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Telemedical Concepts for Heart Failure Patients Treated with a Wearable Cardioverter Defibrillator

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Abstract. Over the last few decades, implantable defibrillators have become an established method of treating malign cardiac arrhythmias. There are some situations, however, in which it would be premature to implant a permanent defibrillator. In such cases, a wearable cardioverter defibrillator (WCD) can provide temporary relief and protect patients from life-threatening cardiac arrhythmias. Treatment with WCD is now included in national and international guidelines. Nevertheless, there are still some deficits in connection with WCD, especially regarding rescue chain optimization. For example, there is currently no telemedical link in place to emergency call centers and healthcare practitioners in the case of an event. Likewise, there are still some problems with rhythm analysis, concerning both shock delivery and cardiopulmonary resuscitation (CPR). These deficits are now to be addressed within the framework of *MiniDefi*, a project funded by the German Federal Ministry of Education and Research (BMBF). The concepts are described here for the first time.

Keywords. heart failure, wearable cardioverter defibrillator, rescue chain, data transfer, telemedicine

1. Introduction

Sudden cardiac death is responsible for approx. 65,000 deaths per annum in Germany alone [1]. Evaluation of electrocardiograms (ECG) in patients who have died in this way show that cardiac arrhythmias, specifically ventricular tachycardia (VT) and ventricular fibrillation (VF), are the most common cause [2] **(Figure 1)**. The primary preventive measure recommended in the guidelines is therefore the implantation of a defibrillator [3].

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Figure 1. Sudden occurrence of VT with transition to VF. Acute danger of sudden cardiac death. Patient from our hospital.

However, there are frequently clinical situations in which the risk of sudden cardiac death is considerably increased, and yet the damaged heart is potentially able to recover (e.g. acute heart attack, acute myocarditis). In such situations it would be premature to implant a permanent defibrillator. For this reason, the current guidelines for this patient category recommend use of an external wearable cardioverter defibrillator (WCD) [3, 4].

A WCD **(Figure 2)** then serves as a bridging device until the final clinical decision can be reached. This usually takes a period of 3-4 months. Either the cardiac function remains poor and the risk of life-threatening arrhythmias remains, in which case a permanent defibrillator is implanted. Or the patient recovers and defibrillator protection is no longer required.

2. Current problems and deficits

Data from more than 20,000 WCD patients in different registry studies have now been published [5]. The results demonstrate the general benefits of the wearable device and have led to WCD treatment becoming established over the last few years. However, the standard WCD used at the moment leaves room for improvement at several levels:

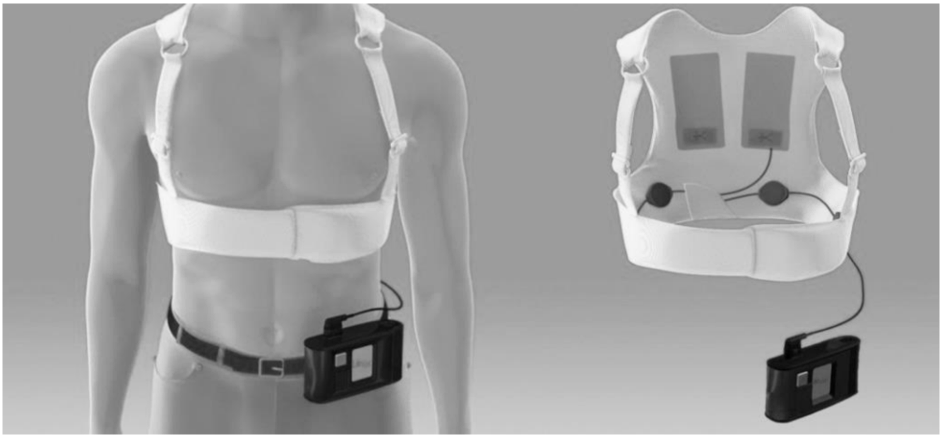

Figure 2. Currently used WCD for temporary treatment of high-risk cardiac patients [6].

