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Feasibility and acceptability of a novel forehead-mounted wireless heart rate monitoring device in preterm infants: a prospective multicenter observational cohort study

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ABSTRACT

Background: Wireless monitoring technologies may offer practical advantages over conventional monitoring approaches in neonatal care. We aimed to evaluate the feasibility and acceptability of a wireless heart rate monitoring device in preterm infants across different neonatal clinical settings.

Methods: Between January 2022 and August 2023, we prospectively evaluated the SurePulse VS wireless heart rate monitoring device (SurePulse Medical Ltd, Nottingham, UK) in 62 preterm infants at birth and during postnatal care in two UK tertiary neonatal intensive care units. Staff completed structured questionnaires assessing the device feasibility and acceptability in this preterm population. Downloaded device data were analyzed as exploratory operational metrics and compared with contemporaneously collected staff assessments of signal availability and heart rate acquisition time.

Results: Staff reported device cap fitting as "Easy" or "Very Easy" in 88% (45/51) of deployments. Heart rate visibility was reported as available for "All" or "Most" of the monitoring period in 82% (42/51) of cases, and heart rate acquisition within 60 s was reported in 69% (35/51) of cases. Downloaded data were available for 51 infants and provided exploratory operational measures of signal availability and acquisition time that broadly aligned with staff-reported assessments.

Conclusions: The SurePulse VS device demonstrated a high level of feasibility and acceptability among clinical staff across a range of neonatal care settings. These findings support the feasibility of wireless heart rate monitoring in preterm infants and provide insight into practical considerations and challenges for implementation in routine clinical care.

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Acquisition time; heart rate; premature; user feedback; wireless neonatal monitoring

Introduction

Around 10% of newborn babies require some form of enhanced support or resuscitation at birth [1]. Preterm infants often require additional interventions at birth to maintain normothermia and to facilitate transition from placental to pulmonary circulation [2]. Heart rate (HR) has been shown to be the reliable indicator of the newborn's condition and response to intervention [1,3]. The latest resuscitation guidelines state that continuous HR assessment methods are preferred when interventions are indicated or during the stabilization of preterm newborns [1,4]. Whilst ECG and pulse oximeters may be used for continuous HR monitoring, they have limitations in the delivery room, as do auscultation and umbilical cord palpation for HR assessment [3,4]. With modern technology, continuous wireless monitoring of HR would potentially be beneficial in neonates, particularly in preterm infants at delivery, to guide stabilization with less cumbersome monitoring. Several promising novel wireless devices using various techniques such as dry-electrode ECG, photoplethysmography, electrical velocimetry, piezo-electric sensors, diaphragmatic EMG have been studied in the last decade but not yet

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translated into routine clinical practice due to a number of challenges [3]. SurePulse VS is a novel wireless device for HR monitoring, which has received CE approval (1434-MDD-297/2020) and FDA 510(k) clearance (K201887) (SurePulse Medical Ltd, Nottingham, UK). It comprises a single-use thermoprotective head cap with an integrated optical sensor which, *via* a module, wirelessly transmits HR data to a display monitor using Bluetooth technology. The optical sensor uses green-light reflectance photoplethysmography from the baby's forehead to derive the heart rate; the forehead, as part of a central circulation, has been demonstrated as a feasible site for sensor placement [5].

So far, a couple of feasibility studies on the usability and acceptability application of the SurePulse VS device have only been studied in stable late preterm and term infants after admission to the neonatal unit and at delivery [6,7]. These real-world studies concluded that the SurePulse VS device has utility in small cohorts of stable babies who did not need any resuscitation.

In the present study, we aimed to evaluate the usability and acceptability of the SurePulse VS device in preterm infants across a range of neonatal clinical settings, including at birth during stabilization and during intensive care. A secondary objective was to explore operational device metrics by comparing downloaded HR data recordings with contemporaneously collected staff assessments of HR acquisition time and signal availability during clinical use.

Materials and methods

This was a prospective multi-center, observational evaluation of the usability and acceptability of the SurePulse VS device in preterm infants in the tertiary-level neonatal units of two large NHS hospitals in the UK: the Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH) between January 2022 and February 2023; and Ashford and St Peter's Hospitals NHS Foundation Trust (ASPH) between March and August 2023. Prior ethics approval was obtained from London—Brighton & Sussex Research Ethics Committee (REC, reference 21/PR/0293).

