Published in final edited form as:

Clin J Pain. 2009 February ; 25(2): 146–152. doi:10.1097/AJP.0b013e3181839ac4.

CRITERION AND CONVERGENT VALIDITY FOR FOUR MEASURES OF PAIN IN A PEDIATRIC SICKLE CELL DISEASE POPULATION

Catherine B. McClellan, Ph.D.¹, Jeffrey C. Schatz, Ph.D.¹, Teresa R. M. Mark, B.S.², Alvin McKelvy, B.S.², Eve Puffer, M.A.¹, Carla Roberts, M.D.³, and Sarah M. Sweitzer, Ph.D.²

¹Department of Psychology, University of South Carolina

²Department of Pharmacology, Physiology, Neuroscience, University of South Carolina

³Department of Pediatrics, University of South Carolina School of Medicine

Abstract

Objective—To evaluate the psychometric properties of four measures of acute pain in youths with sickle cell disease (SCD) during a medical procedure.

Methods—Heart rate, child self-report, parent proxy-report, and observable pain behaviors were examined in 48 youths with SCD ages 2–17 years. Criterion validity for acute pain was assessed by responsiveness to a standardized painful stimulus (venipuncture) in a prospective pre-post design. Convergent validity was evaluated through the correlation across measures in reactivity to the stimulus.

Results—Child self-reported pain, parent proxy-report, and behavioral distress scores increased in response to venipuncture (concurrent and convergent validity). In contrast, heart rate did not reliably change in response to venipuncture. Extent of change in response to venipuncture showed moderate inter-correlation across child and parent pain ratings, and behavioral distress. Pre-procedure pain ratings correlated with pain experienced during the procedure. An item analysis of observable pain behaviors suggested differences in the presentation of pain in SCD compared with previous pediatric research.

Conclusions—Criterion and convergent validity were demonstrated for child-report, parent-report, and observable pain behaviors. These measures appear to tap into distinct, yet overlapping aspects of the pain experience. Assessment of acute procedural pain responses in SCD requires evaluation of pre-procedural pain due to the frequent presence of low-level, baseline pain.

Keywords

sickle cell disease; pain assessment; procedural pain; multi-method assessment; validity

Introduction

Pain is the single most common reason for medical care in the sickle cell disease (SCD) populations and has been described as the hallmark feature of the disease.¹ Pain in patients with SCD is typically conceptualized as the pain associated with vaso-occlusive events; however, research demonstrates that in addition to recurrent periods of vaso-occlusive pain,

youth with SCD also experience elevated rates of daily chronic pain.² Routine medical management of SCD also results in increased frequency of acutely painful medical procedures, including venipunctures for health maintenance, IV starts, and immunizations to reduce risk of infection.³ Given the prominence of pain in SCD, the documented under-treatment of pain in patients with SCD is striking.⁴⁻⁶

The accumulated pain histories of patients with SCD has the potential to impact how children use the self-report scales, their expectancies and anxiety for future pain experiences, and how they react to future pain experiences. For example, researchers have demonstrated that under-treated procedural pain can result in elevated pain ratings for future painful procedures even with the use of pain management interventions.⁷ Furthermore, because persons with SCD experience recurrent and chronic pain, they may experience elevated baseline pain prior to acute painful medical procedures, potentially impacting the validity of these measures of acute pain. For example, youth presenting with pain frequently undergo procedures to start an intravenous line for pain medications and hydration. Without established and valid methods to assess procedural pain patients with SCD may be more likely to experience inadequate pain management.

Research has also demonstrated that belonging to an ethnic minority group, as is the case for the majority of persons with SCD, in itself increases the chances of receiving substandard pain management.^{8,9} Minority groups in general and patients with SCD in particular have been historically underserved by the health care system, resulting in a distrust of the health care system.¹⁰ This sense of distrust may further complicate accurate pain reporting during painful medical procedures.

Poorly managed procedural pain can lead to increased procedure-related anxiety and resistance behaviors in children during painful medical procedures. This resistance can increase the distress and frustration experienced by both parents and healthcare providers during painful medical procedures. This resistance can also extend the duration and intensity of the procedure. Effective procedural pain management is essential to ensure adherence to the increased number of painful medical procedures required for health maintenance in the pediatric patients with SCD and to create a cooperative and trusting relationship between health care providers, patients, and their families.

