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Medical Wearables for Monitoring Cardiovascular Disease

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Medical Wearables for Monitoring Cardiovascular Diseases

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Abstract

Millions of deaths occur each year due to cardiovascular diseases. By improving the management of care for patients with heart diseases, fatalities can be reduced. Innovations in wearable technologies are aiding in monitoring cardiac patients and managing their care more effectively. The objective of this paper is to review current wearable devices that measure pertinent parameters for patients with cardiovascular disease, highlight some of the challenges, and make suggestions to overcome the challenges. Signals for monitoring cardiovascular disease include heart rate, blood pressure, and electrocardiogram. The ability for patient data to be collected and delivered to preset destinations wirelessly adds power in improving care management. Challenges facing wearables include data security and regulatory approval. A few suggestions to overcome the challenges are proposed. In conclusion, the use of wearables enables better monitoring of cardiac patients, facilitating communication with clinicians thereby rendering care management to be more effective.

Keywords

Wearables, Cardiovascular-Disease, Health-Monitoring, Healthcare

Introduction

According to the American Heart Association's 2017 heart disease and stroke statistics update, an estimated 92.1 million adults in the United States live with at least one type of cardiovascular disease.[1] This number is expected to grow, as 44% of the U.S. population is predicted to have some form of cardiovascular disease by the year 2030. Cardiovascular disease continues to be a problem of concern in the medical field, and new innovations in monitoring and management of cardiac patients are needed. Currently, medical wearable technologies are rising to this challenge, as they provide effective collection of important physiological data using an interface that is familiar and comfortable to the user. It is reported by Mostafa Haghi et al. that the present wearable market is expected to rise over $5 billion in 2018, major companies which manufacture activity trackers are Fitbit, Xiaomi, Apple, etc.[2] The merging of activity trackers and medical wearables seems to be a natural progression, with novel medical wearables emerging in the market.

The application of a medical wearable in cardiac monitoring consists of several steps. First, the wearable is integrated with the user in the form of a watch, clothing, chest strap, or other form of placement. Secondly, the sensor of the wearable measures the desired parameters. In cardiac monitoring, useful data includes corresponding to electrocardiogram (ECG), heart rate, blood pressure, etc. Collected data is then translated from the front-end sensor into a processed form that can be displayed to the user. Finally, data is often communicated to the patient's clinician in the form of an electronic health record via a proprietary app or cloud based server.

Wearable technology helps in monitoring patients continually throughout their daily life. The lightweight and unobtrusive nature of a wearable appeals to patients who do not wish to be hindered by their monitoring device. Byeong Wan An et al. states that wearable electronic devices provide real time continuous data acquisition for complex health conditions, and have the potential to improve the length and quality of life of the world's aging population.[3] The objective of this paper is to review current wearables that measure pertinent parameters for patients with cardiovascular disease, highlight some of the challenges and make suggestions to overcome the challenges.

This paper is generally focused on wearables that measure parameters pertaining to cardiovascular diseases. Firstly, definitions of medical parameters relevant to cardiac monitoring are introduced. A multitude of wearable sensors and their detection capabilities of physiological data are reviewed. Then, a discussion is presented regarding the benefits of the wearables and current challenges encountered concerning wearables. Finally, recommendations for future work to improve patient outcomes are suggested.

Background

Cardiac monitoring after heart surgery, heart attacks, and other conditions traditionally consists of getting 12-lead ECG and using the Holter monitor. Electrocardiography is a measurement of the electrical activity of the heart and provides an in-depth assessment of heart rate, rhythm, conduction, and repolarization from multiple lead vectors. Holter monitors are used as a portable ECG for patients, and most can monitor for up to 24 to 48 hours. ECG electrodes sense the tiny electrical charges of a heartbeat arising from the skin. By placing these electrodes on different parts of the body, a comprehensive picture of the heart's activity can be acquired. For example, in a 12 lead ECG, there are 10 electrodes placed that provide 12 perspectives of the heart's activity using various angles among electrical planes, referred to as V1, V2, V3, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6. Typical ECG of a healthy patient is schematically shown in Figure 1, which provides valuable information on whether heart activity is too slow, fast, irregular, or if heart muscles are being over worked.

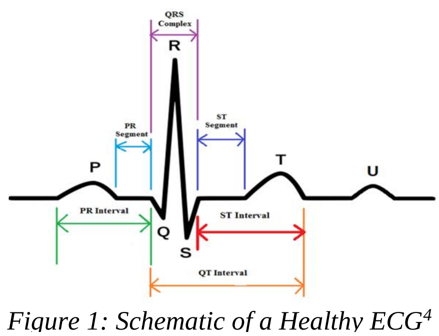

Figure 1: Schematic of a Healthy ECG[4]

Heart rate is derived from an ECG and it can provide information regarding the stress on the heart. The normal resting heart rate for an adult ranges from 60 to 100 beats per minute. The heart beating too fast (tachycardia) or too slow (bradycardia) are types of cardiac arrhythmia, and is a reason why heart rate sensors should be integrated into medical wearables monitoring cardiac patients.