Parental consent was obtained using a written consent form in accordance with Good Clinical Practice (GCP) and with the prior approval from the REC to allow post-hoc consenting as well as pre-birth consenting (SurePulse VS was already CE approved and the noninvasive monitoring device was to be deployed in addition to routine HR monitoring used in both units). This novel consenting model proved to be efficient for both parents and for NHS staff with their time and resources, especially with unexpected preterm deliveries and emergency Cesarean sections. Following births where SurePulse had been deployed as part of routine clinical care, if parents subsequently declined to consent to the use of the routinely collected clinical and SurePulse data, all data were erased from the Monitor and were not downloaded for evaluation. The study adhered to the Declaration of Helsinki guidelines regarding involving human participants in research.

All preterm infants born at 22 + 0 to 36 + 6 weeks' gestation were eligible to be recruited in any clinical setting: immediately following birth by vaginal delivery or Cesarean section, or post admission to the neonatal unit. NNUH planned to recruit a convenience sample of 30 preterm babies (10 on NICU and 20 at birth), and ASPH a convenience sample of 30 preterm babies at birth. The study protocol incorporated the additional use of the SurePulse VS device into the routine monitoring and stabilization protocols used in the neonatal units after birth. The aim was to commence the wireless monitoring as soon as possible after birth and to continue for a minimum of 20 min, or for a minimum of 20 min postnatally after admission to the NICU. At birth, following stabilization of the preterm infant, the device deployment continued while babies had their first cuddles with parents in delivery room or theater in line with the standard practice in both hospitals [8]. Figure 1 shows the SurePulse VS device deployed during Kangaroo Care in NICU.

The same protocol was used in all settings and similar structured user feedback questionnaires (Supplementary Appendix 1) were collected from various staff caring for the babies in both hospitals. Training was offered to research nurses and clinical staff in both centers by the SurePulse team through both classroom training in person, and *via* remote videoconference training (during the Covid-19 pandemic restrictions). Additionally, simulation exercises were undertaken at each center before recruitment commenced to familiarize staff with the equipment and deployment procedures, with ongoing training provided throughout the study period.

Figure 1. SurePulse VS device during Kangaroo Care in neonatal intensive care unit.

The observational evaluations used structured questionnaires to gather NHS staff feedback from various grades of doctors and nurses on the feasibility and acceptability of the SurePulse VS device. The questionnaires asked for staff feedback on the ease of use, workflow integration, the perceived reliability of the device (the proportion of time that a numeric HR was visible on the monitor compared to the total time of cap deployment), the speed of HR signal visibility or the acquisition time (AT - the time from Cap deployment to time of the first visible HR numeric appearing on the monitor) and the effectiveness of the training provided. Recorded HR information was collected, per neonate, through USB-datastick downloads following device deployment and was compared post-hoc to the contemporaneous questionnaire responses. Concordance between the downloaded data and the perceived reliability questionnaire responses were based on the ranges "All of the time" and >90% reliability, "Most of the time" and 50%–89% reliability, "Occasionally" and 30-49% reliability and "Not able" and <30% reliability. Concordance between the downloaded data and the perceived AT was analyzed as binary (i.e. concordance if in agreement to AT or non-concordance if not).

Results

In total, 62 preterm infants were enrolled across the two centers, 43 in theater (Cesarean section deliveries), 9 in the delivery room (vaginal births), and 10 in NICU (during postnatal care). Multiple staff members completed feedback forms for some babies in line with the study protocol and a total of 89 user questionnaires were completed by the staff directly involved in the care of these infants during deployment of the device. Recorded data were not available from 11 babies as 3 recordings had no USB datastick returned, and 8 recordings had no analyzable data. The causes for the data

losses were noted to indicate implementation challenges. Following early feedback, these issues were subsequently addressed through further training and simulation sessions. The final analyses were performed on 51 babies (29 from NNUH and 22 from ASPH). The inclusions and exclusions as per study site are outlined in Supplementary Table 1.

Of the 51 babies studied, 33 were Cesarean section births, 8 were vaginal births and 10 babies were recruited in NICU (including device deployment during babies' skin-to-skin cuddles with parents). The median gestational age was 33 + 5 weeks and the median weight 1860 g. Table 1 shows the baseline characteristics of babies that completed the study.