Adequate pain assessment in the form of reliable and valid measurement is an important first step in improving the pain management received by patients with SCD. The use of valid and reliable pain assessment tools allows for improved pain assessment and is necessary to evaluate pain management interventions. Pain management guidelines emphasize the importance of assessing pain via multiple methods to ensure adequate and reliable pain ratings.¹¹ While a single physiological marker of vaso-occlusive pain has yet to be identified, hematocrit, a measure of anemia severity, has been demonstrated to have a significant negative correlation with pain rate in children with SCD.¹² Multimodal assessment is of particular importance when working with pediatric patients with SCD, as parents frequently serve as proxy-reporters of their child's pain when the child is too young or otherwise unable to report on their pain. Researchers have demonstrated good agreement between self, parent and physician reported SCD pain using the Visual Analog Scales (VAS) of the Pediatric Pain Questionnaire (PPQ).^{13,14} This work provides validation for pain assessment tools used to assess recurrent SCD pain, but does not reflect procedural pain assessment during times of acute pain, such as venipuncture and IV starts. Acute procedural pain is qualitatively different from the recurrent vaso-occlusive and chronic pain experienced by patients with SCD in that it is time limited, intrusive, and occurs exclusively in a health care setting.

Procedure related pain, such as pain experienced during venipuncture or immunizations, has been widely used in the development and evaluation of pain measurement tools.¹⁵ Such experiences are well suited to the development of pain measurement tools as they are generally time-limited, have discrete phases, and allow for both objective and subjective ratings of pain thus facilitating validity assessment through pain responsiveness. Researchers evaluating the validity of pain ratings during procedural pain experiences using multiple data sources have found differing degrees of correspondence between these measures. Parent and child-reported pain using a variety of measures (Oucher, VAS, FACES) generally demonstrate good correspondence in research conducted with children receiving routine immunizations and in children with cancer receiving venipunctures.¹⁶⁻¹⁷ The correspondence between other measures, such as observational assessment and nurse report is somewhat more variable. Several studies have shown that nurse report tends to underestimate pain and demonstrate poor correspondence with child-report in young children undergoing routine immunizations;^{16, 18} though other work has demonstrated adequate correspondence between these measures.¹⁷ Observational measures of procedural pain have been found to generally correspond well to child-reported pain.¹⁸

Because of the unique disease-related pain experiences of patients with SCD, it is problematic to assume that measures validated with the general population have similar validity for this population. The goal of the current investigation is to evaluate the validity of four measures of procedural pain with a population of pediatric patients with SCD. Procedural pain in response to venipuncture was employed, as all patients seen at our site receive venipunctures as part of their routine health maintenance. Based on other research demonstrating the validity of self, parent, physiological (heart rate) and observational measures of pain, we hypothesized: 1) That all four of these measurement methods would demonstrate criterion validity by showing change in response to venipuncture pain, and 2) That the magnitude of the change in response to the stimulus ("reactivity") will be positively inter-correlated across all four measures, showing convergent validity.

Materials and Methods

Sample

Participants were 48 children and adolescents with SCD ranging in age from 2 to 17 years receiving routine venipuncture as part of health maintenance visits. Infants were not recruited due to the rarity with which they receive venipuncture. All participants were recruited from a Hematology Clinic located in Columbia, South Carolina over a 9-month period. Of the 52 families approached, four families refused to participate, citing insufficient available time (2 parents), unwillingness to have the procedure captured on videotape (1 parent), and no reason (1 parent). Exclusionary criteria for this study were history of overt stroke or consumption of narcotic pain medication within the previous 7 days. In addition, participants between the ages of 10-12 years (a transition period between pre- and post-pubescence) were excluded to meet separate study goals of a larger project from which this sub sample was drawn. Table 1 provides information on participant and family demographics.

Measures

Heart Rate—Heart rate has shown validity as a method of assessing pediatric pain for the general pediatric population.¹⁹ A Tanita Pulse Monitor®, which is an electric heart rate monitor, was used to assess participant heart rate as an indicator of physiological changes in response to venipuncture. Pulse is measured by having the child place their fingertip over the sensor for a 10 second period while the phlebotomist holds the monitor and then records the results provided by the digital display. The monitor provides an average of the pulse rate for the 10 second period and has an accuracy of plus or minus 5%. Baseline heart rate was assessed

when the child was checked for vital signs by a nurse at the beginning of the medical appointment for that visit (approximately 45 minutes prior to blood draw). Pre-venipuncture heart rate was assessed immediately prior to the venipuncture by the phlebotomist and post-venipuncture heart rate was assessed approximately 30-60 seconds following the venipuncture by the phlebotomist.

