Early Detection of Developing Left Ventricular Pump Thrombosis: Design of a Portable Monitoring Device

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Abstract

Cardiac insufficiency can lead to an implantation of a HeartWare ventricular assist device (HVAD). These devices support the heart in its pump function. The HVAD technology has highly improved during the last years. However, it has also been limited by complications occurring after the transplantation. A frequent complication is the occurrence of a pump thrombosis in HVAD, which is life-threatening if it is not treated. If the pump thrombosis is detected late, an aggressive lysis or a pump exchange are required. However, an early detection means that the patient can be treated with anticoagulants. These medications breakdown the thrombosis. Consequently, dangerous interventions can be avoided and the patient can be released from clinical observation.

Currently, patients with implanted HVAD are clinically inspected in monthly intervals. These intervals are long and lead to a late detection of the pump thrombosis or to a deathly outcome. Therefore, a method is needed that allows the patient to inspect the HVAD on a daily routine. Objective of this study was to develop this method.

Pump thrombosis in HVAD has been considered by the manufacturer, HeartWare [1]. The current state is that the HVAD gives an alarm in case the power consumption violates a limit. The limit is set to one watt above the average power consumption of the respective month. However, this limit was not satisfying for the detection of a developing pump thrombosis.

In our study, we analyzed the power consumption in seven patients with pump thrombosis. We detected a mild increase starting three to five days prior to the usual limit violation. We defined this increase of the power consumption as characteristic for a developing pump thrombosis.

Based on these findings, we developed algorithms, which could detect pump thrombosis in the early development. Additionally, we designed a portable device, Smart Heart Guard (SHG). The SHG can be connected to the HVAD and monitor the pump consumption. In case of a developing thrombosis in the pump, the SHG will recommend the patient to consult the responsible clinic. The SHG allows a fast daily inspection by the patient himself.

With our study and the designed SHG, we present a solution for the early detection of pump thrombosis in HVAD that has to be approved in clinical trials.

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[*] Designed the algorithms and software

1 Introduction

Cardiac insufficiency defines the malfunction when the heart cannot maintain the blood pressure to support the body. An insufficiency can be caused by congenital malformation, congestive heart failures or myocardial infarctions. Recent statistics indicate an increasing incidence with obvious serious consequences for the health and life of the affected patients. In patients with terminal heart failure the potential treatment option of cardiac transplantation is limited by the current organ shortage. Thanks to modern medical technologies, physicians can use ventricular assist devices (VAD) to support the heart. A VAD consists of a pump attached to the ventricle in order to bypass the damaged heart.

The VAD technology has been developed over the past 40 years. Initially, VAD were engineered as pulsatile systems, which pump the blood with a pulsating flow to imitate the physiological behavior of the heart. However, recent studies have shown that continuous-flow pumps give better results in terms of survival rates [2]. Continuous-flow pumps bypass the heart maintaining a constant blood flow. These systems have significantly improved the quality of life for patients and reduced complications such as strokes and device malfunction. Although originally designed to bridge the short term until heart transplantation, VAD have also shown good results for longer terms, up to nine years. Due to the world-wide organ scarcity, VAD have a very promising future perspective.

The potential complications of implanted VADs are diverse and highly depend on patient characteristics and underlying pathology. One of the main limitation is thrombosis in the pump, which occurs in about 4% of the recorded cases [3]. A thrombosis in the pump results in agglutination of the corpuscular blood components and might end up in a dysfunction of the pump. If a thrombosis is detected in an early stage, it can be treated with intravenous application of anticoagulants (heparin or tirofiban). If detected too late, the thrombosis will require either aggressive lysis therapy (recombinant tissue plasminogen activator, rTPA) which is accomplished with severe bleeding complications (brain and gastrointestinal tract) or the need of a surgical pump exchange.

Currently, a daily inspection of the pump parameters is technically not available. In a routine setting patients are ambulatory at home. In an interval of four to six weeks, patients are seen in the outpatient clinics of their VAD implantation hospital. During the examination, the VAD parameters are analyzed retrospectively (last 28 days). In best cases, a pump thrombosis can be detected and treated after the routine examination. However, it can lead to a life-threatening situation if the pump thrombosis occurs within the interval of up to six weeks and remains untreated.