In total, 78 questionnaires were completed for the 51 included births, 63% (49/78) were from doctors and Advanced Neonatal Nurse Practitioners, and 37% (29/78) were from neonatal and research nurses (Supplementary Table 2). Whilst not prospectively specified in the study protocol, where multiple questionnaires were returned for any individual infant deployment, it is the majority response to the question that has been included in the analysis, or, in the case of a non-majority, the "less advantageous" response (from the perspective of the study device performance).

Overall, in 88% (45/51) of included births, staff recorded device cap fitting as "easy" or "very easy". Where additional breathing support was used, 100% of staff (17/17) said that concomitant delivery of continuous positive airway pressure/nasal high flow integrated with the SurePulse VS device Cap "easily" or "very easily". For 59% (30/51) of the births the training provided was rated 5/5 for effectiveness, for 33% (17/51) rated 4/5, for 6% (3/51) rated 3/5 and for 2% (1/51) rated 1/5 (Table 2).

In the combined analysis, user questionnaires assessed HR signal reliability overall as "Most of the time" (median) and 82% (42/51) reported "All or Most of the time." Median reported HR acquisition time (AT) was "within 60 s" and was reported as "within 60 s" by 69% (35/51) of the questionnaire respondents; 75% (38/51) respondents reported AT "within 90 s", and 24% (12/51) reported AT as over 2 min (one response "Not able") (Table 2). The reported reliability metric ("All or Most of the time") between centers were, respectively, 90% (26/29) at NNUH and 73% (16/22) at ASPH; The reported AT metric ("HR within 60 s") was 62% (18/29) and 77% (17/22) respectively and "HR within 30 s" 45% (13/29) vs 36% (8/22) respectively (Table 2).

Regarding birth locations, 10 babies were recruited on NICU and 41 in the combined analysis in either Delivery Room or Theater. The reported reliability metric ("All or Most of the time") between locations was 100% (10/10) in NICU and 78% (32/41) in DR/Theater. The reported AT metric ("HR within 60 s") was 70% (7/10) in NICU and 68% (28/41) in DR/Theater (Table 3). The median recording duration was 26.6 min. 5 recordings were for less than the minimum 20 min' cap deployment duration that was specified by the protocol (2 recordings from NNUH and 3 from ASPH), with no clear rationale documented.

For the secondary analysis the study collected downloaded data to generate exploratory operational metrics, and to compare these with the perceived questionnaire responses. The median reliability from the data recordings was 77% (IQR: 53% to 86%); The median AT from the data recordings was 32 s (IQR: 17 to 81 s) (Supplementary Table 3). The concordance between

Table 1. Baseline characteristics of the enrolled participants.

	NNUH ($N = 29$)	ASPH ($N = 22$)	Combined ($N = 51$)
Clinical setting (device deployment)	Theater – 14 DR – 5 NICU – 10	Theater – 19 DR – 3	Theater – 33 DR – 8 NICU – 10
Baby's general condition	Good – 18 Fair – 5 Poor – 3 [a]Missing data – 3	Good – 22	Good – 40 Fair – 5 Poor – 3 [a]Missing data – 3
Gestational age, weeks	31 + 5 (24 + 6 to 36 + 6)	34 + 0 (26 + 0 to 36 + 6)	33 + 5 (24 + 6 to 36 + 6)
Birth weight, g	1715 (420 to 3055)	1960 (761 to 3160)	1860 (420 to 3160)

Data are *N* or median (range).
[a]Data items not recorded on questionnaires.
Abbreviations. NNUH, Norfolk and Norwich University Hospitals; ASPH, Ashford and St Peter's Hospitals; DR, Delivery room; NICU, Neonatal Intensive Care Unit; g, Grammes.

Table 2. Staff feedback through questionnaires on 51 babies.