1. Sometimes the WCD can still lead to a faulty cardiac rhythm analysis, which in turn could lead to inappropriate shock delivery [7]. In such cases, patients are able to abort the pre-announced shock by pressing a button. Studies show, however, that patients do not always abort inappropriate shocks [5].
2. Adequate patient monitoring following a shock delivery does not currently exist. Many defibrillator patients fear the life-saving electric shocks and react with sometimes irrational behavior, such as panic attacks [8]. WCDs currently have no voice link to medical staff who could calm patients down and give them medically indicated advice regarding how to behave in this emergency situation.
3. Currently, no integrated support for potential first aiders (often laypersons) is available. Especially when a shock is unsuccessfully delivered, appropriate first aid including sufficient cardiopulmonary resuscitation (CPR) is crucial in order to increase the survival chances of the patient [9, 10]. Qualified instruction and supervision of a first aider would be desirable in order to improve the quality of first aid.
4. If a defibrillation is ineffective, the necessary CPR must currently be halted for a few seconds in order to analyze the cardiac rhythm. This is necessary because the chest compressions otherwise lead to considerable ECG artifacts, thus falsifying the analysis **(Figure 3)**. During this interruption, the blood flow which was artificially maintained by the CPR is halted, negatively impacting the oxygen supply necessary for survival [9].

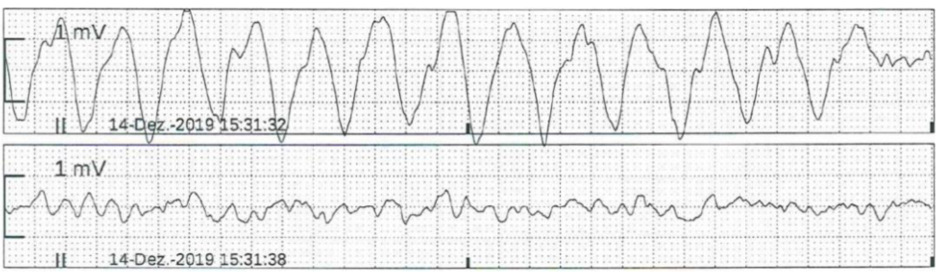

Figure 3. ECG signal with artifact during CPR, followed by the break currently required to analyze the cardiac rhythm status. Patient from our hospital.

5. Currently, following an event there are no standard emergency call center alarms and no information provided on site for the ambulance. Yet this is crucial in the sense of a closed rescue chain if rapid treatment is to be guaranteed.
6. One serious deficit is a lack of access to information about the individual disease and treatment history, so that the treating emergency physician and emergency hospital often do not have important facts at their immediate disposal.

3. Methods and preliminary results

Research project: Within the framework of the *MiniDefi* project funded by the German Federal Ministry of Education and Research (BMBF), a new miniaturized defibrillator for high-risk cardiac patients is being developed. The particular focus is on comprehensive telemedical integration of the device in order to improve the rescue chain, as well as implementation of new algorithms to optimize ECG analysis and CPR execution.

3.1. Improved computer-based rescue chain

The current lack of nationwide communication standards in the emergency services prevents medical devices from being successfully networked. The result is avoidable delays in both diagnosis and treatment. Within the context of this research project, new communication profiles will be drawn up to combine different existing standards in the healthcare system in order to network all the agents involved. Specifically, a telemedical emergency care service for WCD patients is to be set up and improved. Crucial components which need to be developed for this purpose are:

- Adapted WCD → new sensor and communication systems to and from patients
- MiniDefiCloud (MCLOUD) → central database with patient histories and analytical tools
- MedicalPad (MP) → communication to, and visualization in the ambulance
- MedicalPad-Server (MPS) → communication between MCLOUD, MP and emergency call center
- Hospital-Monitor → communication to, and visualization in the hospital.

Emergency care requires differentiation of 4 different scenarios. The overall conceptional process is shown as planned in **Figure 4**.

3.1.1. Scenario 1 (Handover of adapted WCD):

The patient receives the WCD from the treating cardiological hospital. It is configured according to the patient's requirements via Bluetooth (ISO 11073 [11]). Following configuration, data can be sent from the WCD to MCLOUD via a mobile data connection (LTE, WiFi, etc.) based on HL7 FHIR [12].