The objective of this study was to define characteristic pump parameters indicating an early pump thrombosis. Based on these findings, we designed a VAD home monitoring device that can be handed to the patient. The patient is able to check the VAD for pump thromboses on a day-to-day basis. If a developing pump thrombosis is detected, our device alerts the patient and recommends to consult a doctor as soon as possible. This paper presents our algorithms for the detection of a thrombosis and the design of the monitoring device.

2 Methods

For our study, we focused on a continuous-flow VAD system by HeartWare (HVAD) because of its low rate of complications and the excellent long-term results [4], [5].

First, we analyzed seven patients and could detect 11 pump thromboses. For each patient, we loaded the data from the HVAD and analyzed power consumption and rotation speed. These analyses enabled the required insight and information to develop an early thrombosis detection system. The manufacturers alert setting for the thrombosis of one watt deviation of the power consumption were included.

Second, we developed a device, Smart Heart Guard (SHG), which is based on the Raspberry Pi technology. The SHG consists of a touch screen and a Raspberry Pi platinum. We used Raspian as operating system and create a program for the early detection. For that, we used the scripting language Python for the core and Qt for the GUI.

We developed four different algorithms for the thrombosis detection and implemented it in the SHG. Figure 1 illustrates the developed algorithms. We implemented an algorithm to detect upper or lower limit violations (A). Furthermore, a deviation of the mean is measured (B). An alert is given if seven data points in a row lie above or below the mean of the whole measurement array. A local trend detection was used (C), which takes action if seven values in the row increase or decrease steadily. Accordingly, a global trend has been established to measure the behavior of groups of data points (D). The default measuring time was set to 100 seconds. Default measuring time and constraint can be individually adjusted any time but explicitly by the physician.

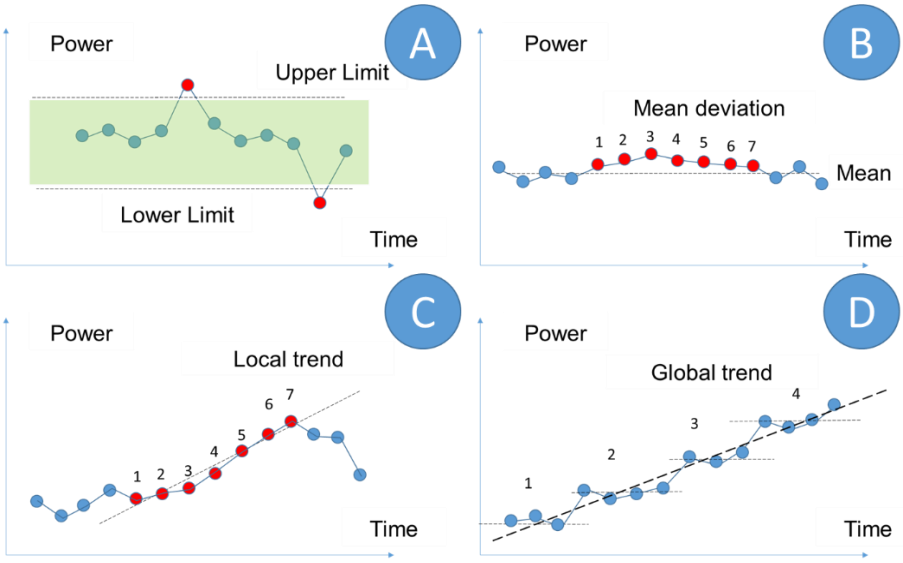

Figure 1: Developed detection algorithms for a pump thrombosis

In order to test our device, we developed a mock circulation with the HVAD consisting of the pump and a tube that connects in- and outflow. The pump was then connected to the controller and the power supply resembling the patient constellation.