	NNUH ($N=29$)	ASPH ($N=22$)	Combined ($N=51$)
Reliability—all/most of the time	90% (26/29)	73% (16/22)	82% (42/51)
Reliability—median	Most	Most	Most
Acquisition times—median	<60 s	<60 s	<60 s
AT < 30s	45% (13/29)	36% (8/22)	41% (21/51)
AT 30-59s	17% (5/29)	41% (9/22)	27% (14/51)
AT 60-90s	10% (3/29)	0 (0/22)	6% (3/51)
AT > 120s	24% (7/29)	23% (5/22)	24% (12/51)
Not able	3% (1/29)	0 (0/22)	2% (1/51)
Aggregate			
AT < 30s	45% (13/29)	36% (8/22)	41% (21/51)
AT < 60s	62% (18/29)	77% (17/22)	69% (35/51)
AT < 90s	72% (21/29)	77% (17/22)	75% (38/51)
AT < 120s	72% (21/29)	77% (17/22)	75% (38/51)
AT > 120s	24% (7/29)	23% (5/22)	24% (12/51)
Overall Cap Fitting "Easy/Very Easy"	86% (25/29)	91% (20/22)	88% (45/51)
Cap fitting with CPAP/ High Flow prongs "Easy/Very Easy"	100% (6/6)	100% (11/11)	100% (17/17)
Training effectiveness 5/5	69% (20/29)	45% (10/22)	59% (30/51)
Training effectiveness 4/5	24% (7/29)	45% (10/22)	33% (17/51)
Training effectiveness 3/5	7% (2/29)	5% (1/22)	6% (3/51)
Training effectiveness 1/5	0% (0/29)	5% (1/22)	2% (1/51)

Abbreviations. AT, Acquisition time; CPAP, Continuous Positive Airway Pressure; s, Seconds; NNUH, Norfolk and Norwich University Hospitals; ASPH, Ashford and St Peter's Hospitals.

Table 3. Staff feedback through questionnaires on 51 babies based on clinical settings.

	NNUH ($N=29$)	ASPH ($N=22$)	Combined ($N=51$)
Reliability—all/most of the time—NICU	100% (10/10)	$N=0$	100% (10/10)
Reliability—all/Most of the time—DR/theater	84% (16/19)	73% (16/22)	78% (32/41)
Reliability—median NICU	All of the time	$N=0$	All of the time
Reliability—median DR/theater	Most of the time	Most of the time	Most of the time
Acquisition times—median NICU	<30s	$N=0$	<30s
Acquisition times—Median DR/theater	<60s	<60s	<60s
AT < 30s NICU	70% (7/10)	$N=0$	70% (7/10)
AT 30–59s NICU	0	$N=0$	0
AT 60–90s NICU	20% (2/10)	$N=0$	20% (2/10)
AT > 120s NICU	10% (1/10)	$N=0$	10% (1/10)
Not able NICU	0	$N=0$	0
Aggregate			
AT < 30s NICU	70% (7/10)	$N=0$	70% (7/10)
AT < 60s NICU	70% (7/10)	$N=0$	70% (7/10)
AT < 90s NICU	90% (9/10)	$N=0$	90% (9/10)
AT < 30s DR/theater	32% (6/19)	36% (8/22)	34% (14/41)
AT 30–59s DR/theater	26% (5/19)	41% (9/22)	34% (14/41)
AT 60–90s DR/theater	5% (1/19)	0	2% (1/41)
AT > 120s DR/theater	32% (6/19)	23% (5/22)	27% (11/41)
Not able DR/theater	5% (1/19)	0	2% (1/41)
Aggregate			
AT < 30s DR/theater	32% (6/19)	36% (8/22)	34% (14/41)
AT < 60s DR/theater	58% (11/19)	77% (17/22)	68% (28/41)
AT < 90s DR/theater	63% (12/19)	77% (17/22)	71% (29/41)

Abbreviations. AT, Acquisition time; CPAP, Continuous Positive Airway Pressure; DR, Delivery Room; s, Seconds; NICU, Neonatal Intensive Care Unit; NNUH, Norfolk and Norwich University Hospitals; ASPH, Ashford and St Peter's Hospitals.

questionnaire reported reliability and the downloaded data was 65% (33/51) and 80% (41/51) for AT (Supplementary Table 3). No adverse device or patient-related events were reported in either cohort.

Discussion

This multicenter, prospective observational study evaluated the feasibility and acceptability of the SurePulse VS device in preterm infants across delivery room, operating theater and NICU settings.

Overall, staff reported high levels of acceptability, with most users rating cap fitting as easy or very easy and reporting successful integration into routine neonatal care and alongside respiratory support.

Our findings are broadly consistent with the previous multicenter observational evaluation conducted at Manchester University NHS Foundation Trust, which reported lower ease-of-use ratings (77% vs 88% reporting cap fitting as "Easy" or "Very Easy") but similar perceived reliability (80% vs 82% reporting HR visibility "All" or "Most" of the time) [6]. In contrast, the earlier University of Nottingham comparative study reported higher median signal availability for HR <60 s (94% vs 77%) [7]. This difference may reflect the more controlled study environment and the use of video-recorded deployment timings in the Nottingham study, whereas the present study evaluated device use under routine clinical conditions across multiple neonatal settings with staff perceived reliability and AT.

