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SSSH: ReSponsive Soothing bassinet feasibility Study for infants with congenital Heart disease after cardiac surgery

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ABSTRACT

Purpose: For infants with congenital heart disease (CHD) requiring surgery, prolonged hospital stays, intermittent caregiver visitation, and constrained unit staffing ratios present barriers to adequately address post-operative stressors and associated need to retain cognitive and physiological reserves. Similar patients requiring high-engagement interventions, such as hospitalized infants with neonatal abstinence syndrome, have found success in utilizing responsive bassinets to soothe infants and save floor nurses' time. However, it remains unclear if such technology can be leveraged in the CHD population given their complex hemodynamics, feeding intolerance, and monitoring requirements.

Methods: This multidisciplinary feasibility study evaluated responsive bassinet use in a cohort of infants with CHD <6 months of age in a medical-surgical unit at a midwestern children's hospital. Specifically assessing 1) implementation requirements, challenges, and potential of utilizing the device, together with 2) ability to perform bedside monitoring (monitoring) and 3) measuring physiologic trends during use.

Results: Between 11/2020–1/2022, nine infants utilized a responsive bassinet over 599 h (mean 13, range 4–26 days per infant). No increase in monitoring alarms and accurate vital signs monitoring during bassinet activity were noted with appropriate physiologic responses for infants with single ventricle and biventricular surgeries.

Conclusions: Feasibility of introducing new technology into care, and successful use of its functionality for soothing was found to be plausible for infants with CHD.

Practice implications: After cardiac surgery, infants with CHD have need for interventions to reduce stress. Use of a soothing bassinet has the potential to aid in doing so without interference with monitoring requirements.

Postoperative care of infants with congenital heart disease (CHD) has traditionally focused on reducing morbidity stemming from the use of cardiopulmonary bypass (Jones & Tucker, 2016). Broadly, this includes physiological complications such as hemodynamic instability, increased inflammatory response, and feeding intolerance (Jones & Tucker, 2016; Tweddell & Hoffman, 2002). Yet emerging research has illustrated the stress of the perioperative environment may also impact an infant's neurodevelopment and is independently associated with adverse downstream outcomes (Gaynor et al., 2015). Thus, in addition to the array of interventions required to achieve clinical stability, there exists a critical need to support the management of infants' distress during recovery (Ryan et al., 2019).

Infants with CHD are known to have both limited cognitive and physiological reserves required for their continued growth and development (Hinton & Ware, 2017; Lantin-Hermoso et al., 2017; Lisanti et al., 2019; Schmithorst et al., 2022). Postoperative experiences of increased pain, frequent clinical assessments, and elements of disrupted attachment all combine to create an overwhelming set of stimuli straining these patients' reserves (Lisanti et al., 2019). Studies in the field of developmental care have taken steps to identify mitigating techniques for several of these stressors (Cassidy et al., 2021; LaRonde et al., 2022; Lisanti et al., 2019; Miller et al., 2020), providing evidence around the calming influences of patient-directed interventions such as skin-to-skin care (Lisanti et al., 2021), swaddling, as well as the value of

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environmental regulation including minimizing sound (Kalvas & Harrison, 2020), and reducing light to promote sleep. Unfortunately, these activities require high-level engagement from the unit nurses and family while handling complex data points and evaluation from cardiac patients (Jones & Tucker, 2016). Parents need support and confidence in their healthcare team caring for their infant with CHD, especially those that have periods of excessive crying (Harskamp–van Ginkel et al., 2023). Given the prolonged nature of these infants' hospital stays, parents cannot always be available, may not be able to hold and comfort their child, and staffing ratios often present a significant barrier to providing immediate attention to a crying infant, making the management of these infants challenging for healthcare providers (Lisanti et al., 2021).

Extremely premature infants and infants with neonatal abstinence syndrome (NAS) serve as examples of patient populations where high-engagement interventions are required for prolonged hospital stays (Nelson, 2016). Like the CHD population, sound and touch are calming in the high stress environment of the neonatal intensive care unit (NICU) (Aita & Snider, 2003; Pados, 2018; Weber & Harrison, 2019). Given the acuity of patients and timescales of admissions, to incorporate these interventions at scale, researchers have turned to technological aids combining multiple forms of infant calming through supine mechanical movement, swaddling, and sound (Moller et al., 2019).

The vestibular proprioceptive stimulation in soothing neonates has been discussed since the early 1970's (Pederson, 1973). The advancing application of technology to leverage soothing cribs with cry response features has been discussed in healthcare and engineering as a system to improve infant sleep and growth (Lohekar et al., 2019). This approach has been expanded and formalized by adopting responsive soothing bassinets, which respond to the infant's cry with movement and noise, like the womb environment (Ponder et al., 2021). A 2022 survey of 146 clinicians across 26 hospitals using a responsive soothing bassinet reported an average of 1.9 h of clinical time per shift was reduced when utilizing the soothing bassinet (Gellasch et al., 2023). Additionally, drug-exposed and fussy infants had a faster time to a calm state, but no infants had significant CHD (Gellasch et al., 2023). There have been some studies which have utilized electrocardiogram (ECG) monitoring during healthy infant sleep states and rocking motions to compare heart rate values, variability, and sinus arrhythmia on soothing interventions (Gates Campos, 1994; Porges et al., 1999; Tsunetsugu & Ishibashi, 2019). While soothing bassinets show promise towards measuring heart rates accurately during use, there is a gap in the literature for evaluating soothing bassinets for infants with CHD along with respiratory rates, additional arrhythmias, and oxygen saturation values.

