



Original Article

Painful procedures and analgesia in hospitalized newborns: A prospective longitudinal study



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A B S T R A C T

Objective: To identify the type and frequency of stressful and painful procedures, the use of pharmacological and non-pharmacological strategies; to identify relationships between demographic and clinical variables with frequency of procedures and pain management.

Design: A prospective longitudinal study was conducted in neonatal intensive care units (NICU) of two hospitals in the city of Belo Horizonte, Brazil. 140 newborns admitted to the NICU between June 2014 and January 2015 were included.

Results: A total of 21,291 procedures were documented, 18,131 (85.2%) stressful procedures and 3,160 (14.8%) invasive skin-breaking painful procedures. Each day of hospitalization increased by 10.9 the number of stressful procedures and by 2.2 the number of painful procedures. Furthermore, for each day of hospitalization, non-pharmacological strategies registered increased by 3.4% and pharmacological strategies, increased by 9.3%.

Conclusion: Neonates underwent a high number of stressful and painful procedures and with infrequent use of pharmacological and non-pharmacological strategies during the entire hospitalization.

Introduction

Newborns admitted to neonatal intensive care units (NICU) are exposed to a high numbers of painful skin breaking procedures such as heel lance and venipuncture, and stressful interventions such as handling. Early life exposure to untreated pain can negatively impact on postnatal growth and brain development, and may affect attention, cognitive, emotional and motor progress (Valeri et al., 2015). Furthermore, a cohort study demonstrated painful procedures were associated with decreased weight gain and head circumference gain in 78 very preterm newborns (< 32 weeks of gestational age) hospitalized in an NICU (Vinall et al., 2012).

However a systematic review of studies conducted worldwide demonstrate that procedural pain prevention and management in newborns is suboptimal (Cruz et al., 2016), and studies published more recently continue to demonstrate similar results (Courtois et al., 2016a, 2016b). However there is little known about the epidemiology of neonatal pain in the Brazilian context (Bonutti et al., 2017; Linhares et al., 2012; Nóbrega et al., 2007; Sposito et al., 2017).

Although the length of hospitalization in NICU may vary from days

to months according to newborns' clinical conditions, the majority of prior studies conducted in developed and developing countries have evaluate pain exposure and pain management practices during the first days of life only (Cruz et al., 2016). Therefore, examining the epidemiology of procedural pain and pain management and exploring the relation between painful procedures and neonatal demographic and clinical variables can contribute to the knowledge base concerning the true burden of pain for sick infants, and inform the creation and implementation of strategies to improve neonatal pain outcomes throughout the hospitalization.

The aims of this study were to identify the type and frequency of stressful and painful procedures, the use of analgesic and comforting strategies for newborn comfort and pain relief, and to identify relationships between demographic and clinical variables with frequency of procedures and pain management during the course of newborns' hospitalization.

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Materials and methods

Design

This is a prospective longitudinal study.

Setting, and ethics

This study was conducted in the NICUs of two different institutions, the Hospital Sofia Feldman and the Maternidade Odete Valadares. Both institutions are public teaching hospitals specialized in women and newborn health care, and located at the city of Belo Horizonte, Brazil. In 2014, a total of 1,104 newborns were admitted to the NICU at Hospital Sofia Feldman, with an average length of stay of 14 days. During the same year, a total of 894 newborns were admitted at the NICU of the Maternidade Odete Valadares, being the average length of stay of 15 days. Protocols or guidelines for neonatal pain management were not available at any of the institutions during data collection period.

The study protocol was approved by local ethics review boards (protocol number: 14547613.5.1001.5149) and parental consent was obtained by research team members prior inclusion of infants in this study.

Recruitment, enrollment, and data collection procedures

Data collection was conducted between June 2014 and January 2015 at Sofia Feldman Hospital, and between October 2014 and January 2015 at Odete Valadares Maternity. All term and preterm infants born during the data collection period and requiring NICU admission upon the first 3 h of life were included. Newborns were excluded in case of death before NICU admission, and if they were transferred to another institution during the study period.

