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ORIGINAL ARTICLE

ALPS-Neo pain and stress assessment scale for neonates—A measure for procedural pain

Bente Johanne Vederhus[1] | Merete Susan Olsen[1] | Geir Egil Eide[2,3] | Hanne Storm[4] | Hans Jørgen Guthe[1]

[1]Department of Paediatric and Adolescent Medicine, Haukeland University Hospital, Bergen, Norway

[2]The Faculty of Health and Social Sciences, Western Norway University of Applied Sciences, Bergen, Norway

[3]Centre for Clinical Research, Haukeland University Hospital, Bergen, Norway

[4]The Skills Simulation Centre, The Acute Clinic, Oslo University Hospital, Oslo, Norway

Correspondence
Bente Johanne Vederhus, Department of Paediatric and Adolescent Medicine, Haukeland University Hospital, Bergen N-5021, Norway.
Email: bente.vederhus@helse-bergen.no

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Abstract

Aim: The aim of this study was to investigate psychometric properties, reliability and validity, of Astrid Lindgren and Lund Children's Hospitals Pain and Stress Assessment Scale for Preterm and Sick Newborn Infants (ALPS-Neo), as a measure for procedural pain.

Methods: This observational, prospective study with a repeated measures design, explored inter-rater reliability by two raters assessing 21 neonates during non-pain and pain events. Construct validity was explored, that is, ability to discriminate between non-pain and pain, and criterion validity by correlating ALPS-Neo with Premature Infant Pain Profile-Revised (PIPP-R) and Skin Conductance Algesimeter (SCA) in 54 neonates without ventilator support and sedation undergoing routine heel-stick procedure in a tertiary neonatal intensive care unit.

Results: Mean gestational and assessment age of 54 infants was 33.8 weeks and 12.7 days respectively. Inter-rater reliability from baseline, skin wiping, heel-stick events for 21 infants demonstrated intraclass correlations with 95% confidence intervals (CI) of 0.49 (−0.27 to 0.79), 0.86 (0.65–0.94) and 0.73 (0.34–0.89) respectively. ALPS-Neo discriminated significantly between baseline, non-pain and heel-stick (mean differences from pain event −2.3 and −1.0 respectively) and correlated during heel-stick with PIPP-R ($r = 0.56$, 95% CI: 0.34–0.72), not with SCA.

Conclusion: ALPS-Neo may be used as a measure for procedural pain.

KEYWORDS
ALPS-Neo, heel-stick, neonatal pain assessment, reliability, validity

1 | INTRODUCTION

Assessment and treatment of neonatal pain continues to be a challenge in neonatal intensive care units (NICU).[1] Procedures as part of the treatment, illness and daily care cause numerous events of pain and stress in the neonates. A systematic review examining exposure to, and treatment of pain, across NICUs in different countries, reported an average of 7–17 invasive procedures per day with heel lance, suctioning and venepuncture as the most frequent events.[2] Pain management was often inadequate, where a majority

Abbreviations: ALPS-Neo, Astrid Lindgren and Lund Children's Hospital Pain and Stress Assessment Scale for Preterm and Sick Newborn Infants; CI, confidence interval; CPAP, continuous positive airway pressure; GA, gestational age; ICC, intraclass correlation coefficient; NICU, neonatal intensive care unit; PIPP-R, premature infant pain profile-revised; SCA, skin conductance algesimeter; SD, standard deviation.

of included studies reported painful procedures performed in the absence of any analgesia.[2] The newborn infant, and especially preterms, are vulnerable to pain both in the short- and long-term run, and it may cause alterations in the pain sensitivity and stress response system.[3–7]

Therefore, it is essential that pain assessment is performed regularly, being the fifth vital parameter,[8] in order to assure optimal pain treatment. Since pain is a subjective phenomenon, self-reporting is considered to be the gold standard,[9,10] but is not an option for neonates. Alterations in the neonates' behaviour caused by pain may represent the infantile form of self-report.[10] Commonly used clinical pain assessment tools include behaviour as an indicator of neonatal pain in addition to physiological measures and contextual factors, defined as multidimensional and the recommended approach to neonatal pain assessment.[11] Although several observational pain scales have been developed for use in the neonatal population, counting around 40,[12] their psychometric properties have not been sufficiently evaluated for the specific population nor for different clinical situations.[12,13] This may impose a risk for over- and under-assessment of pain with unintentionally use of pain medication or absence of preventable pain relief.[12]

