Clinical Utility of HeartLogic, a Multiparametric Telemonitoring System, in Heart Failure

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Abstract
Telemonitoring through multiple variables measured on cardiac devices has the potential to improve the follow-up of patients with heart failure. The HeartLogic algorithm (Boston Scientific), implemented in some implantable cardiac defibrillators and cardiac resynchronisation therapy, allows monitoring of the nocturnal heart rate, respiratory movements, thoracic impedance, physical activity and the intensity of heart tones, with the aim of predicting major clinical events. Although HeartLogic has demonstrated high sensitivity for the detection of heart failure decompensations, its effects on hospitalisation and mortality in randomised clinical trials has not yet been corroborated. This review details how the HeartLogic algorithm works, compiles available evidence from clinical studies, and discusses its application in daily clinical practice.

Keywords
Heart failure, remote monitoring, ICD, cardiac resynchronisation therapy, hospitalisation, HeartLogic

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Chronic heart failure (HF) is a major health problem that affects approximately 64 million people worldwide. It is estimated that 1–3% of the general population in developed countries lives with HF and one in five individuals will be diagnosed with HF at some point in their lives. The burden of HF increases with age: HF affects 10% of individuals >70 years old, and more than 80% of cases are diagnosed in people >65 years old.1,2

Higher baseline cardiovascular risk and lower mortality due to improved treatment of major cardiac and non-cardiac diseases are responsible for the progressive rise in the incidence of HF. The impact of HF on healthcare is also growing. HF is the first cause of admission among the older population, is a leading cause of death (3% of men and 10% of women die from HF) and consumes 1–3% of healthcare spending in developed countries.1–5

The natural history of HF is characterised by periods of stability interrupted by episodes of acute decompensation. Decompensation is defined as the clinical and haemodynamic deterioration caused by an increased cardiac filling pressure leading to systemic and/or pulmonary congestion and, in severe cases, peripheral hypoperfusion. Decompensation becomes more frequent as the disease progresses and is a marker of poor prognosis. In addition, most episodes of decompensation require hospital admission, which is the main healthcare cost related to the disease.5–8 In this context, it is necessary to develop strategies to diagnose and treat episodes of decompensation at early stages to prevent hospital admissions and other adverse events. This is not easy, because the symptoms and signs of decompensation usually appear late in the pathophysiological chain that leads to an HF decompensation (Figure 1).3

Since the early 2000s, several telemonitoring (TM) strategies have been developed in an attempt to detect precordial deterioration in HF. A distinction can be made between non-invasive and invasive TM modalities, as discussed below.

Non-invasive Telemonitoring
Non-invasive TM primarily uses two strategies: structured periodic telephone calls conducted by a trained clinical team, and the automatic registration of symptoms and vital signs, such as blood pressure, heart
In this paper, we focus on HeartLogic (Boston Scientific), a novel multiparametric algorithm that potentially will have a complementary role to guideline-directed management of patients with HF with reduced ejection fraction.

The HeartLogic Algorithm

HeartLogic is a multiparametric algorithm implemented in certain ICDs (with or without CRT) from Boston Scientific, which allows stratification of the risk of decompensation in HF patients. HeartLogic is an automatic, remotely monitored system that combines trend analysis from different sensors implanted in the generator, namely nocturnal heart rate, intensity of the first and third sounds of the cardiac cycle, intrathoracic impedance, respiratory rate, tidal volume and physical activity, integrating them to generate a single numerical indicator, the HeartLogic index. When a patient is at risk of HF decompensation there will usually be a progressive rise in the heart rate and the intensity of the third sound, a decrease in the first sound of the cardiac cycle, breathing will become shallower and faster, diminishing inspiratory volume, pulmonary congestion will reduce intrathoracic impedance and physical activity will be limited by a deterioration in the functional class. It is through the combination of information from the different measures that the HeartLogic index estimates the risk of HF decompensation (Figure 2).

The HeartLogic index is specific for each patient and depends on the value of each parameter at steady state. Its lower value, called the baseline HeartLogic index, is calculated over a 3-month rolling window of

Alternatively, percutaneous non-invasive devices that can measure the intrathoracic water in various ways as a surrogate of pulmonary congestion have been developed. Even though some of these devices showed promising results in observational studies, to date they also have failed to demonstrate a prognostic impact in randomised clinical trials. With regard to cardiac implantable devices, additional functionalities have been developed to implement the follow-up of HF patients with reduced ejection fraction that carry an ICD, a cardiac resynchronisation therapy (CRT) defibrillator (CRT-D) or a CRT pacemaker (CRT-P). The first algorithms tried to associate one parameter, such as changes in heart rate, rhythm or thoracic impedance, with clinical worsening. One of the most well-known algorithms is Optivol (Medtronic), an index that quantifies daily changes in thoracic impedance as a surrogate for lung congestion. Although Optivol and some other one-parameter algorithms have been shown to improve the follow-up of HF patients, none has reduced hospitalisation or mortality in clinical trials. More complex detection systems, combining multiple variables as surrogates for volume status, have been developed in an attempt to impact HF prognosis. In the PARTNERS-HF observational study, an algorithm combining patient activity, heart rate, atrial fibrillation burden, Optivol index and proportion of CRT pacing proved to be useful in selecting patients with HF at higher risk of HF decompensation.

