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Introduction of a neonatal pain and agitation protocol at neonatal intensive care unit Dr. Soetomo Hospital, Surabaya

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Abstract

Background Neonate especially preterm are the most likely to be exposed with pain stimuli in the NICU. Repeated number of painful exposure have the potential for deleterious consequences on vital sign and later neurodevelopmental outcome. Dr. Soetomo Hospital, Surabaya, not implemented neonatal pain and agitation protocol yet.

Objective To analyze the implementation of a neonatal pain management based on *Neonatal Infant Pain Scale* (NIPS) score.

Methods This study was conducted in NICU Dr. Soetomo Hospital, Surabaya, from January to May 2016. The protocol of neonatal pain and agitation management was implemented. Staff behavior in neonatal pain management before introduction vs after implementation were evaluated.

Results There were 72 patients before introduction had gestational age (GA) 34.8 (SD 2.6) weeks, birth weight 2023.8 (SD 437) gram and 30 nurse were include. Forty two patients, GA 35.8 (SD 2.58) week, birth weight 1988 (SD 571) gram, and 15 nurses after implementation of pain management were included. Umbilical puncture was the most procedure that frequently performed (22.9%) followed by ROP screening examination (21.56%), heel lance (13.07%). Compliance of staff in assessment of pain was increase from increasing number of pain assessment from 62.78% (SD 14.07) to 90.49% (SD 14.07). There was a significant increase of lidocain (00.00 vs. 80.62%) and lidocain cream (00.00 vs. 78.97%) use. Inter-observer agreement between nurse to evaluate pain using NIPS score, kappa 0.88, P=0.00.

Conclusion Compliance of pain assessment and management are increased after pain protocol implementation.

Keywords: pain in neonate, pain management

A preliminary study: cerebral function evaluation by using aEEG monitoring in newborn infants with severe hyperbilirubinemia

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Abstract

Background Bilirubin is a potent neurotoxin at high concentrations. An objective method is needed to evaluate the toxic cerebral effects of severe hyperbilirubinemia. aEEG is a potential tool for monitoring cerebral function in high risk infants.

Objective To compare the aEEG traces in newborn infants with severe hyperbilirubinemia during and after treatment.

Methods The aEEG records of infants with severe hyperbilirubinemia during and after treatment were reviewed. Clinical data were collected. The aEEG traces were classified according to background activity, presence of seizures, and sleep-wake cycling (SWC).

Results Seven out of all severe hyperbilirubinemia infants admitted in NICU Harapan Kita Women's and Children's Hospital between October 2015 and April 2016, had been confirmed to get aEEG monitoring. At the initial treatment the aEEG tracings showed continuous normal voltage (n=2), discontinuous normal voltage (n=2), burst-suppression (n=1), flat trace (n=2); presence of SWC (n=2), no SWC (n=5); 6 infants had electrical seizures while only 2 of them had clinical seizures. No infants had normal aEEG, 4 mildly abnormal aEEG, and 3 severely abnormal aEEG. After treatment, aEEG tracings showed continuous normal voltage (n=4), burst-suppression (n=2), flat trace (n=1); presence of SWC (n=4), no SWC (n=3); 5 infants showed persistent electrical seizures. Two infants had obvious aEEG improvement. All infants survived.

Conclusion An aEEG examination can provide important information of cerebral function in infants with severe hyperbilirubinemia. A further research with more subjects is needed.

Keywords: newborn infants, severe hyperbilirubinemia, aEEG

**Introduction of a neonatal pain and agitation protocol at neonatal intensive care unit
dr. Soetomo hospital**

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ABSTRACT

Background : Neonate especially preterm are the most likely to be exposed with pain stimuli in the NICU. Repeated number of painful exposure have the potential for deleterious consequences alter vital sign and later neurodevelopmental outcome. Dr Soetomo Hospital not implemented neonatal pain and agitation protocol yet.

Objective : To analyze the implementation of a neonatal pain management based on Neonatal Infant Pain Scale (NIPS) score

Methods : Location in NICU from January to May 2016. The protocol of neonatal pain and agitation management was implemented. Staff behavior in neonatal pain management before introduction vs after implementation were evaluated.

