Biosensors And Intelligent Algorithms for Heart Failure Monitoring

Zhaoqian Wu*

The Second Affiliated Hospital of Guangzhou Medical University,

Guangzhou Institute of Cardiovascular Disease, Guangzhou, China

* Corresponding Author Email: 2020218712@stu.gzhmu.edu.cn

Abstract. Heart failure is one of the most common causes of mortality and the final stage of cardiovascular disease. The prognosis of individuals with chronic heart failure has improved to some extent which is thanks to our increased understanding of heart failure. Both invasive and non-invasive biosensors have advanced significantly during the previous ten years. It has been demonstrated that biosensors can identify heart failure early and lower the need for hospitalization. In the past, biosensors mainly detected the general condition of patients' vital signs, but now they have been developed into invasive biosensors for monitoring pressure changes such as a pulmonary artery pressure, right ventricle pressure, left atrium pressure and so on. It allows clinicians to observe the function of the heart more intuitively. Non-invasive biosensors can monitor electrocardiograms, heart sounds, pleural effusion and so on, and evaluate the risk of recurrent heart failure by observing the risk factors of heart failure deterioration. Although this kind of sensor cannot cause harm to patients, often not as accurate and timely as invasive sensors. There are intelligent algorithms based on biosensors, which belongs to machine learning, which can greatly improve the specificity of patient diagnosis. These biosensors and intelligent algorithms can further improve the survival rate of patients.

Keywords: Biosensors, Algorithms, Heart Failure.

1. Introduction

Global health issues include heart failure. A "heart failure paradox" has surfaced in this area of heart failure over recent years. Although most cardiac disorders are now effectively treated, there has been no significant advancement in treating heart failure. The estimated incidence of heart failure has been increasing in China simultaneously, and a younger trend has emerged. In actuality, the following factors contribute to the high prevalence of heart failure: a population's aging, the further expansion of the high-risk population of heart failure, and the further improvement of the treatment ability of myocardial infarction due to the current medical condition. At the same time, numerous people who have chronic renal dysfunction, hypertension as well as diabetes might eventually develop heart failure without early intervention and early treatment. The re-admission rate of heart failure is high, and the medical expenses and hospitalization days of the elderly are significantly higher than those of the young, which greatly increases the social and medical burden. Following the guidance of drug treatment is considered the most basic and important treatment for people with heart failure. However, only a few of them can follow [1].

Further improving drug compliance can greatly reduce the incidence of cardiac failure and increase the chance that individuals with heart failure will survive. Mess up in capacity, arrhythmia, infection and excessive physical activity are the main causes of heart failure. Patients often cannot detect these causes early, and some often ignore them even if they find physical abnormalities. When the patient is in the hospital, it develops into decompensated heart failure. Biosensors that detect heart failure can detect whether patients have high-risk factors for heart failure and monitor their treatment. Compared with the tedious blood test and clinical imaging examination, a biosensor is a more convenient tool. It can real-time and accurately let people know whether they have high-risk factors for heart failure, whether they are in a state of heart failure, and how effective they are in treatment. At the same time, these biosensors have good accuracy. For example, Apple Watch Series is a biosensor based on the photoplethysmography (PPG) signal. As long as it is worn on the wrist, people can know the electrocardiogram, blood oxygen, etc. And the accuracy of the data obtained is not significantly different from that of the traditional examination [2]. This article will first introduce invasive biosensors, including CardioMEMS sensors for monitoring pulmonary artery pressure, Chronicle IHM (Implantable hemodynamic monitor) for monitoring right ventricular pressure, and HeartPod sensors for monitoring left atrial pressure. These sensors can directly and accurately measure patients' cardiac function changes. Secondly, the non-invasive biosensor is introduced, including wristband, wearable biological impedance (BioZ) sensor, triaxial activity monitor, etc. This kind of sensor is based on the patient's general physiological status, electrocardiograph (ECG) and other conditions to evaluate the patient's cardiac function. Finally, the intelligent algorithm based on sensor. HeartLogic algorithm is based on MultiSENSE research. Therefore, the purpose of this review would be to establish (1) to introduce biosensors and sensor-based intelligent algorithms that could be utilized to keep a record of heart failure; (2) the monitoring methods and methods of these biosensors; (3) the data monitored by these biosensors play a role in heart failure. This paper will greatly value the research on heart failure and the application of biosensors.