3.1.2. Scenario 2 (Digital support for patients and/or first aiders):

Upon detection of a life-threatening cardiac arrhythmia, the WCD triggers a defibrillation, as before. Simultaneously, an eCall is sent which is similar to those already familiar from the automotive industry. The corresponding ISO 15638-10:2017 [13] standard is used, substituting the vehicle identification number (or a virtual vehicle ID) for a medical product ID. As with other eCalls, the emergency call center can communicate directly with the patient and/or first aider via a voice link wherever they are. Thanks to the Minimum Set Of Data (CSN EN 15722 [14]), a Webcall is additionally sent to the MPS, which queries from MCLOUD the WCD information in real time. The live data are visualized for the staff at the emergency call center via a web interface. They are now able to see the current WCD data, calm the patient down and give the patient and/or first aider instructions regarding what to do.

3.1.3. Scenario 3 (Digital support for arriving ambulance):

Once the emergency call center has received the alarm, communication can then be linked to the ambulance. With the help of a proprietary connection, the relevant data are transferred from the MPS to the MP in the ambulance. This enables the emergency physician to communicate with the patient and/or first aider directly, while the ambulance is still driving towards them. In cases of CPR, the emergency physician can already take a look at the ECG of the patient in the ambulance with the artifacts removed (thanks to the use of new algorithms within MCLOUD) in order to assess the current situation.

3.1.4. Scenario 4 (Drive to the emergency hospital):

Once the patient has been loaded onto the ambulance, the MP communicates directly with the patient WCD via Bluetooth. This direct link guarantees that data can always be read, even if the ambulance drives through a dead spot with no reception. In parallel, data are additionally sent to MCLOUD and analyzed so that any analysis results can be sent back immediately. Via the MP and the MPS, the patient can now be registered with the destination emergency hospital (using a system similar to Ivena [15]). Transmission of real-time data to the emergency hospital supports the medical staff at work there as they prepare for the arrival of the patient. Data are transferred using HL7 FHIR [12].

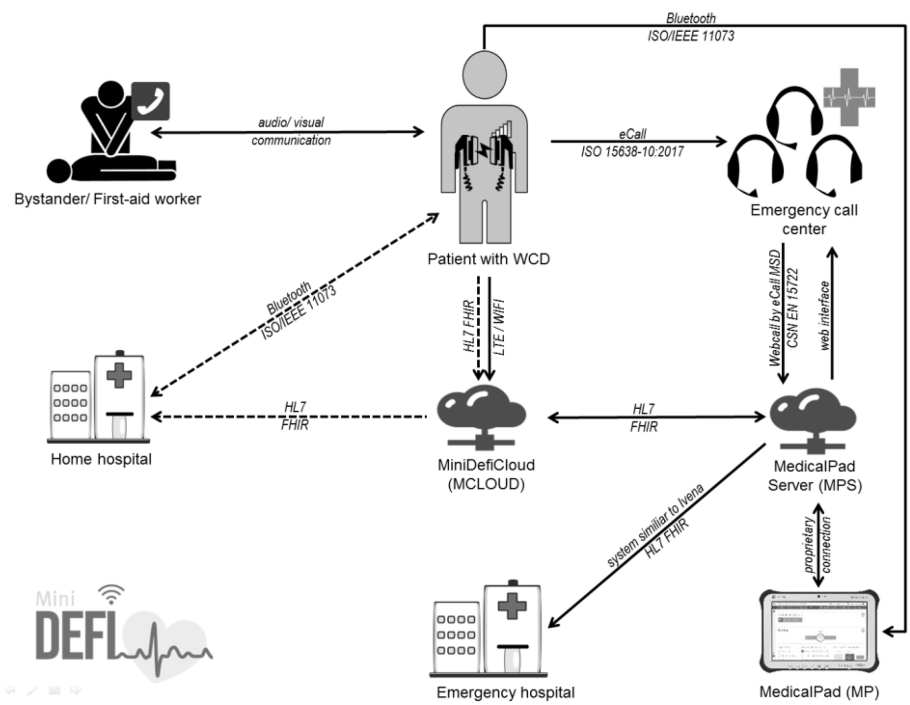

Figure 4. Conceptional process for improved emergency care within the framework of *MiniDefi*.

