

Continuous wireless sensor monitoring with applied diagnostics: Clinical Sensor Pain Scale and Automated Sensor Pain Scale in the NICU

Susan Slattery  ^{1,2,3} Sara Pessano, ⁴ Jaeyoung Yoo, ⁵ Yayun Du, ⁵ Seyong Oh, ⁶ Hyoyoung Jeong, ⁷ John Mascari, ¹ Beth F Lappin, ³ Hannah Alvarez, ³ Tracey M Stewart, ³ Kenny Kronforst, ² Erin Lonergan, ³ Joely Gandler, ³ Casey Rand, ³ Narayanan Krishnamurthi, ³ Aaron Hamvas, ² John Rogers, ⁵ Debra Weese-Mayer ^{2,3}

To cite: Slattery S, Pessano S, Yoo J, *et al*. Continuous wireless sensor monitoring with applied diagnostics: Clinical Sensor Pain Scale and Automated Sensor Pain Scale in the NICU. *BMJ Health Care Inform* 2025;32:e101283. doi:10.1136/bmjhci-2024-101283

► Additional supplemental material is published online only. To view, please visit the journal online (<https://doi.org/10.1136/bmjhci-2024-101283>).

Received 05 September 2024
Accepted 07 October 2025

ABSTRACT

Objectives Inappropriately treated pain can have deleterious outcomes in infants. Current tools rely on intermittent, subjective observation requiring specialised paediatric skills. This study aimed to diagnose infant pain through continuous monitoring with wireless sensors using Neonatal Pain and Agitation Sedation Scale (NPASS)-derived Clinical Sensor Pain Scale (CSPS) and Automated SPS (ASPS).

Methods Clinically stable neonatal intensive care unit infants undergoing phlebotomy were recorded with wireless sensors and video, capturing vital signs, extremity movement and vocalisations. Clinicians and non-clinicians scored the sensor data with CSPS and videos with NPASS; ASPS was applied to the sensor data. Median scores were compared, inter-rater reliability assessed with intraclass correlation coefficients (ICC) and cross-scale comparisons performed using Wilcoxon signed-rank and Kruskal-Wallis tests.

Results CSPS and ASPS closely aligned with NPASS scores, supporting their validity for continuous infant pain assessment. In 32 infants, the median CSPS score was 3 (IQR 2, 5), with excellent reliability (ICC, 95% CI 92 to 97), high internal consistency (Cronbach's $\alpha=0.99$) and 95% absolute agreement, comparable to NPASS ($p=0.95$). Clinician and non-clinician scores were more consistent using CSPS than NPASS. ASPS also performed well, with a median score of 3 (IQR 1, 5), yielding results similar to CSPS ($p=0.94$) and NPASS ($p=0.56$).

Conclusions Wireless biosensors enabled objective monitoring of infant pain. CSPS and ASPS showed validity and reliability for diagnosing acute procedural pain, and feasibility for clinical use. Findings support the development of automated, real-time tools to reduce subjectivity and improve infant pain management, with the potential to advance treatment models and outcomes.

INTRODUCTION

Pain is a relevant autonomic and behavioural response in infants and children, although gaps exist in characterisation and recognition. A limitation in diagnostics and treatment of

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ With >40 infant pain assessment tools available, gaps remain in translational research for an objective, continuous, automated tool that integrates defining features of pain in infants with an emphasis on clinical usability and utility.

WHAT THIS STUDY ADDS

⇒ This study demonstrates that a wireless sensor may be used to monitor infants continuously to detect acute procedural pain and quantify intensity using Neonatal Pain and Agitation Sedation Scale-derived criteria towards an objective, valid and reliable assessment of physiological, behavioural and vocalisation features with Clinical Sensor Pain Scale and instant computerised scoring with Automated Sensor Pain Scale.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ A continuous, objective, automated, easy-to-use system for monitoring pain in infants would offer clinical options to better capture and characterise pain towards adequate treatment, and ultimately, decrease the burden of morbidity associated with undertreatment and overtreatment, particularly in premature infants.

pain is an inability to perceive change in non-verbal infants, a striking vulnerability in this population. Most often, bedside scaled evaluations for infants and children are applied for the diagnosis and, therefore, are the basis for treatment. Pain assessments inform treatment plans with evolving knowledge of existing short-term and long-term risks in infants and children, potentially resulting in overtreatment and undertreatment of pain.^{1,2}

During a painful procedure, such as phlebotomy heel lance, pain is experienced in infants as demonstrated by cortical response



© Author(s) (or their employer(s)) 2025. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ Group.

For numbered affiliations see end of article.