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HeartLogic measurements of each parameter are automatically updated on a daily basis, as is the HeartLogic index. This makes it possible to describe a trend in the patient’s evolution that can be represented on a graph over time. The HeartLogic index remains stable if the clinical situation of the patient does not change acutely. When the HeartLogic index exceeds a prespecified numerical value, the device issues an alarm, the HeartLogic alert, indicating a higher risk of decompensation. This value is predefined at 16, because this value demonstrated the best sensitivity and specificity ratio for detecting an HF event in the MultiSENSE study, but it can be adjusted individually for each patient or group of patients. If the patient improves and approaches the baseline condition, the HeartLogic index decreases (Figure 3). When the index falls below 6, the alert will be resolved.

The information from the HeartLogic algorithm is transmitted via a communicator to the Latitude NXT system, a remote monitoring virtual platform that can be accessed by the medical team, allowing for the follow-up of multiple patients and their stratification according to the risk of decompensation. A patient will only be aware of a HeartLogic alert status if they are directly contacted by their healthcare professional. Of note, the HeartLogic has a minimal effect on the longevity of the on the ICD (cCRT). The reduction in battery durability with HeartLogic sensor data collection and daily alert checks is approximately 2 months.

**Evidence**

The usefulness of the HeartLogic algorithm has so far been evaluated in observational studies. The MultiSENSE study was the first to evaluate the usefulness of HeartLogic in predicting HF decompensation. That study included 900 patients with a COGNIS (Boston Scientific) CRT-D with HF with reduced ejection fraction, NYHA class II–IV or with an admission for HF or need for IV diuretic administration within the past 6 months. The study used one cohort for development of the HeartLogic algorithm and another for its validation. In the MultiSENSE study, the HeartLogic algorithm demonstrated a maximum sensitivity of 70% with an index value of 16 for predicting HF decompensation, defined as a hospital admission or unplanned visit requiring intravenous therapy. Its specificity was 86% and its negative predictive value was 99.9%. The median time from alert (exceeding an index value of 16) to HF decompensation was 34 days, and, of note, there was a low incidence of false alarms (1.47 per patient per year).

The HeartLogic index not only changes throughout a patient’s evolution and predicts HF decompensation, as described above, but its baseline value also seems to select patients with a higher risk of decompensation. Patients that decompensate tend to have higher baseline HeartLogic index values than those who remain stable. In addition, the HeartLogic index has been shown to have a prognostic value independent of N-terminal pro B-type natriuretic peptide (NT-proBNP). An increase in the HeartLogic index above 16 is an indicator of risk of admission in patients with and without elevated NT-proBNP. Moreover, patients who are in alert and have elevated NT-proBNP seem to be at higher risk of decompensation. In a subanalysis of the MultiSENSE study, patients in the HeartLogic alert state had a 24- and 50-fold higher risk of HF decompensation by the 12-month follow-up if their NT-proBNP concentrations were <1,000 pg/ml and >1,000 pg/ml, respectively, compared with patients with NT-proBNP <10,00 pg/ml and a negative HeartLogic index.

Few observational studies have shown how HeartLogic performs in real-life clinical practice (Table 1). In general, these studies demonstrated that the algorithm allows the identification of relevant HF-related conditions with high sensitivity and specificity and enables effective clinical action to be taken remotely, with a low incidence of false alarms. One multicentre study compared 1-year HF hospitalisation before and after activation of the HeartLogic algorithm in 68 patients, showing a 66% reduction in HF admissions, a >50% decrease in the hospitalisation length of stay and a significant reduction in overall health economic costs after...
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The incidence of non-insignificant alerts was reported to be only 0.39 alerts per patient-year, and the rate of unexplained alerts was low (0.39 per patient-year) and that in more than 80% of cases alerts could be resolved by telephone. However, these promising results have not yet been validated in a randomised study. MANAGE-HF (NCT03237858), currently in the inclusion phase, is the first randomised clinical trial designed to assess the impact of HeartLogic on hospitalisation and mortality in symptomatic (NYHA functional class II–III) HF patients with either a previous decompensation or elevated natriuretic peptides. It is planned that MANAGE-HF will include 2,700 patients with a Boston ICD, CRT-D or CRT-P who will be randomised 1:1 to a guideline-directed follow-up with HeartLogic monitoring on versus off. If the results of MANAGE-HF are positive, HeartLogic would be the first algorithm of implantable devices to demonstrate a prognostic impact in HF.