The device is portable so that it can be used at home and in any places with a regular power supply. An important focus was a one-way data system only for data analysis without the option to adjust or manipulate pump settings. SHG is adjusted according to the individual pump setting by the physicians. The individual parameters are speed, the average power consumption and hematocrit. The hematocrit is defined as the volume percentage of red blood cells in the blood. For the patient, hardware and software have to be easy to understand and clear in its application. The SHG has a touch screen and only two cables. One serves exclusively for power supply, the other for the connection to the controller. The software guides the patient through the measuring procedure. Following power-on, the SHG requests the patient to connect to the controller and to start the measurement by pressing a button. The algorithm reads the data (10-60 seconds) followed by an instant analysis.

3 Results

The analysis of pump thrombosis events revealed that power consumption is the significant indicator for the potential early detection. Figure 2 displays the graphical analysis provided by HeartWare highlighting the power consumption (red), blood flow (green) and speed of the pump (black). In all observed events of pump thrombosis, a significant two-phase increase of power consumption occurred. In figure 3, a mild increase (developing thrombosis) is followed by a second sharp surge (fully developed thrombosis). The characteristic second peak violates the manufacturer's limits for the power consumption (one watt above average power consumption). Consequently, it would activate an alarm in the controller. However, we observed an earlier rise of power consumption beside the typical circadian alterations starting three to five days (mean 3.8 days) prior to the additional abrupt increase characteristic for the pump thrombosis. This delay of about four days has critical impact on patient morbidity and mortality influencing treatment options.

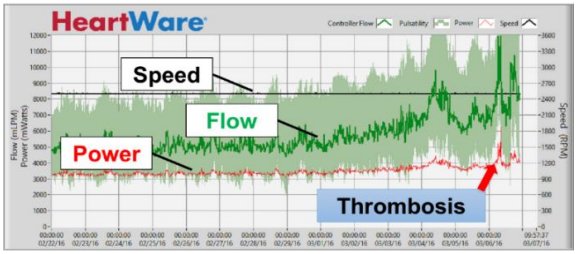

Figure 2: Graphical analysis of pump parameters by HeartWare

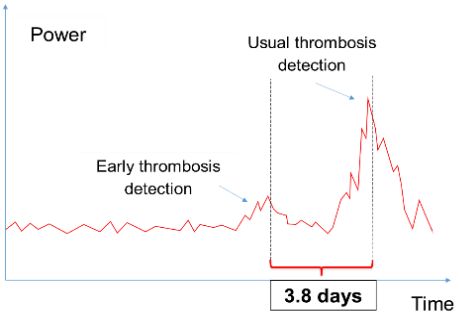

Figure 3: Example of an early thrombosis detection

Based on this finding, we triggered the default values for the limit violation detection and prototyped the first version of SHG. The software design required to set up a measuring procedure which is graphically shown in the following figure 4. The measuring procedure can be divided into four steps which are indicated in the figure by the number 1-4.