Child-Reported Pain Ratings—Self-report of baseline (pre-venipuncture) and procedural (post-venipuncture) pain were obtained for children 5-years-old and older using a Wong-Baker Faces scale.²⁰ The Faces scale is a reliable six-point scale with cartoon faces used as anchors. It is a valid method of child self-reported pain for children within this age range.²¹ The range of possible scores is between 0 to 10. Research indicates that the Faces scale is the preferred method of assessing pain in pediatric SCD.²²

Parent-Reported Pain Ratings—Parent-report of child baseline (pre-venipuncture) and procedural (post-venipuncture) pain were obtained using a Visual Analog Scale (VAS). VASs are 100-mm horizontal lines with anchors of *no pain* and *worst pain possible*. The range of possible scores is between 0 to 100. Research has demonstrated VASs to be a valid method of pain assessment preferable to Likert type scales due to a more even distribution of scores.²³ In a sample of 25 youth with medical conditions resulting in pain, parent ratings of children's pain on a VAS correlate significantly with child report of pain ($r = .72, p < .001$), establishing its validity.²⁴

Observational Measure—A modified version of the Observational Scale of Behavioral Distress (m-OSBD) was used to evaluate videotaped recordings of child behavior during venipuncture. In a sample of 55 predominately Caucasian participants with pediatric leukemia 3-13 years in age with pediatric cancer the OSBD had statistically significant correlations with nine indicators of child distress, with correlations of .69 for nurse ratings of distress and .55 for procedural heart rate.²⁵ Cronbach's alpha ranged between .68 and .72, indicating generally acceptable levels of internal consistency. Instructions for the original OSBD included assigning weights to the individual behavior codes to reflect greater distress when certain behaviors are present, whereas for the m-OSBD distress behaviors are recorded and tallied without assigning weights. Research has shown that the original OSBD procedures do not provide significantly greater validity than those of the m-OSBD.²⁶ The m-OSBD assesses the presence or absence of 11 behavioral indicators of procedural distress (information seeking, crying, screaming, physical restraint, verbal resistance, seeking emotional support, verbal pain, flail, verbal fear, muscular rigidity, and nervous behavior) during the three phases of the procedure. Procedure phases include: (a) baseline (from the time the child sits in the chair to the time that the tourniquet is applied or the site is cleaned), (b) procedural (from the start of the skin cleaning/tourniquet application to the time when the needle is withdrawn), and (c) post-procedural (from the time that the needle is withdrawn to when the child leaves the chair or two minutes post-procedure, whichever comes first). Observational ratings had possible scores from 0 to approximately 528, depending on the length of the procedure and frequency of distress behaviors displayed.

Two undergraduate coders were trained to 95% inter-rater agreement using practice tapes. Following this training, inter-rater reliabilities for the m-OSBD were calculated for 30% of all videotaped observations and weekly review sessions were held to prevent coder drift. Percent agreement ranged from 93-100% agreement across the 11 behaviors, indicating excellent reliability as implemented in our lab. Researchers have recommended using percent agreement over Kappa to evaluate inter-rater agreement for low frequency behaviors.^{27,28}

Procedures

Study procedures were approved by the institutional review board for human subjects research prior to the recruitment of any participants. Participants who met eligibility criteria were identified through medical chart reviews of scheduled patients. Caregivers whose child met the inclusion criteria were presented with basic study information by the attending hematologist. Caregivers who indicated interest in the study were directed to a research assistant in the waiting room of the phlebotomy laboratory who explained the purpose of the study as a way for the medical community to gain a greater understanding of venipuncture pain and SCD pain. Potential risks and benefits to participation were reviewed with caregivers and participants using the consent form to structure this conversation. Consent was obtained from caregivers for all children. In addition, verbal assent was obtained from all participants over the age of 12 years. Caregivers were provided two copies of the consent form, one to sign and one for their personal records. After reading this form and receiving clarification on any questions or concerns about the study procedures and consent form, caregivers and participants completed the consent and assent forms. The research assistant then instructed caregivers and participants in the use of the VAS and Faces pain scales and clarified any questions participants had regarding these scales. Participants then completed the pre-venipuncture forms (parent and child-reports of baseline pain).

To minimize the disturbance to the clinic routine, the research assistant used a remote control to start video-recording the procedure before the child entered the room and stopped the recording after the child exited. Due to equipment malfunction, videotaped observations were not obtained for 4 participants. Upon return to the laboratory waiting room, participants completed the post-venipuncture measures (child and parent procedural pain ratings). Children and caregivers each received a \$5 gift card each as compensation for their participation.

Statistical methods

To test hypothesis one, criterion validity was evaluated by determining if each measure resulted in increased pain response from pre- to post-stimulus. The analyses of criterion validity were also examined within each of three age groups to assess whether the effects for the entire sample were also present within narrower age ranges. Baseline pain ratings for child-report, parent proxy-report, and observational distress ratings were examined with t-tests to determine if each measure differed from zero, suggesting the presence of baseline pain. Baseline pain ratings were also correlated with post-venipuncture measures to determine if post-stimulus measures are associated with baseline pain ratings.