The primary outcome of this study was the frequency of painful procedures performed per neonate over the course of hospitalization. A data collection form was developed based on prior studies and according to the hospitals' clinical records. The data collection form was attached to the newborns' clinical charts and information related to painful procedures (frequency and type of painful procedures) and analgesia (frequency and types of pharmacological and non-pharmacological strategies) were collected in real time, on a daily basis by bedside nurses who provided direct care for infants. Additional data included newborns' characteristics upon admission at the NICU (type of delivery, gestational age and weight at birth, head circumference at birth, sex, Apgar scores at 1 and 5 min, diagnoses), and data at the time of hospital discharge (length of hospitalization, weight and head circumference).

Before the study commencement, all nurses in the participating units were trained on study procedures and data collection to ensure completeness of data. Research team members performed daily quality checks on recruitment and data collection forms. All information on painful and stressful procedures and analgesic interventions listed in the newborns' clinical records were verified and double-checked with the data collection forms by the research team.

Data analysis

Data were stored in a Microsoft Excel for Windows® spreadsheet. Descriptive data are presented as means (standard deviation), median, and ranges. Categorical variables are presented as absolute numbers, percentages, and 95% confidence interval. Correlation analyses between demographic and clinical variables and the stressful and painful procedures and pharmacological and non-pharmacological strategies were conducted using Pearson coefficient. We performed multiple linear regression model to establish the relationships between demographic and clinical factors and the frequency of procedures and pain

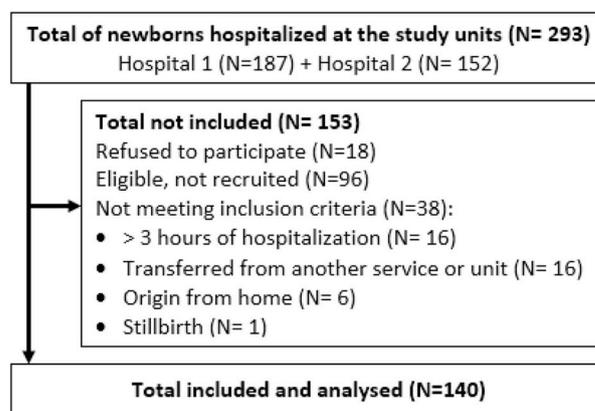


Fig. 1. Flow diagram of the inclusion of participants in the study.

Table 1

Characteristics of the 140 newborns included in the study.

| Characteristics | N ^a | Mean (SD) | Median | Range |
|---------------------------------|----------------|-------------------|--------|--------------|
| Gestational age at birth | 127 | 32.8 (3.6) | 32.0 | 26.0–41.0 |
| Birth weight | 131 | 1876.8 (777.6) | 1715.0 | 540.0–3915.0 |
| Weight at discharge | 94 | 2297.8 (674.5) | 2102.0 | 1150–4375.0 |
| Head circumference at birth | 122 | 29.4 (3.6) | 29.0 | 21.0–43.0 |
| Head circumference at discharge | 63 | 32.3 (4.0) | 31.0 | 27.0–53.0 |
| Sex | | | | |
| Female | 61 (46.6%) | | | |
| Male | 71 (53.4%) | | | |
| Type of delivery | | | | |
| Vaginal | 58 (45.0%) | | | |
| Forceps | 3 (2.3%) | | | |
| Cesarean | 68 (52.7%) | | | |
| Apgar score at 1min | 128 | 6.9 (2.0) | 8.0 | 1.0–10.0 |
| Apgar score at 5 min | 128 | 8.8 (1.0) | 9.0 | 5.0–10.0 |
| Death | 3 (2.1%) | | | |
| Hospital stay | | | | |
| Total days | 140 | 26.1 (21.9) | 20.0 | 1.0–119.0 |
| Days without information | 140 | 3.1 (4.0) | 2.0 | 0.0–27.0 |
| Registered days | 140 | 23.0 (19.9) | 18.0 | 1.0–103.0 |

^a Valid number of participants' data.

management. Missing data were excluded from data analysis. The analyses were performed in SPSS version 17.0 and a significance level of $p < 0.05$ was adopted.

