PROSE 3: EARLY ISCHEMIA DETECTION USING DIGITIZED ST VALUES

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BACKGROUND

Myocardial ischemia is a common cardiac complication that accounts for almost 60% of post-operative (post-op) complications in moderate to high risk patients, and potentially leads to myocardial infarction. This complication results in, at least, an increased hospital length of stay (LOS) that has serious affects on cost of care [1].

The PROSE studies (Perioperative Ischemia Reduction Study) resulted from experience with administering prophylactic β-blockade to patients at risk for myocardial infarction. The results of this study showed a decrease in myocardial infarction, but increased the incidence of post-op stroke. PROSE aims to provide accepted treatment modalities only after patients are identified at risk for myocardial ischemia post-op.

Studies have shown that ambulatory ECG monitoring is an effective non-invasive method of observing patients for ischemia [2-5] that appears as slow dynamic changes in the ST segment of the ECG waveform [2]. Figure 1 below shows an example of slow changes in ST segment during ECG monitoring of a patient.

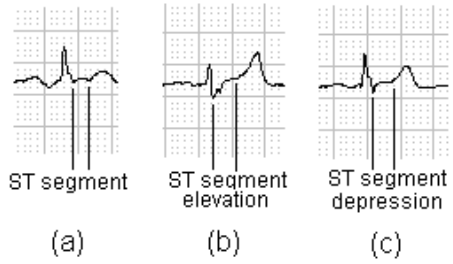

Figure 1 - Example of a significant change in ST segment. Figure (a) is a snippet of a PROSE patients' normal ECG wave showing the ST segment, (b) is a snippet of the same patients' ECG wave showing an elevation in ST segment and (c) is a snippet showing a depression in ST segment

Due to technological limitations, continuous monitoring of ECG readings by an experienced clinician is necessary to correctly identify ST events representing ischemia in time to administer an effective treatment [2]. Automating the process of identifying ischemia and alerting the primary physician could be an efficient way of monitoring high risk patients, and would reduce the rates of morbidity and mortality due to myocardial infarction.

We report our progress with a customizable system for identifying myocardial ischemia in real-time, and remotely alerting the primary physician through a personal digital assistant (PDA).

INTRODUCTION

In PROSE-3, patients are monitored up to 48-hours for signs of ischemia that we define as a sustained ST elevation of ≥+2mm for ≥1 min, a sustained ST depression of ≤-1 mm for ≥1 min, or an elevation or depression in the ST segment by 1 mm over a period of 10 min [1].

PROSE-3 is a blinded study in which clinical staff is unaware of whether or not the patient is monitored in real-time [1]. All patients are monitored by the gold-standard Holter monitor, but only those patients randomized to telemetry are put on the real-time monitoring systems, along with the Holter monitor.

The original system uses commercial patient monitoring equipment (Spacelabs®) to detect changes in ST levels in real-time that resulted in an alarm being sent via a client server (ConnexAll) to the physicians' PDA (BlackBerry®). However, the very large number of false alarms from this system has proved to be unmanageable. A further limitation was that alarms sent to the Blackberry® appear on the screen for a maximum of 3 minutes, leaving

the physician unaware of life-threatening alarms.

The custom PROSE system makes use of digitized ST values extracted from a bedside monitor to identify ischemia, and runs parallel to the original system. The objective is to create an easy-to-use wireless remote real-time ST monitoring system to identify postoperative myocardial ischemia in its early stages, while preserving original alarms.

METHOD

Boolean functions to analyze digitized ST values extracted from the bedside monitor.

When an ischemic event is identified, an email alert is sent to the physicians' BlackBerry that also receives alarms from the original system. To distinguish an email alert from an ordinary email, the BlackBerry® devices carried by the physicians have been customized to play alarm sounds that can not be silenced.

The email alert consists of a graph showing the ST trend for the previous 10 minutes, with the title of the graph indicating the alarm #,

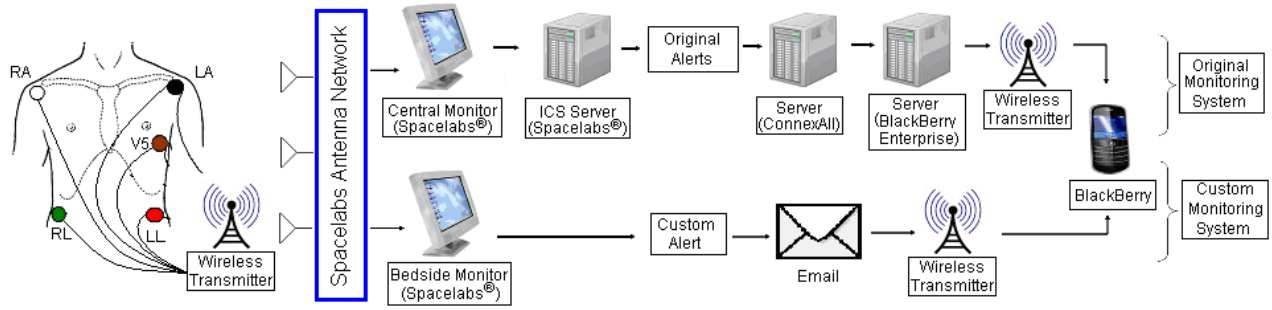

Figure 2: Communication pathways of patient monitoring systems. The original and custom monitoring systems run parallel to each other.

