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DEVELOPMENT OF SCREENING TOOL TO IDENTIFY POTENTIAL IMPLANTABLE CARDIAC DEFIBRILLATOR (ICD) RECEIVER

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ABSTRACT: Sudden Cardiac Death (SCD) has become the top killer in many developed country as its survival rate is extreme low. SCD is caused by the ventricular arrhythmias such as ventricular tachycardia (VT). Implantable Cardiac Defibrillator (ICD) is recognized as gold standard for the prevention of SCD. Therefore, it is important to screen patients who are at high risk of SCD, to be the receiver of ICD. MATLAB had been used in establishing the software to detect Heart Rate Variability (HRV) parameter from ECG. This parameter combines with VT condition, post Myocardial Infarction and other medical parameters, play role to screen the patients according to the SCD selection rule chart. The graphical user interface (GUI) has been developed in order to indicate the result of the HRV parameter, ECG graph and the result of the eligibility of patient to be receiver of ICD.

Keywords: Sudden Cardiac Death, Implantable Cardiac Defibrillator, Heart Rate Variability, SCD selection rule chart, Graphical User Interface

I.INTRODUCTION

Sudden cardiac death (SCD) is defined as abrupt loss of consciousness and unpredicted death.[1] SCD is known as the top killer in many developed countries as it had become the main cause of the death annually. Besides, the survival rate of SCD is extreme low too, which is around 10-15% only. Therefore, Implantable Cardiac Defibrillator (ICD) was introduced as the gold standard therapy for the patients who are at the high risk for ventricular tachycardia (VT).[2] There are 2 major causes of SCD, which are ventricular arrhythmias and dilated and hypertrophic cardiomyopathies. Ventricular arrhythmia is found to be responsible for 75% of all SCD cases, whereas the SCD cases caused by dilated and hypertrophic cardiomyopathies are 25%. There are 2 types of ventricular arrhythmias (VA), which are ventricular tachycardia (VT) and ventricular fibrillation (VF).[3] Ventricular Tachycardia is characterized by rapid but regular ventricular contractions. VT will result in low cardiac output and will degenerate to ventricular fibrillation (VF) if it is not converted. Low cardiac output will lead to the further loss of cardiac output, the lowering of the blood pressure of human and hypoxia and accumulation of toxic waste products in the cardiac cell due to its high beating rate. Onset of VF could lead to the death in about 3 to 5 minutes if defibrillation is not applied on the patient.

Implantable cardiac defibrillator (ICD) is the gold standard therapy for the patients who are at the high risk for VT. The high-risk patients mentioned include those who had survived form the life-threatening arrhythmias, individuals with cardiac disease who are at risk of such VA, but without symptoms.[4] ICD comprises of 2 components, which are pulse generator and leads. Pulse generator is normally implanted in the upper chest below the left shoulder. There are one or more than one leads which connect patient's heart with the ICD, for the purpose of transmitting electrical signal for pacing, sensing and defibrillating.[5] When the ICD detects the occurrence of VT, electrical impulse for defibrillation purpose, in order to terminate the VT, hence prevent the death occur on patient.

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Statistic shows that the amount of patients who are suffering from the Sudden Cardiac Death (SCD) incident annually is highest in most of the developed countries such as United State.[3] Malaysia, as a developing country, is experiencing high occurrence of SCD incident too[6, 7] However, ICD is relatively expensive and could hardly be afforded by patients and government. Therefore, it is necessary to have more systematic, synchronised and organised system in our country to identify those patients who are at the highest risk of SCD, then being delivered with ICD therapy. Therefore, a system with graphical user interface (GUI) is developed in this paper to help doctors especially in state or district level hospital to screen patient whoare at high risk of SCD.

The objectives of the projects are to extract HRV and VT condition from ECG. These parameters combined together with other clinical parameters such as myocardial infarction and Left Ventricular Ejection Fraction (LVEF) and cardiac arresrt history in order to develop automatic identification of patients who are categorized at the highest risk of SCD class and be the receiver of ICD. This system is accessed with the graphical user interface (GUI).

The ECG of patient is plotted in order to verify the VT condition of patient. Heart rate variability is calculated from the ECG signal in order to work as parameter to determine the risk of SCD. At the same time, medical condition report regarding patients' clinical heart failure condition and VT event is collected in order to help the system established to classify SCD risk for the patients.