Results

Population characteristics

A total of 293 newborns were hospitalized in the two participating units during the study period. From the 255 newborns fulfilling the inclusion criteria, 140 were included in this study (Fig. 1). Most newborns were male (71/53.4%), born by cesarean section (68/52.7%), and born at < 36 weeks gestational age (mean 32.8, \pm 3.6). Prematurity (60%) and respiratory distress syndrome (50%) were the most commonly registered reasons for NICU admission. The average length of stay was 26 days per newborn. The average of missing data was 3 days per participant (Table 1).

Frequency and types of stressful and painful procedures

During the study period, a total of 21,291 stressful and painful procedures were recorded in the newborns' charts. From these, 18,131

Table 2
The most frequent stressful and painful procedures and pharmacological and non-pharmacological strategies used during hospitalization.

| Procedures | No (%) ^a | 95% CI |
|--|---------------------|-----------|
| Stressful procedures | | |
| Handling | 15,846 (74.4) | 72.9–76.0 |
| Physiotherapy | 1304 (6.1) | 5.6–6.6 |
| Mechanical and noninvasive positive pressure ventilation | 797 (3.7) | 3.2–4.3 |
| Invasive painful procedures | | |
| Needle related procedures | 1776 (8.3) | 7.3–9.4 |
| Airway suctioning | 721 (3.4) | 3.0–3.7 |
| Nasogastric tube and bladder catheter insertion | 443 (2.1) | 1.6–2.5 |
| Dressings | 90 (0.4) | 0.2–0.6 |
| Orotracheal intubation and extubation | 67 (0.3) | –0.8–1.4 |
| Device removal | 63 (0.3) | 0.0–0.6 |
| Others | 184 (0.9) | 0.6–1.1 |
| Strategies | No (%) ^a | 95% CI |
| Comforting | | |
| Positioning | 5359 (25.2) | 24.6–25.8 |
| Light reduction | 4499 (21.1) | 20.6–21.7 |
| Noise reduction | 4256 (20.0) | 19.5–20.5 |
| Minimum handling | 2946 (13.8) | 13.4–14.3 |
| Analgesic | | |
| Breastfeeding | 1357 (6.4) | 6.0–6.7 |
| Skin to skin contact | 517 (2.4) | 2.2–2.6 |
| Sweet tasting solutions | 422 (2.0) | 1.8–2.2 |
| Nonnutritive sucking | 279 (1.3) | 1.2–1.5 |
| Opioids (Morphine, Fentanyl) | 119 (0.6) | 0.5–0.7 |
| Others | | |
| Sedatives (Midazolam, Chloral hydrate) | 83 (0.4) | 0.3–0.5 |

^a Percentage related to the total number of painful and stressful procedures (N = 21,291) performed in newborns during hospitalization.

(85.2%) were categorized as stressful procedures and 3160 (14.8%) were considered as invasive painful procedures. Most commonly performed stressful procedures were handling, physiotherapy, and mechanical and noninvasive positive pressure ventilation (NPPV). The most frequently documented invasive painful procedures were needle related procedures (venipuncture, heel lance and arterial puncture), airway suctioning, and nasogastric tube and bladder catheter insertion (Table 2).

Newborns underwent an average of 226.6 (± 226.0; range = 4–1252) painful and stressful procedures during the hospitalization period, a mean of 6.7 (± 10.1; range = 0–20) procedures per day of hospitalization, and an average of 8.6 painful and stressful procedures per newborn during the first 24 h of hospitalization. For invasive painful procedures only, the average number of procedures per newborn during the hospitalization period was 33.4 (± 38.2; range = 0–188), while the average of number of painful procedures per patient-day was 1.0 (range = 0–4). Higher number of painful procedures (2.9 procedures per newborn) occurred during the first 24 h of hospitalization.