Results : There were 72 patients before introduction had gestational age (GA) 34.8 (SD 2.6) weeks, birth weight 2023.8 (SD 437) gram and 30 nurse were include. Forty two patients, GA 35.8 (SD 2.58) week, birth weight 1988 (SD 571) gram, and 15 nurses after implementation of pain management were included. Vein puncture was the most procedure that frequently performed (62.09%) followed by ROP screening examination (21.56%), heel prick (13.07%). Compliance of staff in assessment of pain was seen from increasing number of pain assessment from 62.78% (SD 22.19) to 90.49% (SD 14.07). There was a significant increase of sucrose (00.00 vs 80.62%) and lidocain cream (00.00 vs 78.97%) used. Inter-observer agreement between nurse to evaluate pain using NIPS score, kappa 0.88, $p = 0.00$.

Conclusion: Compliance of pain assessment and management were increased after pain protocol implementation

Keywords: *pain in neonate, pain management*

BACKGROUND

Invasive medical procedures are performed routinely on newborn infants, and pain is the most common adverse effect of such procedures. In addition to ethical considerations, scientific data point to both short-term and long-term harm arising from untreated pain in the neonatal period.¹⁻³ Acutely, unmanaged pain can lead to distress and physiologic instability. In the long term, conditioned anxiety and heightened pain responses develop in anticipation of and in response to subsequent invasive procedures. Over the past decade, efforts to reduce neonatal pain during medical procedures have included the development of clinical practice guidelines, and implementation of analgesia-based protocols and initiatives aimed at increasing the use of analgesics.^{4,5} Unfortunately, these efforts have resulted in only modest improvements in analgesic uptake. The absence of empirical data has been identified as a major barrier to implementation of optimal pain-control strategies.

The American Academy of Pediatrics and the Canadian Pediatric Society policy statements on prevention and management of pain in neonates advocate routine pain assessment and the use of protocols for the management of pain and sedation in neonates.^{5,6} Until December 2015, an instrument to assess nor a protocol to treat pain, agitation, and sedation not successfully implemented in our institution. The management of pain, agitation, and sedation had thus far been based on irregular and subjective evaluations of the patient's condition in terms of pain and sedation and resulted in team dissatisfaction. The Neonatal Infant Pain Scale is an easier method, requires less personnel training, facial expression as a whole and values other behavioral parameters and one physiologic pain parameter. The Neonatal Infant Pain Scale is the best tool for evaluating pain and also a valid and suitable instruments for neonatal pain evaluation.^{7,8}

We hypothesized that implementing a protocol for the management of neonatal pain and agitation on the basis of a validated assessment instrument would improve frequency and quality of pain assessment. We analyze the implementation of a neonatal pain management based on Neonatal Infant Pain Scale (NIPS) score. Our primary aim is to Evaluate implementation of pain protocol using medical record, secondary aim is to evaluate the nurses capability to recognize pain using NIPS and evaluate the management of pain according to NIPS.

METHODS

Setting

Neonatal Intensive Care Unit of Soetomo Hospital is a tertiary perinatal center with 2000-3000 deliveries and admitting, 180 preterm infants weighing less than 1500 g per year. The project started in January 2016 at 20-bed NICU with the establishment of a study protocol upon approval by the local ethics committee.

