

EFFECTIVENESS OF ORAL DEXTROSE GEL 40% FOR PAIN MANAGEMENT IN INFANTS DURING HEEL LANCE

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Abstract: Newborns are subject to pain during routine invasive procedures. Pain caused by blood collection through heel lance is routinely underestimated and often untreated. The aim of this study was to compare the effectiveness of oral Dextrose Gel 40% to actual standard of care Glucose 25% to control infant's pain during routine heel lance blood collection for metabolic disease screening at 72 hours of age in healthy term neonates. In this prospective, randomised clinical trial we enrolled 100 healthy term newborn infants at 72 hours of age, who underwent blood collection and were randomized to two treatment groups: Glucose 25% and Dextrose 40% Gel oral. Pain was measured by the Preterm Infants Pain Profile (PIPP Scale). Pain was significantly lower in infants in the Dextrose 40% Gel group than those in Glucose 25% (standard of care) group. Dextrose Gel 40% is an effective pain management method during heel lance blood collection procedure.

INTRODUCTION

From birth, normal newborns are subject to procedural pain from routine care, such as vaccines, vitamin K injections for hemorrhagic disease prophylaxis and blood collection through heel sticks for metabolic disease screening.(1) The pain and distress imposed by procedure and surgical interventions in neonates were first brought to scientific and public attention by a small but seminal study conducted in the 1980s on neonates undergoing thoracotomy.(2)

Without the advantage of self report, clinical assessments of pain in neonates are dependent of indirect measures that include physiological, behavioural and contextual parameters.

Despite the documented dissociation between physiological and behavioural indicators especially in preterm and ill neonates, composite scoring tools that include both parameters have been reasonably validated and are widely accepted.(3)

Heel lance is one of the most common and most studied painful stimuli in neonatal acute care. Like other European Countries, Romania has been able to implement a number of programmes that benefit children from to address the United Nations Millennium Development Goals, one of which were to reduce the mortality of children below the age of 5 years by two thirds by 2015 including here the newborn screening for metabolic congenital diseases.(4)

The administration of sucrose with and without non-nutritive sucking has been of the most frequently studied nonpharmacologic intervention for relief of procedural pain in neonates.

Sucrose has been examined for its calming effects in

crying newborns (5) and for its pain relieving effects for invasive procedures in term and preterm neonates.(6,7) Sucrose has been frequently studied in the neonatal population as an alternative analgesia to opioids in minor painful procedures including heel lances and venipunctures.(8)

PURPOSE

The purpose of the present study was to assess the effectiveness of oral Dextrose Gel 40% compared to actual standard of care Glucose 25% to control infant's pain during routine heel lance blood collection for metabolic disease screening at 72 hours of age in healthy term neonates. Descriptive data, including demographics were analyzed for group differences.

MATERIALS AND METHODS

The randomized double blind placebo-controlled experimental study recruited a sample of 100 infants who undergo routine blood collection heel lance for metabolic disease screening in the first 72 hours of age at the Maternity of the County Hospital of Tirgu-Mures over 6 months (September 2014 to February 2015). Randomized clinical trial was used to compare the efficacy of oral Dextrose Gel 40% and Glucose 25% on newborn infant pain; physiologic parameters (heart rate, oxygen saturation, and gestational age) and behavioural parameters (facial actions, neurobehavioral state) associated with heel lance blood collection. Inclusion criteria were the infants healthy with no acute or chronic disease, born after 36 completed weeks of gestation, breastfeed or formula feed without parenteral nutrition, without any neurological symptoms and able to receive fluids by mouth, Apgar score greater than or

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equal to 7 at the first and fifth minute after birth, mother healthy without substance abuse. Newborns were excluded by these criteria: congenital anomalies, documented sepsis or other conditions requiring surgical treatments. Parents of infants who met the study criteria received informed consent form. Interested parents returned the response sheet to the researchers, who then explained the study objectives and obtained the parental consent. The study was approved by the site institutional review board. Premature Infants Pain Profile (PIPP) and Premature Infants Pain Profile-Revised (PIPP-R) scale was developed and revised to assess pain in non verbal children.(9,10) This scale variable included: changes in heart rate, oxygen saturation, facial action and neurobehavioral state, weighted for gestational age and his reliability score (Cronbach's alpha) 0.89 or greater.(11)

Randomization and masking was done using a computer-generated blocked randomization to assign babies (1:1) stratified by gestational age.