Another useful cardiac measurement is that of systolic and diastolic blood pressure. High blood pressure (known as hypertension), can lead to many serious effects to the heart if left untreated, including aneurysms, coronary artery disease, stroke, heart failure, kidney failure, dementia, and more. A healthy blood pressure should read around 120/80 mmHg.

Results

There are a variety of wearable products currently on the market that utilize sensors to monitor at-risk cardiac patients. In the following section, current technologies are discussed with available wearables models and their effectiveness at monitoring cardiovascular diseases

Qardiocore, a medical grade wearable, provides continuous monitoring of single channel ECG, heart rate, skin temperature, and respiratory rate. Different from the Holter monitor, Qardiocore is free from external wires. The hardware consists of a strap that wraps around the chest directly on the skin just below the sternum, a model is shown on the left in Figure 2. The front of the device contains the electrode sensors covered by silver plated brass.

Figure 2: Qardiocore device[5]

Figure 3: Alive Cor Kardia Mobile Device[6]

A second medical wearable that monitors ECG is the AliveCor Kardia Mobile device, an FDA cleared single channel cardiac event recorder. Kardia Mobile is not a wearable in the conventional sense, rather the device hardware attaches to the back of a smartphone. The user has the choice of performing a Lead 1, Lead II, or Anterior Precordial Lead ECG. In all cases, the device must be within one foot of the connected smartphone. After a 30 second calibration period, a continuous single-channel ECG is displayed on the smartphone for the duration of contact between the user and sensor, shown in Figure 3. Kardia Mobile specifically looks for signs of atrial fibrillation in users. Nicholas Lowres's et al. study found the AliveCor product to be a non-invasive, inexpensive, feasible way to monitor AF recurrence in post-cardiac surgery patients, as well an effective way to reduce patient anxiety through heightened understanding of the condition.[7]

Another medium in which wearables are attached to the user are through peel and stick adhesives, like Medtronic's SEEQ patch and iRhythm's Zio Patch. The SEEQ patch attaches to the user's chest as depicted in Figure 4, and records heart activity for up to 7.5 days. Therefore, this product is geared towards patients who are experiencing frequent symptoms and need continuous cardiac monitoring.

Figure 4: Medtronic SEEQ patch and transmitter[8]

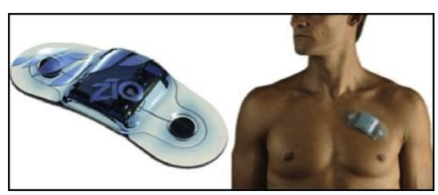

Figure 5: iRhythm Zio Patch[9]

The iRhythm Zio Patch, similar to the SEEQ patch, has a single lead ECG feature and provides continuous cardiac monitoring for time periods up to 14 days. The device attaches to the left side of the user's chest as depicted in Figure 5. In a 146-day patient study conducted by Paddy

M Barret et al., an arrhythmia event was defined as detection of supraventricular tachycardia, atrial fibrillation/flutter, pause greater than three seconds, atrioventricular block, ventricular tachycardia, or polymorphic ventricular tachycardia/ventricular fibrillation. The Zio patch proved to detect a higher percentage of arrhythmia events compared to a Holter monitor. The Zio Patch detected 96 arrhythmia events compared to 61 arrhythmia events by the Holter monitor. [9]

HeartGuide by Omron is reported to be still in development, it consists of a wrist wearable blood pressure monitor. The monitor has the same components of a traditional blood pressure pump, only miniaturized to the size of a watch, an example given in Figure 6. The watch contains a pump and a valve that inflates and applies pressure to the wrist. Stainless steel threads run along the band of the watch to insure maximal pressure is applied to the wrist. The user must hold watch to their chest to take measurement. After 30-45 seconds, systolic, diastolic, and heart pulse are shown digitally on the watch. Other features of the watch include messaging, sleep activity, step count, calorie count, and distance walked.

Figure 6: Project Zero 2.0 attached to user's wrist[10]

Wearables have been developed for patients who experienced or are at risk for sudden cardiac arrest. A wearable cardioverter defibrillator (WCD) is an option for patients who do not wish to undergo surgery for an implantable cardiac defibrillator (ICD), or need cardiac monitoring during the transition to an ICD. A WCD is worn outside the body, using dry, non-adhesive sensing electrodes to monitor the heart for life-threatening abnormal heart rhythms. If such an abnormal heartbeat is detected, the device alerts the patient via vibration and delivers a treatment shock. It allows a conscious patient to delay a treatment shock if the patient chooses. In the case that the patient becomes unconscious, the device releases a gel over the defibrillation electrodes and delivers an electrical shock.

Figure 7: Wearable Cardioverter Defibrillator[11]

The components of the WCD system include three defibrillation electrodes and four ECG sensing electrodes. An overview of how the product fits onto the patient is displayed in Figure 7. The system is fitted with a garment to be worn by the patient. The defibrillation electrodes release a gel to deliver a treatment shock. The ECG sensing electrodes are non-adhesive dry tantalum oxide capacitive electrodes. The defibrillator unit is carried on a waist belt. In a report by Johnson Francis and Sven Reek, the system uses heart rate, template matching and event persistence to decide if defibrillation is needed.[11] If the device decides a defibrillation is necessary, an ECG recording is stored during the period of the defibrillating shock so it can be sent for analysis subsequently.