2. Invasive biosensors

2.1. A sensor dominated by monitoring pulmonary artery pressure

2.1.1 CardioMEMS sensors

CardioMEMS sensor is a remote monitoring technology about the size of a paper clip. It can directly recognize changes in pulmonary arterial pressure and convert the data into usable information graphs by connecting to the database. The sensor needs to be implanted into the patient's pulmonary artery through minimally invasive surgery to monitor changes in cardiac pressure. It can transmit patients' daily changes data to doctors and nursing teams to judge the changes of patients' conditions. Participants in the prospective CHAMPION trial had formerly been hospitalized and had symptoms of New York Heart Association (NYHA) Class III heart failure. There are 550 participants were observed by CardioMEMS sensors and those in the treatment group who received pulmonary artery pressure management. In the treated group, the chance of dying or the first hospital treatment due to heart failure was 23% fewer compared to the placebo group (HR 0.77 [95%CI 0.60-0.98]) [3]. The German Federal Commission ordered this PASSPORT-HF trial [4]. The study recruited 554 patients to determine, through the CardioMEMS sensor system, whether remote monitoring of pulmonary artery pressure would prevent decompensation, which translates into reducing unplanned HF-related re-admissions or deaths within 12 months after randomization. According to Christiane et al, based on a 12-month follow-up stretch of time in research involving 234 participants who had NYHA Class III grade, individuals with CardioMEMS sensor implantation reduced hospitalization due to heart failure by 62% [5].

2.1.2 Cordella pulmonary artery pressure transducer

The sensor is similar to the CardioMEMS sensor. It can also provide data including bodyweight, heartbeat, blood pressure, blood oxygen levels. The SIRONA test is a small sample study demonstrating the relationship between pulmonary artery pressure obtained from right cardiac catheterization and that obtained by Cordella sensors [6]. At present, the second phase of the project is being tested. The PROACTIVE-HF study is a prospective study that is anticipated to further highlight the advantages of managing heart failure under the direction of pulmonary arteries pressure throughout NYHA Class III sufferers [7].

2.2. A sensor dominated by monitoring right ventricular arterial pressure

2.2.1 Chronicle IHM

It is a kind of sensor placed under the chest cavity and placed through the vein to measure its right ventricular pressure, in the septum or right ventricular outlet tract. A randomly selected, single-blind, paralleled scientific experiment called Compass-HF involved 274 individuals with heart failure in NYHA Class III and IV. There wasn't any decrease in heart failure-related incidents compared to the untreated. However, the treatment group's relative risk in heart failure-related inpatient treatment has dropped by 36% [8].

2.3. A sensor dominated by monitoring left atrial pressure

2.3.1 HeartPod

There is a certain error in the measurement of left atrial pressure according to pulmonary arterial pressure, particularly in individuals suffering from heart failure with extremely low cardiac function. They lack a certain compensatory function, and heart failure occurs before the pulmonary artery pressure increases. It can measure the pressure and waveform of the left atrium through the lead. The HOMEOSTASIS trial showed that left atrial pressure-guided heart failure treatment significantly reduced hospitalization for heart failure by 41% at 12 months [9].

2.3.2 The V-Lap system

V-Lap system is an implantable left atrial pressure monitoring system based on integrated circuit technology. The VECTOR-HF test showed that at a period of 6 months, of the 20 study patients, 8 improved in the average NYHA Class [10]. This is shown in Table 1.

Table.1. Invasive biosensors

Device Type	Device	First Author	Number of Patients	Follow-up	Main Findings
Monitoring pulmonary artery pressure	CardioMEMS[3]	William T.A, et al.	550	13 months	Patients with NYHA Class III had long-term benefits
	Cordella[6]	Wilfried M, et al.	15	90 days	Heart failure can be accurately monitored
Monitoring Right ventricular arterial pressure	Chronicle IHM[8]	Robert C.B et al.	274	6 months	No appreciable decrease in the frequency of any heart failure-related incidents.
Monitoring right ventricular arterial pressure	HeartPod[9]	Jay R, et al.	40	25 months	Potential to improve advanced heart failure
	V-Lap[10]	Leor P, et al.	24	6 months	May reduce clinical symptoms of heart failure

3. Non-invasive biosensors

3.1. Wear it on the wrist

3.1.1 Wrist strap

Smartwatches and wristbands currently use photoelectric plethysmography to detect irregular rhythms, which is a non-invasive technique. The photoelectric plethysmography instrument has an infrared light-emitting diode. The bloodstream first absorbs infrared photons that has entered into subcutaneous tissue. Then it is reflected and then again absorbed by a different photosensitive transistor. A study of 97 patients recruited between October 2015 and March 2016 conducted cross-sectional analysis and modeled analysis to help to classify heart failure. When combined with 14 variables such as age, race and history of atrial fibrillation, AUC increased to 0.87and specificity increased to 72% (90% sensitivity) [11]. In 2019, Seysha Mehta et al., conducted an investigation in which 23 patients were invited to wear Microsoft Band for 2 weeks to evaluate heart failure and objective NYHA classification. The experiment found that of the 13 patients who completed the study, 8 doctors changed their health status and 5 patients' NYHA Class changed [12]. This study also suggests the necessity of using objective data to supplement the diagnosis of NYHA grading.

