DIASTOLIC TIMED VIBRATIONS FOR PRE-HOSPITALIZATION TREATMENT OF MYOCARDIAL INFARCTION

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Keywords: Heart attack, MI pre-hospitalization treatment, Coronary thrombosis.

Abstract: Heart attack or myocardial infraction is the leading cause of deaths in the modern world. In order to increase survival chance of patients, action should be taken during the first hour from the onset of symptoms, which is most often impossible with the current technology. To this end, we propose a method of heart attack treatment based on low frequency diastolic timed vibrations. This method can be used in ambulatory setting by unspecialized personnel as it is noninvasive and safe for the patient. It is based on applying low frequency mechanical vibrations synchronized with the heart cycle of the subject along with application of thrombus dissolving drugs. We present an analysis of the proposed methodology and provide experimental results obtained with a prototype device.

1 INTRODUCTION

In the developed world, heart diseases are the leading cause of death, presenting higher mortality rate than cancer (American Heart Association Statistics, 2010). In the United States alone, over 7 million men and 6 million women are living with some form of coronary heart disease and over a million people suffer a (new or recurrent) coronary attack every year. About 40% of heart attacks result in death (American Heart Association Statistics, 2010). Myocardial Infarction (MI) or heart attack is most often caused by formation of a blood clot (thrombus) blocking the arterial vasculature surrounding the heart. MI refers to myocardial cell death and occurs due to a complete coronary obstruction which results in a profound blood flow impairment causing inadequate oxygen delivery to the heart muscle. Once such an obstruction begins, cell death can occur in as little as 20 minutes. Complete death of all myocardial cells at risk can occur in, at the earliest, 2 to 4 hours (Kostuk, 2008). Various methods have been developed to dissolve or remove thrombus before MI occurs. Preferred invasive methods such as angioplasty require significant setup time and resources in order to be successful. Incidentally, the most effective treatment occurs during the first 60 minutes of the symptoms known as the golden hour. However, by the time an average patient reaches a hospital most deaths have already occurred (Turner and Rosin, 2008). This is worsened by the fact that those who manage to reach a hospital spend additional time undergoing examinations or being transported to a cardiac cathlab before the actual treatment can begin. As a result, speed of intervention is the biggest factor in saving a patient's life and is the key to effective heart attack treatment. Thus, if treatment could begin during transportation to a hospital, it would play a key role in ensuring the survival of patients.

To this end, we propose a method of treatment that could be safely applied by unspecialized personnel on-site or during patient transportation to the hospital. We believe that this method could drastically improve the survival rate of heart attack patients.

2 PROPOSED METHOD

We present a safe non-invasive method suitable for treatment of heart attack and other states of low coronary blood flow. It is based on applying low level mechanical vibrations in the chest area along with application of clot dissolving drugs. By performing vibrations during the diastolic period of the cardiac cycle (the relaxation of the heart) it is expected that coronary flow is increased and thrombus dissolution is achieved. In this study, we first aim at developing a vibrating system that is independently controlled by a real-time ECG signal. The triggering of the vibrating

Marzencki M., Khosrow-Khavar F., Ammar Zaidi S., Menon C. and Kaminska B..
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DOI: 10.5220/0003130604050408
In *Proceedings of the International Conference on Bio-inspired Systems and Signal Processing* (BIOSIGNALS-2011), pages 405-408
ISBN: 978-989-8425-35-5

system should be synchronized with the ECG signal in such a way so as to remain vibrating in the diastole and cease all vibrations in the systole of the ECG signal.

Our goal is to create a device for field use - a Diastolic Timed Vibrator (DTV) to be employed by medical emergency personnel to remediate acute states of low coronary blood flow, such as those exhibited in angina pectoris (chest discomfort secondary to coronary artery narrowing) or heart attack (an acute blockage of a coronary artery, usually by a blood clot). The DTV will impose mechanical vibrations to the chest of the patient in order to improve coronary blood flow. We aim at creating an inexpensive and portable system requiring minimal intervention of specialized personnel.

2.1 Mechanical Vibrations

There is strong experimental evidence that diastolic mechanical vibrations on the chest wall increase coronary blood flow (CBF). In past studies, diastolic vibrations performed on patients with coronary arterial disease (CAD) and on normal subjects resulted in an immediate increase of CBF as measured by both transesophageal doppler and coronary flow wire. The CBF increase in CAD patients was significantly larger than those of normal subjects (Taihei et al., 1994). In addition, clinical studies performed on humans and canines (Koiwa et al., 1997) have shown that external diastolic vibrations can release incomplete relaxation (IR) and improve the systolic function of the heart. Similar studies (Koiwa et al., 1997) consisting of external vibrations applied on human patients with aortic regurgitation (AR) and ischemic heart disease (IHD) resulted in a decrease of left ventricle systole pressure; proving that vibration induced depression does occur in humans. Clinical studies have shown that diastolic timed mechanical vibrations around 50 Hz improve coronary blood flow and left ventricular (heart muscle) performance in human volunteers, with and without coronary artery disease (Taihei et al., 1994). Low frequency vibration is a known potent vasodilator, especially for arteries with a degree of active tension or spasm, which is often the case in heart attack (Oliva and Breckinridge, 1977), and it has further been shown to significantly enhance clot dissolution with or without a thrombolytic agent both in-vitro and in commercially available catheter systems (Evans et al., 2003).