Implementation Plan

Choice and Translation of a Pain and Sedation Assessment Tool

A multidisciplinary team including neonatologists, NICU nurses, resident, and a pharmacist extensively reviewed the published literature and agreed on the introduction of the Neonatal Infant Pain Scale (NIPS). The Neonatal Infant Pain Scale (NIPS) is a behavioral assessment tool for measurement of pain in preterm and full-term neonates. This can be used to monitor a neonate before during and after a painful procedure such as venipuncture. Parameters: (1) facial expression (2) cry (3) breathing patterns (4) arms (5) legs (6) state of arousal. Relaxed muscles (facial expression): restful face neutral expression, grimace tight facial muscles furrowed brow chin jaw (negative facial expression – nose mouth brow), no cry (quiet not crying), whimper: mild moaning intermitend, vigorous cry (loud scream rising shrill continuous). Relaxed was usual pattern for the baby, change in breathing was indrawing irregular faster than usual gagging breath holding. Relaxed/restrained: no muscular rigidity occasional random movements of limb, flexed/extended: tense straight rigid and/or rapid extension flexion, sleeping/awake: quiet peaceful sleeping or alert and settled, fussy: alert restless and thrashing neonatal infant pain scale = SUM (points for the 6 parameters). Interpretation of NIPS is minimum score 0 and maximum score is 7.

Development of the Protocol for Neonatal Pain and Agitation

The pain protocol is a detailed protocol for the management of pain, and sedation and includes frequency of assessments, drug type, dosage, and a flowchart indicating when to use which drug according to NIPS values. Strategies for non-pharmacologic interventions such as swaddling, nonnutritive sucking, and sucrose for escalation and de-escalation of continuous sedative and analgesic drugs were defined. We aimed for NIPS values between 0 and 3 as a mild pain, 4 and 5 as moderate pain, 6 and 7 as severe pain. Regular NIPS assessments were performed in patients receiving mechanical ventilation or continuous positive airway pressure; in patients requiring

.40% oxygen; in cases of severe dyspnea, postoperative care, sepsis, indwelling pleural or abdominal drains, or large skin defects; and in patients receiving palliative care. The NIPS was assessed 30 minutes after any procedure, escalation, or de-escalation of analgesic drug infusions but at least every 8 hours. In all cases, the physicians gave the orders to change medication according to the presented protocol, following the flowchart with regard to NIPS values established by the bedside nurse.