Observational pain assessment scales are normally developed for either acute procedural, continuous or post-operative pain. Continuous pain, embracing terms like persistent and prolonged,[14] have received lesser attention than procedural pain, which is reflected by the number of available assessment tools. A tool developed for measuring continuous stress and pain is the Astrid Lindgren and Lund Children's Hospital Pain and Stress Assessment Scale for Preterm and Sick Newborn Infants (ALPS-Neo), which is a unidimensional scale.[15] ALPS-Neo is commonly used by nurses in Sweden[16] and Norway,[17] also for procedural pain.[18] Concerning clinical feasibility, one tool for different pain situations would be ideal. ALPS-Neo has not being sufficiently validated, only reliability and face validity for continuous pain and stress evaluation have been investigated, which was found to be acceptable.[15] Subsequently, there is a need to investigate further the psychometric properties of this tool in different clinical conditions.

The aim of the present study was to investigate the reliability and validity of the Norwegian version of the ALPS-Neo as a measure of procedural pain, specifically the heel-stick procedure. We hypothesised that ALPS-Neo would be able to discriminate pain from a non-pain event and that it would correlate with other procedural measures of pain.

2 | PATIENTS AND METHODS

This was a prospective observational measurement study with a repeated measures design. The setting was a 16-bed, level III NICU at a Norwegian regional university hospital. Approximately 450 children are admitted to this unit every year, including sick term born infants and preterm infants, born after 23 weeks of gestational age (GA).

Key Notes

- The psychometric properties of ALPS-Neo is limited, and is absent when used for procedural pain.
- This study demonstrates beginning reliability and validity of ALPS-Neo as a measure for procedural pain.
- ALPS-Neo may be used for both continuous and procedural pain in preterm and sick term infants, making it possible to have only one observational tool for pain in neonatal intensive care units.

2.1 | Participants

We used a convenience sample of 55 neonates, both term (GA ≥37 weeks) and preterm (GA < 37 weeks) admitted to the NICU from February 2019 to June 2020. Exclusion criteria included conditions that could possibly interfere with the pain response: 1. morphine or other sedatives the last 72 h, 2. surgical intervention the last 7 days, 3. newborns treated with therapeutic hypothermia and 4. congenital heart failure.

2.2 | Measures

ALPS-neo was developed for continuous pain and stress evaluation in preterm and sick newborn infants. The scale takes into consideration the preterm born infants' behavioural responses to stress and pain according to the Newborn Individualized Developmental Care and Assessment Program (NIDCAP).[15] It is unidimensional with the following five items: facial expression, breathing patterns, tone of extremities, hand/foot activity and level of activity. The items are scored along a scale from zero to two and summed up to a total of maximum 10 points. The scale includes a manual containing scoring instructions. Two neonatal nurses in a Norwegian NICU had translated ALPS-Neo from Swedish to Norwegian according to principles for cultural adaptation,[19] with a two-way translation process and finally accepted by one of the developers.

Premature Infant Pain Profile—Revised (PIPP-R) is a multidimensional pain assessment tool widely used to assess procedural pain with seven indicators; three behavioural (facial expression with brow bulge, eye squeeze, nasolabial furrow), two physiological (heart rate and oxygenation) and two contextual (GA and behavioural state).[20] PIPP-R has demonstrated acceptable psychometric properties.[20] Each indicator is scored along a 4-point scale from zero to three and summed up to a possible score from zero to maximum 18 for full term and 21 for preterm with GA < 28 weeks. We used the Norwegian version.[21] The PIPP-R may be considered as an observational 'gold standard' tool for procedural pain.

Skin Conductance Algesimeter (SCA) has the potential to evaluate the emotional stress response to a painful stimuli as it measures

changes in the skin conductance as a result of neurophysiologic arousal with increased sympathetic nervous activity causing palmar sweating.[22] The MedStorm Pain Monitor (Oslo, Norway) records changes in skin conductance, and number of peaks per second is recommended for use in neonates,[22] from 25 weeks GA.[23]

2.3 | Data collection

From blood sampling by the heel-stick procedure, we identified potential participants during ground rounds and collected informed consent from one of the parents.

Infants included were normally continuously monitored with registration of heart rate and respiration together with oxygen saturation. If the infant was not monitored, a minimum of 10 min before the procedure, the infant was connected to the monitor, and in addition, three small electrodes were positioned on the sole of one foot to measure the skin conductance. This was to secure that the infant would be at rest before beginning of the procedure. The infant's heart rate, oxygen saturation, and skin conductance values, and the infant's face and body expressions, were recorded by four video cameras simultaneously before and during the procedure. We recorded three events of 60 s each to be able to answer the aims of the study: baseline, disinfection of the heel, that is, skin wiping, representing the non-pain event and the heel-stick being the pain event. Standard care during the procedure was performed, that is, sucrose 2 min before heel-stick and if preferred, a pacifier during all events and positioning support by a parent or nurse.