Purpose

It remains unclear if the soothing bassinet can be effectively utilized in postoperative CHD patients due to complex hemodynamics, challenges to feeding tolerance, and distinct monitoring and movement requirements. Taking the first steps to address this knowledge gap, this nurse-led study aimed to evaluate the feasibility of deploying a responsive soothing bassinet in the postoperative recovery of infants at a large midwestern children's hospital. This study addresses three overarching research objectives:

1. Characterize logistics requirements of using a responsive soothing bassinet in pediatric postoperative cardiac care. Identify and address logistical barriers to introducing a soothing bassinet device into clinical and research workflows.
2. Determine the ability to perform reliable bedside monitoring (monitoring) during device use. Evaluate if the device's movement or infant positioning impact standard-of-care monitoring systems to capture data during use as defined by an increase in monitoring alarms or changes in the quality of recorded data.
3. Assess feasibility of measuring physiologic trends during responsive soothing bassinet use. Quantify changes in vital sign measurements during periods of infant crying as they relate to escalation in response level from the soothing bassinet device.

Design and methods

Sample and setting

This was a single-site, cross-sectional, mixed-methods feasibility study performed at a large freestanding pediatric hospital in the Midwestern United States that annually admits approximately 300 infants under 6 months of age for cardiac surgery. All patients were recruited from a cross-sectional sample of patients admitted to a 23-bed medical/surgical unit specializing in the care of pediatric cardiac patients between 11/2020 and 01/2022. The initial sample size goal for this feasibility study was 10 to 15 infants to account for attrition.

Inclusion criteria required infants to have achieved postoperative clinical stability to transfer out of the intensive care setting, have a weight <11 kg, be <6 months of age, and have English or Spanish-speaking parents or legally authorized representatives able to consent for the study. Exclusion criteria included those infants with weights over 11 kg, over 6 months of age, have secondary neurological concerns, critical cardiac shunts (defined as high-risk pulmonary blood flow) determined by the clinical team, and postoperative stage II single ventricle palliative surgery (Glenn surgery) due to head-of-bed elevation requirements.

For eligible patients, parents were approached, provided with a verbal overview of the study, and left with an introductory letter. Study staff later returned to gauge interest in the study and answer questions. Those families who indicated an interest in the research then underwent the parental permission process with a study team member and completed written documentation of informed parental permission. All procedures and materials were approved by the local Institutional Review Board (Study protocol STUDY00001376) and registered under clinicaltrials.gov NCT04534335.

Implementation

Device

The device utilized throughout this study was the SNOO® Smart Sleeper bassinet developed by Happiest Baby, Inc. The SNOO is a Food and Drug Administration (FDA) approved device that responds to an infant's cries with movement and white noise. The bassinet employs elements of swaddling, back sleeping position, shushing, and swinging. If an infant continues to cry beyond a brief period, the device responds with increasing levels of movement and noise until the infant calms or the device times out. The infant's sleep patterns and the device's reaction to periods of crying were then captured on an electronic sleep log. As part of this feasibility study, all soothing bassinet devices were set up with a *Motion Limiter* feature, which prevented bassinet movement intensity from exceeding Level-2 (out of four available response levels).

Two soothing bassinet devices were obtained, one was loaned to our institution by Happiest Baby and the other was purchased. The soothing bassinets utilized an associated mobile application installed on a hospital mobile iOS device (App: v2.6.11, Sleeper Firmware: v1.14.12) and user accounts were established for each device. The devices were stored in a locked storage room accessible to study staff, limiting use to only study subjects. The soothing bassinet device was set up in the patient room in addition to the hospital bassinet. After obtaining parental permission for study participation, the soothing bassinet device was available for staff or parents as desired without a minimum or maximum time in the device. Once a hospital discharge plan was finalized, the soothing bassinet was removed from the patient room at least two days prior to discharge to ensure the infant's transition to sleep in a stationary bassinet.

Research informatics

The study institution uses Cerner and GE Healthcare CARESCAPE Monitor B650 for monitoring. The central monitor allows the user to view and print numeric trends at a selected time interval, but at the time of initiation of this study, there was no way to automatically download the data in a usable format. Through collaboration with health informatics and the study team's data scientist, it was discovered that Smartlinx CARESCAPE Gateway Biomedical Device Interface (BMDI) would allow the nurse to select and save vital sign information from the associated monitor to the subject's EMR, as well as save these data temporarily on a relational database for further analyses compared to the subject's sleep log data.

Data

Data for this study included the qualitative ethnographic experience of the study team, logistics elements of implementation, and quantitative clinical data measurements for enrolled infants. Four primary electronic sources of infant-level data were collected. These included:

1. *Clinical data:* Demographic and clinical data were extracted from the electronic medical record (EMR)
2. *Alarm data:* Bedside monitoring alarm data was available for all participants and were extracted from the Tiger Connect Analytics software program and then classified across four main categories: Critical [*ventricular tachycardia, asystole*], Advisory [*frequent premature ventricular contractions, >2 beats of ventricular tachycardia, SpO_2 high*], Warning [*bradycardia, SpO_2 low, tachycardia*], or System [*arrythmia sensor paused, ECG leads fail, no SpO_2 probe detected*].
3. *Responsive soothing bassinet data:* Time-stamped data from the device's sleep log were obtained, including the start and end time of soothing bassinet usage, motion and/or sound levels as well as indications for cry detection. These data were provided directly from the device manufacturer after the patient study enrollment was completed.
4. *Monitoring data:* Granular (minute-level) vital sign data automatically were extracted from the bedside monitor of the final three infants. These data included heart rate (HR), oxygen saturation (SpO_2), and respiratory rate (RR). This information was extracted through the Smartlinx biomedical device interface (BMDI).