3.2. Improved algorithms for ECG analysis

Cardiac arrhythmias are always distinguished between:

1. those requiring an electric shock (VT or VF)
2. those not requiring an electric shock (e.g. atrial fibrillation (AF), asystole [ASY] or pulseless electrical activity [PEA])

The American Heart Association (AHA) demands a sensitivity of ≥90% and a specificity of ≥95% [16] for the shock advice algorithms (SAA) used. These values are currently only reached if the SAA is calculated during a break in reanimation. Without a break, the CPR-caused artifacts interfere with the recorded signals **(Figure 3, Figure 5)**.

In the future, analysis should also be reliably performable during CPR. However, the corresponding filter algorithms do not yet meet the criteria demanded by the AHA. The main cause here is that use of filters can be concomitant with the addition or retention of noise. In ASY cases in particular, this leads to problems because the resulting ECG signal cannot be correctly interpreted, thus complicating the SAA calculation [17].

3.2.1. Reanimation data:

A major obstacle to improving the current filter algorithms is the generation of a large and realistic data set for research purposes. Reanimation data cannot be generated experimentally.

In order to meet this challenge, data are to be collected from emergency applications of automated external defibrillators (AED), in which first aiders (usually laypersons) performed reanimation. Likewise, ECG data under reanimation conditions are to be collected from hospital intensive care units.

In hospitals, reanimations can be performed by hand (through medical staff) or by using a mobile automated reanimation device. The resulting artifacts usually differ in characteristics between manual reanimation **(Figure 5)** and automated device-based reanimation **(Figure 3)**.

Within the framework of *MiniDefi*, the algorithms are to be fed with data sets as they develop, taken from layperson reanimations (via AED), reanimations by medical staff (hospital) and reanimations using mobile automated reanimation devices (hospital). This should facilitate a realistic mapping of all the different versions of reanimation currently performed.

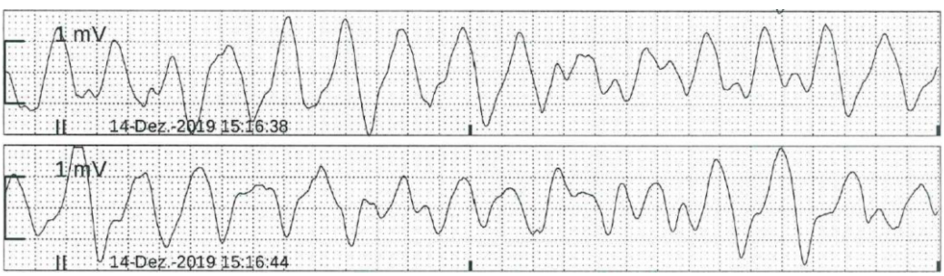

Figure 5. ECG signal with artifacts during CPR. Reanimation performed by hand through medical staff. Patient from our hospital.

3.2.2. Additional sensors:

Another way of filtering out the current CPR artifacts is acquisition of additional information. For example, acceleration sensors integrated in the WCD could be used to reflect the chest compressions. In this way, characteristics could be extracted and then used to model the CPR-induced ECG artifacts.

Moreover, such sensors could serve as CPR feedback for the first aider, as notification of frequency and impression depth. This in turn could considerably improve the quality of the first aid, accompanied by better cerebral perfusion for the patient.

4. Discussion

Telemedical solutions have been on the advance for the past few years, but have yet to be applied successfully in all areas of medicine. Particularly in emergency situations – such as the occurrence of life-threatening cardiac arrhythmias requiring the delivery of defibrillator shocks – telemedicine still has huge, as yet unexploited potential. Its application could mean a networking of all the agents involved and an optimization of their collaboration to help the patient.

However, there is to date no such telemedical concept for the WCD currently used. The *MiniDefi* research project seeks to considerably improve the rescue chain through optimized exchange of data and adequate supervision of patients and/or first aiders. Moreover, innovative algorithms are to be developed for the further improvement of rhythm analysis. In this way, inappropriate shock deliveries are to be avoided and sufficient rhythm analysis facilitated, even during CPR conditions.

Cloud-based solutions, with their flexible architectures and scalable computational power, promise innovative solutions and approaches. The highest priority in this context is to uphold data privacy and authentication.

With regard to further potential, ECG analysis removed of artifacts will most certainly find its way into routine use away from WCD treatment, simply because corresponding algorithms are urgently needed in the treatment of other patient groups, whether in the ambulance or in hospital intensive care units or both.

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