Correspondence to
Dr. Susan Slattery;
sslattery@luriechildrens.org

using electroencephalography, although they may reveal no observable physical signs.³ Apart from neuroimaging, subjective and objective measures related to paediatric pain are collectively insensitive and have various limitations.^{1 4 5} As a result, the diagnosis of pain is a focus of paediatric research with over 40 described clinical assessment surveys available with ranges of reliability and validity, often with barriers to usability.^{6 7}

Neonatal Pain and Agitation Sedation Scale (NPASS) is recognised as one of the most reliable and valid tools for infants and children up to 36 months of age in determining pain, as also endorsed by the American Academy of Pediatrics.^{1 6-9} With high inter-rater reliability (intra-class correlation coefficient (ICC)=0.93–0.99), NPASS consists of assessments made across five subcategories including crying and irritability, behaviour state, facial expression, extremities and tone and vital signs.^{9 10} The limitations of NPASS assessments include subjective scoring that requires a trained assessor to be bedside and, therefore, is scored at intervals, often every few hours.

Recent advances in technology offer opportunities to support this process with objective and automated approaches that do not require continuous bedside observation. Automated systems have also been developed, including facial expression-based approaches such as PainCheck Infant and Pain Recognition Automated Monitoring System (PRAMS).^{11 12} While these tools demonstrate feasibility, they remain limited in neonatal intensive care unit (NICU) application and rely on camera-based inputs. Wireless biosensors, coupled with diagnostic algorithms, provide a potential means of capturing autonomic and behavioural signals in real time and reducing reliance on subjective assessment.

This study aimed to develop a pain assessment system for late preterm and term infants by using non-invasive, wireless biosensors to continuously monitor NPASS-derived subcategories and allow for clinical ease of use by applying Clinical Sensor Pain Scale (CSPS) to the recordings. This system is without prerequisites of paediatric clinical expertise but examines a machine learning algorithm to score using Automated SPS (ASPS) to objectively diagnose and quantify mild to moderate pain during a routine NICU phlebotomy.

METHODS

Study design and cohort

This observational study included clinically well, non-anomalous infants born late preterm (>34 0/7 weeks) or term gestational age (GA) admitted to Northwestern Medicine Prentice Women's Hospital NICU between November 2022 and May 2023. Infants were included if they had scheduled blood draws and were under parental custody for consent. Infants were excluded if they had an active illness, defined as requiring high flow nasal cannula, invasive or non-invasive positive pressure, vasopressors or systemic steroids or antibiotics for

a culture-positive infection. Eligible participants were screened and reviewed with the clinical care team.

Using an a-error=0.05, 1-b=0.8, and a mean:SD ratio of 2:1 for clinical-based pain scores (based on clinical infantile studies of procedural pain), a clinically perceptible difference in pain, or a 1-unit change in the clinical pain score, would require 20 infants in the dataset.¹³ Therefore, the study plan included recruitment of ≥20 infants.

Data collection

Cohort characteristics included date of birth, GA, weight, sex assigned at birth, parent self-reported race or ethnicity and admission diagnosis, as well as chronological age, corrected GA and weight at the time of the study recordings.

Video recordings were obtained using a research iPhone Operating System (iOS) device and included blocks defined as the infant's baseline (quiet, resting period of 30s to 1 min) and the phlebotomy procedure (heel lance and subsequent heel squeeze). A video file was transferred for storage and review to apply the NPASS criteria (table 1).

Vital signs (heart rate (HR), respiratory rate (RR), SpO₂, blood pressure) were also collected at 1 min intervals (Philips Monitoring, Amsterdam, The Netherlands/Cambridge, Massachusetts, USA). HR and RR were averaged over the time blocks, the per cent difference between baseline and the procedure was determined and the value was then subcategorised by a score of 0–2 as shown in table 1.

Sensor recordings were performed using flexible wireless biosensors. The sensor devices were constructed (online supplemental material) and contained an accelerometer and gyroscope to detect three-dimensional position data, allowing movements to be translated to vital signs including HR, RR and vocalisations. Two sensors were adhered to each infant's chest and the dorsal aspect of a foot using a hydrogel adhesive and Masimo NEO Adhesive tape (Irvine, California, USA) (figure 1). A sensor recording was performed and included the time blocks of baseline and procedure. The sensor data were recorded locally to the device, then wirelessly transmitted using the Discovery RA app Sibel (Chicago, Illinois, USA) onto a research iOS device, and transferred for data storage and analyses in .shrd and .xlxs formats.

The sensor-derived data by infant were processed as discrete measures per second in CVS format and was transformed into waveforms and graphics in a jpeg file, as shown in figure 1. Mean HR and RR were calculated during the time blocks; the per cent difference between the two was determined and the change in values was subcategorised as a score of 0–2 (table 1).

The start/stop times of the sensor recording were also documented to ensure they aligned with the video recordings.

