A wearable monitoring system for nocturnal epileptic seizures

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***Abstract*—For people suffering from nocturnal epileptic seizures it is crucial to have a system that can detect such seizures in real-time. In this paper, we present a preclinical demonstrator for real-time detection of nocturnal seizures based on the heart rate. The system is built on the VITRUVIUS body sensor platform, which consists of a body hub (a smart phone) and sensors communicating via Bluetooth. The seizure detection application running on the body hub has an online classifier that is triggered by an adaptable cumulative sum (CUSUM) algorithm. In case of an event, an alarm message can be sent to the seizure monitoring application or to the caregiver's phone. We present the architecture of the system with emphasis on the detection algorithm and the applications. The off-line evaluation of the system on five patients achieved a sensitivity of 95% and a positive predictive value of 85%. The preliminary results are encouraging and the system will be implemented in a clinical trial at Kempenhaeghe epilepsy clinic in the Netherlands.**

I. Introduction

Epilepsy affects more than 50 million people in the world. In about 30% of the patients, the epileptic seizures cannot be controlled with medication despite medical efforts. This condition can affect dramatically the life of patients, their families, and society. A major source of disturbance is anxiety of not knowing when the next seizure will occur and how severe it will be. This anxiety is aggravated by the prospect of SUDEP (Sudden Unexpected Death in Epilepsy) [1]. SUDEP is an extreme complication of the epileptic seizure, which accounts for about 18% of all deaths in epilepsy [2]. The seizure can induce changes on physiological parameters such as breathing and heart rate that result in death of the patient. A major risk factor of SUDEP is the frequency of convulsive epileptic seizures (e.g tonic-clonic seizures). The possibility of SUDEP increases at night because the seizure might be missed by the caregiver. Therefore, it is necessary to have a system that can monitor the patient in ambulatory settings for the presence of convulsive seizures during the night.

Several devices and systems have been proposed and developed for detecting and monitoring nocturnal convulsive seizures [3], [4], [5]. These systems use information collected from sensors such as motion [6], sweat [7], breathing, heart rate [8], and audio [9]. The signals acquired with these systems can be analyzed in time, frequency or time-frequency domains [10]. The common approach records motion using an accelerometer sensor worn on the dominant hand of the patient. This approach is shown to have a good sensitivity for detecting convulsive seizures [3]. However, it has the following disadvantages:

- It cannot properly detect the start and the end of the seizure. With tonic-clonic seizures, changes of the acceleration signal in the tonic phase are small and difficult to be recognized by an automated algorithm. At the end of the seizure the motion can be subtle, but the changes of the heart rate and breathing levels may still be large.
- If the patient is not moving, it is difficult to know whether something dangerous is happening to the patient or not.
- The sensitivity of the system may depend on the placement of the sensor on the body and the number of sensors.

For patients, a system designed for ambulatory monitoring has to be unobtrusive, easy to use while still reliable with high performance [11]. We propose such a system for real-time detection of nocturnal seizures based on the heart rate. The system is built on the VITRUVIUS body sensor platform [12], which consists of a *body hub* (a smart phone) and sensors communicating via Bluetooth. The seizure detection application running on the body hub has an online classifier that is triggered by an adaptable CUSUM algorithm. In case of an event, an alarm message can be triggered on the body hub or the caregiver's phone.

The rest of the paper is organized as follows. In Section II the architecture of the system is presented together with the seizure detection and monitoring applications. The seizure detection algorithm is described in detail in Section II-B. Section III presents the evaluation of the detection algorithm. Finally, Section IV gives the discussion and conclusion.