Demographic and medical data were collected from the medical chart; gender, GA, postmenstrual age, current age, birth-weight and current weight and respiratory status.

2.4 | Assessment procedure

Four neonatal intensive care nurses, being experts with more than 20 years in the field, individually performed all evaluations of the recordings. PIPP-R baseline values were noted from the 15 first seconds of the video-recordings, and values for all the three measurements were assessed within 30 s following the baseline, the non-pain stimulus and the pain stimulus.

One nurse expert with extensive experience with the PIPP scored PIPP-R during the events. One nurse expert with knowledge of the MedStorm Pain Monitor assessed the skin conductance response, which was calculated as the maximum response, peaks/sec, during the events, as recommended by the developer. One nurse expert, being a NIDCAP observer, scored the ALPS-Neo during the events (rater 1).

For the purpose of *inter-rater reliability*, the 4th nurse expert (rater 2) scored independently ALPS-Neo for 21 randomly selected infants during the three events.

2.5 | Statistical analyses

We intended to examine inter-rater reliability, construct validity and criterion validity according to the taxonomy proposed by COSMIN (Consensus-based Standards for the selection of health Measurement Instruments).[24] *Construct validity* was evaluated by comparing ALPS-Neo scores during baseline, non-pain and pain event, that is, the ability of discriminating between non-pain and pain. *Criterion validity* was primarily evaluated by comparison of the ALPS-Neo and PIPP-R scores during the painful event, and by SCA as a secondary criterion.

We estimated sample size for the construct validity, which was calculated in the STATA program (StataCorp LP Statistics/Data Analysis) based on an expected effect size of 2 and standard deviation (SD) 2.9 on the PIPP-R for a two sample paired *t*-test yielding a sample size of 45 with a power of 90% and an α-value of 0.05. In case of missing data, 55 participants were included.

Descriptive statistics with means (SD) and counts *N* (%) were applied for demographic data. Intraclass Correlation Coefficient (ICC) comparing scores of the two nurses for 21 infants during the three events, analysed the inter-rater reliability for the ALPS-Neo scores. Criterion validity was analysed by Pearson's correlation coefficient (*r*) and construct validity by mixed linear modelling taking the dependence structure into account. The SPSS (Statistical Software for the Social Sciences) version 26 was applied.

2.6 | Ethics

The study was approved by the director of the Department of Paediatric and Adolescent Medicine, and the protocol was considered ethically sound by the Data Protection Official (Personvernombudet) and approved as a quality control project. One parent provided informed consent for their child to participate in the study with the information to withdraw at any time. The study was reviewed by the Regional Ethical Review Board in the region.

3 | RESULTS

One infant was excluded due to low data quality, leaving 54 infants included in the analyses of validity, except analyses of the SCA with 42 included due to artefacts causing low data quality. One neonate was assessed eligible though having received morphine within the last 72 h. The majority of the neonates were born preterm (44/54), with mean GA of 32.4 weeks. Mean age at assessment was 12.7 days. Approximately 15% received oxygen on nasal cannula or heated humidified high flow nasal cannula, none on ventilator support, nor continuous positive airway pressure (CPAP) (Table 1). Table 2 presents the inter-rater reliability of the two raters based on the three events (baseline, skin wiping, heel-stick) for 21 infants demonstrating ICC (95% CI) of 0.49 (−0.27 to 0.79), 0.86 (0.65–0.94) and 0.73

(0.34–0.89) respectively. The construct validity demonstrated by the ability of ALPS-Neo to discriminate between baseline, non-pain and pain was statistically significant with estimated mean difference from the pain event −2.3 and −1.0 respectively. Furthermore, ALPS-Neo correlated significantly during heel-stick with PIPP-R ($r = 0.56$, 95% CI: 0.34–0.72), however not with SCA (Table 3).

TABLE 1 Demographic and clinical characteristics of 54 infants in a validation study of ALPS-Neo.