2.2 ECG Synchronization

Our method provides a new technique for disrupting and clearing the thrombus present in a patient's arterial vasculature surrounding the heart. During systole the heart is contracting and pressure needed for driving the blood is being generated within the chambers of the heart. As a result, vibrations should only be applied in the diastole (Koiwa et al., 1997). Furthermore, it has been demonstrated in clinical studies that vibrations timed exclusively to the diastole of the cardiac cycle advantageously facilitate heart muscle relaxation and paradoxically improve the strength of the heart contractions and hence can be utilized safely (Koiwa et al., 1994). In order to be able to synchronize mechanical vibration with the heart cycle, the ECG signal has to be analyzed and QRS complexes indicating the onset of systole have to be identified. Automatic detection of QRS complexes has been a subject of intensive research in the last several decades. Proposed algorithms range from simple filters to very calculation intensive machine learning algorithms (Kohler et al., 2002). Currently, most algorithms use a discrete or continuous wavelet transform which gives both the time and frequency characteristics of the signal. Machine learning algorithms such as Hidden Markov Model, Neural Networks and/or Support Vector Machine (SVM) are used to classify different parts of the ECG signal. The extensive amount of training that is required prior to use is a serious limitation of these methods in certain cases. We decided to use the widely employed "Tompkins" algorithm due to its implementation simplicity and robustness in finding abnormal QRS complexes.

2.3 System Architecture

The proposed system is composed of four main parts: vibrator, accelerometer, ECG system, DC power supply, and a LabView VI containing signal processing and control. Figure 1 schematizes the system architecture.

The mechanical vibrations were generated using a commercially available massager device (Human Touch HT-1280) driven by a DC voltage source interfaced with LabView. This setup generates the linear movement of the plate attached to a patient. An active damping stage is added to adjust the amplitude of generated vibrations and allow for rapid stopping of the motor. In order to be able to generate vibrations only in the desired periods of the heart cycle, an electromagnetic relay is introduced on the power line of the motor. This setup allows for efficient control of on-off time of the motor along with its rotational frequency. Furthermore, a MEMS accelerometer (LIS3L02AL) has been integrated into the vibrating plate to provide a feedback on the generated vibration amplitude and

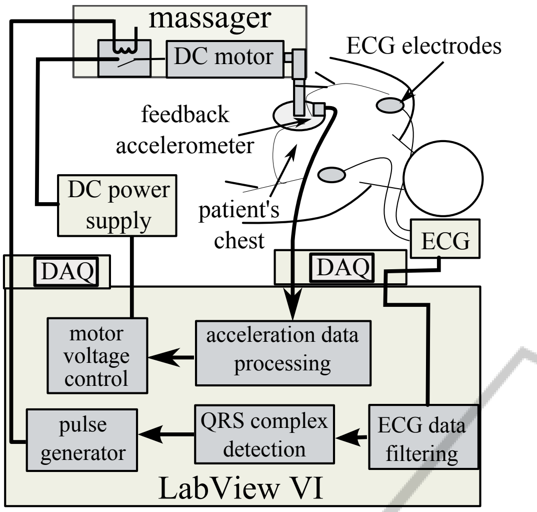

Figure 1: Block diagram of the proposed diastolic vibration system.

frequency.

An ECG acquisition system Burdick EK10 is employed to amplify and filter the ECG signal. The resulting signal is digitalized by a DAQ at 14bit and 200Hz and further processed in LabView.

An algorithm has been developed to detect the systole and diastole in a real time ECG signal in order to allow diastolic timed vibration. We created a virtual instrument using National Instruments LabView. The VI software implements the real-time Hamilton and Tompkins QRS complex detection algorithms. Figure 2 presents the stages of the algorithm. The ECG signal is band-pass filtered with a combination of low and high pass filters to separate the high energy QRS complex from the rest of the ECG signal. The resulting signal is differentiated to extract the onset of R-wave. Next, the signal is squared to make it positive prior to integration. The integrator sums the area of the positive wave form. The width of the integrator is chosen carefully to be long enough to consider abnormally long QRS complexes and short enough so that it does not overlap with the T-wave. The operator can pick the window size and the detection threshold in the software.

