *JAMA Netw Open.* (2020) 3:e1918962. doi: 10.1001/jamanetworkopen.2019.18962
- Austin DE, Lee DS, Wang CX, Ma S, Wang X, Porter J, et al. Comparison of machine learning and the regression-based EHMRG model for predicting early mortality in acute heart failure. *Int J Cardiol.* (2022). doi: 10.1016/j.ijcard.2022.07.035. [Epub ahead of print].
- Urban S, Błaziak M, Jura M, Iwanek G, Zdanowicz A, Guzik M, et al. Novel phenotyping for acute heart failure-unsupervised machine learning-based approach. *Biomedicine.* (2022) 10:1514. doi: 10.3390/biomedicine10071514
- Wilstrup C, Cave C. Combining symbolic regression with the Cox proportional hazards model improves prediction of heart failure deaths. *BMC Med Inform Decis Mak.* (2022) 22:196. doi: 10.1186/s12911-022-01943-1
- Perl L, Soifer E, Bartunek J, Erdheim D, Köhler F, Abraham WT, et al. A novel wireless left atrial pressure monitoring system for patients with heart failure, first ex-vivo and animal experience. *J Cardiovasc Transl Res.* (2019) 12:290–8. doi: 10.1007/s12265-018-9856-3
- Perl L, Meerkin D, D'amarico D, Avraham BB, Gal TB, Weitsman T, et al. The V-LAP system for remote left atrial pressure monitoring of patients with heart failure: remote left atrial pressure monitoring. *J Card Fail.* (2022) 28:963–72. doi: 10.1016/j.cardfail.2021.12.019
- D'Amario D, Restivo A, Canonico F, Rodolico D, Mattia G, Francesco B, et al. Experience of remote cardiac care during the COVID-19 pandemic: the V-LAP™ device in advanced heart failure. *Eur J Heart Fail.* (2020) 22:1050–2. doi: 10.1002/ehf.1900
- D'Ancona G, Murero M, Feickert S, Kaplan H, Öner A, Ortak J, Ince H. Implantation of an innovative intracardiac microcomputer system for web-based real-time monitoring of heart failure: usability and patients' attitudes. *JMIR Cardio.* (2021) 5:e21055. doi: 10.2196/21055
- Perl L, Ben Avraham B, Vaknin-Assa H, Ben Gal T, Kornowski R. A rise in left atrial pressure detected by the V-LAP™ system for patients with heart failure during the coronavirus disease 2019 pandemic. *ESC Heart Fail.* (2020) 7:4361–6. doi: 10.1002/ehf2.13033