Algorithm of Pain And Agitation Management Based on NIPS

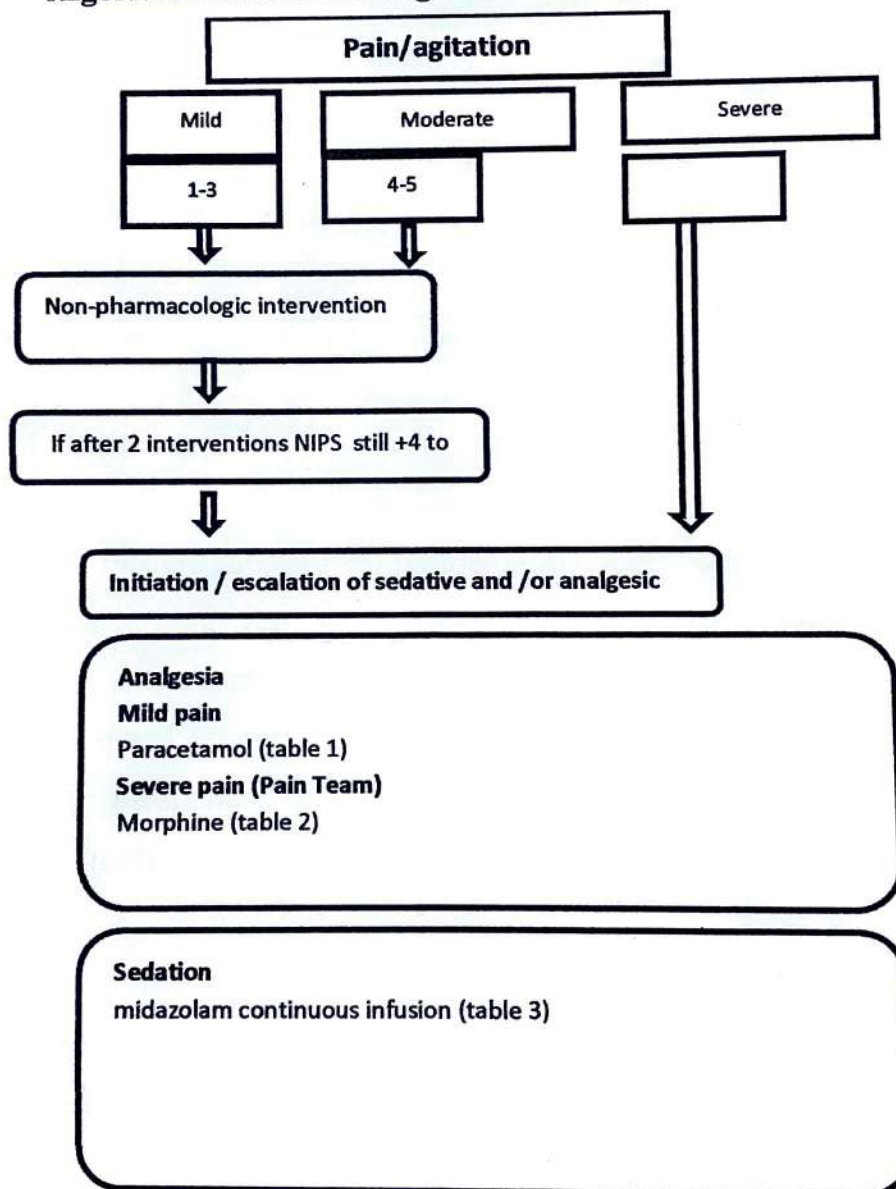


Figure 1. Algorithm of Pain And Agitation Management Based on NIPS

Table 1. Paracetamol dosage according PMA (post menstrual age)

Post Menstrual Age	Loading Rectal (mg/kg)	Maintenance Rectal (mg/kg/day)	Loading Oral	Maintenance Oral (mg/kg/day)	Extra Dose	Minimal Interval
>1 month post-term	40	90 in 3dd	No	90 in 4 dd		
>36 wk	30	60 in 3dd	No	60 in 3 dd	10-15 mg/kg Max 2 dd	4 hr
32-36 wk	30	40 in 2dd	No	60 in 3 dd	10 mg/kg max 2 dd	4 hr
28-32 wk	20	40 in 2dd	No	30 in 3 dd	No	
<28 wk	Contraindication					

Citation : richtlijnen afdeling neonatologie universitair medisch centrum Groningen. versie november 2014: 4.8 - 1

Staff Training and Education

We introduced the pain and agitation protocol on several occasions (eg, scheduled teaching sessions, ward rounds). Posters showing the protocol's flowchart were placed in every room of our NICU and a laminated small version was placed at every bedside. We chose an interactive tutorial for training purposes and created short movies of patients after parental consent had been obtained. The tutorial aimed to train NIPS assessment in a stepwise approach. Nurses were trained to first observe the patient in a calm, undisturbed state, then during a routine care procedure, and finally during consolation after the care procedure.

Evaluation of Baseline Level of Care

We evaluated local problems and assessed staff satisfaction before the introduction of the protocol. We administered anonymous questionnaires to the NICU nursing staff and physicians. The team was asked to rate by using a 4-item rating scale the following aspects of pain and agitation management: (1) frequency of documentation, (2) incidence of severe pain/agitation, (3) time to intervention in case of severe pain/agitation, (4) effectiveness of pain therapy, (5) frequency of withdrawal symptoms, and (6) overall quality of pain management. There was also a free comments section (possible contributing factors that should be improved).

Inter observer Agreement

Reassessment and retraining of the staff was performed throughout the entire intervention phase. Trained members of the study team randomly evaluated patients independently of the care-giving nurse to ensure quality of assessments. Patients were assigned for simultaneous assessment by using simple randomization. Two months after implementation of the protocol, we evaluation of the protocol implementation result.

Staff Interaction, Communication, and Satisfaction

With the use of anonymous questionnaires, nurses and physicians were asked to estimate the incidence of pain and agitation in neonatal patients and to score the success rate of the administered pain relief as well as the interaction and communication between physicians and nurses.

Statistical Analysis

This study is a prospective study, located in NICU Dr. Soetomo Hospital Surabaya. The exclusion criteria is patient in sedation and all neonates who experienced minimal invasive procedures enroll in this study. Statistical analysis using Paired T-test and Inter-observer test.