II. Seizure detection and monitoring system

A. System architecture

Our system is developed based on the VITRUVIUS body sensor platform [12]. The overview of the system with the

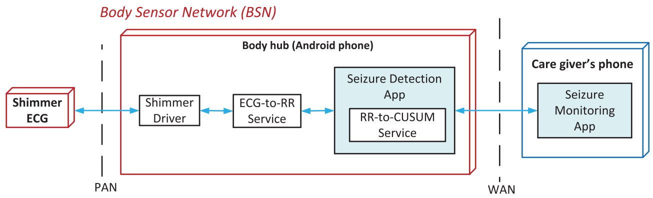

Fig. 1. The system overview with the seizure detection and monitoring applications.

seizure detection and monitoring applications is shown in Figure 1. The Body Sensor Network (BSN) consists of the body hub and the sensors (e.g., Shimmer ECG), communicating via the personal area network (PAN) using a short-range wireless network technology like Bluetooth. The body's information (e.g., ECG signals) collected from the sensors are sent to the body hub. Signal processing components, which preprocess the data (e.g., calculating heart-rates from ECG signals), are running either on these sensors or on the body hub. The configuration decision of where such algorithms are running is dependent on the application's requests and the system context. The body hub connects to the monitoring applications on the caregiver's phone for the purpose of exchanging data and alarming.

The VITRUVIUS platform is chosen since it can fulfill the practical requirements of the system. In our system, we want to provide an algorithm to detect epileptic seizures with tunable parameters and thresholds. We learn from our use case that a doctor searching for the right diagnoses for his patient may want to adjust the parameter settings to collect characteristics of any epileptic-like seizure for this particular patient. This requires a platform that can be reconfigured via installing a personalized software package. The system also needs to be flexible to integrate multiple sensors, which can be combined to give a more accurate detection, e.g., a fusion of both motion and heart rate data. To achieve these requirements, the platform has the following capabilities:

- The basic platform can be installed on an Android smart phone (the body hub) as a regular app.
- A new sensor is attached by downloading a driver indicated by a QR-code on the sensor.
- New services (e.g., *RR-to-CUSUM* service) and applications (e.g., *Seizure Detection* application) that operate on collected data are added as apps as well. The system components and downloaded apps rely on a shared ontology. For example, the heart-rates detected by an *ECG-to-RR* service can be shared with both the seizure detection app and a stress monitoring app.
- The platform has also a particular part that is dedicated to managing security, privacy, and trustworthiness of the system (see details in [12]).

As a sensor node, the Shimmer platform is chosen. This sensor module is small (53mm x 32mm x 25mm) with a high versatility [13]. For our study we use the ECG module with 100Hz sampling/tranmission frequency. The sensor node is inserted into an armband placed on the left upper arm of the patient. Standard wires make the connection between patient and the Shimmer sensors via electrodes placed in the V2-V6 configuration.

B. Seizure detection algorithm

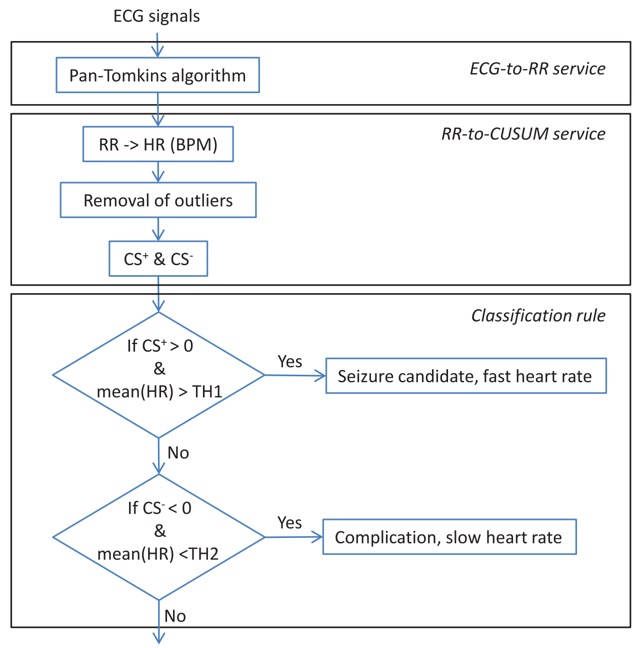

Fig. 2. The overview of the seizure detection algorithm.

The overview of the seizure detection algorithm is shown in Figure 2. The presence of nocturnal seizures is known to be a risk factor in SUDEP [14]. This situation mainly occurs because the seizures can be missed by the caregiver. One of the mechanism thought to lead to SUDEP is represented by the arrhythmias. These can be tachyrhythmia or bradycardia [15].