To test hypothesis two, convergent validity was examined by assessing whether the extent of reactivity to the stimulus correlated across measures. Linear regression was used to compute a residual score for each post-stimulus measure that was independent of the pre-stimulus measure. In an effort to evaluate alternative explanations for the initial pattern of results, some additional analyses were preformed. First, partial correlations were also computed between pain measures controlling for current hematocrit as a global indicator of disease severity. The alpha level for tests was set at .05. Cronbach's alpha and an item analysis were also conducted with the m-OSBD scale to determine the scale's reliability. Finally, correlations between individual items and total score were examined as a measure of item-criterion correlation.

Analysis

Three of the four measures of pain (child-reported, parent-reported, and observational) demonstrated a significant positive skew in the distribution that did not conform to the assumption of normality. A log transformation procedure was performed to reduce the skew in these variables. Pre-venipuncture refers to the period just prior to the procedure. Post-venipuncture refers to child and parent ratings of the procedure immediately following the

procedure, heart rate taken immediately following the procedure, and observational pain assessment during the procedure phase of the venipuncture.

Results

Criterion validity

Hypothesis one states that venipuncture would produce reliable and measurable changes in child pain report, parent proxy pain report, behavioral signs of distress, and an elevation in heart rate. Analyses indicated no significant differences between baseline and pre-procedural heart rate, $t(44) = 0.39$, $p = .70$, and a large correlation between these two measures, $r = .49$, $p < .01$. Pre-procedure heart rate was therefore used for further analyses. As shown in Table 2, child-report, parent-report, and observational measures all showed significant changes from pre- to post-venipuncture indicating sensitivity of the measures to procedural pain. Heart rate did not show the expected increase from pre- to post-venipuncture. These results show criterion validity in using child and parent pain reports and observational coding of distress as measures of acute procedural pain in children with sickle cell disease. In contrast, measuring changes in heart rate did not demonstrate validity as a marker of pain reactivity to acute procedural venipuncture across participants.

Criterion validity was further examined within each of three age groups: 2-4 years of age ("preschoolers"; $n = 12$), 5-9 years of age ("children"; $n = 16$), and 13-18 years ("adolescents"; $n = 20$). For preschoolers parent-report, $t(11) = 4.31$, $p < .01$, the m-OSBD, $t(11) = 3.86$, $p < .01$, and heart rate, $t(11) = 1.98$, $p < .05$, all showed pre- to post-venipuncture increases. Self-report was not measured in preschoolers. Children showed a similar pattern to the analyses across all participants with statistically significant pre- to post-venipuncture increases for self-report, $t(15) = 3.52$, $p < .01$, parent-report, $t(15) = 3.81$, $p < .01$, and the m-OSBD, $t(12) = 1.94$, $p < .05$, but not for heart rate, $t(14) = 0.57$, n.s. Adolescents showed pre- to post-venipuncture increases for self-report, $t(19) = 4.38$, $p < .01$, and parent-report, $t(18) = 3.28$, $p < .01$, but not for the m-OSBD, $t(18) = 0.33$, n.s., or heart rate, $t(18) = 1.32$, n.s. An item level examination of the m-OSBD for adolescents indicated reliable increases from baseline to venipuncture in only one of the eleven m-OSBD behaviors: verbal pain, $t(18) = 2.12$, $p < .05$.

Baseline pain ratings

This study found significant pain at baseline in this pediatric sickle cell population. Twenty-two percent of child self-reports, 40% of parent-report, and 54% of observational distress ratings indicated baseline greater than zero (Table 2). One-sample t-tests comparing baseline ratings to a value of zero indicated significant baseline pain according to child-report ($M = 0.7$, $t(36) = 2.84$, $p < .01$), parent-report ($M = 3.2$, $t(47) = 3.33$, $p < .01$), and observational distress ratings ($M = 5.1$, $t(42) = 2.69$, $p < .05$).

Baseline scores were correlated with post-venipuncture scores for heart rate, $r(45) = .35$, $p < .05$, child-report, $r(36) = .33$, $p < .05$, and observational distress ratings, $r(43) = .41$, $p < .01$. Baseline scores for parent ratings also showed a similar trend, $r(45) = .27$, $p < .08$, indicating that pre-procedure pain experience was related to post-procedure ratings of pain experienced during the venipuncture.

Magnitude of reactivity to stimulus

Hypothesis two stated that these four different measures of pain have convergent validity. An examination of scatterplots indicated the presence of outlier data points for these correlations. Therefore, Spearman rank order correlations were used to assess these associations. Extent of reactivity to the venipuncture was computed for each measure using residual scores from linear regression with post-stimulus measures as the dependent variable and pre-stimulus measures

as the independent variable. Results of the linear regression demonstrated that pre and post-stimulus were significantly correlated for child report [$R^2 = .11$, $F(1,34) = 4.10$, $p < .05$], observational ratings [$R^2 = .23$, $F(1,35) = 10.38$, $p < .01$], heart rate [$R^2 = .14$, $F(1,43) = 6.96$, $p < .05$], but not for parent ratings [$R^2 = .03$, $F(1,43) = 1.39$, $p = .24$]. As shown in Table 3, all comparisons showed statistically significant correlations with the exception of the correlation between heart rate and child-report.