Lastly, the system with graphical user interface (GUI) is built by using MATLAB software too, in order to enhance the user experience in accessing this application.

II.METHOD

The overall work flow of this project is shown in Figure 1. Each block is explained in following subsections. First, the raw ECG signal was downloaded from *Physionet* for being processed in order to extract the HRV to determine the SCD risk.

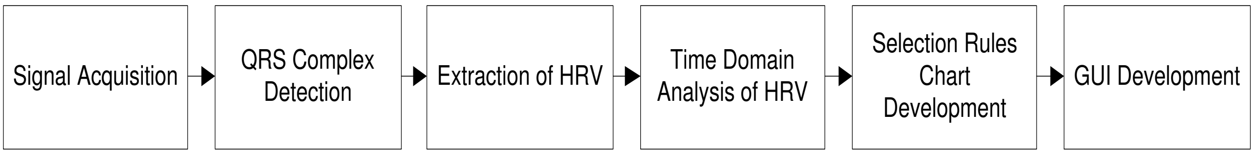

Figure 1 Overall Work Flow of Project

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II.1 QRS COMPLEX DETECTION (PANAND TOMPKINALGORITHM)

Pan and Tompkins (1985) had introduced an algorithm to detect the QRS complex of ECG. The algorithm is as shown as in Figure 2. Low Pass filter was used to remove noise caused by the muscle contraction and 50 Hz power line noise. High pass filter was used to remove the motive artifacts, P wave and T wave. Then, the differentiation process functions to obtain the information on the slope and overcame the baseline drift problem. After that, squaring was used to emphasis the component with higher frequency and attenuates the component with lower frequency. As result, R-peak can be seen clearly. Lastly, the moving average filter functioned to smooth the signal. Thresholding process was used to determine whether the detected event is true QRS complex or not.[8]

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The result of each process is shown in Figure 3.

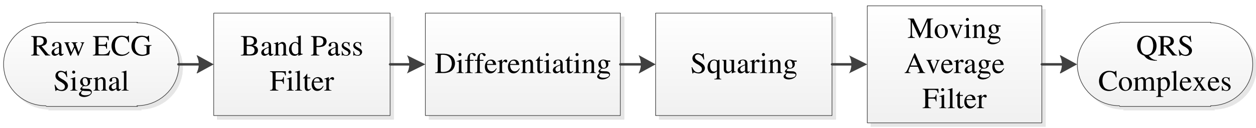
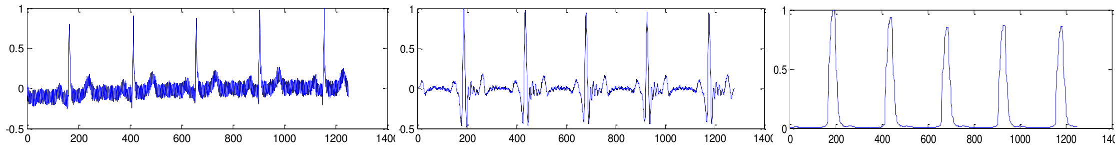


Figure 2 Block Diagram of Pan and Tompkins Algorithms in the Detection of QRS Complex[8]



(a) Raw ECG Signal (b) After Filtration(c) After Moving Average

Figure 3 Result of Signal After Processes

II.2EXTRACTION OF HRV

Figure 4 shows the process of extraction of HRV

Figure 4 Algorithms for the Extraction of HRV

The removal of outliers removed unwanted part of signals such as ectopic beats or any missed detection of QRS complexes by using 1st quartile and 3rd quartile formula. The signals that exceeded third quartile and below than first quartile were eliminated. After that, the resampling process by using interpolation-resampling provided equidistant time and prevented RR interval from the distortion. Detrending process was used to remove the trend from the signal by substracting the signal with its means as the trends was modeled as linear equation. The result of HRV was shown in Figure 5.