To reduce the risk of SUDEP and at the same time to alert for seizure onset, we devised the algorithm based on the heart rate. It was shown in the literature that in more than 70% of seizures, the heart rates increase to values higher than 100 beats per minute (BPM) [16]. The increase can occur before, during, and after the electroencephalographic onset [17]. The abrupt increase of the heart rate (tachycardia) occurs due to a sympathetic activation of the autonomic nervous system during the seizure. The increase pattern usually has a linear acceleration trend that can be followed by a small plateau with an exponential decrease [8]. The bradycardia however can also occur during or after the seizure with new evidences showing that it is an important factor leading to SUDEP [15]. Therefore, the algorithm detecting seizures has to alert for both tachycardia and bradycardia events. For the real-time detection, we focus on identifying the moments when the heart rate enters these regimes. The proposed seizure detection algorithm contains four steps as below.

1) Detecting heart rates from ECG signals: The Shimmer ECG sensor transmits raw ECG signals via Bluetooth to the body hub. The *ECG-to-RR* service running on the body hub detects the RR intervals

from the ECG signals using the Pan Tompkins algorithm [18] in real-time. Then, the RR intervals (ms) are converted into heart rates (BPM).

2) Filtering heart rates for positive and negative outliers: The heart rates are filtered for outliers that may occur. The filtration uses an autoregressive model of first order to predict the heart-rates using a decision block. A positive/negative outlier is detected when the current heart-rate differs more than a predefined value (e.g. 10 BPM) from the previous one.

3) Computation of the adaptive CUSUM algorithm: Change point detection methods can be used for our problem, as they can be computed iteratively and be implemented for real-time use. A modified version of the CUSUM algorithm [19] is used to detect the tachycardiac (CS^{+}) and bradycardic (CS^{-}) events. This algorithm is implemented as the *RR-to-CUSUM* service running on the body hub.

$$CS^{+}(i) = max[0, hr(i) - (\mu_0(i) + K(i)) + CS^{+}(i-1)]; \quad (1)$$

$$\mu_0(i) = mean(hr(i-n:i)); \quad (2)$$

$$K(i) = |\mu_1 - \mu_0(i)|/2; \quad (3)$$

$$CS^{-}(i) = min[0, hr(i) - (\mu_0(i) + K'(i)) + CS^{-}(i-1)]; \quad (4)$$

$$K'(i) = |\mu_1' - \mu_0(i)|/2; \quad (5)$$

where constants μ_1 = 110 BPM and μ_1' = 50 BPM are out-of-control values for positive and negative trends, $CS^{+}(1) = CS^{-}(1) = 0$, and hr(i) is the instantaneous heart rate.

The value of *n* in Equation (2) is 99 seconds, which was found via the simulation. The CUSUM baseline is 0, at any time an increase in mean is detected the CUSUM becomes positive. After this increase, the CUSUM recovers to the baseline. The recovering time is controlled by the value of *n*. The larger the *n* the longer it takes for CUSUM to reach the baseline even if the heart rate recovered. Ideally, we want the CUSUM to get to the baseline in the same time with the heart rate. In this way if a second increase in heart rate will occur fast after the previous one, the CUSUM will respond also. In simulations, we varied *n* to observe for which value, both the heart rate and CUSUM recover to baseline. We have found that 99 seconds was a good value for *n*.

4) Classification rule: The classifier detects the onset of a possible event when the heart rate is higher than threshold *TH1* with $CS^{+} > 0$ for a certain period of time. The heart-rate increase during night can be caused by different reasons such as arousal states, emotions, and seizures. In general, the convulsive seizures are accompanied by a lot of motion which can also lead to heart-rate increase.

We propose the threshold *TH1* a value of 70% from the highest heart rate attainable for each person. The maximum heart rate is calculated as 207-(0.67*age) [20]. A similar approach is used in fitness for computing the target heart rate. For the patients investigated in this work the value for *TH1* is about 130 BPM and for *TH2* is 40 BPM. The complications such as bradycardic events are determined if the heart rate is lower than the threshold *TH2* with a negative CUSUM for twenty consecutive seconds.