Table 1 Assessment criteria for NPASS and CSPS

NPASS criteria			
Assessment criteria	Normal	1	2
Crying and irritability	Appropriate crying, not irritable	Irritable or crying at intervals, consolable	High-pitched or silent—continuous cry, inconsolable
Behaviour state	Appropriate for gestational age	Restless, squirming, awakens frequently	Arching, kicking, constantly awake or arouses minimally/no movement
Facial expression	Relaxed, appropriate	Any pain expression intermittent	Any pain expression continual
Extremities and tone	Relaxed hands and feet, normal tone	Intermittent clenched toes, fists or fingers splayed	Continual clenched toes, fists or finger splay, body is tense
Vital sign changes: heart rate, respiratory rate, blood pressure	Within baseline or normal for gestational age	Increase 10%–20% from baseline	>20% from baseline
CSPS criteria			
Assessment criteria	0	1	2
Crying and irritability	Variable pitch <450 Hz 'x' not clustered 'x' rare overlap No prolonged time intervals 'x'	Moderate pitch (200–450 Hz) 'x' some clustering 'x' some overlap Longer time intervals of 'x'	High-pitched (>450 Hz) 'x' often densely overlapping 'x' some or dense overlap Longer time intervals of 'x'
Behaviour state	Movements are smaller (<0.2 g) Without clustered movement Short time intervals of movements (no squirming)	Movements are smaller (<0.2 g) Clustered, frequent movements Short time intervals of movements (restless, squirming)	Movements are larger (>0.2 g) Longer time intervals of movements (arching, kicking)
Vital sign changes: heart rate, respiratory rate	Within baseline	Increase 10%–20% from baseline	>20% from baseline

Pain is scored from 0 to +2 for the physiological and behavioural criteria, then summed.
The total NPASS score is documented as a positive number between 0 and +10, and the total CSPS score is between 0 and +6.
CSPS, Clinical Sensor Pain Scale; NPASS, Neonatal Pain and Agitation Sedation Scale.

Data scoring

Scorers included four paediatric neonatologists with clinical expertise and four non-clinicians with paediatric research experience. All scorers received NPASS training using the standardised approach adopted in the local NICU, which has been validated for internal consistency.¹⁰ The eight scorers were divided into two groups (group 1, n=2 and group 2, n=6). The first group provided feedback on the CSPS training that mirrored NPASS training and included a review of the criteria with visual examples of scored waveforms (not part of the testing set) and provided clinical explanations. The feedback from the first group focused on the instructional training materials, while the CSPS criteria remained consistent between scorer groups. All NPASS and CSPS training materials were available as a reference during scoring. Scorers independently scored the recordings at baseline and the procedure, applying NPASS criteria to the video recordings and CSPS criteria to the sensor recordings (table 1).

The sensor recordings were assessed and scored using two approaches: (1) CSPS and (2) ASPS (table 1).

1. The CSPS criterion was derived from NPASS.⁹ Crying and irritability, behaviour state with movement and vital sign changes were chosen measures to record with the sensor and transform into waveform data for visualisation and scoring.^{8,9} Like NPASS, CSPS has subcategories, each corresponding with a score of 0–2, and is scaled by summing the subcategories for a total score of 0–6; 0 being the absence of pain and 6 being a moderate level of pain. A maximum score of 6 would capture a response to a procedure such as a heel lance. The subcategories of CSPS were defined by literature review, previous sensor research and expert opinion from nursing, field researchers, neonatologists and bioengineers (table 1).^{4,6,9,14–19} An example of an assessment using CSPS is illustrated in figure 1. Of note, the CSPS differs from the NPASS assessment in that it does not include facial expression, as this can be subjective and involve identifiable patient data, nor infant tone, since it can be subjective even with handling.^{4,11,12}
2. The ASPS criterion was formulated using the CSPS criteria (table 1). The CVS data were analysed using

