Non-invasive method for pre-hospitalization treatment of heart attack patients

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Abstract—We propose a novel method of heart attack treatment by low frequency diastolic timed vibrations. It can be applied quickly after the onset of symptoms by unspecialized personnel drastically improving the survival chances of the patient. The method is based on applying low frequency mechanical vibrations in synchronization with the heart cycle of the patient to facilitate disruption and clearance of acute coronary thrombosis. We present an analysis of the proposed methodology and provide experimental results obtained with a first prototype of diastolic timed vibrator. We show that vibrations of required frequency can be successfully synchronized with a real time ECG signal.

I. INTRODUCTION

Diseases of the heart are the leading cause of death in the United States, with higher mortality rate than cancer (malignant neoplasms) [1]. Over 7 million men and 6 million women are living with some form of coronary heart disease. Over a million people suffer a (new or recurrent) coronary attack every year, and about 40% of them die as a result of the attack [2]. This means that roughly every 65 seconds, an American dies of a coronary event.

Myocardial Infarction (MI) or heart attack is most often caused by a blood clot, also known as thrombus, in 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 [3]. Various methods have been developed to treat thrombus before MI occurs. The techniques vary from surgical procedures, such as coronary artery bypass grafting to minimally invasive procedures such as angioplasty, atherectomy, thrombectomy, and intra-arterial thrombolysis [4]. Procedures such as angioplasty involve pressing the thrombus against the walls of the vessel using a balloon catheter or drawing it out of the vessel. Alternative invasive procedures such as intra-arterial thrombolysis involve direct insertion of thrombolytic agents i.e. tissue plasminogen activator (TPA) into the artery through a process known as catheterization. These agents are capable of dissolving the thrombus and are inserted after the location of the thrombus is determined by another catheterization process known as coronary angiography [5]. Other methods include exposing the blood clots to low frequencies of continuous wave ultrasound. In these methods, known as ultrasound induced clot dissolution, the treatment is dependent on the intensity and duration of the ultrasound [6]. Preferred invasive methods such as angioplasty require significant setup time and resources in order to be successfully used for treatment. Before the treatment method itself can begin, patients are required to undergo a number of clinical diagnosis tests which include, but are not limited to, electrocardiogram, blood tests, coronary catheterization and the like [3]. 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 (approximately 2.7 hours after the onset of symptoms) most deaths have already occurred [5]. This is worsened by the fact that those who manage to survive this deadly period of illness have to spend additional time in the hospital undergoing examinations or receiving transport to a cardiac cathlab before the 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. It has been suggested [7] that instead of being transported to regional revascularisation centers, heart attack patients should receive immediate care at their nearby hospitals or other facilities. In addition, if treatment could begin during transportation to the hospitals, it would play a key role in ensuring the survival of the patient.

In this paper, we propose a method 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. It consists in applying low frequency mechanical vibrations synchronized with heart cycle of the patient, preferably along with injection of thrombus dissolving drugs.

Our paper is organized as follows. After the introduction, we present our method in details, including review of state of the art and analysis of the underlying idea. Subsequently, we present the architecture of the proposed system and we discuss various aspects of its implementation. In the following part, we describe a prototype system and the experimental results obtained. We close this paper by providing conclusion and proposition of future works.
II. PROPOSED METHOD

We present a novel, non-invasive method suitable for treatment of heart attack and other states of low coronary blood flow in a human. It is based on applying low level 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. Instead of continuous vibrations, diastolic timed vibrations must be performed in order to ensure the heart is not interrupted during the systolic period of cardiac cycle (contraction of the heart), which can have very negative effects, especially on a weakened heart. 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 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 used as medical emergency system 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.

A. Diastolic mechanical vibrations

There is strong experimental evidence that diastolic mechanical vibrations on the chest wall increase human 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 [8]. In addition, clinical studies performed on humans and canines have shown that external diastolic vibrations can release incomplete relaxation (IR) and improve the systolic function of the heart [9], [10]. Similar studies consisting of external vibrations performed 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 [11].

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 [8], [9]. Low frequency vibration is a known potent vasodilator, especially for arteries with a degree of active tension or spasm [12], which is often the case in heart attack [13], 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 [4]. Low frequency external tapping has also been documented to lead to reliable and immediate clearance of acute coronary thrombosis in animal models presumably by enhancing dis-adherence of clot from a narrowed intraluminal surface [14]. We suggest that the efficacy of disrupting and clearing thrombosis could be maximized by providing vibrations at different frequencies (via frequency sweep or random frequency variation) as this would facilitate rupture of the different chemical bondings of the clot and add turbulence in the vascular system. It would improve mixing of clot dissolving agent and enhance erosion of clot surface. Vibrations in the 40-60Hz range fall within the resonance frequency spectrum of the heart muscle [15] which would thereby ensure a maximized therapeutic effect.

B. 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, vibration, which can interfere with the heart's contractile process, cannot be performed on the heart during this phase and should only be done when the heart is in relaxation phase - diastole [11]. 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 [10], [16]. We propose to develop a device that would apply mechanical vibrations to the chest to augment coronary perfusion, disrupt blood clots and generally improve blood circulation. The therapy could be performed by a paramedic in an ambulance or by a trained person in a clinic or an emergency room.

C. System architecture

The proposed system is composed of four main parts: a vibrator, accelerometer, ECG system and a LabView VI containing signal processing and control. Fig. 1 presents a schematic of the system architecture.