The combination of both conditions (see classification rule II-B) decreases potential false positives. While CUSUM indicates that the heart rate entered in a different regime, the heart-rate threshold indicates whether the regime is normal or not.

When a possible event is detected, an alarm is generated and sent to the caregiver's phone. After each alarm, the system waits for a period of five minutes until a new monitoring session starts. It is assumed that the caregiver will react towards the patient in this period.

C. Seizure detection application

The seizure detection application runs on the body hub and can be configured by the caregiver, both for parameters such as thresholds used in classification rule and how alarms will be generated. The application is implemented according to the seizure detection algorithm discussed in Section II-B. Our designed system targets to two types of patients: 1) the children or people living in sheltered facilities, who rely on a caregiver sleeping in a different room than the patients; and 2) the patient sleeping in the same room with their partner or the caregiver. In this case, the body hub phone can act as the alarm device. The current application works as follows.

It assumes that the Shimmer ECG sensor is already charged and the electrodes attached on the skin in the V2-V6 configuration. Upon starting, the application asks the user or the caregiver to initiate the connection to the sensor. A list of available sensors with their serial numbers will be shown on the GUI of the application. This serial number can also be given by a QR-code attached on the sensor node. Once the sensor is connected, the screen for setting alarms appears. There are two alarm options for the user: 1) sending an alarm via a SMS message to the caregiver's phone; and 2) generating an alarm on the body hub itself. After the settings are done and saved (for the next use), the application starts the seizure detection phase. The detection service runs like an Android service in the background and generates an alarm when a seizure event is detected.

D. Seizure monitoring application

As we discussed above the general system can be used in two situations. In the first situation, the body hub (the smart phone) generates the alarm on itself. In the second situation, the body hub sends the alarm via a SMS message to the monitoring application installed on the caregiver's phone. In both cases, the GUIs of alarm setting are the same.

The main user interfaces (GUIs) of the applications are shown in Figure 3. The nurses from Kempenhaeghe epilepsy clinic assisted us in designing these GUIs. An important finding is that in case of alarms they will always check the patient and additional functionalities such as real-time video or audio connection are not necessary. The content of the SMS alarm contains the information about the detected event and a mean of the heart rates for the last 20 seconds. This applies for both the tachycardia and bradycardia events. The SMS

Fig. 3. The main user interfaces of the seizure monitoring application running on the caregiver's mobile phone.

message also contains a special prefix code that can be filtered out from normal messages and interpreted by the monitoring application. The application also receives a SMS when the connection with the sensor is lost.

A novelty in our approach is that the alarm is generated using the high priority alarm sound from the ISO/IEC 60601-1-8 medical equipment standard, along with vibrations in the same pattern. The alarm is repeated until it is canceled by the caregiver. In this way, the caregiver will know that the SMS is coming from the alarm system. Furthermore, the caregiver has the option to choose the type of the alarm (sound, vibration, or both). In case of an alarm, the sound is automatically set to the highest possible volume. After the alarm is canceled, the sound level is returned to the original level. When the monitoring app is not working or accidently stops, the SMS is still received as the normal SMS of the phone.

When the option of the alarm on body hub is chosen, the alarm is generated by the decision making block (see Section II-B) and shown directly on the body hub. The rest of operations is the same as above.

III. EVALUATION

In this work, we focus on evaluating the system functionality and the performance of the detection algorithm. First, the functionalities of the sensor, the body hub and applications were tested on healthy volunteers. A short movie showing the general operation of the system is available on the author's website ($http://www.win.tue.nl/~vinh/$). Second, the performance of the detection algorithm was evaluated on a desktop PC because we did not take into account the acquisition time of data. Available ECG recordings from five patients with a history of convulsive seizures were used for the evaluation of the seizure detection algorithm. The ECG and video of these patients were recorded using portable recorders [1] for at least one night until seizures were recorded. The epilepsy experts visually inspected and annotated the data for the seizures. For the evaluation, the ECG data of these patients were introduced into a custom Matlab program as being acquired in real-time. The information about these patients, the sensitivity (SEN) and the positive predictive value (PPV) are shown in Table I.