Objective 1: characterize logistics requirements of using a soothing bassinet in pediatric postoperative cardiac care

This study explored the necessary logistical considerations to bring a FDA approved device into patient care, including training and education required to conduct the study. This required coordination and approval from numerous stakeholders including Hospital and Nursing Administration, Biomedical Engineering, Information Security, Informatics, Nursing, Infection Prevention and Control, and Linen Services. The study team was multidisciplinary and included experts in pediatric cardiology, clinical nursing, pediatric cardiac research, and data science.

Objective 2: determine the ability to perform reliable bedside monitoring during device use

As bedside monitoring is a standard of care for postoperative cardiac patients, the study team performed a series of quantitative analyses to evaluate if the movement, positioning (swaddling), or other aspects of the soothing bassinet would interfere with the ability to collect reliable monitoring data.

First, the team assessed alarm patterns for infants when using the device compared to time outside. Data were drawn from the alarm system as hourly totals stratified by alarm type. As infants can move in and out of the soothing bassinet, the team designated hours for which there were 0 min in the device as the control group and those hours with >45 min of active device time as the comparison group. Alarm data for hours where the infant was in and out of the device between 0 and 45 min were excluded from analysis as the alarms could not be properly associated with infant placement. A linear mixed model was fit for each alarm type independently. The total number of alarms for a given hour (dependent variable) was estimated using a binary independent variable for in-device/not in-device (reference-level), and further adjusted for time of day – known to impact alarm frequency. Time was designated as *daytime* between 0700 and 1900, and *night* otherwise. A random intercept was used for each subject as subjects may be intrinsically more or less likely to have certain alarm types or frequencies based on their clinical status.

The study team next sought to determine if monitoring data captured during bassinet use was inherently noisy as compared to data captured when the infant was outside the device. To do so, start- and end-times of soothing bassinet usage (taken from device logs) were used to extract matching segments of monitoring data (HR, RR, SpO_2). Data reliability was assessed as a percentage of recorded vital signs found to be outside of physiologically plausible ranges (henceforth referred to as anomalous values). These anomalous values were defined as: heart rates >200 or < 60 beats per minute, respiratory rates >100 or < 20 breaths per minute, and oxygen saturations <60% as this population had frequent cyanotic heart disease with oxygen values in the 70% range (Bae et al., 2020; Ghanayem et al., 2003). The number of anomalous data points captured while the bassinet was active was compared to the frequency of these data points occurring while the device was not active using a Fisher's exact test.

To further explore if the movement of the device had a unique impact on monitoring data beyond simply being in a sleep sack within a non-moving device, the team performed a sub-analysis using the bassinet weaning mode. In this mode, the baseline level no longer provides the rocking movement. A Fisher's exact test was used to compare the count of anomalous values during periods in which the infant was in the device, but it was not moving *vs.* times in the device with movement.

Objective 3: assess the feasibility of measuring physiologic trends during soothing bassinet use

For the final analysis, the feasibility of utilizing soothing bassinet data to capture trends in an infant's physiologic state (as measured by changes to vital signs) was assessed. As the bassinet escalates or de-escalates movement and sound due to an infant's continued or concluded crying, this analysis sought to utilize observed vital sign trends during various levels of bassinet activity in comparison to expected patterns based on the clinical physiology of the infant's CHD. Again, the raw soothing bassinet logs were extracted to capture the time points the device was activated and the start/stop times of each level to segment. Distributions of vital sign data observed during the time spent at different levels were then compared using a linear mixed model to predict each vital sign measurement, independently, using bassinet level (reference-level: Baseline). A random intercept was placed for each bassinet "session", representing a singular instance of placing the infant in an online device. The session resets when the infant is removed from the safety clips, or the device is turned off. In this way the study team aimed to avoid bias from sessions with many activations that may dominate the comparison should the infant's physiologic state be fundamentally different across sessions based on latent clinical conditions. Sessions lasting <15 min or with <15 overlapping measurements of EMR vital signs were excluded to provide more robust cluster sizes for the mixed model and prevent bias from any system testing or situations in which the infant needed to be quickly removed for feeding or care, precluding reliable analysis of vital signs to responsive soothing-levels.

Results

Objective 1: characterize logistics requirements of using a soothing bassinet in pediatric postoperative cardiac care

The logistics of introducing a soothing bassinet device into clinical and research workflows required evaluation, training, and approval from multiple stakeholders across Administration and Operations. Details of the specific activities undertaken within each area are detailed in the respective sections to follow.

Administration

Clinical. Administration and Nursing Leadership had to approve the use of nursing resources for the study. The unit in which this study took place is a 23-bed unit, with 24-h staffing of hospitalists, nurse practitioners, nurses, and care assistants. A training plan was developed with Nursing Leadership to ensure the frontline staff were well equipped and knowledgeable regarding the responsive soothing bassinets, their indications for use, contraindications, and whom to contact with any questions or concerns.

The Heart Center and the Children's High Acuity Monitoring Program (CHAMP® – internal team who follow high-risk cardiac patients while inpatient and after discharge while in the home-setting) were consulted and engaged in the design and implementation of this study as well. These discussions directed the inclusion and exclusion criteria regarding patients to be approached for participation. A pediatric electrophysiologist was engaged in planning and agreed with the requirements and potential benefits of the study. These introduction and communication meetings began early in the planning phase and stakeholders had input and feedback on the research protocol and implementation plans.