Table 2. Pain management for minimal invasive procedures

Procedures	Treatment
Arterial puncture	sucrose 24% 0.5-1.5 ml PO
Venous puncture	sucrose 24% 0.5-1.5 ml PO
Heel prick	sucrose 24% 0.5-1.5 ml PO
Lumbal puncture	sucrose 24% 0.5-1.5 ml PO if \geq 34 weeks \rightarrow topical EMLA
Dressing change	sucrose 24% 0.5-1.5 ml PO could repeat and or morphin 0.025-0.05 mg/kg IV
Endotracheal suctioning	N/A
Intramuscular injection	sucrose 24% 0.5-1.5 ml PO if \geq 34 weeks \rightarrow topical EMLA

Sumber : Hansen. AR. preventing and treating pain and stress among infants in the newborn intensive care unit. In: Linda J. Van Marter Cp, editor. *Manual of neonatal surgical intensive care*, 2004:664-73.¹¹

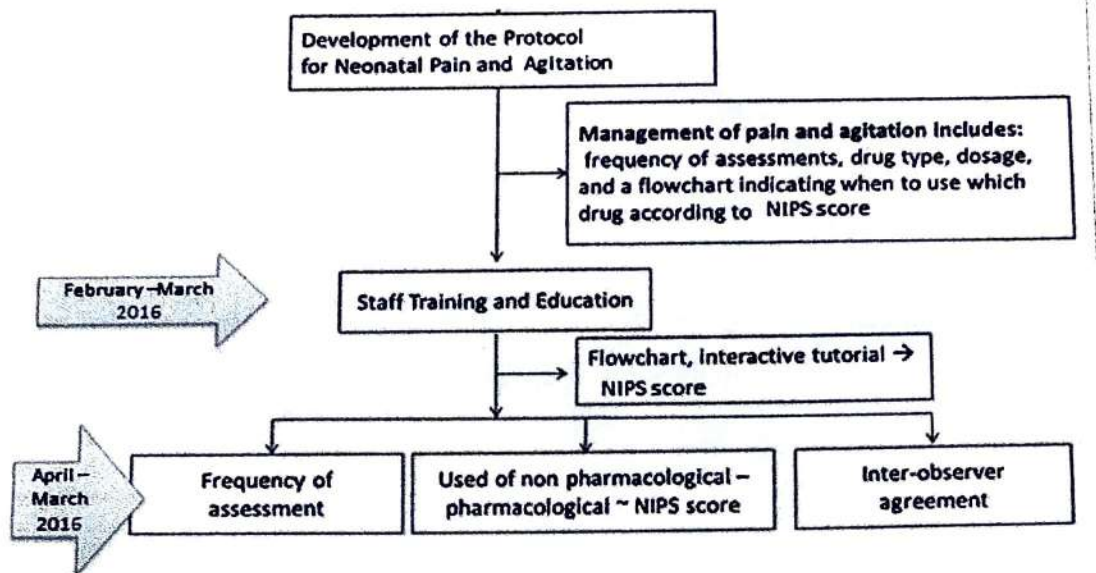


Figure 2. The Timeline of Study

Table 2. Neonatal infant pain scale parameters

Parameter	Finding	Points
facial expression	relaxed	0
	grimace	1
cry	no cry	0
	whimper	1
	vigorous crying	2
breathing patterns	relaxed	0
	change in breathing	1
arms	restrained	0
	relaxed	0
	flexed	1
	extended	1
legs	restrained	0
	relaxed	0
	flexed	1
	extended	1
state of arousal	sleeping	0
	awake	0
	fussy	1