The classifier was run on the data set for the interval from 8 PM to 9 AM of the next day. Figure 4 shows the heart rate, CS^+, CS^-, and alarm for the case of patient 5.

[1](Porti 24/36 channels, TMS, Enschede, the Netherlands)

TABLE I. THE INFORMATION ABOUT THE PATIENTS AND THE TESTED DATA, TOGETHER WITH THE CLASSIFICATION RESULTS.

Patient	Age	Type of seizure	N seizures	SEN	PPV
1	22	hypermotor	4	100	100
2	32	hypermotor	3	100	75
3	25	tonic clonic	4	75	100
4	17	tonic clonic	2	100	100
5	43	tonic clonic	2	100	50

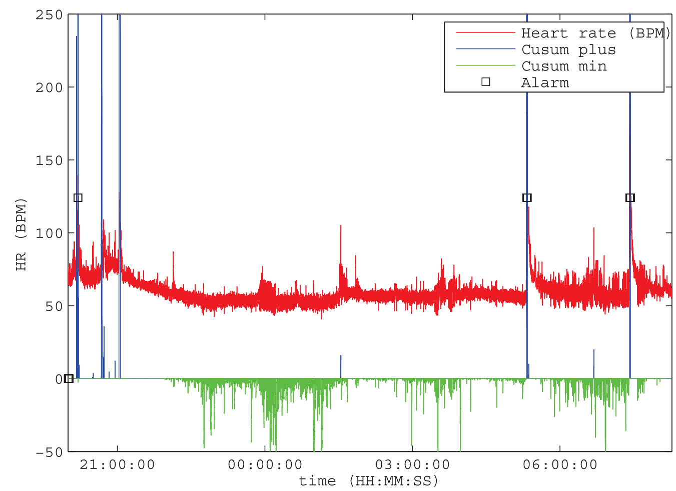

Fig. 4. The heart rate, CS^+, CS^-, and alarms with two generalized tonic clonic of patient 5. The black squares represent the detected events and the alarm points, which coincide with the seizures indicated by the epilepsy experts; One false positive is detected at 8:20 PM, patient was awake and active.

The evaluation results show that the proposed algorithm has a SEN of 95% with the average PPV of 85%. The seizure missed in the case of patient three was short. All false positives occurred early in the night or late in the morning when the patient was awake and active. If we consider only the sleeping time, the PPV increases to 100%. In case of patient two, one bradycardic event was also detected, which was not related to a seizure.

IV. DISCUSSION AND CONCLUSION

We have presented the wearable monitoring system (consisting of the smart phone and sensors) that can detect major nocturnal convulsive seizures in real-time. The system is designed and implemented based on the VITRUVIUS body sensor platform, which is flexible to integrate multiple sensors. The seizure detection and monitoring applications can be installed as regular apps on the Android smart phone. Therefore, a personalized software package that has customized algorithm parameters for different patients can be downloaded and installed easily. The user interfaces of the applications for both the body hub and caregiver apps are designed with simple and maximum functionalities. The system is designed to be used not only in specialized centers but also in homes. In this case, the special alarm with unique pattern in sound and vibration will be easily recognized by anyone.

For the seizure detection algorithm, we focused on using the heart rate because it can provide rich information about health status of the patient. We built a relatively simple classifier that computes both positive and negative CUSUM. Further, we combined this information with a heart rate threshold that is derived from the age of the patient. The offline evaluation of the algorithm provided promising results.

For the future work, we want to improve the detection algorithm by combining the information from multiple sensors (e.g., heart rate and motion sensors) and the system context (e.g., the time of the day) to reduce the false positives. The tachycardia alone is an indicator that the seizure occurs but we require more parameters to provide more information about the status of the heart. Also, we currently investigate approaches to compute and monitor heart rate variability parameters when the CUSUM becomes positive or negative. As shown in the literature [21], these parameters have a correlation with the vagal activity that restores the heart rate to normal values. Moreover, the system will be implemented in a clinical trial at Kempenhaeghe epilepsy clinic.

V. ACKNOWLEDGEMENT

This work has been conducted within the VITRUVIUS and Tele-Epilepsy projects. We would like to thank IOP GenCom and ZonMV for the financial support.

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