Baseline pain scores were correlated with the residual scores, representing the extent of reactivity to the pain stimulus, to evaluate the relative impact of baseline pain on pain reactivity. All r values were less than .17 and all p values were greater than .36. These data suggest that baseline pain was related to post-procedural pain largely in an additive manner. That is, baseline pain measures correlated with the post-procedural pain measures, but did not relate to the extent of reactivity to the painful stimulus.

Given the significant heterogeneity in disease severity in SCD, partial correlations controlling for hematocrit percent were also conducted to determine if the observed correlations may have been related to differences in overall disease severity. The partial correlations indicated a significant association between heart rate and parent-report, $r(40) = .31$, $p < .05$, child-report and observational ratings, $r(28) = .57$, $p < .05$, and parent-report and observational ratings, $r(37) = .27$, $p < .05$. Thus, the significant convergence across the measures of pain reactivity appeared to be related to pain experience over and above what might be accounted for by differences due to disease severity within the sample.

Item analysis of behavioral distress

Item analysis of the m-OSBD scale was modeled after that reported by the developers of the scale.²⁵ Although there are no widely agreed upon standards for internal consistency, Cronbach's alpha values of $\geq .7$ are recommended for research purposes, with .70 indicating acceptable, .80 indicating moderate and .90 indicating high levels of internal consistency.^{29, 30} Using all 11 items of the scale the Cronbach's alpha values for baseline and procedural periods for our sample with SCD were .72 and .64, respectively, indicating acceptable levels of internal consistency for the scale for the baseline period. Item analyses indicated seven of the eleven items showed large correlations with the total score ($r \geq .50$) for both baseline and procedural periods (crying, screaming, physical restraint, verbal resistance, seeking emotional support, flail, and muscular rigidity). Information seeking, verbal pain, verbal fear, and nervous behavior all correlated less than $r = .16$ with total score. Excluding these four items the Cronbach's alpha values for baseline and procedural periods were .87 and .74, respectively indicating moderate and acceptable levels of internal consistency respectively. Excluding adolescent participants from this item-criterion analysis did not have a significant impact on the pattern or magnitude of the correlations.

Discussion

The goal of the current work was to investigate the validity of measures of acute procedural pain in the pediatric SCD population. Multimodal assessment of pain during venipuncture was used to establish criterion and convergent validity. Similar to other research investigating acute procedural pain in children, our results indicate good criterion and convergent validity for parent, child and observational assessment.²³ As in other research examining physiological indicators of distress, heart rate did not demonstrate strong indicators of validity.³¹ These results support the use of parent, child and observational assessment as a valid means to assess procedural pain in youth with SCD. The correspondence between parent and child ratings of pain is of particular importance, as parents of children with SCD are frequently called upon to provide proxy-reports of their child's pain. By including an assessment of baseline pain, we

were able to explore the role of pre-existing pain in how children with SCD experience procedural pain.

Methodological issues in pain assessment

This work represents an improvement over other procedural pain research by including observational assessment and baseline measures of pain. Including an observational measure of pain response allowed us to more fully evaluate the validity of parent and self-report measures of procedural pain in a pediatric SCD population. Elevated rates of baseline pain are likely to occur in SCD, as well as in other populations with acute pain due to trauma or ongoing health conditions, such as Polyarticular Arthritis.³² The current work found that baseline pain ratings generally correlated with ratings of procedural pain, indicating that baseline pain experience increases the peak level of reported pain during acute procedural events. In one of the few investigations of procedural pain that included a baseline assessment of self-reported pain, Goodenough and colleagues (1997) found that 12% of their physically healthy sample of children ages 4 to 6 years reported some degree of pain prior to their routine immunizations.¹⁸ The rate of baseline pain in the current sample (22-54% depending on the measure examined) was higher than that found by Goodenough and colleagues (1997). Although the baseline pain report might reflect measurement error rather than pain *per se*, the indications of low levels of pain or discomfort based on three converging measures (child-report, parent-report, and observable distress) strongly suggests that the child was experiencing a degree of discomfort prior to their procedural pain experience. The clinical significance of this baseline pain could be debated; however, assuming mild degrees of pain are not clinically significant runs counter to current recommendations for clinical pain management.³¹

The correlation observed between baseline pain and procedural pain could be due to a systematic bias from raters to provide higher ratings across situations. However, this explanation does not account for the same correlation found for observable distress behaviors. A more parsimonious explanation would be that baseline pain and procedural pain have an additive impact on total pain experienced during venipuncture.