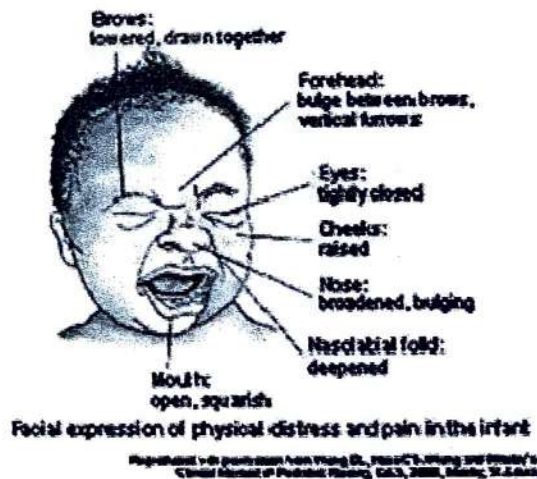


Figure 3. Facial expression in NIPS

RESULTS

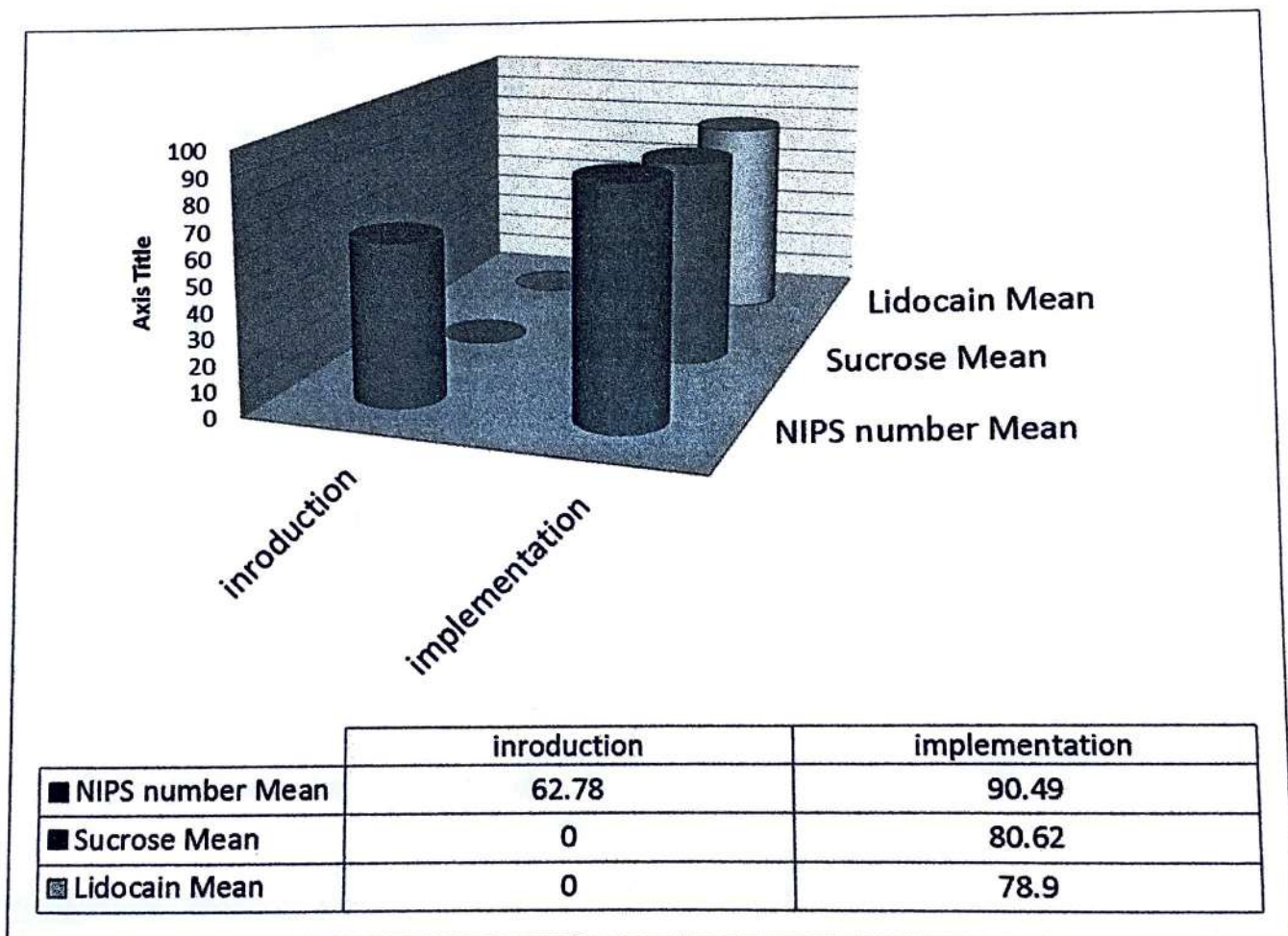
Impact of the Implementation on Therapy and Outcome