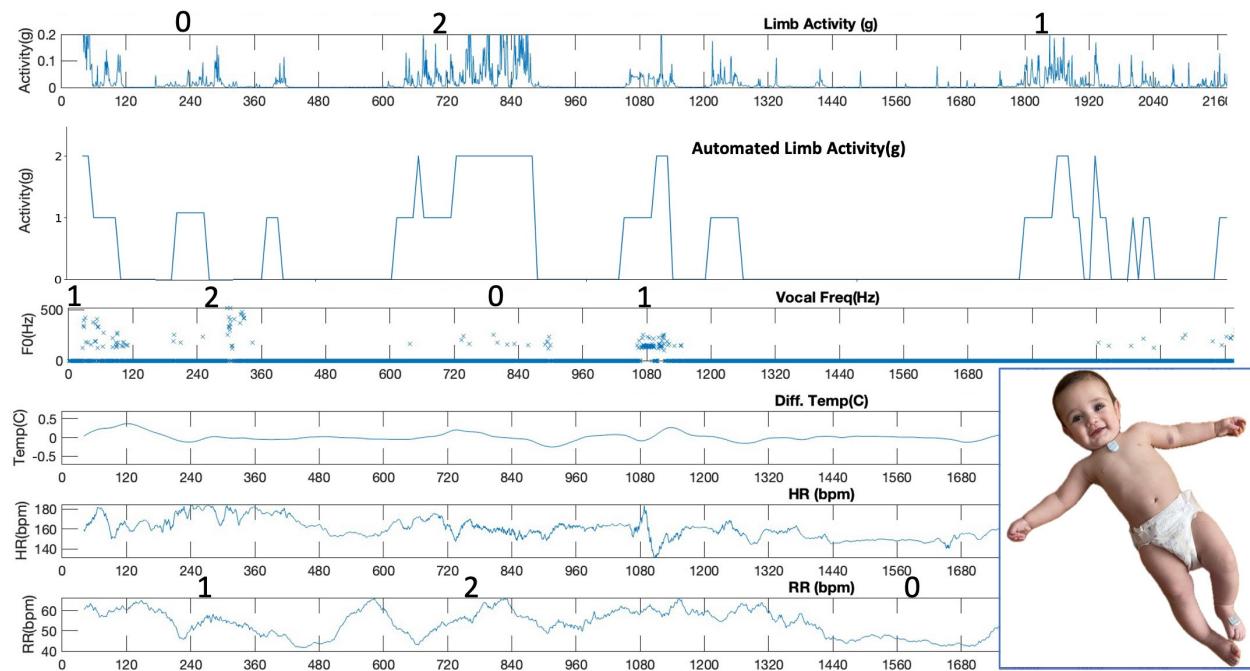


Figure 1 Example of waveform data from a chest and limb sensor recording over nearly 3000s. The recording is scored as if there is an ongoing mildly painful procedure to provide examples of the application of the sensor pain score criteria. There are three subcategories represented: crying/irritability by vocal frequency (Hz), behaviour state/lower extremity movement and vital sign changes. The data are numerically scored to provide examples of the applied criterion (0–1–2). Diff. Temp, differential temperature; HR, heart rate; RR, respiratory rate.

a semi-automated decision tree model with branching logic and artificial intelligence with support vector regression learning. For the crying and irritability subcategory, the data were sampled over a 3s, 300-sample window. The frequency outcome was labelled '0' for windows with averages <50 Hz; '1' for those with a frequency SD under 30 Hz signifying prolonged crying and '2' for windows that have max frequency exceeding 450 Hz. For the behaviour state subcategory, a machine learning model was initially trained to classify the data by manually scoring results against the criteria in [table 1](#). A 60s rolling window was used with a 50% overlap, and each window was classified into a score of 0, 1 or 2. The support vector machine model was trained to follow criteria listed in [table 1](#). Largely, 0 was assigned to windows most often without movement, label 1 to windows with movement most often ranging from 0.1 to 0.2 g (gravitational acceleration constant) and level 2 to movement most often exceeding 0.2 g. The vital sign subcategory score was derived from the per cent difference in HR and RR during the laboratory draw compared with the baseline measures.

Video recordings of infants at baseline and during the procedure were scored using the NPASS criteria ([table 1](#)). If consent to video record was not obtained, the time blocks were scored at bedside by a clinician expert in real-time using the NPASS criteria.^{8,10}

Statistical analyses

Cohort characteristics were analysed using descriptive statistics and compared using χ^2 analysis.

Sensor and video recordings were scored using the CSPS, ASPS and NPASS, with both subcategory and total scores assessed at baseline and during the phlebotomy procedure. The CSPS and NPASS results were examined for inter-rater reliability with ICC estimates and 95% CIs based on a mean-rating ($k=6$), consistency, two-way random-effects modelling by total score as well as Cronbach's α for internal consistency.²⁰ The median total score and median subcategory scores of the CSPS and ASPS were compared with NPASS scores using the Wilcoxon signed-rank test and overall with the Kruskal-Wallis test. Bland-Altman plots were made to illustrate systematic differences between the measurements and outliers.

RESULTS

Forty infants were consented for study enrolment and 36 were available for recordings during the phlebotomy procedure. Thirty-two infants were included in the analyses with CSPS, ASPS and NPASS scores available (one excluded for technical issues with the sensor recording and three with video recording). Two infants had bedside NPASS assessments performed.