1) Vibrator: We use a standard electromagnetic motor driven by a 50 Hz source to generate rotary movement translated into linear movement of a plate. Furthermore, a variable damping stage is added to adjust amplitude of generated vibrations. In order to be able to generate vibrations only in the desired periods of the heart cycle, a fast electromagnetic relay\(^1\) is introduced on the power line of the motor. The relay is driven from a DAQ\(^2\) connected to the LabView interface.

2) Accelerometer: A MEMS accelerometer\(^3\) has been integrated into the vibrating plate to provide a feedback on the generated vibration amplitude. All three axes can be monitored for added reliability. Signal from the accelerometer is digitalized using the DAQ and sent to the LabView interface for further processing.

\(^1\)Panasonic APE30106
\(^2\)A NI9205 with analog inputs and a USB6008 with analog outputs are used in our system.
\(^3\)STMicroelectronics LIS3L02AL
3) ECG: An ECG acquisition system Burdick EK10 is employed to amplify and filter human ECG signal. The resulting signal is digitalized by the DAQ and further processed in LabView.

4) LabView VI: 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. As shown in Fig. 2, a real-time ECG signal is first filtered to eliminate noise. We use a low pass filter to eliminate unwanted high frequency components. Subsequently, it is high-pass filtered to detect the QRS complex. The resulting data is then used for heart rate calculation and detection of the R peak in the QRS complex.

The QRS complex is used to calculate the heart beat rate by finding the ratio between the number of QRS complexes over the elapsed time for a specific interval. After the heart rate is determined, and therefore the period of the ECG signal, lengths of two counters are calculated for running the vibrating system. These counters, 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 set to match with the completion of the systole cycle), 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 incorrect counter length calculation, the systole counter has priority over the diastole counter; thus ensuring that any detection of R peak would 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. Based on the data collected in these studies, a 30 BPM (2 second period) heart rate would have an approximate QT interval of 0.5 seconds. As a result the systole counter was set to be 1/4 length of the period [17]. This approximate calculation was used during the early phase of the testing and will be replaced with a more efficient regression based algorithm.

The resulting system ensures that vibrations stop before the QRS complex begins. The counters are updated in real time to adapt to varying heart rate value.

III. EXPERIMENTAL RESULTS

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

In order to determine if an external vibrating system can be controlled by an ECG signal, we used a 5V DC gear motor as the vibrator and the ECG signal was generated by a Multiparameter Patient Simulator Fluke PS420. The 50 Hz vibration was simply generated by attaching an eccentric weight to the shaft of the DC motor and adjusting the driving voltage. The ECG signal was kept at a heart rate of 30 BPM.

Fig. 3 shows the generated mechanical vibrations 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±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. There was some overlap of vibrations onto the outer edges of the P and T waves of the ECG signal; however it was ensured that vibrations never occurred during the critical QT interval.

After having successfully synchronized a DC motor with a real-time ECG signal, a commercially available massager device Human Touch HT-1280 (which has frequency and stroke amplitude suitable for clinical use) was tested as the vibrator. Fig. 4 shows the modified massager with mounter MEMS accelerometer on the vibrating plate. In this setup, a relay was placed between the power supply and the massager.
allowing the triggering of the massager through the Labview VI. This device has much higher rotary inertia, therefore a special damping system had to be introduced in order to allow more precise timing of the generated vibrations. Fig. 5 shows the experimental results obtained with the vibrating system synchronized with the ECG signal. The driving signal is used to indicate when the vibrations are triggered based on the counter algorithm described earlier in the system architecture section.

It can be seen that although there is a delay between deactivating the driving signal and the actual stopping of the vibrations, all vibrations stop at the beginning of the QRS complex. The delay was measured to be approximately 17 ms between the end of the driving pulse and the actual termination of the mechanical vibrations. The delay caused the vibrations to overlap onto the beginning of the PR interval and the last portion of the T wave. For the most part, the QT interval was free of vibrations and with a more precise damping system and ECG processing algorithm the delay will also be eliminated. The approximated counter based algorithm will be replaced with a more concise regression based algorithm; thus ensuring precise calculations of the QT interval and precise triggering of the vibrations.

**IV. CONCLUSION**

The presented diastolic timed vibrating system is a novel and innovative method for rapid treatment of heart strokes and other low blood flow cases. It has been shown through clinical studies that mechanical vibrations are instrumental in increasing the coronary blood flow, as well as aiding in the improvement of the systolic function of the heart. In case of heart attack, mechanical vibrations along with application of thrombolytic agents can improve clot dissolution and thus increase chances of patient’s survival. We presented the first prototype of a diastolic timed vibrator driven by a LabView VI and synchronized with a commercial ECG system. We first demonstrated successful ECG signal synchronization using a simple DC motor. Subsequently, we modified a massager device and successfully verified its functionality as a diastolic timed vibrator as well. The algorithm used in the control Labview VI relied on the triggering of counters based on the
length of the systolic and diastolic cycles of a real-time ECG signal. Results showed that we can accurately synchronize mechanical vibrations with real time systolic and diastolic ECG cycles.

V. Future work

Our next goal is to utilize our test system on a live subject to determine the effectiveness of the diastolic timed vibrations on an actual thrombus. Initially, these tests will be performed on animal subjects. We also plan to build a diastolic timed vibrator with integrated miniature ECG acquisition system and a microcontroller with timing algorithms implemented. It would enable us to have a stand-alone device, suitable for clinical use. A further technical challenge will be to reduce the time delay between inactivation command for vibration and vibration to actually stop, such as to enable termination of vibration upon initial sensing of an R wave, to prevent systolic vibration for irregular rhythms.

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