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SHORT REPORT

Advanced wireless monitoring for children in the cardiac perioperative setting

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Abstract

Introduction: More than 40,000 children undergo surgical interventions annually for the treatment of congenital heart defects. Intraoperative and postoperative vital sign monitoring is a cornerstone of pediatric care.

Methods: A single-arm prospective observational study was performed. Pediatric patients undergoing a procedure with a planned admission to the Cardiac Intensive Care Unit at Lurie Children's Hospital (Chicago, IL) were eligible for enrollment. Participant vital signs were monitored using standard equipment and an FDA-cleared experimental device (ANNE®) consisting of a wireless patch positioned at the suprasternal notch and index finger or foot. The primary goal of the study was to assess real-world feasibility of wireless sensors in pediatric patients with congenital cardiac defects.

Results: A total of 13 patients were enrolled, ranging in age from 4 months to 16 years with a median age of 4 years. Overall, 54% ($n=7$) were female and the most common anomaly in the cohort was an atrial septal defect ($n=6$). The mean admission length was 3 days (range 2-6), resulting in more than 1000 h of vital sign monitoring (⟩60,000 data points). Bland–Altman plots were generated for heart rate and respiratory rate to assess beat-to-beast differences between the standard equipment and the experimental sensors.

Conclusions: Novel, wireless, flexible sensors demonstrated comparable performance to standard monitoring equipment in a cohort of pediatric patients with congenital cardiac heart defects undergoing surgery.

KEYWORDS
vital sign monitoring, wearables

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Hope Chen and Alan Soetikno shared first authorship.

Congenital heart disease (CHD) is the most prevalent congenital defect. One of every 4 children with CHD will undergo at least one surgical intervention prior to the age of 18.[1,2] Vital sign monitoring is an essential part of pediatric cardiac perioperative management. Current monitoring systems traditionally consist of sensors adhered to the patient and wired to large, bulky base units. These systems constrain intraoperative patient positioning, compromise surgical, anesthetic, and nursing access, limit mobility during recovery, and interactions between patients and parents or guardians. These systems can also cause iatrogenic skin injuries including adhesive-related tears, burns, infections, or pressure sores, leading to long-term morbidity.[3]

Advances in engineering and material sciences have led to the development of lightweight, flexible, wireless sensors capable of comprehensive vital sign monitoring.[4,5] The ANNE® sensors used in this study are bioinspired, encapsulated with medical grade silicone, and designed to be mechanically invisible through matching properties of human skin (Figure 1A). Using near-field communication (NFC) Bluetooth technology, the sensors wirelessly exchange data over short distances using short wavelength radio waves. The ANNE® sensors are FDA cleared for comprehensive physiological monitoring of adults (K211305) and pediatric (K221530) patients and have been used in neonatal and pediatric intensive care units.[4,5] The aim of this study was to assess the real-world feasibility of wireless sensors in the perioperative setting of pediatric patients with congenital heart defects.

This single-arm prospective observational study enrolled pediatric patients undergoing planned admission to the Cardiac Intensive