Information security. The soothing bassinet mobile application and software had to be evaluated by the Information Security department through a security questionnaire to ensure there was no data security risk to the institution with the intended research procedures. The Heart Center Information Systems (IS) leader facilitated the process of submission and evaluation of the device and IS requirements. The research team coordinated a meeting between IS and Happiest Baby to ensure the accurate completion of the questionnaire. The capture of sleep log data requires the use of the associated mobile application although the soothing bassinet itself is functional without it. Initially, the study team planned to use the institution's guest Wi-Fi for internet connectivity to obtain soothing bassinet data. However, the soothing bassinet and associated mobile application were found to not be compatible with the enterprise network and thus necessitated the use of Wi-Fi hotspots to capture sleep log data.

Operations

Biomedical engineering. Before patient use, the two soothing bassinets obtained for this study had to be evaluated for safety and approved for use in the hospital by the Biomedical Engineering department. The study team was able to obtain one Wi-Fi hotspot through the institution and although this was suitable for purposes of this feasibility study, the use of these hotspots would not be an ideal long-term solution for device connectivity. The power cord for the hotspots was inadvertently disconnected on more than one occasion resulting in the loss of sleep log data. Additionally, use of multiple soothing bassinets would require close physical proximity or multiple hotspots.

Infection prevention and control. The device had reusable and disposable infection control covers for hospital use and a recommended cleaning protocol evaluated and approved by the Hospital's Infection Prevention and Control team. The device had specific sheets and sleep sacks that were required to be laundered in accordance with the strict guidelines for patient linens. The hospital rents linens from a large linen service serving multiple hospitals. A small batch linen process was needed to ensure that the device-specific linens were cleaned according to infection control guidelines and returned to the medical/surgery unit where this study was taking place. There were multiple delays in the return of these linens and the study team incurred many losses of device specific linens. Unfortunately, no workable solution was found related to this problem, even after escalation through internal reporting mechanisms. This is a challenge that will need to be more fully addressed for future use of the soothing bassinets.

Frontline implementation. All unit staff received training about the study, soothing bassinet functionality, operation, and procedures at one of two scheduled Unit Update meetings. The study team created job aids that were laminated and attached to the soothing bassinet. These resources were added to the unit's education intranet page and included links to the manufacturer's website to aid in frontline implementation. Despite these efforts to address any questions and fully explain and introduce the soothing bassinet to the nursing staff, several of the floor nurses still felt more comfortable using existing infant swings to comfort their patients as opposed to utilizing the soothing bassinet. This led to several of the initial patients not being placed in the bassinet for extended periods of time, and thus limiting the amount of bassinet-related data collected on these infants. With additional education and nurse discussions with other staff who utilized the bassinet for their patients, the reluctant nurses eventually felt comfortable with the soothing bassinet and utilized it in a more consistent manner. Additionally with each enrollment, family members received training on the operation of the responsive soothing bassinet to ensure they were comfortable placing their infant in the device-specific sleep sack and operating the soothing bassinet.

Several patient clinical factors were identified during the study that at minimum, resulted in increased subject surveillance and, at maximum, resulted in withdrawal from the study. The parent of one subject became overwhelmed with how to manipulate the soothing sleep sack, so the study team withdrew the subject from the study. Despite access from upper and lower zippers, changing the device specific sleep sack proved to be challenging with lower extremity central line intravenous tubing attached, so some staff members would avoid using the soothing bassinet. Postoperative cardiac infants additionally often have drains, capped pacer wires, gastrostomy tubes and other medical devices that are positioned under the swaddle band of the sleep sack and could be a risk to skin integrity. Nursing is attentive to this risk with all infant sleep sacks and no pressure related skin concerns were reported during the study.

Feeding intolerance and significant reflux are common in patients with complex CHD. Two subjects had documented feeding intolerance that continued after enrollment in the study. The care team was advised to position one subject upright after each feed which resulted in less sleep log data for this participant because the soothing bassinet does not have the ability to elevate the head of bed. Additionally, one subject had severe postoperative vocal cord paralysis and the soothing bassinet was not able to detect the subject's cries to initiate soothing bassinet activity levels. This subject was withdrawn from the study and vocal cord paralysis may be suggested as an exclusion criterion for future studies.

Study cohort. In total, the families of 13 patients meeting the inclusion criteria were approached to participate in the study, 84.6% (11/13) of whom agreed to participate and nine (9/11 = 81.8%) remained in the study without withdrawal. The two subjects who were withdrawn after initial parental permission had been obtained. One participant was withdrawn after day one of enrollment and the other occurred six days after enrollment. All discussion of study cohort and experiences are limited to the 9 remaining infants. These infants had a mean age of 5.5

weeks with a range of 2–17 weeks, and a mean weight of 3.45 kg (kg) with a range 2.42–4.11 kg at time of enrollment. Four infants (44.4%) had female sex assigned at birth and seven families (77.8%) reported a white race or ethnicity for their child with one Hispanic child and one multiracial child. Five of the nine (55.6%) infants had single ventricle CHD which provides expected oxygen saturations to be >75% on room air, while the other four had biventricular CHD with normal oxygen saturation levels >92% on room air.

Parents and caregivers were encouraged to hold their children and frontline staff could put the infants in the main hospital bassinet or other available comfort devices at any time. Across the study cohort, the soothing bassinet was available for use over a mean of 13 days with a range of 4 to 26 days. While there were no prespecified recommendations for the minimum or maximum use of the bassinet by the study team, two infants were removed from further analysis as they had <6 h of device usage (one due to WiFi hotspot issues and one due to full-time parent care). In total, the remaining seven infants accrued 599 total hours of device usage, spending a mean of 33.5% of total hours from enrollment to discharge in the device. Given the expected sleep requirements of this population, this percentage of usage is encouraging and representative of a high degree of engagement. All infants remained on their standard of care continuous monitoring during the study period.