Original Monitoring System

Figure 2 above shows the path taken by data collected from the patient using ECG digital telemetry in a 5 lead configuration. This data is transmitted to the (Spacelabs®) central and bedside monitors via the antenna network installed on the wards. The central monitor analyzes the data for significant alarms that are sent in XML format to a client server (ConnexAll), and then to the physicians' BlackBerry® via the BlackBerry Enterprise Server.

Custom Monitoring System

The custom system runs parallel to the original system and uses a bedside monitor, provided with a digital ST output option, to process the same data sent to the central monitor.

The custom alert block in Figure 2 consists of the ST Deviation Detection (STDD) algorithm based on a rule-based technique developed in a commercial data processing software (Matlab®). The algorithm makes use of simple alarm type, patient identifier (without any confidential information), date and time the alarm was sent. To help the physician monitor the patient more effectively, a second ST trend graph is sent 20 minutes after an alarm. Figure 3 below shows an example of what the physician will see on their BlackBerry® when they receive an alarm from the custom system.

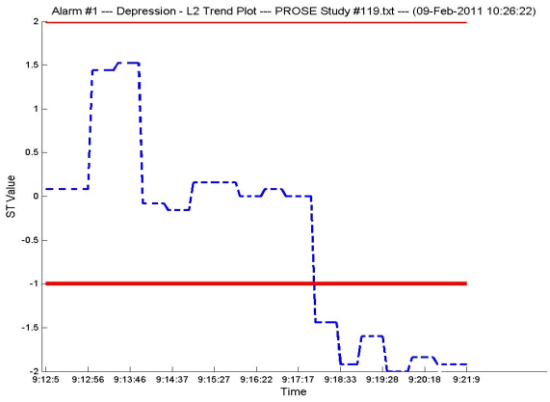

Figure 3: Example of alarm as received on physicians' BlackBerry

The solid lines in Figure 3 indicate the alarm limits of +2mm and -1mm, and the dashed line represents the trend in ST values over the previous 10 minutes. The user has the option of changing these limits prior to the start of monitoring, or may restart the STDD algorithm with new parameters whenever they choose.

Identifying Significant ST Changes

The STDD algorithm is the main part of the custom system as it is what identifies significant ST changes representing ischemia. In order to identify an elevation or depression in ST levels, the algorithm makes use of a baseline value for each lead being monitored. The baseline value is based on a sliding window average of the previous ST values for the past 1-2 min, based on how long the algorithm has been running. The ST value at any moment in time is compared with the baseline value and the user-set alarm limits in order to detect significant ST changes. Due to motion artifact, the monitors will, at times, output very large ST values for small periods of time (for example, +9mm for 10-15 seconds). With the help of the baseline value, the STDD algorithm will filter out such spikes in ST values that the original system analyzes as alarm conditions and immediately sends an alarm for each spike.

In order to check for a change of 1 mm over a period of 10 minutes, the STDD algorithm uses a sliding window method to search for ST values with a difference of 1 mm, 10 minutes apart. It then calculates and keeps count of the slope for every 10 values within those 10 minutes.

An alarm condition would be when the count exceeds 10, representing approximately 9 minutes of the 10 minute window, at which time an alarm is sent to the physician in the form of a graph showing the ST trend over the previous 20 minutes. Once again, this parameter can be changed according to the needs of the physician.

Together, the subroutines used to detect elevation, depression and a 1mm change in ST segment level help identify significant ST changes that would suggest ischemia. There is no confidential information in the alarm screen so the physician can safely receive them as email on a PC or the BlackBerry®. The alarms stay in the inbox until deleted by the physician, unlike the alarms of the original system that appear only on the BlackBerry® and disappear after 3 minutes.

RESULTS AND DISCUSSION

Figure 4 shows how the original and custom systems compare in terms of the number of alarms received by each system. Both use the same scale for the axes: x-axis is from 9 AM on Nov. 26 to 9 AM on Nov. 28 2010, and the y-axis ranges from 0 to 30 alarms.