Collecting data of the patient's health status via sensors is the first step in effective cardiac disease management. Data is then transferred to a display device by a method such as Bluetooth. Proprietary methods are also used, such as AliveCor's system that translates user input into high frequency ultrasound signals transmitted to the smartphone's microphone. Nicholas Lowres et al.[7] confirmed that this method saves battery consumption by more than 92% compared to Bluetooth.

Medical data is often presented to the patient and clinician in the form of a smartphone or web-based application. Efforts are being made to design these electronic health records to have similar features between products, arranging and presenting information to the patient, allowing them to view and manage their health history. In some cases, like Qardiocore and AliveCor, there is also a web portal that clinicians can choose to use to monitor their patient's data, ideally allowing them to monitor patients without a physical visit.

Discussion

Based on review of information on various cited wearable devices, the results show positive applications of wearable devices for cardiovascular disease monitoring. Hence the wearable devices are well suited for use in managing care of cardiac patients. However there are a few challenges encountered with wearable devices. Some factors currently hindering wearable medical devices include interoperability, security/privacy of data, and by regulatory approval.

For any wearable device to be effective, data is generally to be transferred from the wearable to either a cloud server or other proprietary server. This presents challenges related to data collection, memory and security. The patient's data needs to be secured so that the details recorded by the device are seen mainly by the patient's and their medical professionals. Increase in healthcare cyber-attacks has been noted in the last several years. Flaws in some implantable devices have been found leading to actions such as the FDA's recall of St. Jude Medical's ICD to receive a software update to prevent cybersecurity vulnerability.[12] Similar flaws can exist in medical wearables. Nir Menachemi and Taleah H. Collum state that for medical devices, data encryption must be secure enough to pass HIPPA protocols and the HITECH Act.[13] Software authentication and near-field communication can be implemented into wearables to improve security. All applications or servers associated with wearables should require a strong password or PIN code that only the authorized individuals have access to. Near-field communication allows for a smartphone and a wearable to initiate connection by bringing the two devices in close range of each other, thus preventing hackers from altering information during data transfer. A second obstacle for many wearables devices is receiving approval from regulatory agencies such as the FDA and FCC.

In wearables, the stakeholders defined by the FDA include patients, health professionals, researchers, medical device industry firms, and mobile application developers. The FDA has attempted to make the transition of wearable technology smooth by downgrading software working with medical data from a Class III (high risk) to a Class I (low risk) device. This lessens the burden on app developers however, the wearable manufactures will still have to make a proper design decision. If a wearable provides a suggestion for diagnosis, treatment, or advice that could pose a risk to a patient, it will be regulated by the FDA. However, as stated in the 2015 FDA guidance on medical mobile applications, if a wearable only provides general health advice, they can avoid going through FDA regulation process.[14]

Future Work

Reviewing the current technology on medical wearables, a few recommendations can be made for future developments. A common trend exists in successful wearable devices; patients are engaged and can comprehend and utilize their personal health data. The ability to keep patients motivated in a wearable is crucial, as Emil Chiauzzi et al. state that one third of U.S. owners of wearable devices stop using them within six months of first use.[15] Some improvements that could aid in this venture are better data collection, and continued miniaturization.

Currently there are some downfalls for wearables in their effectiveness in monitoring signals due to their use in uncontrolled settings. One such example presented by Nicholas Lowres et al. is in noisy electrode reading due to motion artefacts in products like Kardia Mobile.[7] Dirty electrodes, bad electrode placement, and outside electrical interference can worsen the ECG reading of a wearable. In addition, traditional silver chloride electrodes may cause skin irritation during long-term monitoring and require skin preparation, seen in the SEEQ patch and Zio patch. Atte S. Joutsen et al present one potential solution to this obstacle in textile-integrated dry electrodes.[16] Electrodes that integrated into fabric are of research interest. Firm and constant contact is needed for the electrode to be effective.

Continued miniaturization of wearable device is also important for continued improvement of wearables. Some options include wearables that can be slipped over the skin or clothing, possibly in the form of a sock or a shoe. Using skin patches pediatric patients is another option. A skin patch on a young newborn may transmit information that is useful to the clinician. These skin patches are also miniaturizing, becoming tattoo-like wearables that uses materials such as conductive fabric or graphene to create paper thin electrical circuits sticking to the skin. To achieve cost-effectiveness, disposable wearables are an option. They would be simple to manufacture, and the manufacturer would not have to worry about deterioration of product performance over time.

Conclusion

In conclusion, a variety of medical wearables for monitoring cardiovascular diseases have been reviewed in this paper. These products are used to yield valuable information regarding patient conditions such as ECG, blood pressure, and heart rate. It was shown that current medical wearables can provide benefits to the patient's care delivery. It is expected that the technologies will continue to improve and overcome most of the current challenges. These challenges include security of patient data, FDA approval, and patient engagement. Some suggestions that can improve wearables for cardiac monitoring include reducing error, continued miniaturization, and other improvements are in progress to bring about overall enhancement in the monitoring and care delivery.

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