

Healthcare and Remote Monitoring System Solution on the Cloud

Our Clinical Experience on 100 Patients

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Abstract. The Authors were involved in a free of charge clinical trial on 100 patients suffering from arrhythmia, using a medical device FDA-cleared and CE-medical marked on a cloud-based platform. The trial, conducted in Sanpietro Medical Center in downtown Milan during the months of November and December 2013, was aimed to confirm the adherence of the solution to our defined clinical protocol, the performance of the device vs. the already known initial diseases, and to test the platform on the cloud, to detect possible technical and clinical issues, the signal quality and adverse events. The overall satisfaction level was high: a system based on continuous remote patients monitoring while they live their normal daily lives, with clinical access anywhere and anytime, allows a better control of therapies, can save healthcare cost and reduce readmissions.

I. INTRODUCTION

Medical practice and medicines allow people suffering from chronic diseases to live longer, with related increasing costs for healthcare (in Italy > 105 billions of euro in 2013).

A pragmatic way to lower costs is to use technological devices to reduce hospitalizations and readmission, to have a better control of therapies, to monitor patients continuously in a regular life, to let them forgetting to be “under the wings of technological, medical angel”.

II. MATERIALS AND METHODS

We used an FDA cleared - CE medical device for arrhythmias named BodyGuardian™ provided by Preventice™ (Minneapolis - USA) and powered by

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STMicroelectronics® (Italy), to be put on the chest through a bandage patch. Biometric data (ECG, heart rate including HR variability and HR reliability, respiration rate, activity level, body position) are delivered securely to a smartphone and from this to our platform resident on the cloud provided by Telecom Italia™ whose cloud solution ensures complete security of the data, while meeting medical standards.

Physicians and clinicians can access their patients’ data, and review alerts securely anytime, anywhere via the web or on pc/iPad. Event thresholds can be set for each patient, allowing personalized tracking and care plan support. Biometric data are delivered securely from the devices through the Telecom Italia network to the Preventice care platform host on Telecom Italia “Nuvola”™, a cloud-based mHealth platform that collects real-time data and delivers information to medical monitoring professional by web terminals or tablets.

This is a cutting edge approach to monitor patients with a small, non-intrusive, wearable body sensor (BG) transmitting to the platform a 120 seconds ECG baseline every hour or in case of event; moreover the patient can push a button on the device itself in case of symptoms to inform the Operating Room.

This solution allows an automatic detection of *atrial fibrillation, atrial flutter, bigeminy, trigeminy and further, AV block, pauses, sinus brady or tachycardia, slow v-tach, supraventricular tach, ventricular tach* related with respiration rate, activity level and body position.

The primitive target of the clinical trial was to verify the adherence of the solution to the specific clinical protocol and the correspondence between a known disease with the data received from BG. More targets were: verify the quality of the signals, the false or real positivity of automatic alerts, the transmission BG - smartphone - platform - cloud - Physician, and the compliance of Physicians – BG – patients to this new way to control physiological parameters.

We enrolled 100 patients suffering from arrhythmia, average 50 years old (range 33-85), 60% male and 40% female, monitored seven days average.

For 63 patients (35 male, 28 female) we added a

Bluetooth blood pressure device, and for 18 patients with Chronic Obstructive Pulmonary Disease (COPD) and/or diabetes a Bluetooth weight scale.

We used two Operating Rooms: one in TeSAN™ for technological problems and recalling patients (first level support), and one in Sanpietro Medical Center where Cardiologists monitored all the patients 24/7.

III. CONCLUSION

We obtained very satisfying results from this trial where 99 patients underwent to the monitoring for the full prescribed period except an elderly man plagued from this new technological system.

Two patients had skin allergy to the adhesive of the patch, and three patients had erythema after three days of monitoring, also changing the position of the patch on the chest.

The FDA approval attested a high level of QRS sensitivity and predictability confirmed from our experience, here calculated on more than 20.000 ecg received from the patients' monitoring during the trial.

DATABASE	FDA	TRIAL
QRS sensitivity	98,52 %	99,15 %
QRS positive predictivity	98,07 %	99,04 %
VEB sensitivity	63,20 %	75,42 %
VEB positive predictivity	72,33 %	86,93 %

The VEB detection was yet clinically acceptable as certified by FDA. Thanks to a new software powered by Monebo™ the VEB sensitivity and predictivity increased, and a continuous work on it will be further gratifying.

All the diseases were confirmed with a full adherence to our target. We detected and monitored minor episodic cardiac events without symptoms in 45 patients. This allowed to adjust the medical therapies.

In the starting of the trial we have seen 13% of signals received during the night were too low even changing the position of the BG on the chest. Amplifying the signal during the night (11 pm- 6 am) the signal quality became good.

The artifacts due to movements are substantially the same as expected using a classic cardiac diagnostic Holter, depending from the lifestyle of the patients.

We received 100% of the data from the BG to our servers on the cloud.

Summarizing, this kind of continuously monitoring system of physiological parameters allows to follow

and control patients suffering from arrhythmia during a normal lifestyle. The possibility to have a 24/7 contact between Patients and the Operating Room – Clinical Staff improves quality life and patients' self-efficacy in managing an important cardiologic disease. Moreover it guarantees a safe and sure control on themselves from the Medical Staff.

In our opinion this solution can help saving healthcare costs in monitoring cardiac and metabolic diseases, can reduce hospital admissions and readmissions, and allows to monitor treatment effectiveness, post ablation procedure in hospital and at home, cardiac and respiration rhythm in combination with activity levels remotely anywhere and anytime.

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