Assessing baseline pain allows researchers to more accurately understand the factors contributing to the post-procedural pain ratings (e.g., pre-existing pain and actual procedural pain) and better understand relationships between these two sources of the child's pain experience. The present study suggested these two sources of pain are largely additive, that is, relatively independent. Further research is needed to examine whether this additive relationship holds true across different subgroups of individuals. For example, there may be differences across developmental stages in childhood or across individuals with differences in the extent of prior pain that alters the relationship between baseline pain and acute procedural pain.

Our analysis of the m-OSBD items suggested adequate internal consistency as a research tool and potential differences in the presentation of procedural distress for children with SCD compared with that reported for a predominantly Caucasian sample with leukemia. Elliott and colleagues also found that verbal fear and nervous behavior did not demonstrate adequate correlations with total scores for the m-OSBD; however, unlike our data muscular rigidity did not show adequate item-criterion correlation in their data.²⁵ Unlike the findings in the Elliott study our data indicated information seeking and verbal pain showed poor item-criterion correlation in our SCD sample. These data are suggestive that the behavioral content of procedural distress may differ between pediatric sickle cell disease and other pediatric populations. A more direct comparison of procedural distress across pediatric conditions and race/ethnicity groups is needed to better understand potential differences in the presentation of distress given that the prior study was conducted nearly 20 years ago with some minor methodological differences between our study procedures. We also found that the m-OSBD

may not be useful at the scale level for adolescents, although behavioral signs of distress from venipuncture were found for this age group for verbal expressions of pain or discomfort.

Heart Rate

The results did not generally support the criterion validity of our heart rate procedures. Limitations inherent in the methods used to obtain heart rate may provide a possible explanation for these results.¹⁹ The pre and post-procedures measurements of heart rate, while similar to those employed by other researchers, could have provided too few data points to serve as a valid method of assessment physiological pain response. Additionally, the precise time window of these assessments may have differed across participants. For example, venous access can be highly variable and result in a longer procedure for some participants. Age-related differences in the timing of heart rate reactivity may have also influenced the current results as suggested by the pre-post changes in heart rate for preschoolers but not for older children and adolescents. Thus, the utility of changes in heart rate as a physiological measure of pain is uncertain. Future work should include continuous assessment of heart rate over the course of the procedure to allow for a more precise and complete analysis of physiological response to venipuncture pain.

Limitations

The study findings should be considered in light of some limitations. First, the current work included children across a broad age range. Given developmental differences in children's pain experience, validating these measures across narrower age bands is needed; our ability to examine validity within narrower age groups was limited by the current sample size. Although the present report accounted for baseline pain level prior to venipuncture, the role of prior pain history was not examined. Given the established connection between prior pain experiences and increased sensitivity to future pain, future work is needed to evaluate the role of pain history in reactivity to procedural pain. Additionally, research investigating cultural differences in pain experiences has suggested that African-American adults differ from European-American adults in the way they employ standardized pain assessment tools to report on chronic pain experiences.³⁴ The present report indicates the validity of these pain assessment tools in a sample of African-American children with SCD; however, the present study does not inform us as to whether these tools are used differently in this population than in other populations. Additional research is needed to provide direct comparisons between youth and parent-report of procedural pain between ethnic minority and majority groups, and groups with and without chronic pain conditions to clarify differences in the use of these tools. Future research should also focus on the factors that mediate procedural pain experiences in youth with SCD.

Conclusions

Procedural pain experiences in youth with SCD is an under investigated area. Researchers have demonstrated good agreement between self, parent and physician reported SCD pain using the Visual Analog Scales (VAS) of the Pediatric Pain Questionnaire (PPQ).^{19,14} This work provides validation for pain assessment tools used to assess recurrent SCD pain, but does not tell us about pain assessment during times of acute pain, such as IV starts. Because of the unique pain history experienced by patients with SCD and the presence of elevated baseline levels of pain, it is problematic to assume that measures validated with the general population have similar validity for this population. Specifically, evaluating variables such as child age, frequency of procedural and SCD pain experiences, and use of coping methods may be helpful in identifying factors that predict increases in procedural pain. In the present study we establish criterion and convergent validity for child-report, parent-report and observational measures of procedural pain in a pediatric SCD population. This work also demonstrates the importance of

assessing baseline pain in children undergoing painful procedures. These assessment methods are an essential component to refining pain management interventions for pediatric SCD and determining the best methods of implementing such interventions.

Acknowledgments

We thank the children and families who participated in this research and Nathan Jones, Jeet Guram, Rabiah Ali, and Brad Peper for their assistance in data collection, coding and management.