This study also provided valuable insight into real-world implementation challenges associated with introducing a novel monitoring technology into neonatal care. Recorded data were unavailable in 11 births, largely because of operational and training-related issues related to device deployment encountered during earlier recruitments. Although these missing data may have introduced bias into the exploratory analyses, they also highlight the importance of training, familiarity and workflow integration when implementing new monitoring approaches in a complex clinical environment. A higher rate of signal availability was observed in NICU deployments than following birth in delivery room or theater, suggesting that clinical setting and deployment conditions may influence device deployment and signal acquisition.

Downloaded data provided exploratory operational metrics regarding signal availability and acquisition time. However, these measures should be interpreted cautiously, as the study was designed as a feasibility and acceptability evaluation rather than a comparative performance study and was not powered for formal performance analyses. Therefore, differences between the two study centers cannot be critically analyzed further. The study also identified practical considerations for incorporation in future evaluations, including more standardized recording of key time points and clinical events to improve interpretation of operational data.

Despite the widely recognized benefits of providing early delivery room cuddles to all preterm babies, a recent UK survey [9] has shown that it is not yet practised in all hospitals for various reasons. Equipment issues have been reported to be one of the barriers to implementing this practice [9]. We have been able to show integration of wireless monitoring during delivery room and skin-to-skin cuddles in NICU through this feasibility study as our two centers routinely support these practices. The wireless approach offers improved flexibility over existing HR monitoring modalities in such situations to support family centered care throughout the neonatal journey.

Additional limitations should also be considered. The sample size was determined pragmatically and was not powered to detect differences between centers, clinical settings or patient subgroups, nor to support formal assessments of device performance. The primary outcomes were based on staff-reported questionnaire responses which, although collected contemporaneously, remain subjective and may have been influenced by the clinical demands of stabilization and resuscitation. Multiple questionnaires were completed for some births to obtain real-world feedback from different staff groups as per the protocol. This introduces the possibility of correlated observations as the analysis has been conducted at the infant level to avoid falsely elevating the sample size. Finally, the study was commercially funded and the sponsor contributed to protocol development, training and technical support. Although the sponsor was not involved in interpretation of the findings or the decision to submit the manuscript, this involvement should be considered when interpreting the results.

Conclusions

Current approaches to HR monitoring at and after birth all have limitations. This multicenter observational study demonstrated a good level of feasibility and acceptability of the novel SurePulse VS wireless HR monitoring device among neonatal staff caring for preterm infants across a range of clinical settings.

The findings suggest that wireless HR monitoring using a cap-mounted sensor is a feasible approach both at birth and during neonatal intensive care in preterm infants alongside routine stabilization. As well as potentially supporting healthcare professionals with timely vital signs data at birth we believe this device has the potential to allow parents greater autonomy and staff the opportunity for less obtrusive monitoring of newborns during first cuddles with their babies in the delivery room, and during skin-to-skin and kangaroo care in the NICU. The study also identified important implementation considerations, including the role of training and operational deployment challenges. Further studies are required to evaluate device performance and to explore its potential role in routine neonatal care.

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Authors' contributions

CRediT: **Vennila Ponnusamy**: Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Writing – original draft, Writing – review & editing; **Nicky Holland**: Data curation, Investigation, Project administration, Resources, Software, Supervision, Writing – review & editing; **Jasmine Myhill**: Data curation, Investigation, Project administration, Resources, Software, Supervision, Writing – review & editing; **Lucy Pocock**: Data curation, Investigation, Project administration, Resources, Software, Supervision, Writing – review & editing; **Paul Clarke**: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Writing – review & editing.

Disclosure statement

No author has any conflict of interest or financial disclosure relevant to the study to declare.

Open access statement

For the purpose of open access, the authors have applied a Creative Commons Attribution (CC BY) license to any Author Accepted Manuscript version that may arise from this submission.

Prior presentation

Preliminary data from this study was presented in abstract form at the 5th Congress of joint European Neonatal Societies (jENS 2023); Rome, Italy; 19–23 September 2023.

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Data availability statement

The raw data are available upon reasonable request by contacting the corresponding author.

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