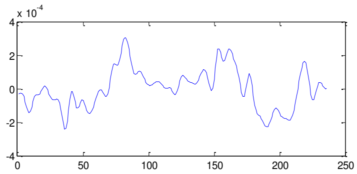


Figure 5 HRV Signal

II.3 TIME DOMAIN ANALYSIS OF HRV

Time domain analysis provided information's from statistical method or geometrical method which can be determined by using simple mathematics equation. As mentioned earlier, there were many parameters included in time domain analysis. However, in this project, we were only interested in finding the standard deviation of NN interval (SDNN) which its unit was in ms.

Task Force of the European Society of Cardiology the North American Society of Pacing Electrophysiology (1996) discovered that depressed HRV is a powerful predictor of mortality and of arrhythmic complication, such as sustained

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Ventricular Tachycardia (VT) after acute Myocardial Infarction (MI). This report suggested that the value of HRV is similar to that of left ventricular ejection fraction (LVEF) in the prediction of all-cause mortality. This report also suggested that the HRV should be considered prior compared to LVEF value in predicting arrhythmic event such as sudden cardiac death (SCD). The result of this report as indicated in Figure 6 shows that survival rate of the patients after MI with different SDNN value. The result indicates that patients with SDNN value less than 50ms has about 60% of survival rate for time being, which is very low compared with patients with SDNN value greater than 50ms.[9] Hence, in this project, 50ms had been used as a benchmark to indicate the depreessed HRV and determine the SCD risk.

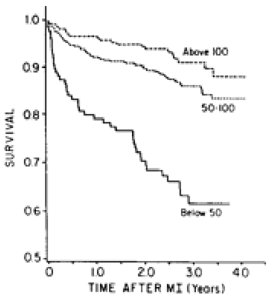

Figure 6 Cumulative Survival of Patients After MI According to Different SDNN Value

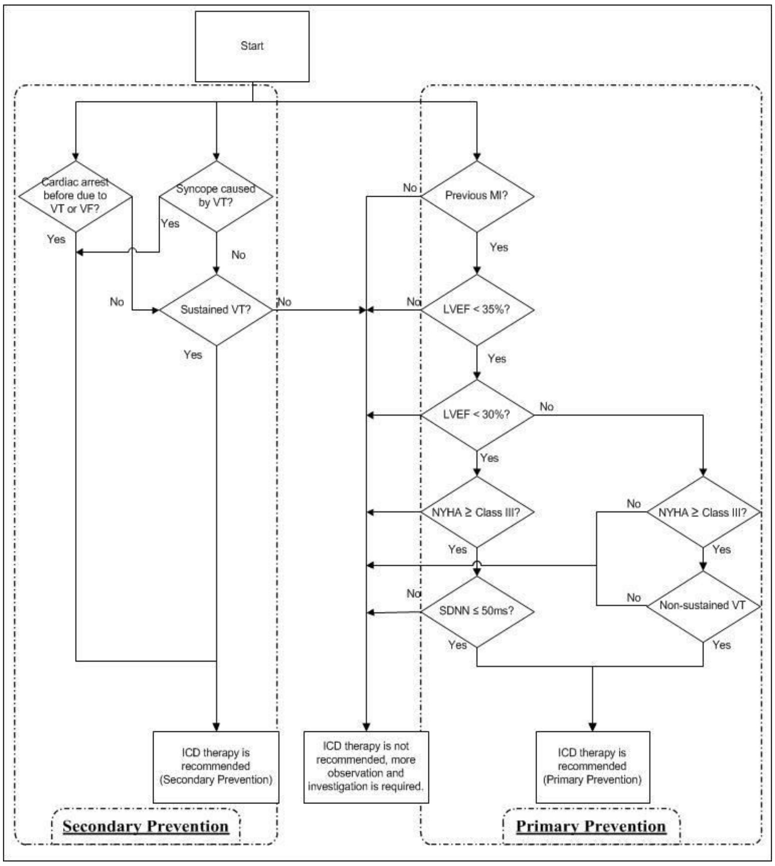

Figure 7 Selection Rule Chart in Determining the ICD Receiver

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II.4 SELECTION RULE DEVELOPMENT

Selection rule chart was developed in order to determine the risk of sudden cardiac death (SCD) of patients, by considering physiological parameters of patients. Implantable Cardiac Defibrillator (ICD) therapy maybe recommended for the patients under two different types of prevention which are primary prevention and secondary prevention of SCD. The selection rule chart is shown in Figure 7. Primary prevention of SCD refers to the use of ICD in patients who are at the risk for but have not experienced life threatening arrhythmic events such as VT or VF. Secondary prevention of SCD refers to patients who have survived a prior cardiac arrest, life threatening event such as sustained VT.[10] Hence, the selection rule chart was developed by in order to determine the eligibility of patient to be ICD receiver and under which prevention too.