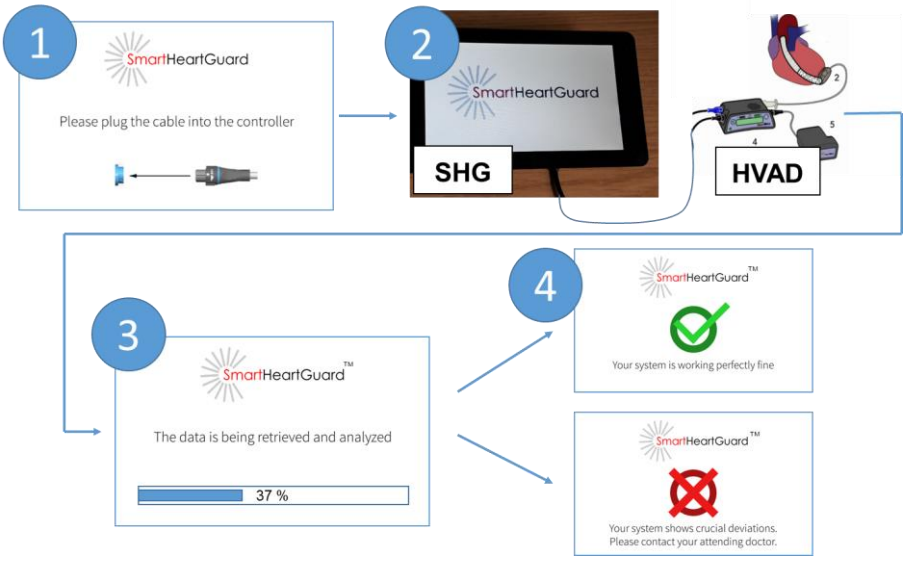

Figure 4: Measuring procedure of the SHG from a patient point of view

The graph shows the SHG measuring procedure from a patient's point of view. After the SHG has been switched on, the patient is requested to plug the cable into the controller of the HVAD (1). As soon as the connection is established (2), the patient initiates the measurement by clicking the "start" button. Consequently, the data is retrieved and analyzed by the SHG (3). When the measurement has been completed, which takes 10-100 seconds by default, the patient is informed about the system's status (4). If the HVAD system is working properly, a green arrow appears. In case of any deviation, a red cross is shown and the patient is advised to consult his physicians immediately.

In order to test the SHG, we simulated the occurrence of a pump thrombosis. For that, we increased the pump resistance by bending the tube of the mock circulation. In consequence, the power consumption decreased. We could increase the power consumption again by releasing the bended tube. Through multiple of these in situ tests, we could prove that the first version of SHG is a robust and reliable device.

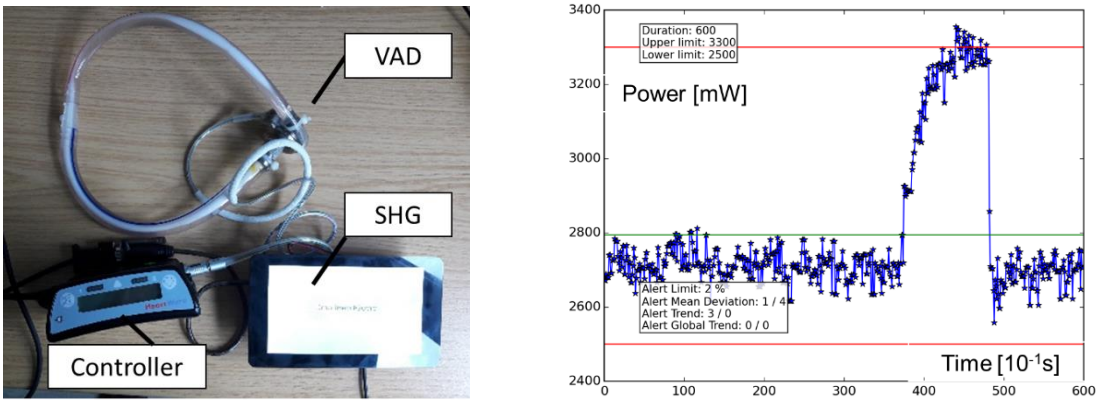

Figure 5: Mock circulation setup (left) and results of a simulated pump thrombosis (right)

Figure 5 shows the result of our simulation test. On the left, the setup for the mock loop is given, showing controller, VAD and SHG. On the right side, a measurement of a simulation experiment is shown. The measuring time was set to 60 seconds, the upper limit to 3300mW and the lower limit to 2500mW. In this experiment we focused on the limits. The upper limit was violated at about 40 seconds.

4 Conclusion

We have successfully detected pump thromboses during development focusing on HVAD systems. We chose the power consumption as indicator for the occurrence, which we could prove with a clinical prospective analysis of pump thrombosis events. Consequently, we developed the SHG, a portable monitoring device that allows the patient to check the implanted HVAD and alerts in case of a developing abnormality. Instead of the monthly examinations, the SHG enables a daily check. We implemented four detection algorithms to ensure the reliability. The functionality and the default setting are awaiting approval by a clinical trial.

In summary, we investigated a main complication of HVAD systems. Additionally, we present a technical solution to possibly improve the system. SHG can help to prevent device dysfunction due to pump thrombosis.

5 References

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