Application of HeartLogic in Daily Clinical Practice

The HeartLogic algorithm allows daily TM of patients with HF and the detection of those at increased risk of decompensation. Its simplicity and the encouraging results of the observational studies described above have motivated its incorporation into the protocols of centres with HF units. Figure 4 shows the follow-up protocol based on monitoring with the HeartLogic algorithm in the centres included in the Spanish RE-HEART registry.

Table 1: Performance of HeartLogic in the MultiSENSE and Real-world Studies

| Study          | Year of Publication | No. Patients | Follow-up (Months) | Sensitivity (%) | Specificity (%) | Positive Predictive Value (%) | Unexplained Alert Rate (Patient-year) | Time in Alert (Patient-year) | Time in Alert (% Observation Period) |
|----------------|---------------------|--------------|-------------------|----------------|----------------|-------------------------------|--------------------------------------|-----------------------------|-----------------------------------|
| MultiSENSE (validation dataset) | 2017 | 400 | 12 | 70 | 87.5 | 11 | 1.47 | 17 |
| Capucci et al. | 2019 | 58 | 5 | 100 | N/A | 58 | 0.41 | 12 |
| Santini et al. | 2020 | 104 | 13 | 69 | N/A | 60 | 0.37 | 15 |
| Treskés et al. | 2021 | 68 | 12 | 90 | 89 | 73 | 0.16 | N/A |
| De Juan Bagudá et al. | 2021 | 2021 | 101 | 10 | 100 | 93 | 27 | 0.52 | 8 |
| Blinded phase | 2021 | 101 | 10 | 100 | 93 | 27 | 0.52 | 8 |
| Unblinded phase | 2021 | 267 | 16 | 98 | 90 | 57 | 0.39 | 11 |

HeartLogic was demonstrated to be useful in identifying events and individualising patient follow-up, knowing that decompensation outside the alert state is unlikely. It is also of note that the reported rate of unexplained alerts was low (0.39 alerts per patient-year) and that in more than 80% of cases alerts could be resolved by telephone.

We have recently published an ambispective study with the first data from the RE-HEART registry, which included 288 patients from 15 centres across Spain. In that study, the HeartLogic algorithm was shown to predict a HF decompensation or clinically relevant event in more than half of the alerts, on average 20 days in advance. Sensitivity and negative predictive value were close to 100%, with a specificity of over 90%. The mechanism of the HeartLogic algorithm typically involves the use of machine learning techniques to analyze and predict patient outcomes based on a combination of clinical, biochemical, and physiological data. This approach allows for tailored interventions and predictive care, which can significantly improve patient outcomes and reduce the risk of hospitalization. Further studies are necessary to validate these findings and to expand the application of HeartLogic to a broader range of clinical settings.
considering that this is a higher-risk patient, closer remote follow-up can be performed.

In our experience, the threshold value of 16 for the HeartLogic alert performs well in most patients and its individual adjustment is rarely needed. However, we have seen a small group of patients with a worse prognostic profile who are persistently above this value, like those with persistent congestion, diuretic resistance, low adherence to treatment or in advanced HF, in such patients, raising the alert threshold could be considered. Other very rare conditions could be patients with HF events but whose HeartLogic index does not reach the in-alarm status (false negatives), for whom a lower threshold value would make sense.

Most HeartLogic alerts can be resolved via telephone by trained nursing staff with low time consumption. In the RE-HEART registry, only 60 minutes of clinical care time per week was consumed for every 30 patients monitored with HeartLogic. Among the limitations of the HeartLogic system, it should be noted that this system only allows the monitoring of patients with a Boston Scientific ICD. Implantation is due to the presence of specific indications in HF, and therefore excludes many patients with a diagnosis of HF without indication for this therapy, such as those with a left ventricular ejection fraction >35% or those in NYHA functional class I. Furthermore, although the HeartLogic system has been shown to select patients at higher risk, it is not yet known whether it has an effect on hard clinical events, such as hospital readmission or mortality in the demanding setting of HF with reduced ejection fraction under optimal prognostic treatment. The MANAGE-HF clinical trial will resolve this issue. Finally, although initial data are promising, the role of the HeartLogic system in reducing direct and indirect costs in the follow-up of HF needs to be further evaluated.

Conclusion

HeartLogic seems to be a useful tool in the daily practice of HF program. It can help to both identify patients at increased risk of decompensation, to enable prompt action to try to avoid an impending decompensation, and reassure patients out of alert, who can be followed in a more lenient way. Most patients can be managed by telephone, thus avoiding unnecessary visits to the clinic, improving patient environment. This proactive way of following patients is promising and will hopefully lead to improvements in the prognosis of HF. 

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