Objective 2: determine the ability to perform reliable bedside monitoring during device use

Table 1 presents the results of the mixed model assessing differences in total monitor alarms per hour for infants when using or outside the bassinet device. For each of the four primary alarm types, this analysis compared alarm counts over 1819 distinct hours for seven infants. Directionality of the effect highlighted consistently lower total of hourly alarms while the infant was in the device. However, tight confidence bounds, and small effect size strongly indicate alarm totals can be considered extremely similar when using the device.

Device use on the quality of monitoring vital signs data was then assessed. The data capture process improved throughout the course of the study enrollment from the retrospective collection of validated charted data to an automated process to export vital signs from the bedside monitor at a minute-by-minute level. As the frequency of the charted data varied by patient acuity, the analysis of data quality was limited to the three infants with vital signs data from the automated process. Despite the smaller sample size, the extended monitoring period of enrolled patients provided a robust sample for this feasibility analysis with concurrent data capturing 16,656 HR, 16,402 RR, and 16,302 SpO_2 distinct vital sign measurements.

Table 2 (A) provides a detailed breakdown of the number of vital signs considered to be in-range or anomalous, for each infant during bassinet use as compared to non-bassinet use, and Table 2 (B) highlights the same comparison between periods of bassinet use with and without motion. Note, the third subject did not utilize the weaning mode and did not have any data reported for non-motion periods of aligned data. Broadly, the HR and SpO_2 were found to be extremely reliable, with an average of <1% of all measurements found to be anomalous or noise outside of the expected range. RR was overall found to have a higher degree of anomalous data. However, rates of such data did not appear to significantly increase while in the device, or while the device was moving.

Table 1
Mixed model results comparing the average number of hourly alarms when infants were in the soothing-bassinet as compared to hours they were not. Adjusted for time of day with a random intercept by subject.

Alarm type	Coefficient in-device (95% CI)	*p*
Advisory	−0.171 (−0.500–0.158)	0.31
Critical	−0.058 (−0.095 to −0.020)	<0.01
System	−0.235 (−0.533–0.063)	0.12
Warning	−1.086 (−1.674 to −0.497)	<0.01

Objective 3: assess feasibility of measuring physiologic trends during soothing bassinet use

The distribution of mean vital sign data per infant across each of the device's activation levels can be found in Fig. 1. The associated table within Fig. 1 highlights the results of the mixed model, again focused on the three infants with aligned device and bedside monitor data. Note, a subject's weaning baseline data were not considered for this analysis. As the movement was always present in upper levels, the study team did not wish to bias results by comparing against a baseline where the movement was not performed should that have a latent impact on an infant's physiologic response.

To better align with the mixed model, the mean of each vital sign was computed for each level within a given device session and the distribution of these averages across all sessions were plotted for each infant. As levels increased (due to sustained crying), patterns were noted of increasing mean heart rate in both subjects A and B. Subjects B and C both presented stable averages of RR and SpO_2 across the levels (note, widening confidence intervals correspond to fewer vital sign measures taken at upper levels of the device – as there is a timeout feature built into the device to prevent high-levels of movement for sustained periods).

As proof of concept, the study team worked to ensure that data from the bassinet device and monitoring system could be matched with clinical data extracted from the local EMR. To do so, the team matched the medication administration data from the medication administration record (MAR) to the study data of subject B who had the most complete device and monitoring data. A visual representation of this alignment can be found in Fig. 2.

Discussion

Infants with CHD are a high-acuity population in the pediatric hospital setting and often require specialized nursing care and knowledge (Jones & Tucker, 2016). Soothing interventions are critical to maintaining infant reserves necessary for growth and development. Nursing staff within a pediatric, medical surgical unit were interested in identifying potential opportunities for baby, parent, nurse, and inpatient solutions, such as the use of a responsive soothing bassinet with a mobile application to assist in the postoperative care of infants after cardiac surgery (Lisanti et al., 2021). While this device had frequently been used in other high risk pediatric inpatient care areas, no record of the use of the device in the CHD population had been reported (Gellasch et al., 2023). Additionally, the comparative evaluation of continuous monitoring data with sleep and activity logs had not been researched. The study team sought to explore the logistics, acceptability, and feasibility of vital sign collection during a study with a soothing bassinet for infants with CHD while on continuous monitoring. This study successfully demonstrated that continuous monitoring vital signs could be recorded and not significantly disturbed while infants were in the soothing bassinet.

Regulatory and operations

This study was undertaken as a research project instead of a quality improvement or an evidence-based practice project due to the current lack of standardization regarding the use of the soothing bassinet in the post-surgical pediatric cardiac population. Once standards related to the use of the soothing bassinet in this population have been formalized, examinations of this as an evidence-based practice can be performed.

Initially, the decrease in the pediatric patient census at the start of the pandemic allowed for extra time to work on the regulatory aspects and approvals of the project in 2020. Once enrollment began, the

Table 2
Count (%) of anomalous monitoring values. (A) presents counts when the infant was in the bassinet as compared to values recorded outside the device. (B) presents a sub-analysis within the bassinet, of all captured data during device use comparing periods of movement *vs* non-movement. All *p*-values represent one-sided Fisher's Exact Tests assessing if the count of anomalous data is more frequent when (A) the infant is in the device or (B) the device is moving.