The patient demographic and recording details are described in [table 2](#). Of the 32 infants in the cohort, 12 were female (20 male) with more than six race and ethnicities (not Hispanic white n=15, black or African-American n=5, Hispanic white n=4, Hispanic, Latino or Spanish origin 'none of the above' n=3, not Hispanic, Latino or Spanish origin 'none of the above' n=3, Asian

Table 2 Patient cohort characteristics and durations of recordings (n=32)

Patient characteristics and recording details	Median	Q1, Q3
Gestational age at birth (weeks, days)	34w3d	(33w0d, 35w5d)
Corrected gestational age at procedure (weeks, days)	35w3d	(34w2d, 36w5d)
Birth weight (g)	2155	(1830, 2625)
Weight at procedure (g)	2260	(2014, 2515)
Duration of video recording (min)	45	(43, 49)
Duration of sensor recording (min)	48	(45, 56)
Q, quartile.		

or Asian Indian n=2). The admitting diagnosis was most often prematurity (n=26), followed by respiratory distress (n=2), desaturations (n=2), hypoglycaemia (n=1) and low birth weight (n=1).

Apart from two term infants, patients had a CSPS, ASPS and NPASS score >0 during the procedure (94%). As shown in **table 3**, median CSPS, ASPS and NPASS scores were statistically similar by Kruskal-Wallis testing (0.092, p=0.96), supporting comparable assessment across the three tools. In the second group of scorers (n=6), the CSPS demonstrated excellent reliability and internal consistency, with higher inter-rater reliability than NPASS, particularly for non-clinicians. The ASPS also performed well, yielding results consistent with CSPS and NPASS.

The median CSPS and ASPS scores were not significantly different from NPASS scores during the procedure (CSPS: z=-0.07, p=0.95; ASPS: z=-0.28, p=0.56), indicating the scores were comparable. The Bland-Altman plots (**figure 2**) show close agreement between NPASS and CSPS (mean difference -0.20; limits of agreement of -1.9 to 1.4) and between NPASS and ASPS (mean difference 0.22; limits of agreement of -1.6 to 2.0). The median CSPS and ASPS scores during the procedure were also statistically similar (z-score 0.08; p=0.94). The Bland-Altman

plot between CSPS and ASPS scores (**figure 2**) had close agreement, with a mean difference of -0.016 and limits of agreement of -1.27 to 1.30. Score differences across CSPS, ASPS and NPASS were evenly distributed around the line of mean difference within these limits, indicating consistent assessment of mild and moderate pain by the assessment tools (**figure 2**).

By criteria subcategory, CSPS and NPASS median scores during the procedure were different for cry and irritability (CSPS 0 (Q1 0, Q3 2; NPASS 0 (0, 0.5); z-score 2.5; p=0.01) and similar for behaviour state (z-score 1.2; p=0.22) and vital signs (z-score 0.01; p=1.0). By criteria subcategory, ASPS and NPASS procedure scores were similar (crying and irritability z-score 1.09, p=0.27; behaviour state z-score 1.65, p=0.10; vital signs z-score 0.01, p=1.0). By subcategory score, ASPS scores were statistically similar to the CSPS scores in crying and irritability, behaviour state and vital signs (z-score 0.94; p=0.35; z-score 0.69; p=0.49; z-score 0.01; p=1.0).

DISCUSSION

This study confirmed the successful application of a wireless, wearable, non-invasive device to monitor key behavioural and autonomic features of pain in preterm and term infants, capturing continuous changes in vocalisations, movement and vital signs during an acute nociceptive stimulus.

We applied CSPS and ASPS, NPASS-derived criteria, to distinguish pain from rest and quantify mild to moderate discomfort. The scored features of sensor recordings using CSPS and ASPS were determined to be statistically similar to one another and the NPASS score, a valid and reliable recommended infant pain assessment tool for use with acute pain.^{16 7 9 10} The pain scores by CSPS were more reliable than NPASS scores for those with less clinical expertise, as determined by higher inter-rater reliability. With the application of ASPS, the computerised, rule-based voting function provided an additional objective option for continuous pain monitoring in infants.

Table 3 CSPS, ASPS and NPASS procedure score results using sensor and video recordings

Outcome measure	CSPS	ASPS	NPASS
Baseline median score (IQR)	0 (0)	0 (0)	0 (0)
Procedure median score (Q1, Q3)	3 (2, 5)	3 (1, 5)	3 (2, 5)
Overall ICC (%) (CI)	95 (92 to 97)	--	90 (84 to 94)
Clinician ICC (%) (CI)	96 (93 to 98)	--	93 (86 to 95)
Non-clinician ICC (%) (CI)	95 (92 to 97)	--	87 (79 to 93)
Cronbach's α	0.99	--	98
Absolute agreement (%)	95	--	90

First quartile (Q1), third quartile (Q3); ICC consistency of agreement (%) (95% CI).

ASPS, Automated Sensor Pain Scale; CSPS, Clinical Sensor Pain Scale; ICC, intraclass correlation coefficient; NPASS, Neonatal Pain and Agitation Sedation Scale; Q, quartile.