3.1.2 Non-invasive Venous Waveform Analysis (NIVA)

Lung capillary wedge pressure reflects the change of left atrial pressure and indirectly reflects the change of left ventricular pressure. When patients develop pulmonary edema, pulmonary capillary wedge pressure will become higher. A piezoelectric sensor called NIVA is affixed to the wrist's metacarpal vein complex. Alvis et al. limited sample analysis shows a linear relationship between the NIVA value and the lung capillary wedge pressure [13].

3.2. Wear on the trunk

3.2.1 Wearable bio-impedance sensor

Bioelectrical impedance technology is a non-invasive technique for human physiological detection based on the electrical characteristics and changes of biological tissues and organs. With the help of the electrode system placed on the body surface, it does this by applying a modest measuring current or voltage to the object being detected, detecting changes in the electrical impedance that correlates to those changes, and gathering the pertinent physiological and pathological data. SeulkiLee et al. believe that wearable biosensor measurement can be used as an index to evaluate the overall health of hospitalized patients with persistent congestive heart failure [14].

3.2.2 Triaxial activity monitor

The triaxial activity monitor installed at the waist is an accelerated wearable device. The proprietary digital filtering algorithm of three-axis accelerometer and activity recorder is used to measure the amount and frequency of human motion. The cardiac index can be examined based on the triaxial activity monitor, which tracks the daily activity of individuals suffering heart failure and a reduced ejection fraction [15].

3.2.3 Wearable vest

Pulmonary edema is a common complication of congestive heart failure patients, therefore wearable vests use the difference in permittivity between water and air to evaluate pleural fluid. Amir et al. conducted 50 participants suffering acute decompensated heart failure were evaluated 90 days after discharge, and data provided by a remote dielectric sensing system based on wearable vests reduced the re-admission rate by 87% [16].

3.3. Portable tool

3.3.1 Non-invasive intracardiac pressure monitoring (ICPM)

Patients suffering heart failure will have abnormal hemodynamics. Pulmonary artery floating catheter is the gold standard for hemodynamic measurement, but it is often used in critically ill patients, and it is lack of convenience because of the need for invasive operation. The portable ultrasonic measuring technology known as ICPM is non-intrusive. The procedure has been successful in sheep [17], and a multicenter human verification study is under way.

3.3.2 Heart sound sensor

Heart sound can be obtained through cardiac auscultation, which is helpful for clinical diagnosis and treatment, but heart sound auscultation is subjective and limited by auscultation experience. The heart sound is amplified by a signal amplifier and converted into a pulse signal by a filter circuit, and the processed signal can be displayed on the heart sound sensor. According to studies, the S3 heart sound and NT-proBNP levels are moderately and highly specific as the prediction of left ventricular insufficiency; both have a high specificity (97%). Studies using the PARADIGM-HF model revealed a relationship between S3 heart sounds and cardiovascular events. If S3 heart sound can be detected by sensor, heart failure can be predicted early, and cardiovascular events can be reduced [18]. This is shown in Table 2.

Table.2. Non-invasive biosensors

Device Type	Device	First Author	Number of Patients	Follow-up	Main Findings
Wear it on the wrist	Wrist strap[11]	Amit J.S, et al.	97	Not mentioned	Helps in the classification of heart failure
	NIVA[13]	Bret D.A, et al.	96	Not mentioned	NIVA was linearly related to pulmonary capillary wedge pressure
Wear on the trunk	Triaxial activity monitor[15]	Massar O, et al.	63	7 days	Lower activity of daily living is associated with worse cardiac function
	Wearable vest[16]	Offer A, et al.	50	90 days	Reduce the number of individuals suffering from heart failure who is readmitted
Portable tool	Heart sound sensor[18]	Senthil S, et al.	8330	4 months	Related to the occurrence of cardiovascular events

NIVA=Noninvasive venous waveform analysis

4. Intelligent sensor-based algorithms

4.1. HeartLogic algorithm

The HeartLogic algorithm is based on data collected by implantable cardioverter defibrillator (ICD) or implantable cardiac resynchronization therapy defibrillator (CRT-D) devices, including HeartLogic index, heart rate and activity, and combines them to assess heart failure suffers [19]. 200 individuals who had heart failure, ejection fraction less than 35%, and NYHA Class II to III participated in the MANAGE-HF investigation. The median NT-proBNP dropped from 1316pg/ml at the start of the research to 743pg/ml among those who finished the 12-month follow-up (P <0.001) [20]. At the same time, according to a retrospective investigation, the HeartLogic algorithm might become useful for identifying HF worsening, similar to the conclusion of the MANAGE-HF study [21].