First, the selection rule in determining ICD receiver under secondary prevention was established based on three criteria. Patients who fulfilled either one of these three criteria would be considered as receiver of ICD under secondary prevention. Those three criteria are prior cardiac arrest before due to Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF), Sustained-VT and Syncope caused by VT before.

On the other hand, in order to determine the receiver of ICD under primary prevention, a few criteria had been included and considered as such priormyocardial infarction (MI), Left Ventricular Ejection Fraction (LVEF) value, New York Heart Association (NYHA) class, Standard Deviation of NN interval (SDNN) and non-sustained VT condition. The selection chart is shown as in Figure 5. For example, patients who have the prior MI record, LVEF less than 30%, NYHA class is greater than Class III and experienced the depressed Heart Rate Variability (HRV) with the Standard Deviation of NN intervals (SDNN) less than 50ms, are eligible to be qualified as ICD receiver under primary prevention. In the another scenario, patients who have the prior MI record, LVEF value in between 30% and 35%, NYHA class greater than Class III and experienced non-sustained VT, are eligible to be the receiver of ICD under primary prevention too.

However, for those patients who are in the condition where no sustained VT, cardiac arrest, syncope caused by VT and prior MI record, LVEF value greater than 35%, NYHA class less than class III, SDNN value more than 50ms and with no non-sustained VT will neither be consider as ICD prevention under secondary prevention nor primary prevention.

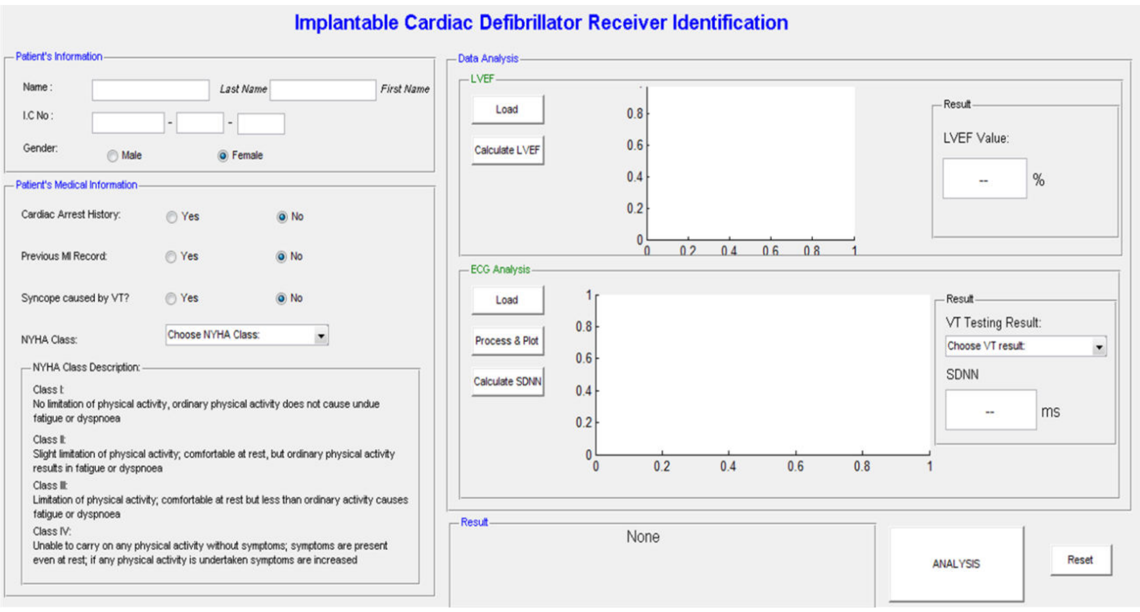

Figure 8 Graphical User Interface (GUI) of Application

II.5 GRAPHICAL USER INTERFACE (GUI) DEVELOPMENT

A GUI was developed by using MATLAB software. The time domain analysis of HRV was done in MATLAB too. The user had to insert some medical condition and ECG signal of patients, and let the system to go through the selection rule chart to determine if patient is eligible to be ICD receiver. The GUI is shown in Figure 8.