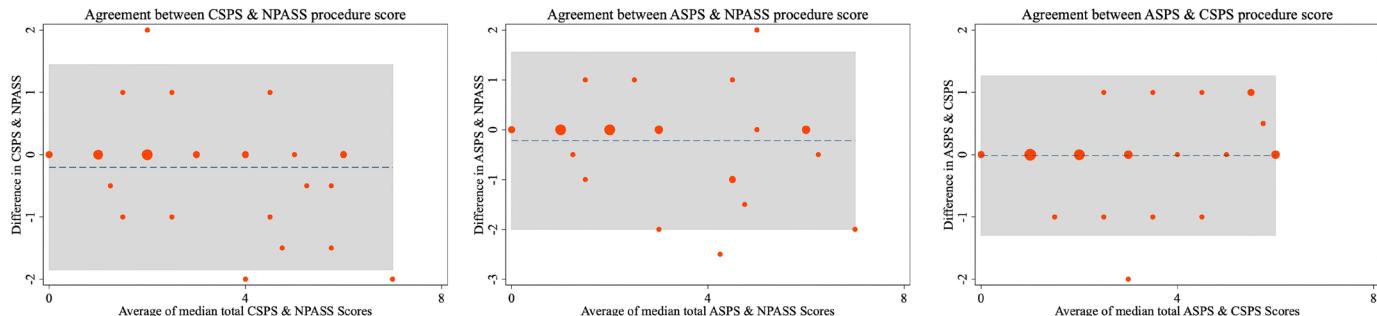


Figure 2 Bland-Altman plots for Clinical Sensor Pain Scale (CSPS), Neonatal Pain and Agitation Sedation Scale (NPASS) and Automated Sensor Pain Scale (ASPS) and NPASS scores during the procedure. The dashed line represents the mean difference, and the grey box denotes the upper and lower limits of agreement. Size of the data points proportionally represents the number of patients with the same assigned scores.

Our results are consistent with prior systematic reviews of infant pain assessment. A recent meta-review on infant pain assessment across 36 current pain scales (NPASS not included) reported that most available scales are focused on categorising acute pain using multiple variables, as was the focus of our study.⁶ Comparing previous systematic reviews, the authors found Face, Legs, Activity, Cry and Consolability (FLACC) and COMFORT were most frequently recommended for general infant pain assessments, although the reviews were heterogeneous, making it difficult to recommend a single tool.⁶ The IRR and measures of validity for FLACC and COMFORT were reported to be high in some, but not all reviews.⁶ A systematic review on NPASS reported the tool to have good to excellent reliability and validity for infants of all GAs in assessing acute pain (ICC=0.93–0.99 and internal consistency (α)=0.837–0.971).⁹ In our study, ICC and internal consistency of CSPS were excellent and comparable to the NPASS measures of validity and reliability, and with significantly similar median scores to ASPS.

Beyond validity, our study addressed usability and clinical utility. While limited data exist for other infant pain assessment tools, our work contributes a modernised method of continuous monitoring while demonstrating ease of use, similar to a pulse-oximeter.⁶ Although the physiological data capture is comparable with other wearable biosensor studies analysing pain, particularly in adult medicine, the sensor used here is uniquely small and able to capture sensitive vocalisations and behavioural data in a non-cumbersome manner.²¹ Equally important, our study also demonstrated clinical utility. CSPS and ASPS showed versatility compared with other tools that require a highly trained bedside assessor.^{5 9 10} Although structured training was provided, non-clinicians achieved high inter-rater reliability using CSPS. This suggests that interpretation does not require advanced paediatric expertise. While the system involves reading waveform data, the reliability achieved by non-clinicians indicates that it may in fact be simpler to apply than bedside NPASS scoring. This supports the potential for broader applicability with streamlined training materials, similar to existing clinical pain scales. Furthermore, as integration with automated aids such as ASPS advances, and as sensor-based

monitoring becomes more commonplace in NICUs, barriers related to training and waveform interpretation are likely to diminish, further enhancing generalisability and ease of clinical use.

Notably, CSPS and ASPS were designed to provide objective measures that allow for accurate and rapid patient assessment while reducing interpreter bias, variation in scoring and interval limitations. The most prominently used infant assessments for acute pain are based on subjective observations, such as with NPASS, Premature Infant Pain Profile-Revised, Neonatal Facial Coding System and Neonatal Infant Pain Scale.^{14–6 9} Like the objective measures of CSPS and ASPS, PRAMS and PainCheck Infant are contemporary semi-automated pain assessment tools that measure changes in infant facial expressions for classification of pain.^{11 12} By contrast, biosensor-based systems such as ours offer objective pain assessment through waveform data or automated algorithms, with additional advantages of patient mobility, reduced reliance on identifiable patient data and lower storage/computing costs. As objective tools, CSPS and ASPS are important for diagnosing infant pain and may help balance the risks of both overtreatment and under-treatment, which carry long-term neurodevelopmental risk in this vulnerable population.^{12 22 23}