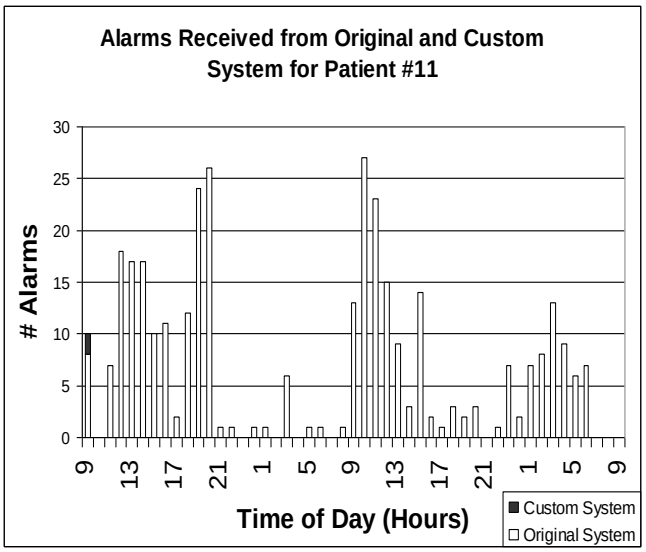

Figure 4 – Charts showing the total number of alarms per hour for Patient #11 for original and custom systems.

Figure 4 indicates 146 alarms received from the original system over 48 hours, all of which were confirmed false when compared to the gold-standard Holter monitor report. Two alarms were received from the custom monitoring system, but both these alarms were high heart rate alarms and not related to ST changes. The Holter results for this patient came back negative for any significant ST change which shows the custom system is able to filter out the majority of the alarms being generated by the original monitoring system.

Since the PROSE-3 study is an ongoing project, much work is still to be done with the STDD algorithm so it filters out the majority of the false alarms, but correctly identifies true

events representative of ischemia. As suggested by Figure 4, one major problem is the large number of false alarms, seen as sudden spikes in Figure 5, due to motion artifact or sudden postural changes [5].

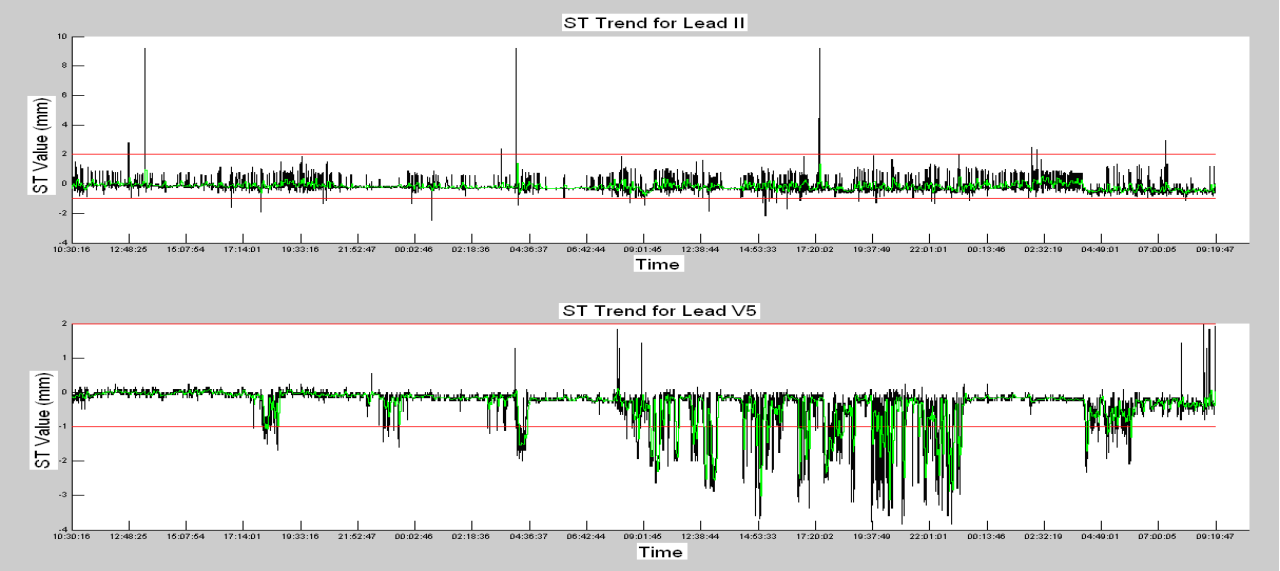

Figure 5 – Plot showing ST trend for Patient #11 over 48-hour period of monitoring.

Since the majority of these spikes last less than 1 minute, the STDD algorithm will not read them as alarm conditions. The customizable option is set to alert the physician when the ST elevation or depression lasts for ≥1min, unlike the original system which lacks this option and alerts the physician immediately, hence the large number of false alarms.

CONCLUSION

Initial tests with simulators, volunteers and patients show the custom system is capable of identifying ST changes relevant to PROSE-3, while ignoring the majority of the false alarms detected by the original system. Work is currently being performed using standard ECG waveforms to prove the custom system algorithm does not miss true ischemic events.

The next stage is to mold the custom system into a robust and accurate monitoring system compatible with other commercial monitors. Once complete, the White Box will allow efficient automation of ischemia detection and reduce response time, which in turn will help reduce postop cardiac complications resulting in death.

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