Control and intervention groups were similar (Table 3). At baseline, 10% of all patients received sucrose 24% for a median (interquartile range [IQR]) duration of 5.1 (1.6–17.5) days at a median (IQR). After intervention, the percentage of patients receiving continuous opiate infusions was comparable (55%; $P = .2$) as was the median (IQR) duration of treatment (4.9 [1.0–14.1] days; $P = .3$). In the intervention group, significantly more pharmacologic interventions (escalation and deescalation) were performed

Table 3. Baseline characteristic

Baseline data	Introduction Mean (n=72)	Implementation Mean (n=42)
Gestational age, mean (SD) wk	34.8 (SD 2.6)	35.8 (SD 2.58)
Birth weight, mean (SD) gram	2023.8 (SD 437)	1988 (SD 571)
Diagnosis n(%)	17 (23.6)	11 (26.1)
Sepsis	4 (5.5)	6 (14.2)
Ischemic Encephalopathy	16 (22.2)	10 (23.8)
Multiple congenital anomaly	9 (12.5)	4 (9.5)
Neural tube defect	7 (9.7)	6 (14.2)
Abdominal wall defect		
Procedure invasive minimal (N(Mean/patient))	N = 226 (3.01)	N= 115 (2.7)
Vein puncture (n (%))	140 (62.09)	67 (58)
Heel prick (n (%))	29 (13.07)	10 (8.7)
Wound dressing (n (%))	2 (0.88)	17 (40.4)
Intramuscular injection (n (%))	7 (3.09)	5 (11.9)
ROP examination (n (%))	48 (21.56)	16 (38)

At baseline there were 15 (50%) nurses fill the questionnaire and the most contributing factors for nurse dissatisfaction with pain management at baseline were treatment not effective (36%),no no protocol available (28%), and medical intervention initiated too late (10%).



Figures 4. Percentages of nurse compliance in pain management

There were high compliance after implementation of pain protocol, where mean number of evaluation of pain assessment using NIPS score was improved after implementation (90.49%). Using of sucrose and lidocain as one of the pharmacological analgetic on neonates in minimal invasive procedures is significant increasing after implementation.

Table 4. Inter-Observer agreement using NIPS score

		Nurse 2			Total	
		mild	moderate	severe		
Nurse 1	mild	Count	4	0	0	4
		Expected	1.4	1.7	.9	4.0
	moderate	Count	1	6	0	7
		Expected	2.5	3.0	1.5	7.0
	severe	Count	0	0	3	3
		Expected	1.1	1.3	.6	3.0
Total	Count	5	6	3	14	
	Expected	5.0	6.0	3.0	14.0	
	Count					

Systemic measure Kappa 0.88, p 0.00

Table 4 show the inter-observer agreement of 2 nurses using NIPS score. There were good systemic measure with kappa 0.88.

Discussion

Neonates had more than 134 pain procedure in their 2 weeks of life, where 124 were preterm infants (Gestational age was 27-31 weeks). Most invasive procedures were venous catheter and endotracheal suctioning (Steven 1999).¹² In our study there were 226 minimal invasive procedures, where mean gestational age was 34 weeks. Philipp Deindl, 2013 in their study, the implementation of a pain protocol give more aggressive pain control. The result of this study is medical staff using higher doses of opiates, significant increase in pharmacologic interventions, without impacting morbidity or mortality. In our study higher frequency of pain assessment using NIPS was higher than introduction group where significant increase in sucrose and lidocain cream used. We achieved good inter-observer agreement regarding the pain and agitation subscale of the NIPS

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