Frequency and types of analgesia

During the study period, a total of 23,124 non-pharmacological

Table 3
Demographic and clinical characteristics' correlation coefficient with stressful and painful procedures and pharmacological and non-pharmacological strategies.

| Demographic and Clinical characteristics | Stressful procedures | Painful procedures | Pharmacological strategies | Non-pharmacological strategies |
|--|----------------------|---------------------|----------------------------|--------------------------------|
| Gestational age at birth | –0.587 ^a | –0.483 ^a | –0.601 ^a | –0.156 ^a |
| Birth weight | –0.508 ^a | –0.415 ^a | –0.140 ^a | –0.534 ^a |
| Weight gain during hospitalization | 0.791 ^a | 0.685 ^a | 0.682 ^a | 0.351 ^a |
| Hospital stay | 0.964 ^a | 0.818 ^a | 0.897 ^a | 0.368 ^a |
| Head circumference gain during hospitalization | 0.427 ^a | 0.358 ^a | 0.393 ^a | 0.097 |

^a Pearson correlation coefficient is significant at the 0.01 level.

strategies, and 221 pharmacological strategies for pain relief and comfort were documented. The mean number of times non-pharmacological strategies were used per newborn during the entire hospitalization, was 261.5 (± 264.6; range = 0–1464), while the mean number of times pharmacological strategies were used per newborn was 2.5 (± 6.4; range = 0–41). The most commonly documented non-pharmacological strategies were those used mostly for comfort, such as positioning, light and noise reduction, and minimal handling. Non-pharmacological analgesic strategies most frequently used were breastfeeding, skin to skin contact, sweet tasting solutions, and non-nutritive sucking. Opioids and sedatives were the most commonly reported pharmacological strategies, although rarely used (Table 2).

Demographic and clinical characteristics' correlations with stressful and painful procedures, pharmacological and nonpharmacological strategies

Positive statistically significant correlations were seen with the number of stressful and painful procedures, and pharmacological and non-pharmacological analgesic strategies with length of hospital stay, weight gain and head circumference growth during hospitalization (Table 3). Gestational age and birth weight were negatively correlated to stressful and painful procedures and comforting and analgesic strategies.

Factors related to the stressful and painful procedures, pharmacological and non-pharmacological strategies

In a multiple linear regression model, each day of hospitalization increased by 10.9 the number of stressful procedures and by 2.2 the number of painful procedures. In relation to the head circumference, for each centimeter increased, the number of stressful procedures decreased by 10 and the number of painful procedures decreased by 1.8.

In addition, for each week of gestational age at birth, the number of painful procedures increased by 2.9, the use of non-pharmacological strategies decreased by 0.06%, and the pharmacological strategies, increased by 23.7%. Furthermore, for each day of hospitalization, non-pharmacological strategies registered increased by 3.4% and pharmacological strategies, increased by 9.3%.

Finally, the independent variables explained stressful procedures in 96.5%, painful procedures in 88.4%, nonpharmacological strategies in 77.6% and pharmacological strategies in 49.8% (Table 4).

Discussion

This prospective, longitudinal study aimed to identify type and frequency of neonatal stressful and painful procedures, use of strategies for neonatal comfort and pain relief, and to identify factors related to frequency of procedures and pain management over the course of newborns' hospitalization.

Limitations of this study include data collection processes. Although trained, some of the staff did not include precise information on the data collection forms attached to the newborns' clinical charts. Some eligible newborns were not recruited in a timely manner. Lack of time and increase of workload were the most commonly reasons provided by the staff for incomplete data collection, and loss of eligible newborns.

Table 4
Multiple linear regression model of stressful and painful procedures and pharmacological and non-pharmacological strategies.

| Dependent Variables | Independent Variables | Coefficient (R) | 95% CI | P value | R ² |
|--------------------------------|--------------------------|----------------------|---------------|----------------------|----------------|
| Stressful procedures | Gestational age at birth | 2.296 ^a | −5.027–9.620 | 0.532 | 0.965 |
| | Weight gain | 0.006 ^a | −0.067–0.078 | 0.877 | |
| | Hospital stay | 10.900 ^a | 9.060–12.740 | < 0.001 ^c | |
| | Head circumference gain | −10.001 ^a | −15.624–4.377 | < 0.001 ^c | |
| Painful procedures | Gestational age at birth | 2.951 ^a | 0.718–5.185 | 0.011 ^c | 0.884 |
| | Weight gain | −0.013 ^a | −0.035–0.009 | 0.225 | |
| | Hospital stay | 2.253 ^a | 1.692–2.814 | < 0.001 ^c | |
| | Head circumference gain | −1.891 ^a | −3.606–0.176 | 0.031 ^c | |
| Non-pharmacological strategies | Gestational age at birth | 0.940 ^b | 0.934–0.947 | < 0.001 ^c | 0.776 |
| | Weight gain | 0.999 ^b | 0.999–1.000 | < 0.001 ^c | |
| | Hospital stay | 1.034 ^b | 1.033–1.036 | < 0.001 ^c | |
| | Head circumference gain | 1.015 ^b | 1.011–1.020 | < 0.001 ^c | |
| Pharmacological strategies | Gestational age at birth | 1.237 ^b | 1.158–1.320 | < 0.001 ^c | 0.498 |
| | Weight gain | 1.000 ^b | 0.998–1.000 | < 0.001 ^c | |
| | Hospital stay | 1.093 ^b | 1.076–1.111 | < 0.001 ^c | |
| | Head circumference gain | 0.976 ^b | 0.931–1.019 | 0.280 | |