		Subject A			Subject B			Subject C		
Vital Sign		In Range	Anomaly	*p*	In Range	Anomaly	*p*	In Range	Anomaly	*p*
A					*In-Device vs Outside Device*					
HR	In Bassinet	1182 (100)	0 (0)	*1*	14,029 (100)	0 (0)	*1*	1445 (100)	0 (0)	*1*
	Out of Bassinet	500 (98.43)	8 (1.57)		19,575 (99.99)	2 (0.01)		10,684 (100)	0 (0)	
RR	In Bassinet	625 (81.81)	139 (18.19)	*0.63*	13,937 (98.41)	225 (1.59)	*0.99*	1442 (97.7)	34 (2.3)	*0.17*
	Out of Bassinet	129 (81.13)	30 (18.87)		18,724 (95.12)	961 (4.88)		10,588 (98.1)	205 (1.9)	
SpO_2	In Bassinet	1149 (100)	0 (0)	*1*	13,755 (99.97)	4 (0.03)	*0.99*	1394 (100)	0 (0)	*1*
	Out of Bassinet	502 (99.6)	2 (0.4)		19,091 (99.75)	47 (0.25)		10,444 (99.99)	1 (0.01)	
B					*In-Device Moving vs In-Device Stationary*					
HR	Moving	179 (100)	0 (0)	*N/A*	8225 (100)	0 (0)	*N/A*	1445 (100)	0 (0)	*N/A*
	Non-Moving	1003 (100)	0 (0)		5804 (100)	0 (0)		–	–	
RR	Moving	64 (79.01)	17 (20.99)	*0.29*	8226 (98.68)	110 (1.32)	*0.99*	1442 (97.7)	34 (2.3)	*N/A*
	Non-Moving	561 (82.14)	122 (17.86)		5711 (98.03)	115 (1.97)		–	–	
SpO_2	Moving	173 (100)	0 (0)	*N/A*	8038 (99.99)	1 (0.01)	*0.97*	1394 (100)	0 (0)	*N/A*
	Non-Moving	976 (100)	0 (0)		5717 (99.95)	3 (0.05)		–	–	

frontline implementation provided numerous insights and some challenges. Although the goal sample size of 10 to 15 subjects was met for acceptability and feasibility, the enrollment period was extended due to issues associated with the COVID-19 pandemic and related policy changes. Similar to other ongoing pediatric research studies, once the pandemic began affecting pediatric population admissions and the mental health crisis emerged, hospital resources were diverted to manage the increasing patient census and unprecedented staff turnover negatively impacting the ability to enroll participants in a timely manner (Weiner, Balasubramaniam, Shah, Javier, and on behalf of the Pediatric Policy Council, 2020).

The study had good acceptability from parents at an 84.6% enrollment rate. When approached about the study, parents were willing and excited to use the soothing bassinet for their postoperative cardiac infants, and it was hoped this would result in robust sleep log data. However, most subjects had a parent present for much of the hospital stay, meaning that the subject spent much of the daytime hours being held. Even with the limited number of responsive soothing bassinet hours for some subjects during the day, the device was widely accepted with an average use of two weeks, and one family even rented a responsive soothing bassinet to have in their home after hospital discharge.

With respect to clinical staff operations, it was encouraging there were no reports of clinical events for subjects while in the responsive soothing bassinet. Additionally, there was no increase in total alarms when infants were in or outside the device, as alarm fatigue is known to contribute to adverse patient events (Shih et al., 2022). However, as many clinical staff members were accustomed to using a particular infant swing for intermittent soothing, comfort with the introduction of the new device presented some challenges. To bolster nurse adoption of the device, the study team worked on job aids and collaborated with Happiest Baby, Inc. to update handouts that could be used as reminders of safe sleep benefits, as well as made instructions available to hang with the responsive soothing bassinet. Several staff members expressed concerns that the infants would develop a dependence on the movement of the device over the course of the hospitalization and were reluctant to leave the infant in the device for extended periods of time. These concerns persisted throughout the study despite there being a procedure to wean the subjects before discharge and no family reports of subjects having issues after discharge. The study team is interested in examining these concerns during further soothing bassinet research, especially when utilized in the home setting for longer-term use.