Although encouraging, these results must be interpreted considering several limitations. First, the ASPS algorithm could be refined further, since the ASPS vocalisation subcategory had higher scores than CSPS and NPASS (eg, labelled '2', rather than a '1'). With additional subjects and data, more sensitive rules can be used in ASPS such as including a duration of a defined frequency that meets a score. Second, additional sensor features such as more detailed electrocardiography and electromyography may provide more detailed diagnostic information.²¹ Lastly, the cohort was representative of a diverse, populous US city, and CSPS and ASPS diagnosed pain in each race and/or ethnicity group within the cohort, but underpowered for any defined associations. Likewise, as a single-centre study, results may not fully reflect practice across other NICU settings. While not excluded from the study, the use of sensors was not explored in infants with hypotonia and airway differences such as vocal cord anomalies and

intubations, which may limit sensitivity where movement or vocalisations are varied.

Future research should focus on validating CSPS and ASPS in larger and more diverse infant populations, including younger preterm infants, and across different NICU settings. These studies will be important to confirm generalisability and to further establish the reliability of sensor-based pain assessment in clinical practice. In the long term, integration of ASPS into routine NICU monitoring could provide continuous, objective pain scores that support clinical judgement, alerting staff to changes in infant comfort.

CONCLUSIONS

This study demonstrated the feasibility of continuous wireless biosensor monitoring with applied diagnostics in the NICU. Both CSPS and ASPS aligned closely with NPASS scores and showed excellent reliability, while capturing infant vocalisations, behaviours and vital signs to objectively assess for mild to moderate acute pain in late preterm and term infants. These findings provide initial validation of biosensor-based approaches to infant pain assessment, supporting further research in larger and more diverse cohorts to confirm the validity and reliability of CSPS and ASPS.²⁴

Author affiliations

¹Division of Neonatology, Ann & Robert H Lurie Children's Hospital of Chicago, Chicago, Illinois, USA

²Department of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA

³Autonomic Medicine, Ann & Robert H Lurie Children's Hospital of Chicago, Chicago, Illinois, USA

⁴Pediatric Clinic and Endocrinology Unit, IRCCS Istituto Giannina Gaslini, Genova, Italy

⁵Querry Simpson Institute for Bioelectronics, Northwestern University, Evanston, Illinois, USA

⁶Division of Electrical Engineering, Hanyang University - ERICA Campus, Ansan, The Republic of Korea

⁷Electrical and Computer Engineering Department, UC Davis College of Engineering, Davis, California, USA

Contributors SS is responsible for the overall content as guarantor. All authors have met authorship requirements. Specifically, SS, SP, JY, YD, SO, HJ, TMS, KK, EL, CR, NK, AH, JR and DW-M made substantial contributions to conceptualisation, investigation, methodology design, project administration and study resources. SS, SP, JY, YD, SO, HJ, JM, BFL, HA, TMS, KK, EL, JG, CR, NK, AH, JR and DW-M contributed to data curation, formal analysis, interpretation of data and results and validation. SS, SP, JY, YD, SO, HJ, CR, NK, EL, AH, JR and DW-M contributed to software and data visualisation. SS, SP, JY, YD, SO, HJ, JM, BFL, HA, TMS, KK, EL, JG, CR, NK, AH, JR and DW-M drafted the article, revised it critically for intellectual content and editing and provided final approval of this version to be published. Research supervision was provided by SS, SP, JY, YD, SO, HJ, EL, CR, NK, AH, JR and DW-M. During the preparation of this work, YD and JR used open-source Python packages for signal processing, data loading, data labelling and Support Vector Machine modelling to classify the level of pain perceived by patients. Their approach involved inputs of limb movement, chest movement, heart rate and respiratory rate, all extracted from tri-axial acceleration data gathered from networked chest and limb sensors. After using this tool/service, the authors reviewed and edited the content as needed and took full responsibility for the content of the publication.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Consent obtained from parent(s)/guardian(s).