^a Linear regression.

^b Poisson regression.

^c Significant at the 0.05 level.

Finally, both participating institutions have minimal handling protocols which may explain the high frequency of comforting strategies registered.

For this study, procedures that were considered to cause physical discomfort, such as handling, physiotherapy sessions, mechanical ventilation, and NPPV were categorized as stressful events whereas invasive and skin-breaking procedures were considered as painful events (Carbajal et al., 2008; Grunau, 2009; Kyololo et al., 2014). The high number of stressful and painful procedures that sick newborns were daily exposed to during hospitalization in the Brazilian settings is consistent with previously published research (Cruz et al., 2016). In addition, our results highlight that most painful and stressful procedures are performed during the first 24 h of hospitalization (mean of 8.6 for painful and stressful procedures per newborn, and 2.9 for painful procedures per newborn) however, sick and preterm newborns do continue to undergo painful procedures throughout their hospitalization. This pattern was also reported by Harrison, Loughnan, Manias e Johnston for 55 sick infants hospitalized during 28 days or more in a NICU in Australia (Harrison et al., 2009).

Conversely, the relatively low mean number of painful procedures per newborn per day compared to other studies may be explained by the extended length of our data collection period. A decrease in the number of procedures is expected due to newborns' health improvement and clinical stability throughout the hospitalization. This is consistent with a Brazilian study that showed a total of 52 newborns underwent a mean number of 1.4 painful procedures per day over a mean length of stay of 20 days (Nóbrega et al., 2007).

Regardless the length of follow up, studies consistently demonstrate a high number of painful procedures as well as insufficient pain management practices. Studies fail to investigate; however, the type of pain neonates are exposed which may be a result of the uncertainties around the definition of pain in neonates and infants. For example, acute recurrent pain experienced by sick newborns throughout their hospitalization differs from acute episodic pain experienced in a single procedure. Acute recurrent pain may result in moderate to severe primary hyperalgesia and mild to moderate secondary hyperalgesia. Moreover, the neonate's behavioral response may be weakly reactive or reflexive, which may hinder pain assessment (Anand, 2017).

In terms of comforting and analgesic strategies documented, the majority of these interventions were not exclusively related to stressful and painful procedures. For example, positioning, lights and noise reduction are strategies derived from developmental care theory and its implementation rely on routine care in the units where data were collected.

The use of breastfeeding, skin to skin care and, sweet tasting solutions was minimal in our study (12%) in spite of high quality synthesised evidence supporting these interventions as safe and effective for neonatal procedural pain relief (Benoit et al., 2017; Bueno et al., 2013; Harrison et al., 2017a; Johnston et al., 2017; Pillai Riddell et al., 2015; Shah et al., 2012; Stevens et al., 2016). Once again, these results are consistent with findings from prior studies conducted worldwide which showed infrequent use of these strategies (Cruz et al., 2016).

Pharmacological analgesia was infrequently administered although newborns experienced mechanical ventilation and moderate to severe painful procedures over the course of hospitalization. Although the use of pharmacological agents is recommended by a high quality guideline published by the American Academy of Pediatrics (American Academy of Pediatrics, 2016), the use of opioids, sedatives-hypnotics, or general anesthetics was also found to be inconsistent in a study that investigated pharmacological analgesia practices in 243 NICUs across Europe (Carbajal et al., 2015).