4.2. The combined algorithm

The combined algorithm is an algorithm that combines the occurrence of high-frequency events in specific data sets based on implanting CRT-D suffers. A comprehensive score based on the diagnosis of existing tools, the length of atrial fibrillation and the spectrum of patient activity, was produced by the Partners-HF project, a prospective multicenter observational study. The study analyzed the data of 694 patients who received cardiac resynchronization therapy. These patients were assessed and grouped with a combination algorithm every month. The findings revealed that the high-risk group's risk of heart failure hospitalization was five times more than that of the low-risk group [22].

4.3. Remote dielectric sensing (RedS) system

The changes in pulmonary effusion not only led to heart failure but also affect the prognosis. RedS technique is a clinical algorithm based on measuring pulmonary effusion using a radar beam. The SMIL-HF trial showed that RedS technology guided treatment to reduce heart failure rehospitalization (48%) [23].

4.4. Audicor remote patient monitoring system

The non-invasive Audicor remote patient monitoring technology allows for the remote monitoring of heart failure patients. Through machine learning algorithms created on vast clinical databases, cardiac acoustic indicators are generated automatically from dozens of simultaneous ECG and heart sound data. Based on a sizable clinical database that includes information on the third heart sound intensity and heart electromechanical activation time, the Audicor remote patient monitoring system was created. A recent randomized controlled trial showed that heart failure management guided by the Audicor telemonitoring system reduced the number of major end-point events compared with symptom-based heart failure management [24].

4.5. The Cardiosense monitoring platform

The Cardiosense monitoring platform consists of CardioTag and machine learning technology. The platform analyzes the ECG and photoelectric volume pulse wave signals captured by the wearable device CardioTag to non-invasively evaluate the changes in pulmonary capillary wedge pressure (PCWP). In 20 NYHA Class III or IV participants with a left ventricular ejection fraction under 40%, new regression model was created, and it was discovered that PCWP changes could be precisely approximated [25]. This is shown in Table 3.

Table.3. Algorithms

Device	First Author	Number of Patients	Follow-up	Main Findings
HeartLogic[20]	John P.B, et al.	900	1 years	The HeartLogic algorithm effectively predicted impending HF decompensation
Combined algorithm[22]	David J.W, et al.	694	11.7 months	Hospital treatment is more likely to occur in high-risk groups.
RedS[23]	William T.A, et al.	268	9 months	The use of daily REDS assessment can reduce rehospitalization rates for acute decompensated heart failure
Audicor[24]	Shih-Hsien S, et al.	225	1 years	Rehospitalization for heart failure and overall mortality were significantly reduced in the EMAT-guided group
Cardiosense[25]	Mobashir H S, et al.	20	Not mentioned	Accurate estimation of PCWP changes

EMAT=electromechanical activation time

5. Discussion

This essay examines various strategies for keeping tabs on heart failure patients. In the current global COVID19 epidemic situation, the biosensor effect is also more significant [26]. Biosensors make it easier to determine when heart failure will occur. However, the efficacy, safety and possible complications must be carefully weighed when choosing biosensor devices. Mobile phone is an important way to connect biosensors. The development of mobile phone applications and the security of data are not guaranteed. The cost is also within our consideration, and invasive sensors are significantly higher and more difficult to maintain than non-invasive sensors. This will also increase the cost of heart failure treatment and further weaken the advantage of invasive sensors. The sensor design's appearance and beauty should also be considered. At the same time, due to different types of heart failure leading to different pathophysiology, different biosensors may only be appropriate for a certain type of heart failure. Considering invasive sensors, sensing pressure change is the main mechanism because the pressure increase caused by capacity overload is the main way of feeling. CardioMEMS sensor is widely used because of its high effectiveness and safety. The infection caused by invasive equipment exists in HeartPod sensor. The study of invasive sensors included patients with more pronounced heart failure signals, primary participants in NYHA Class III and IV. Despite guided drug treatment, there is still cardiac decompensation. The general condition of these patients is worse than that of other patients, and the increase in the cost of biosensors may be reasonable.