Characteristics	Mean (SD)	Range
Gestational age weeks	33.8 (4.0)	26.5–42.3
Term born ($n = 10$)	40.0 (1.7)	
Preterm born ($n = 44$)	32.4 (2.9)	
Postmenstrual age (weeks)	35.7 (3.3)	30.1–43.0
Age at assessment (days)	12.7 (12.8)	1.0–49.0
Birth weight (g)	2254 (1029)	580–4730
Current weight (g)	2303 (862)	887–4395
	Number (%)	
Female	26 (48)	
Respiratory support at assessment—high flow or low flow oxygen cannula	8 (14.8)	

Abbreviations: ALPS-Neo, Astrid Lindgren and Lund Children's Hospitals Pain and Stress Assessment Scale for Preterm and Sick Newborn Infants; SD, standard deviation.

4 | DISCUSSION

This study investigated if ALPS-Neo is a reliable tool between observers and a valid tool for assessing procedural pain by evaluating two different measurement properties, that is, construct validity and criterion validity. We found that the ALPS-Neo demonstrated acceptable reliability and validity in the present clinical situations.

When evaluating the inter-rater reliability of ALPS-Neo, the ICC was applied with variable results for the observed events. Interpretation of the ICC is usually described as less optimal when the value is less than 0.5, moderate between 0.5 and 0.75, good between 0.75 and 0.9 and excellent above 0.9.[25] In this study, lowest ICC value was obtained for the baseline event when the infant was at rest and was according to guidelines poor and not significant. However, the 95% CI was wide, therefore may be described as poor to good. For the skin wiping, the ICC was good, but when including the CI in interpretation, the description varies from moderate to excellent. For the pain event, the ICC was moderate, but considering the CI, it is from poor to nearly excellent. It is difficult to understand the inconsistencies in scores dependent on the events. Reliability is, including the scale

TABLE 2 Inter-rater reliability for ALPS-Neo in 21 infants.

ALPS-Neo	Rater 1 ($N = 21$)		Rater 2 ($N = 21$)			
Measuring event	Mean (SD)	Minimum–maximum	Mean (SD)	Minimum–maximum	ICC, 95% CI	*p*-Value
Baseline	1.7 (1.5)	0–5	1.5 (1.1)	0–4	0.49 (−0.27, 0.79)	0.073
Skin wiping	2.2 (1.9)	0–5	1.7 (1.7)	0–5	0.86 (0.65, 0.94)	<0.001
Heel-stick	4.1 (1.8)	0–7	3.6 (1.7)	0–6	0.73 (0.34, 0.89)	0.002

Abbreviations: ALPS-Neo, Astrid Lindgren and Lund Children's Hospitals Pain and Stress Assessment Scale for Preterm and Sick Newborn Infants, score range 0–10, higher scores indicate more pain/stress; ICC, Intraclass Correlation Coefficient.

TABLE 3 Construct and criterion validity of the ALPS-Neo for 54 infants.

Events	ALPS-Neo, mean score (SD)	ALPS-Neo, minimum–maximum score	ALPS-Neo difference from pain event, mean, 95% CI	*p*-Value[a]
Baseline	1.7 (1.4)	0–5	−2.3 (−2.9, −1.7)	<0.001
Skin wiping	3.0 (2.2)	0–10	−1.0 (−1.6, −0.5)	0.001
Heel-stick	4.00 (2.1)[b]	0–8	0	
Comparing tools at heel-stick		**Minimum–maximum score**	**Pearson correlation coefficient**	***p*-Value**
PIPP-R score	6.8 (2.9)	1–14	0.56[b]	<0.001
SCA	0.27 (0.2)	0.00–0.60	−0.01[c]	0.976

Abbreviations: ALPS-Neo, Astrid Lindgren and Lund Children's Hospitals Pain and Stress Assessment Scale for Preterm and sick Newborn Infants, range score 0–10, higher scores indicate more pain/stress; PIPP-R, Premature Infant Pain Profile – Revised, range score 0–18 (21), higher scores indicate more pain; SCA, Skin conductance algesimeter.

[a]From mixed linear model of analysis.

[b]Missing = 1.

[c]Missing = 12.

itself, dependent upon the context, the assessor and the infant.[26] One possible explanation is that a more pronounced behaviour, as expected during skin wiping and heel-stick, will more likely correlate the assessments. Observational scales are subjective in a way that may influence the results. When comparing our results to the primary article of ALPS-Neo,[15] it is difficult to conclude due to different set-ups. The original set-up comprised three different reliability tests, one video test with 25 sequences assessed by 25 nurses, which reached unsatisfactory results with the weighted kappa. Two different real-time assessment in two different NICUs with several nurses involved, demonstrated good ICC.[15] The present study used video assessment, and implies several opportunities for reviewing the different events, which is not the case for real-time assessment. When assessing ALPS-Neo, other vital signs and environmental aspects are important to consider along with the behavioural signs, underlined in the two real-time assessments.[15] This was not considered in the present study, and it might have influenced the results. Nevertheless, the reliability of ALPS-Neo was satisfactory. Together with the study of Lundqvist et al.,[15] the reliability of the scale is strengthened.