III.RESULTS AND DISCUSSION

III.1 TIME DOMAIN ANALYSIS

The ECG signal of patients who has normal ECG signal and VT ECG signal were inserted into the system to determine its SDNN value. The signal of normal and VT ECG can be seen by user as it was plotted in the graph area, and helped users to determine VT condition of patient. Then, when the button of calculate SDNN was pressed, the SDNN value of the ECG signal was appear in the column. The result is shown as in Figure 9. The value of SDNN resulted from normal ECG is more than 50ms, which means it was not in the depressed HRV condition. Whereas, the value of SDNN resulted from VT signal was very low, with 30ms. This indicated that low SDNN symbolize depressed HRV and has high possibility to lead to SDN and mortality as well. As the result, the combination of this SDNN result with other parameter such as post MI history and LVEF value generated accurate result in determining receiver of ICD for primary prevention.

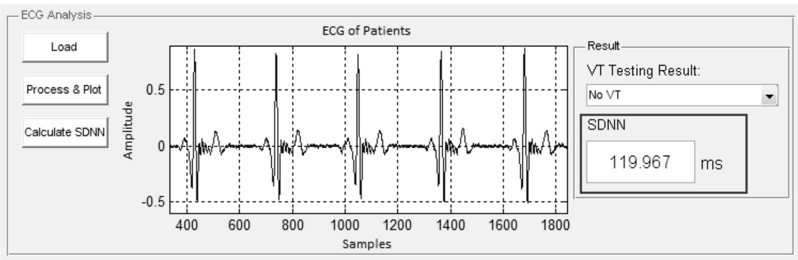

Figure 9 Plotted Normal ECG and Calculated SDNN Value

III.2 GRAPHICALUSER INTERFACE

When the medical condition and ECG signal of patient have been inserted, the system will be able to identify the eligibility patient to be ICD receiver. If the patients' medical condition fulfill the criteria of the ICD receiver under primary prevention, the result column in the will appear the statement of "Patient should be delivered ICD therapy under Primary Prevention", while if patient fulfill the criteria of secondary prevention, the statement of "Patient should be delivered ICD therapy under Secondary Prevention". If the patient is not eligible, the statement of "ICD therapy is not necessary to patient" will appear to clearly give clarification on the eligibility to doctor.

IV.CONCLUSION AND RECOMMENDATION

Screening of patient according to their SCD risk to determine ICD receiver would be difficult for the doctor especially in state or district level. This difficulty may be caused of the lacking of facility in accessing some medical parameter such as SDNN of HRV. This automated system could play the role to provide accurate and systematic result in determining the SCD risk, by considering all the parameters of patients. As the systematic system is established and applied by doctors in respective hospital, doctor could be able to identify those patients who are at the high risk of SCD, hence, forward the patients to National Heart Institute for the delivery of ICD therapy. As the result, patients who are at the high risk of SCD will be implanted with ICD, which may secure them from the death caused by VT. Therefore, the overall mortality caused by SCD will be reduced.For future recommendation, it is recommended that this software is tested with the real case. The result of this system shall be compared with the result of diagnosis from the doctor who are specialised in this area such as doctors from National Heart Institute. Besides, the real time ECG should be recorded on the real patient and inserted into this system to examine its SDNN value. On the other hand, World Health Organisation should have more study about the parameter to determine the risk of SCD, and set a gold

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standard for the screening of ICD receiver which has standardised criteria and parameter considered. This will ensure that all patients with high SCD risk which may expose them to death to be identified and being delivered with ICD therapy.

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BIOGRAPHY

MB Malarvili received both the B.Eng and M.Eng in electrical engineering from UniversitiTeknologi of Malaysia at Skudai, Johor, Malaysia in 2001 and 2004 respectively. She then obtained her Ph.D in biomedical signal processing at the Perinatal Research Centre (PRC), The University of Queensland in Brisbane, Australia. She is now a senior lecturer at The Faculty of Biosciences and Medical Engineering, UniversitiTeknologi Malaysia. Her research interests include biomedical signal processing, pattern recognition and time-frequency signal analysis.

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