The frequency of QRS complexes is used to calculate the heart beat rate and the period of the ECG signal. Furthermore, lengths of two counters are calculated which, in coordination with the R peak detection, are time controlled to stop the vibrating system during systole and enable it during diastole. After detecting the R peak, systole counter is reset disabling the vibrating system until the systole cycle is complete. Once the systole counter reaches its limit (which is derived from the period of ECG signal), the vibrating system is enabled again for a duration determined by the diastole counter. The diastole counter is accordingly set to reach its limit before the beginning of the systole cycle. In case where the two counters overlap due to arrhythmic operation of the heart, the systole counter has priority over the diastole counter; thus ensuring that any detection of an R peak would immediately disable the vibrating system. The systole counter duration was approximated based on the QT interval calculations performed during past clinical studies of heart disease patients (Alexander et al., 1951).

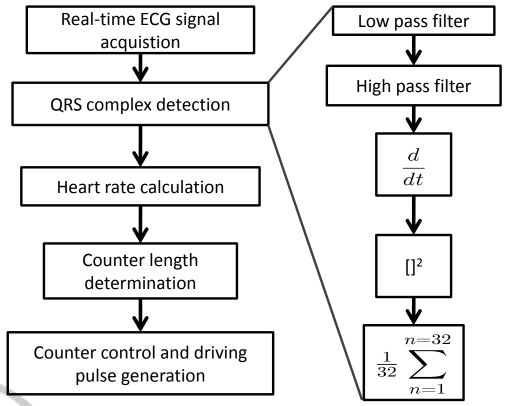

Figure 2: Block diagram of the ECG signal processing used to generate driving signal for mechanical vibrations synchronized with the diastole of a cardiac cycle.

3 EXPERIMENTAL RESULTS

In order to verify the accuracy of our predictions concerning the effectiveness of diastole timed vibrations, we built a prototype system. We concentrated on proper synchronization of the mechanical vibrations with the ECG signal.

Figure 3 shows mechanical vibrations generated with the massager synchronized with a real-time ECG signal. The overall period of the heart beat is 2 seconds in which the PQRST region of the ECG lasts for $0.55 \pm 0.05s$. Although the systole (QRST region) only lasts for 0.41 ± 0.04 seconds, the vibrating system is turned off before the PQRST region begins in order to ensure that vibrations occur only when the heart is in its relaxation state. During the diastolic cycle, the DC motor is allowed to vibrate for 1.40 ± 0.04 seconds. The massager device has high rotary inertia, therefore a special damping stage was introduced in order to allow more precise timing of the generated vibrations. The delay between the end of the driving pulse and the actual termination of the mechanical vibrations was measured to be approximately $17ms$. Therefore, the vibration spill defined as the amount

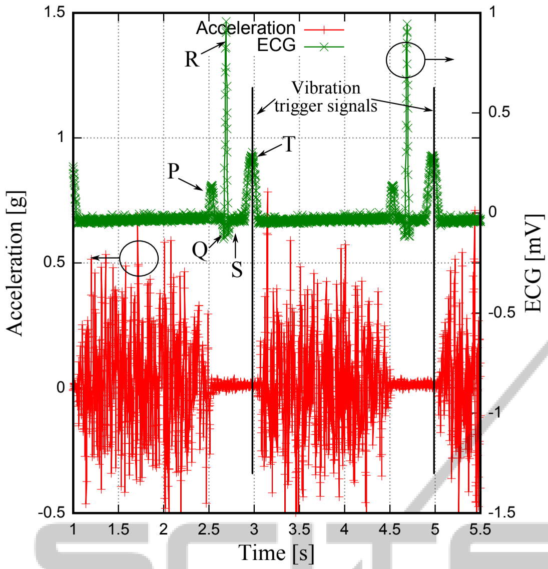

Figure 3: Experimental results for mechanical vibrations (represented by acceleration amplitude) synchronized with diastolic period of the cardiac cycle.

of vibrations present in the systole is minimal. For the most part, the QT interval was free of vibrations and with the predictive termination of vibration based on a regression algorithm, it was possible to completely avoid vibration spill on the QRS complex in most cases.

4 CONCLUSIONS

The proposed diastolic timed vibration system is a safe and innovative method for rapid treatment of heart strokes and other low blood flow cases. Clinical studies have shown that mechanical vibrations help increase the coronary blood flow and aid in the improvement of the systolic function of the heart. In case of a heart attack, mechanical vibrations along with application of thrombolytic agents can improve clot dissolution and thus increase chances of patient's survival. We presented a prototype of a diastolic timed vibrator controlled by a custom LabView VI and synchronized with a commercial ECG system. We demonstrated that mechanical vibrations generated by a massager device can be synchronized with a real time ECG signal from a patient. We developed algorithms used in the control Labview VI used to trigger the vibrator only in the diastole. The presented results show that we can accurately control the mechanical vibrations and thus avoid application of vibrations in the critical part of the QT interval.

ACKNOWLEDGEMENTS

This project was supported by Simon Fraser University in collaboration with Ahof Biophysical Systems Inc. The authors would like to thank Andrew Hoffman for valuable inputs to the project.

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