Ethics approval This study was approved by Ann & Robert H Lurie Children's Hospital of Chicago Institutional Review Board (#2018-1668). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. After the date of publication, de-identified data that do not violate confidentiality can be made available on reasonable request after signing a data use agreement. Data can only be used for research purposes and cannot be shared with a third party or involved with product-related work. Study documents and analyses code, including the study protocol, can be made available on reasonable request to the corresponding author.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <https://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iD

Susan Slattery <https://orcid.org/0000-0003-1894-0044>

REFERENCES

- 1 COMMITTEE ON FETUS AND NEWBORN and SECTION ON ANESTHESIOLOGY AND PAIN MEDICINE. Prevention and Management of Procedural Pain in the Neonate: An Update. *Pediatrics* 2016;137:e20154271.
- 2 McPherson C, Miller SP, El-Dib M, et al. The influence of pain, agitation, and their management on the immature brain. *Pediatr Res* 2020;88:168–75.
- 3 Maitre NL, Stark AR, McCoy Menser CC, et al. Cry presence and amplitude do not reflect cortical processing of painful stimuli in newborns with distinct responses to touch or cold. *Arch Dis Child Fetal Neonatal Ed* 2017;102:F428–33.
- 4 Maxwell LG, Fraga MV, Malavolta CP. Assessment of Pain in the Newborn: An Update. *Clin Perinatol* 2019;46:693–707.
- 5 Llerena A, Tran K, Choudhary D, et al. Neonatal pain assessment: Do we have the right tools? *Front Pediatr* 2022;10:1022751.
- 6 Arabiad D, Mörelius E, Hoti K, et al. Pain assessment tools for use in infants: a meta-review. *BMC Pediatr* 2023;23:307.
- 7 Giordano V, Edobor J, Deindl P, et al. Pain and Sedation Scales for Neonatal and Pediatric Patients in a Preverbal Stage of Development: A Systematic Review. *JAMA Pediatr* 2019;173:1186–97.
- 8 Hummel P, Lawlor-Klean P, Weiss MG. Validity and reliability of the N-PASS assessment tool with acute pain. *J Perinatol* 2010;30:474–8.
- 9 Morgan ME, Kukora S, Nemshak M, et al. Neonatal Pain, Agitation, and Sedation Scale's use, reliability, and validity: a systematic review. *J Perinatol* 2020;40:1753–63.
- 10 Benbrook K, Manworren RCB, Zuravel R, et al. Agreement of the Neonatal Pain, Agitation, and Sedation Scale (N-PASS) With NICU Nurses' Assessments. *Adv Neonatal Care* 2023;23:173–81.
- 11 Hoti K, Chivers PT, Hughes JD. Assessing procedural pain in infants: a feasibility study evaluating a point-of-care mobile solution based on automated facial analysis. *Lancet Digit Health* 2021;3:e623–34.
- 12 Manworren RCB, Horner S, Joseph R, et al. Performance Evaluation of a Supervised Machine Learning Pain Classification Model Developed by Neonatal Nurses. *Adv Neonatal Care* 2024;24:301–10.
- 13 Roué J-M, Morag I, Haddad WM, et al. Using sensor-fusion and machine-learning algorithms to assess acute pain in non-verbal infants: a study protocol. *BMJ Open* 2021;11:e039292.
- 14 Bellieni CV, Sisto R, Cordelli DM, et al. Cry Features Reflect Pain Intensity in Term Newborns: An Alarm Threshold. *Pediatr Res* 2004;55:142–6.



- 15 Runefors P, Arnbjörnsson E, Elander G, et al. Newborn infants' cry after heel-prick: analysis with sound spectrogram. *Acta Paediatr* 2000;89:68–72.
- 16 Oh S, Yoo J-Y, Maeng W-Y, et al. Simple, miniaturized biosensors for wireless mapping of thermoregulatory responses. *Biosens Bioelectron* 2023;237:115545.
- 17 Jeong H, Kwak SS, Sohn S, et al. Miniaturized wireless, skin-integrated sensor networks for quantifying full-body movement behaviors and vital signs in infants. *Proc Natl Acad Sci U S A* 2021;118:e2104925118.
- 18 Yoo J-Y, Oh S, Shalish W, et al. Wireless broadband acousto-mechanical sensing system for continuous physiological monitoring. *Nat Med* 2023;29:3137–48.
- 19 Chung HU, Rwei AY, Hourlier-Fargette A, et al. Skin-interfaced biosensors for advanced wireless physiological monitoring in neonatal and pediatric intensive-care units. *Nat Med* 2020;26:418–29.
- 20 Koo TK, Li MY. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. *J Chiropr Med* 2016;15:155–63.
- 21 Chen J, Abbot M, Shieh J-S. Pain and Stress Detection Using Wearable Sensors and Devices—A Review. *Sensors (Basel)* 2021;21:1030.
- 22 Selvanathan T, Zaki P, McLean MA, et al. Early-life exposure to analgesia and 18-month neurodevelopmental outcomes in very preterm infants. *Pediatr Res* 2023;94:738–46.
- 23 Hall RW, Anand KJS. Pain Management in Newborns. *Clin Perinatol* 2014;41:895–924.
- 24 Hummel P. Psychometric evaluation of the neonatal pain, agitation, and sedation (N-PASS) scale in infants and children up to age 36 months. *Pediatr Nurs* 2017;43:175.