Abstract

Continuous Remote Monitoring of Vital Signs in Pediatric Population

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Abstract

Background: Wearable sensor technologies coupled with secure patient portals allow for continuous real-time data acquisition from a patient in a hospital or home setting. This combination renders more effective health-management system with faster patient-recovery times and reduced healthcare costs. VitalConnect Inc. has developed a fully-disposable, FDA-cleared (for adults) wireless biosensor (VitalPatch®) that is worn on chest. VitalPatch captures multiple medical-grade biometrics and transmits the physiological data continuously (via Bluetooth) for up to 96 hours to a relay (tablet, wireless hub). Like adults, pediatric patients (5-17 years of age) could also benefit from such small and low-profile biosensor that can collect and stream vital signs uninterruptedly to a secure patient-portal. This data can then be monitored by a clinical triage center or healthcare-provider.

Objective: Continuous remote monitoring of heart rate (HR) and breathing rate (BR) is critical during acute or chronic illnesses. The primary purpose of this study was to evaluate the performance of the VitalConnect platform in pediatric subjects during activities of daily living (ADL) to confirm accuracy of sensor measurements for HR and BR with respect to a clinical reference device, Capnostream20 (Oridion). Additionally, information on comfort and usability of VitalPatch at home was assessed for the total duration of wear.

Methods: Thirty-five children were enrolled in the study (24 between 9-17 years, 11 between 5-8 years). All subjects participated in 96-hour wear-period of the VitalPatch biosensor and performed one hour of in-lab protocol on Day1 of the wear duration. Each participant underwent stationary breathing exercises (spontaneous, metronome), ADLs with postural maneuvers and treadmill walking. The study was conducted in presence of a nurse after approval from Institutional Review Board. The performance of heart rate, respiration rate, posture and number of steps were assessed for each subject separately using the mean absolute error (MAE) between the true and measured values. The reference for posture and step count was manual observation.

Results: During the stationary condition, MAE (across 35 children) for HR and BR was 2.1±1.0 beats per minute (BPM) and 2.2±0.8 breaths per minute (BrPM) respectively compared to Capnostream20. During ADLs, MAE was 4.3±2.7 BPM for HR and 3.7±1.7 BrPM for BR. Accuracy of posture (standing, supine, walking) was >93% and step-count was >95% overall. Moreover, 80% participants rated wearing VitalPatch ‘comfortable’ without any itchiness during 96-hour wear.

Conclusions: The VitalPatch biosensor demonstrated clinically-acceptable accuracy compared to a standardized reference device for both heart rate and breathing rate. It also provided sufficiently accurate measures for activity in terms of posture and number of steps. Furthermore, when used for up to 4 days at home, there were no adverse events (i.e. rashes, dermatitis, mechanical skin injury) and user experience was satisfactory. The accuracy of vitals and ease-of-use in the home environment in children aged 5-17 illustrate the potential of VitalPatch as a non-invasive and cost-effective vital sign monitoring alternative. VitalPatch biosensor can be integrated into state-of-art devices to monitor vital signs for pediatric patients with diseases like congenital heart abnormalities and adolescent fatigue.

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