When applying a tool to assess neonatal pain and stress, it is important that it captures the phenomenon. This may be investigated by different psychometric properties. Optimal pain assessment is essential to optimal pain management; therefore, it is important that neonatal nurses have the right knowledge and skills to use the right tool for clinical practice. It is challenging to succeed, and one possible reason is the need for different tools depending on the pain condition, that is, acute or more prolonged/continuous pain. From a clinical point of view, it would be feasible and an advantage with one tool covering different pain situations, even though not recommended due to possibly different pain responses to the pain conditions.[1,14,27] However, another observational scale, the Neonatal Pain, Agitation, and Sedation Scale (N-PASS) was developed to assess both prolonged and acute-procedural pain and has been validated for both pain situations.[28] We know that ALPS-Neo is used also as a measure of acute pain, and therefore, it is important to examine the validity. To be able to answer this question, both construct and criterion validity were investigated. Construct validity was significant in the way that ALPS-neo was able to discriminate between the non-pain and the pain event. However, the figures were small where estimated mean difference between skin wiping and heel-stick was only one. Altogether low scores for the pain event, being a mean of four, may explain this. The exact figure for an acceptable difference between pain and non-pain on a scale from 0 to 10 is not known. According to the ALPS-Neo manual, scores below four are acceptable, and equal to and above four require interventions. Altogether, the construct validity was satisfactory.

PIPP-R was the primary criterion when assessing criterion validity. There was a positive correlation between ALPS-Neo and PIPP-R, which was acceptable, and statistically significant. This coincides well with the results reported from the validity study of the N-PASS.[29] In that study, PIPP-R was used also to establish criterion validity, and the scores of N-PASS and PIPP-R correlated significantly during a heel-stick procedure.[29]

The pain scores of ALPS-Neo and SCA did, however, not correlate. The SCA is an objective physiological response to painful stimuli based on skin sympathetic nerve activity mirrored by changes in skin conductance, and it reacts within a few seconds to a painful stimulus, also in infants from 27 weeks GA.[22,23] To be noticed is that SCA and observation tools assess the pain response differently in the body, and therefore, it might not be expected that the SCA measure would correlate with ALPS-Neo. Still, the SCA was found to correlate during venepuncture, in healthy full-term neonates, with the Neonatal Facial Coding System, another behavioural measure of pain.[30] A limitation of the present study was the challenge with artefacts of the SCA, resulting in unreliable values and subsequently, several missing observations.

The strength of this study was an acceptable sample size and the repeated measures design, that is, each neonate serves as its own control. Included neonates represented the general population in a NICU, being both preterm and term born. However, we were not able to include the extreme preterm born infants in their first weeks of life due to the set-up and the challenge to capture their behavioural signs when on CPAP or ventilator in an incubator. This was a weakness of the study, which must be investigated in future studies. ALPS-Neo may be an insufficient tool to measure pain in sedated ventilated neonates, a concern also expressed by the developers and it is necessary to develop the tool further.[15] A major limitation of the study-set up was the inability to blind the assessors to the events, which potentially could have influenced scores.

5 | CONCLUSION

ALPS-Neo has demonstrated acceptable reliability and beginning validity as a tool to measure procedural pain, in non-sedated neonates. With the opportunity to apply only one observational pain tool, neonatal pain assessment may be more feasible and performed more regularly.

AUTHOR CONTRIBUTIONS

Bente Johanne Vederhus (BJV) had primary responsibility for protocol development, patient screening, enrolment, outcome assessment, preliminary and final data analysis and writing of the manuscript. Merete Susan Olsen (MSO) participated in the development of the protocol, patient screening, enrolment, outcome assessment, preliminary and final data analysis and contributed in writing of the manuscript. Geir Egil Eide (GEE) participated in the development of the protocol, participated in and supervised the data analyses and contributed in writing of the manuscript. Hanne Storm (HS) participated in the development of the protocol and contributed in writing of the manuscript. Hans Jørgen Guthe (HJG) participated in the development of the protocol and contributed in writing of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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ORCID

Bente Johanne Vederhus https://orcid.org/0000-0002-7540-5972

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