Bedside monitoring and physiologic trends

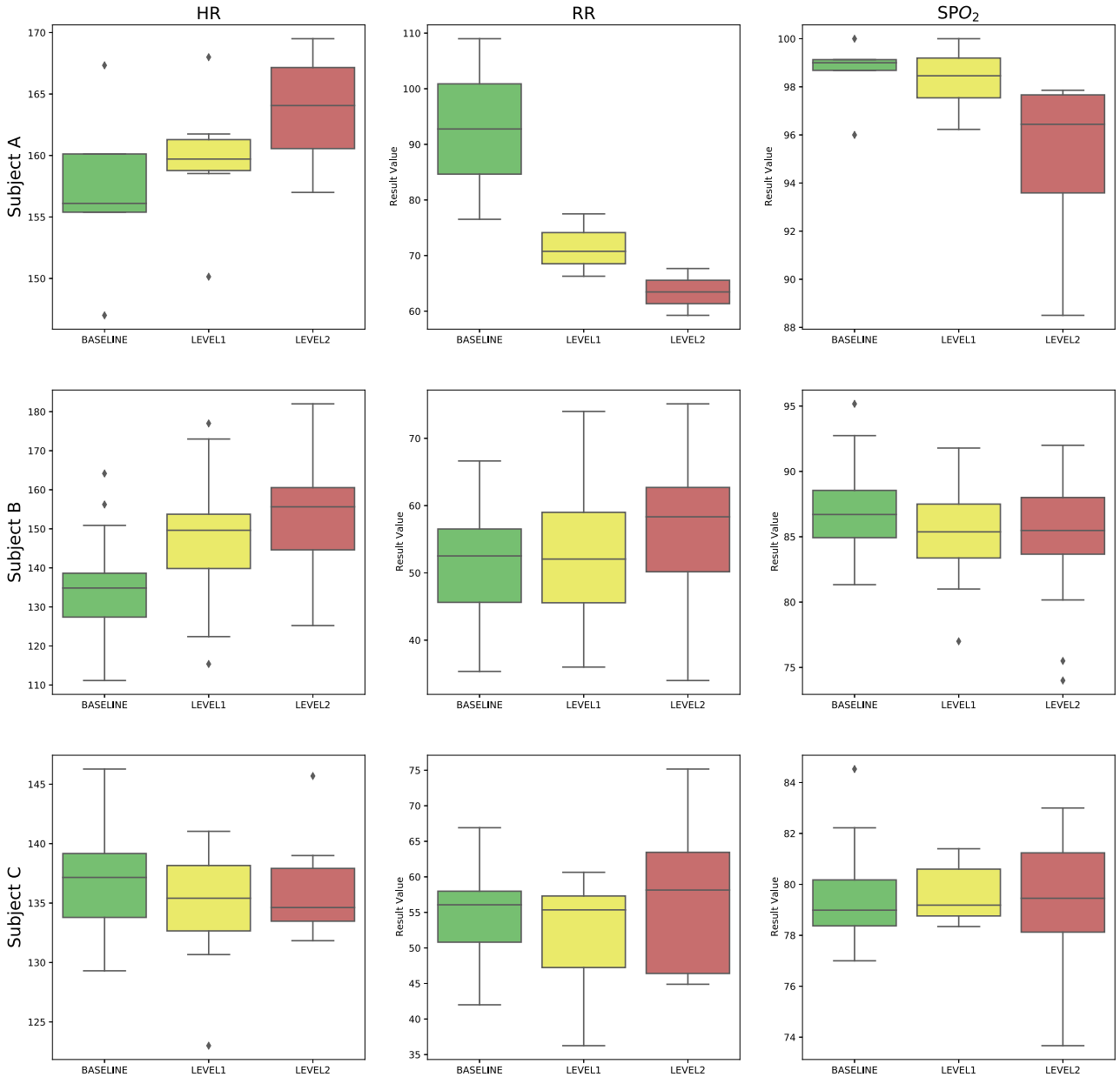
To the study team's knowledge, this is the first study where vital sign and alarm data were intentionally pulled to align with concurrent soothing bassinet data. This alignment provided reassurance that data quality of monitors was not impacted during device use for heart rate and oxygen saturation. For the three subjects who had concurrent bassinet and vital sign data, 100% of the heart rates and 99.97% of oxygen saturation values were in age-appropriate ranges, and the rate of anomalous values did not significantly different between infant's time in and outside the bassinet, and persisted as very minimally anomalous if the subject was moving or non-moving. Notably, there was a lower rate of in-range respiratory rate measures while in the bassinet, but respiratory rate on the biomedical vital sign monitors is notoriously difficult to measure correctly especially with infants that are awake, so the activity movement with the bassinet may possibly have impacted the values recorded and needs to be further studied (Liu et al., 2019).

Given reliability of simultaneously collected vital signs, Fig. 1 and Table 2 can then be utilized to discuss scenarios that occurred while infants were in the bassinet. Subject A's mean oxygen saturations at baseline where higher than the baseline rates for subjects B and C. While subject A showed decreases in SpO_2 during sustained crying with leveling up after progressive tachycardia, subjects B and C had sustained oxygen saturations from baseline to level 2. Subject A was two weeks old at enrollment and had bi-ventricular CHD, so cyanosis and systemic shunting was not an expected finding (Gawalkar et al., 2021). Subjects B and C were five and six weeks of age at enrollment and had single ventricle CHD, both with versions of hypoplastic left heart syndrome.

The soothing bassinet was developed based on concepts of the 5 S's which have been effective for pain reduction and less crying time after painful procedures (Harrington et al., 2012). The technique involves simulating the environment of the womb and includes: swaddling, side or stomach position, shushing, swinging, and sucking. Fig. 1's findings point to potential protection of oxygen saturation values during stress time, especially for subjects with single ventricle physiology. Albeit a small sample size, there was a robust amount of data and minimal anomalous values for subjects B and C. Also, the proof of concept for overlay visualization was successful in subject B giving opportunities for future research projects expanding on this concept.

Limitations

Given the feasibility nature of the described study, there exist several notable limitations to the results. First this was a single-site study, and



		Subject A		Subject B		Subject C	
Vital Sign		Coefficient (95% CI)	p	Coefficient (95% CI)	p	Coefficient (95% CI)	p
HR	Level 1	0.75 (-2.24 — 3.75)	0.62	14 (12.95 — 15.05)	<.01	-1.9 (-3.32 — -0.48)	0.01
	Level 2	4.28 (0.58 — 7.99)	0.02	17.5 (16.49 — 18.51)	<.01	-1.36 (-3.65 — 0.93)	0.24
RR	Level 1	-14.4 (-27.83 — -0.97)	0.04	2.11 (0.94 — 3.28)	<.01	-2.98 (-5.78 — -0.19)	0.04
	Level 2	-20.61 (-37.74 — -3.49)	0.02	5.14 (4.01 — 6.27)	<.01	-0.68 (-5.13 — 3.77)	0.77
SpO_2	Level 1	-1.26 (-3.8 — 1.28)	0.33	-0.6 (-0.85 — -0.34)	<.01	0.01 (-0.57 — 0.58)	0.99
	Level 2	-6.64 (-9.83 — -3.45)	<.01	-0.79 (-1.04 — -0.54)	<.01	0.06 (-0.85 — 0.98)	0.90

Fig. 1. Average vital signs by device activation level per subject. A) Boxplots represent the distribution of mean vital signs within levels across sessions. B) Mixed model results comparing the differences between vital signs to baseline level with random intercept by session.