In terms of non-invasive biosensors, PPG is a technology for monitoring biomedical variables, which has been applied to many non-invasive biosensors and has been proven to detect many important physiological data. In addition, the combination of PPG and ECG, oximeter, wearable bioimpedance and other technologies make wearable devices more sensitive in diagnosing heart failure. However, non-invasive biosensors also have their shortcomings. For example, although the pulse oximeter can quickly detect the blood oxygen in the patient's arterial blood, it may not reflect the patient's actual blood oxygen saturation, and blood gas analysis is often needed in clinic. Calculate the oxygenation index to know the true blood oxygen of the patient. Although many different biosensors have been proved helpful in identifying and treating heart failure, the diagnostic specificity will inevitably decrease with the complexity of patients' individualization.

In the aspect of intelligent algorithms based on multiple sensors, the combination of different data of intelligent algorithms can not only complement each other in testing the lack of sensitivity of heart failure, but also improve the specificity of the heart failure diagnosis. The intelligent algorithm can evaluate the trend data according to the individual setting of each patient, automatically issue the alarm of the risk of decompensation of heart failure according to the set threshold, identify the deterioration of heart failure early and intervene and adjust the drugs in time, to reduce the risk of re-admission. Although most patients with decompensated heart failure can be well warned, it has only been discussed in patients with cardiac resynchronization defibrillator implantation, and that particular treatment has not been investigated for this sensor method. At the same time, intelligent algorithms must combine different parameters, and different biosensors may need to be worn in the future, making patients lack compliance and making the research of intelligent algorithms difficult. Although biosensors can obtain detection results, individualized heart failure treatment still needs clinicians' face-to-face guidance. Virtual heart failure consultation is a system that enables cardiologists, heart failure nurses and patients to conduct video conferencing on the Internet [27]. Treatment can be optimized through videoconferencing. After remote consultation, biosensor data can make treatment more effective. In some emergency situations, large clinical studies are still lack to confirm the need for biosensors. At the same time, there are still no clear guidelines on when, under what circumstances and which biosensors should be used. This review does not track consumer monitoring after using biosensors, nor does it explore the privacy of biosensor data. At the same time, the device status of FDA (Food and Drug Administration) is not included.

6. Conclusions

Heart failure's heavy hospitalization rate significantly affects the country's medical and health systems. Although some patients do not have obvious discomfort, they cannot complete many daily activities, such as climbing the stairs, riding a motorbike, etc. Therefore, clinicians should think about monitoring the high-risk factors for heart failure, halting its progression of heart failure and using different medications to deal with different types of heart failure patients' ventricular remodeling. A biosensor is an important tool to prevent heart failure and monitor heart failure's physiological and pathological process. Although the drug therapy reduces the mortality and hospitalization rate of heart failure, drug treatment does not completely stop the development of heart failure nor completely reduce the possibility of recurring heart failure. Therefore, there is still much room for biosensor treatment of heart failure. Biosensors can be invasive biosensors, such as Cordella sensors, CardioMEMS sensors, which can directly measure pressure changes and are particularly sensitive to decompensation in congestive heart failure. Invasive sensors are also gradually reduced in size, reducing resistance to invasive treatment in patients.

Heart failure biosensors can also be flexible wearable devices, such as wristbands, non-invasive venous waveform analysis, heart sound sensor, etc., to judge the progress of heart failure by measuring high-risk factors and inducements of heart failure.Non-invasive biosensors provide a more portable and accessible solution to heart failure monitoring. At the same time, there is no lack of intelligent algorithms based on different sensors. Machine learning can make intelligent algorithms more adaptable to individual needs and constantly improve the diagnosis of heart failure. Among them, it has been demonstrated that numerous biosensors can help patients with heart failure have better prognoses or forecast when they develop heart failure.

At the same time, the combination of intelligent algorithms can also improve the specificity and sensitivity of diagnosis. The information collected by biosensors is often gathered and presented to clinicians to analyze the worsening factors of patients' clinical symptoms, reducing the costs to patients. Beyond that, a sound biosensor system will further reduce the incidence of other complications due to heart failure. Especially under the epidemic today, the corresponding treatment plan can be customized through remote monitoring, reducing unnecessary risks. Although these biosensors currently only target relatively small or specific subgroups of individuals suffering from heart failure, they not only take care of the clinical requirements of these heart failure patients also enhance their quality of life, and lay the foundation for the future exploration of more accurate and perfect biosensors.

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