This study received support from the following programs: USC Magellan Scholars Program (TRMM); USC School of Medicine Translational Research Grant (SMS, CR); USC School of Medicine Department of Pharmacology, Physiology, and Neuroscience Seed Grant for Translational Research (SMS, JCS); National Institutes of Health Grants R25-GM066526-SC Post-Baccalaureate Education Program for Minorities (ADM), and the Pfizer Fellowship in Health Disparities (CBM).

References

1. Shapiro BS, Dinges DF, Orne EC, et al. Home management of sickle cell-related pain in children and adolescents: Natural history and impact on school attendance. *Pain* 1995;61:139–44. [PubMed: 7644237]
2. Dampier C, Ely B, Brodecki D, et al. Characteristics of pain managed at home in children and adolescents with sickle cell disease by using diary self-reports. *J Pain* 2002a;3:461–70. [PubMed: 14622732]
3. American Academy of Pediatrics. Health supervision for children with sickle cell disease. *Pediatrics* 2002;109:526–35. [PubMed: 11875155]
4. Alleyne J, Thomas VJ. The management of sickle cell crisis pain as experienced by patients and their carers. *J Adv Nurs* 1994;19:725–32. [PubMed: 8021394]
5. Maxwell K, Streetly A, Bevan D. Experiences of hospital care and treatment seeking for pain from sickle cell disease: qualitative study. *BMJ* 1999;318:1585–90. [PubMed: 10364116]
6. Jacob E, Miaskowski C, Savedra M, et al. Quantification of analgesic use in children with sickle cell disease. *Clin J Pain* 2007;23:8–14. [PubMed: 17277639]
7. Weisman SJ, Bernstein B, Schechter NL. Consequences of inadequate analgesia during painful procedures in children. *Arch Pediatr Adolesc Med* 1998;152:147–9. [PubMed: 9491040]
8. Green CR, Anderson KO, Baker TA, et al. The unequal burden of pain: confronting racial and ethnic disparities in pain. *Pain Med* 2003;4:277–94. [PubMed: 12974827]
9. Todd KH, Deaton C, D'Adamo AP, et al. Ethnicity and analgesic practice. *Ann Emerg Med* 2000;35:11–6. [PubMed: 10613935]
10. Armstrong K, Ravenell KL, McMurphy S, et al. Racial/ethnic differences in physician distrust in the United States. *Am J Public Health* 2007;97:1283–1289. [PubMed: 17538069]
11. American Academy of Pediatrics. Committee on Psychosocial Aspects of Child and Family Health: The assessment and management of acute pain in infants, children and adolescents. *Pediatrics* 2001;108:793–797. [PubMed: 11533354]
12. Al-Haggag M, Al-Marsafawy H, Abdel-Razek N, et al. Acute painful crises of sickle cell disease in Egyptian children: Predictors of severity for a preventive strategy. *Int J Hematol* 2006;83:224–228. [PubMed: 16720552]
13. Graumlich SE, Powers SW, Byars KC, et al. Multidimensional assessment of pain in pediatric sickle cell disease. *J Pediatr Psychol* 2001;26:203–14. [PubMed: 11329480]
14. Walco GA, Dampier CD. Pain in children and adolescents with sickle cell disease: a descriptive study. *J Pediatr Psychol* 1990;15:643–58. [PubMed: 2283573]
15. Blount RL, Cohen LL, Frank NC, et al. The Child-Adult Medical Procedure Interaction Scale-Revised: an assessment of validity. *J Pediatr Psychol* 1997;22:73–88. [PubMed: 9019049]
16. Schneider EM, LoBiondo-Wood G. Perceptions of procedural pain: parents, nurses, and children. *Child Health Care* 1992;21:157–62. [PubMed: 10120457]
17. Manne SL, Jacobsen PB, Redd WH. Assessment of acute pediatric pain: do child self-report, parent ratings, and nurse ratings measure the same phenomenon? *Pain* 1992;48:45–52. [PubMed: 1738574]