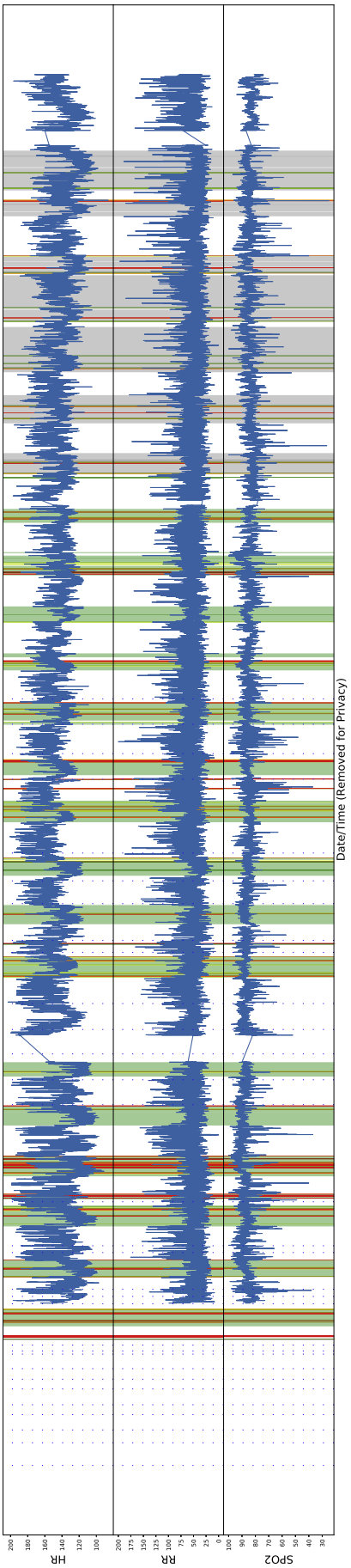


Fig. 2. Visual representation of alignment between responsive soothing bassinet logs, monitoring data, and EMR warehouse data for subject B. Overlaid over the streaming RR, HR and SpO_2 data (blue), the bassinet levels are indicated by colored windows (green: moving baseline, grey: weaning baseline, yellow: level 1 motion, and red: level 2 motion). Dashed vertical lines indicate pain medication administrations to the infant. Note: As the motion limiter was applied at level 2, sustained crying that would otherwise escalate to levels 3 and 4 are indicated as "level 2". (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

procedures and implementation details may not directly generalize to institutions with fundamentally different organizational structures. Nonetheless, we believe the outlined framework of approvals, training, staff engagement, along with fundamental challenges to adoption are valuable broadly for the implementation of new devices into clinical workflows. Second, this study utilized only a single brand and manufacturer of bassinet. As such, we recognize results and conclusions pertaining to the impact of a device's safety and impact on bedside monitoring are contingent on use of the same device. However, the studied device is already widely adopted. It is FDA approved and currently in use in studies and care at over 160 hospitals across the United States. It has not to date been used in the setting of cardiac step-down units. We believe this work adds valuable knowledge to literature around the use of such devices for infants with complex monitoring needs. Third, we recognize the sample size was limited, however, the objective of this work was to establish feasibility for implementing the device into workflows and to ensure the device could be used safely for the postoperative cardiac population. To establish specific areas of utility and guidelines for the device, future works should adopt longitudinal examinations comparing variability in patient conditions during use of the soothing bassinet.

Practice implications

Along with a roadmap for nurses to be aware of when implementing a new device in their inpatient units, this research additionally gives opportunities for the evaluation and larger scale adoption of a soothing bassinet as a standard of care in this population. Additionally, future studies should focus on the parasympathetic response with stress, age, physiology, and crying while in a soothing bassinet in larger clinical cohorts. For the estimated 30,000–40,000 infants who are expected to undergo cardiac surgery in the United States each year, the implementation of a soothing bassinet to assist in the postoperative soothing of these patients will enable the clinical staff caring for these patients to better manage their ever-increasing work demands (Pasquali et al., 2020). These bassinets will also allow the patients' parents, who are often overwhelmed with other responsibilities and not able to be in the hospital at all times, to hold and comfort their children when they are able, and to know that their children are able to rest comfortably in their absence.

Conclusion

This single-center's study has demonstrated that infant postoperative cardiac patients can safely utilize soothing and comfort measures provided through an electronic bassinet that acts in response to infant movement and cry without interfering with bedside monitoring. Future studies examining the use of this bassinet in this patient population will allow for further refinement of potential contraindications for its use postoperatively. Knowledge gained through the development and implementation of this nurse-led study can be seen as a guide for other nurse investigators as they develop study protocols within their institutions and areas of interest.

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CRediT authorship contribution statement

Shannon Lysaught: Conceptualization, Funding acquisition, Investigation, Resources, Data Curation, Writing-Original Draft, Project Administration. **Lori Erickson:** Conceptualization, Methodology, Data curation, Writing – review & editing. **Jennifer Marshall:**

Conceptualization, Methodology, Writing – review & editing, Project administration. **Keith Feldman:** Conceptualization, Methodology, Validation, Formal analysis, Data curation, Writing – review & editing, Visualization, Supervision.

Declaration of Competing Interest

None.

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