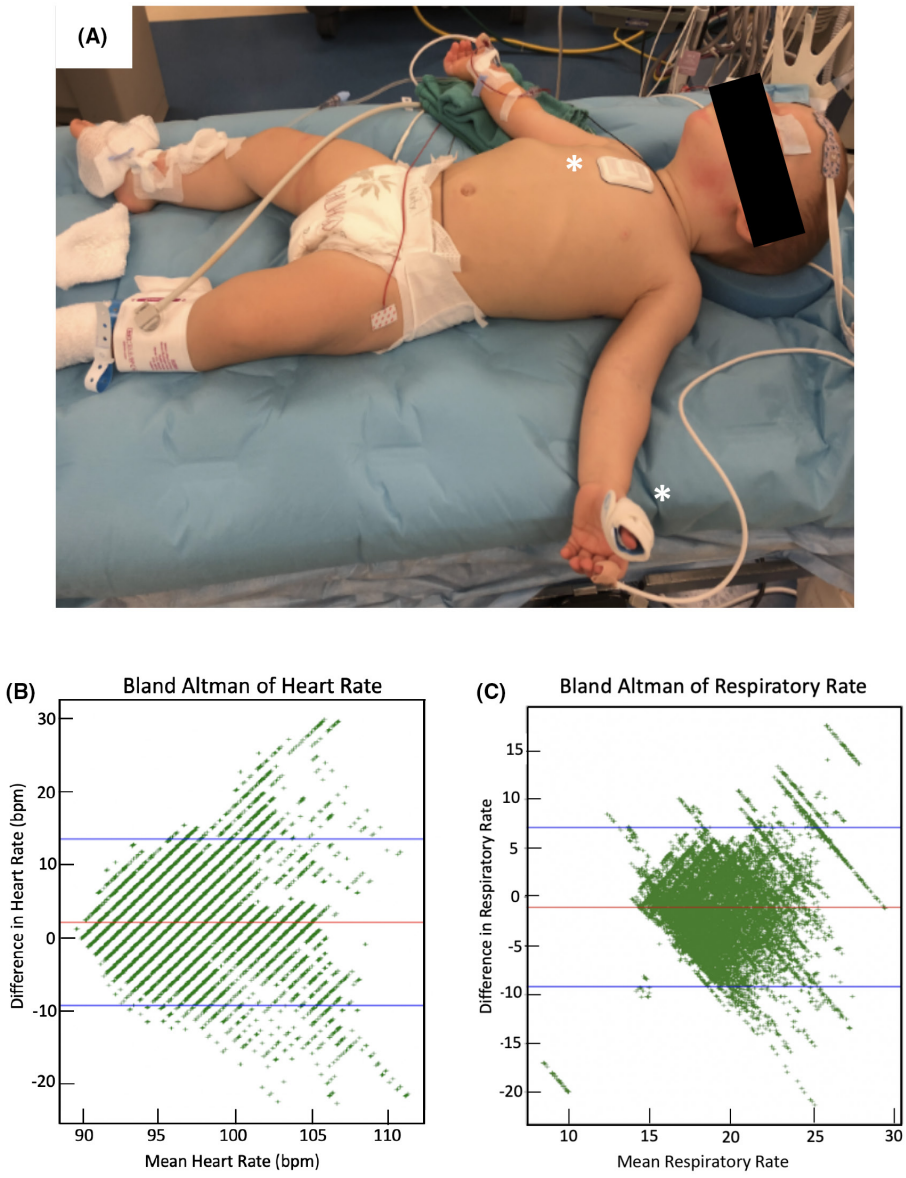

FIGURE 1 Panel A demonstrates an intraoperative photograph of a patient wearing the standard monitoring and ANNE® system (chest and limb sensor designated by asterisk). Panel B Bland Altman demonstrating beat-to-beat heart rate differences and Panel C demonstrating respiratory rate differences between ANNE® sensors and standard equipment.

Care Unit at Lurie Children's Hospital between the ages of 2 weeks to 17 years old. Subjects were required to obtain vital sign monitoring during admission, including heart rate, electrocardiography, respiratory rate, pulse oximetry, and blood pressure. This study was approved by the Lurie Children's Institutional Review Board. Parents or legal guardians provided written informed consent.

Enrolled participants underwent routine vital sign monitoring with standard equipment, while simultaneously wearing the experimental sensors. The experimental sensors consisted of a chest patch which collects electrocardiography (ECG), heart rate, respiration rate, and temperature and a limb sensor (placed on either the index finger or foot) measuring pulse oximetry and blood pressure. The sensor adhesives were changed daily and otherwise remained in place for the duration of admission. Skin assessments were performed at the time of sensor adhesive change. ANNE® sensor data were time synced with gold standard telemetry monitoring by aligning ECG peaks. Vital sign measurements were compared for each subject. Bland Altman plots of heart rate and respiratory rate were created to assess overall agreement, mean difference, and systematic biases in the performance of the sensors.

Overall, 13 patients (median age 4 years, range 4 months to 16 years) were enrolled, of which 54% ($n=7$) were female. Patients were admitted for cardiac evaluation or preprocedural monitoring related to underlying congenital anomalies, including atrial septal defects ($n=6$), ventricular septal defects ($n=2$), vascular rings ($n=2$), coarctation of the aorta ($n=1$), partial anomalous pulmonary venous congestion ($n=1$), and transitional arteriovenous canal defect ($n=1$). The mean length of admission was 3 days (range 2–6 days). A total of 42 days of data (approximately 1000 monitoring hours and over 60 000 data points) were collected. The mean heart rate was 97 beats per minute (SD = 5), with an overall bias of −2 beats per minute (95% Limits of agreement: −9 to 14) (Figure 1). Mean heart rate variability was 22 ms (SD = 14.2). Mean respiratory rate was 19 breaths per minute (SD = 3). Mean pulse oxygenation was 95% (SD = 2.5). There were no adverse outcomes related to use of the sensors.

Each year, an estimated 40 000 children undergo congenital heart surgery, with readmission rates as high as 15%.[2] Given high acuity and frequency of interactions with the healthcare system, improvements in pediatric monitoring systems are particularly relevant for children with CHD. We demonstrated feasibility and safety of wireless monitoring in the perioperative setting that may improve the safety of patient transfers, care across multiple environments (such as inpatient wards and operating rooms), and care coordination. The ergonomic, waterproof, and wireless design is mechanically unobtrusive providing continuous, ICU-grade vital sign monitoring with traditional vital signs and advanced metrics (eg. Heart rate variability) without interrupting sleep, compromising patient accessibility or mobility.

AUTHOR CONTRIBUTIONS

HC, AS, SS, JRW, and SX contributed directly to project conception, material preparation, manuscript and figure generation and editing, and data analysis. HC, SS, and AS assisted with participant recruitment and study support. All authors contributed to editing of the manuscript.

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CONFLICT OF INTEREST STATEMENT

SX: Equity interest in company commercializing technology. JRW: Spouse has equity interest in company commercializing technology.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

SPONSOR'S ROLE

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