In terms of factors potentially related to the number of painful procedures infants were exposed to, our results are similar to previously published research demonstrating a negative correlation between number of painful procedures and gestational age and birth weight (Cruz et al., 2016). Conversely, opposite results were demonstrated in the regression model. This may be explained by the influence other variables may have in the model, as well as to the length of data collection per newborn. In addition to that, the two participating units had minimal handling protocols as their routine care, thus preterm newborns may have benefitted from these protocols in terms of reduction of painful and stressful events.

Significant and strong correlations between birth weight and head circumference with painful procedures were shown in our study. Results are similar to a prior study in which greater neonatal pain exposure was related to decreased postnatal weight and decreased head circumference in the early period of life of 78 preterm newborns at 32 weeks postconceptional age (Vinal et al., 2012).

Our findings highlight a knowledge to action gap that persists between evidence and clinical practice in terms of neonatal pain management. The studies that initially investigated neonatal procedural pain exposure and analgesia were published in the mid to late-1990's and their results indicated neonates experienced a high number of invasive procedures performed with minimal pain control (Barker and Rutter, 1995; Johnston et al., 1997). Two decades later, studies continue to report insufficient pain management practices in neonatal units across developed and developing countries regardless of increasingly

robust evidence of analgesic effects of various pain management interventions published over time.

Efforts on knowledge translation on neonatal pain management should become a priority given the evidence on potential harmful short and long-term effects on physiological and psychological outcomes due to repetitive and untreated pain. In a prospective cohort comparative design conducted in 32 hospital units across Canada, a multifaceted knowledge translation intervention was implemented in half of the sample with the ultimate goal to improve pain practices and clinical outcomes on pediatric pain (Stevens et al., 2014a). Results indicated that units that received the intervention improved the use of validated pain assessment measures as well as use of pain management interventions.

Several barriers may impact the use of knowledge in the clinical settings, including staff time and engagement, leadership support, and system's communication (Stevens et al., 2014b). Overcoming these barriers is crucial as an attempt to effectively manage pain in neonates and infants.

Few knowledge translation initiatives developed in different Brazilian settings have been reported to date. An educational intervention targeted at health care professionals was carried out in a single NICU and reached 86.4% of the health care professionals (De Aymar et al., 2014). Changes on pain assessment and management practices were perceived by 79.6% of the health care team although no clinical outcome data on pain assessment or management were collected for the study.

The Be Sweet to Babies series of videos is available in Portuguese and is named 'Seja Doce com os Bebês' (Harrison et al., 2017b). The videos present evidence-based content on safe, effective and costless strategies for neonatal and infant pain management during needle related procedures (i.e. breastfeeding, skin to skin care, and sweet solution). Studies involving parents and nurses demonstrate the video is considered useful and easy to understand, and is a feasible educational tool to be implemented in clinical settings (Almeida et al., 2018; Bueno et al., 2018). In addition, results of a pragmatic clinical trial indicate greater parental participation in pain relief during blood sampling for newborn screening as well as greater satisfaction with the information received for mothers who were exposed to the video (Candido, 2017).

Although promising, these initiatives are limited in terms of reach. Ideally, national guidelines and policies should be developed and implemented nationwide. The utilization of high quality synthesised evidence in neonatal pain management is fundamental (American Academy of Pediatrics, 2016; Lee et al., 2014). Therefore, we highlight the importance of adapting these guidelines as a means of improving evidence implementation, through local tailoring, involving *trans*-contextual and *trans*-cultural adaptation and/or modification of the format with the ultimate goal of making them more relevant to the context in which they will be implemented (Fervers et al., 2018).

Conclusions

This study confirms newborns are exposed to a high number of stressful and painful procedures with infrequent use of effective recommended pain management strategies during the entire hospitalization. Tailoring and implementing knowledge translation strategies based on high quality synthesised evidence is crucial for improving neonatal pain management practices.

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Ethical statement

This study was approved by the local ethics committee at Federal University of Minas Gerais, protocol #14547613.5.1001.5149.

Conflicts of interest

None.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jnn.2018.08.003>

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