18. Goodenough B, Kampel L, Champion GD, et al. An investigation of the placebo effect and age-related factors in the report of needle pain from venipuncture in children. *Pain* 1997;72:383–91. [PubMed: 9313279]
19. Sweet, SD.; McGrath, PJ. Physiological Measures of Pain. In: Finley, GA.; P.J. McGrath, PJ., editors. *Measurement of Pain in Infants and Children, Progress in Pain Research and Management*. Vol. Vol. 10. IASP Press; Seattle: 1998. p. 59-81.
20. Wong DL, Baker CM. Pain in children: comparison of assessment scales. *Pediatr Nurs* 1988;14:9–17. [PubMed: 3344163]
21. Bieri D, Reeve RA, Champion GD, et al. The Faces Pain Scale for the self-assessment of the severity of pain experienced by children: development, initial validation, and preliminary investigation for ratio scale properties. *Pain* 1990;41:139–50. [PubMed: 2367140]
22. Luffy R, Grove SK. Examining the validity, reliability, and preference of three pediatric pain measurement tools in African-American children. *Pediatr Nurs* 2003;29:54–9. [PubMed: 12630508]
23. McGrath, PJ. *Pain in Children: Nature, assessment, and treatment*. Guilford Press; New York: 1990.
24. Varni JW, Thompson KL, Hansen V. The Varni/Thompson pediatric pain questionnaire. I. Chronic musculoskeletal pain in juvenile rheumatoid arthritis. *Pain* 1987;28-27, 38.
25. Elliott CH, Jay SM, Woody P. An observation scale for measuring children's distress during medical procedures. *J Pediatr Psychol* 1987;12:543–51. [PubMed: 3430286]
26. Jay SM, Elliot C. Behavioral observation scales for measuring children's distress: The effects of increased methodological rigor. *J Cons Clin Psych* 1984;52:1106–1107.
27. Uebersax JS. Validity inferences from interobserver agreement. *Psych Bull* 1988;104:405–416.
28. Cicchetti DV, Feinstein AR. High agreement but low kappa: II. Resolving the paradoxes. *J Clin Epidemiol* 1990;43:551–558. [PubMed: 2189948]
29. Clarke LA, Watson D. Constructing validity: Basic issues in objective scale development. *Psychological Assessment* 1995;7:309–319.
30. Groth-Marnat, G. *Handbook of Psychological Assessment*. Vol. 4th edition. John Wiley & Sons; Hoboken, NJ: 2003.
31. Buttner W, Finke W. Analysis of behavioural and physiological parameters for the assessment of postoperative analgesic demand in newborns, infants and young children: a comprehensive report on seven consecutive studies. *Paediatr Anaesth* 2000;10:303–318. [PubMed: 10792748]
32. Schanberg LE, Anthony KK, Gil KM, et al. Daily pain and symptoms in children with polyarticular arthritis. *Arthritis and Rheumatism* 2003;48:1390–1397. [PubMed: 12746912]
33. Quality improvement guidelines for the treatment of acute pain and cancer pain. American Pain Society Quality of Care Committee. *Jama* 1995;274:1874–1880. [PubMed: 7500539]
34. Cassisi JE, Umeda M, Deisinger JA, et al. Patterns of pain descriptor usage in African Americans and European Americans with chronic pain. *Cultur Divers Ethnic Minor Psychol* 2004;10:81–9. [PubMed: 14992632]

Table 1

Descriptive information for the study sample (N = 48).

Variable	Descriptive data
Age (years)	M = 9.6; SD = 5.1 Range = 2.1 - 17.8
Gender (males : females)	24 : 24
Insurance type	
Medicaid only	n = 26 (54%)
Medicaid and private	n = 8 (17%)
Private only	n = 11 (23%)
None	n = 3 (6%)
Current hematocrit percentage	M = 27.5 SD = 4.8 Range = 17.3 - 44.6
Prior transfusion(s)	N = 22 (46%)
History of:	
Acute chest syndrome	n = 15 (31%)
Sepsis	n = 1 (2%)
Aplastic crisis	n = 4 (8%)
Priapism	n = 5 (10%)

Table 2
Pre-post venipuncture values for the measures of pain response.

Measure	Pre-Venipuncture			Post-Venipuncture			Paired t-test
	M	SD	Range	M	SD	Range	
Heart rate (n = 45; beats/minute)	92.0	(21.2)	54-147	96.5	(31.3)	40-182	$t(44) = 0.99$
Child report (n = 36; Faces scale)	0.7	(1.5)	0-6	3.2	(2.8)	0-10	$t(35) = 5.41^*$
Parent proxy report (n = 45; Visual analogue scale)	3.2	(6.6)	0-25	29.5	(28.7)	0-100	$t(44) = 6.25^*$
Observational rating (n = 43; m-OSBD system)	5.1	(12.5)	0-79	15.8	(26.3)	0-108	$t(42) = 3.43^*$

Notes: Degrees of freedom and n's differ due to missing data points for individual children.

* $p < .01$

Table 3

Associations across pain assessment methods for the extent of pre-post change to the painful stimulus.

Variable	1.	2.	3.
1. Heart rate	-		
2. Child self-report	.19	-	
3. Parent proxy report	.38 [*]	.43 [*]	-
4. Observational rating	.33 [*]	.40 [*]	.33 [*]

Spearman rank-order correlations were used due to the presence of outlier variables.

* Notes: $p < .05$.