The researchers entered data into computer that provided a randomization number corresponding to a numbered treatment pack containing two syringes, each containing 2 ml of liquid: either Dextrose Gel 40% or 25% glucose, which was identical in appearance. Study packs were prepared by an independent health care provider, who had no other involvement in the study. Clinicians, families and all study investigators were all masked to group allocation until data analysis was complete.

Pain relief interventions: all newborn infants without any feed 30 minutes prior to intervention were placed in a side-lying position and the sensors for oxygen saturations and heart rate have been applied. Two minutes before the procedure the researcher administered 0.5 ml/kg liquid into the bucal mucosa, and the baby was encourage feed.

The blood collection heel lance included followed steps: prepare the materials needed and select the site for heel lance, stabilize the infants leg, cleanse the injection site with alcohol cotton balls, the baby ankle area was hold with 3 fingers while placing thumb behind the heel and the second finger was placed just below the ventral surface of the toes, blood was collected by pressing the lateral three fingers, followed by a milking motion of the second finger allowing large droplets to form, the drops were collected as they form into the paper filter strips.

Measures: outcome variables included newborn infant's pain, physiological responses and behavioural state (PIPP scale). Preterm Infants Pain Profile scale is an observational measure of physiological and behavioural parameters in response to pain. PIPP scale scores 1, 2 or 3 the following parameters: gestational age, behavioural state, change in heart rate, change in oxygen saturation, brow bulge, eye squeeze, nasolabial furrow. Sum for all 7 indicators score the pain intensity (minimum score 0, maximum score 21) the higher the score, the greater the pain behaviour.

For each baby the PIPP scale was scored by observing the infant for 15 seconds at 5 different moments during the procedure: before the heel lance (base line, BL) at the heel lance (HL), at 1 minute recovery (R1), at 2 minutes recovery (R2), at 5 minutes recovery (R3). Each code was scored and summed for every different phase of the procedure and entered into paper forms. Infants were placed in side lying position and facial actions, oxygen saturation and heart rate registered track was videotaped using a real-time colour video recorder.

Data Analysis: data of infants in the two groups (Dextrose 40% and Glucose 25%) were entered into a database along with demographics, obstetrical and perinatal data.

Data were analyzed using SPSS for Windows Version 10.0.0. P-values less than 0.05 were considered statistically significant.

RESULTS

The study participants were 26 males and 24 females newborn infants in Dextrose Gel group and 27 males and 23 females in glucose 25% group (n=50), and a total sample of 100 was analyzed. Infant's basic characteristics did not differ significantly among the two groups (table no. 1).

Infants in the Dextrose Gel group had significant lower PIPP score than Glucose group at all phases of heel lance except the last time of observation Recovery 3 (table no. 2).

Infant's pain scores increased during and in the first minute after heel lance procedures and significantly decrease afterward.

Table no. 1. Characteristics of newborn infants included in two groups

Characteristics	Dextrose Gel 40%		Glucose 25%		P value
	Mean	Standard Deviation (SD)	Mean	SD	
Gestational age (weeks)	38.56	1.68	38.92	1.19	0.303
Birth weight	3281	508.92	3218	511.29	0.542
Age (days)	3.2	0.6	3.1	0.4	0.06
Number of prior painful experiences	2.3	0.5	2.2	0.4	0.8
Times since previous feeding (hours)	2.05	0.45	2.16	0.51	0.841
Apgar score					
First minute	8	0	8	0	
Fifth minute	9	0	9	0	
Gender					
Male	26		27		
Female	24		23		
Delivery methods					
Vaginal delivery	39		35		0.303
Cesarean section	11		15		

Table no. 2. Changes in PIPP score of Dextrose Gel 40% and Glucose 25% calculated by Wilcoxon Ranked Test

Variable	Mean Difference PIPP score	W value	Z value	Mean	p-value
Time of observation					
Base-line.					
No stimulation	-2.15	27	-4.52	280.5	<0.05
Heel lance	6.22	193.5	-3.65	517.5	<0.05
Recovery 1	5.04	311	-2.50	540.5	<0.05
Recovery 2	3.43	214	-3.56	540.5	<0.05
Recovery 3	2.4	389	-1.01	473	0.31

DISCUSSIONS

Our study demonstrated that Dextrose Gel 40% is an effective pain management method during heel lance procedures. This finding supports our hypothesis that pain during heel lance procedure would be relieved better in neonates receiving Dextrose Gel than in those receiving standard care (Glucose 25%). The study advances knowledge of term infant's response to procedural pain in terms of PIPP score, stress-related behaviour and physiologic response across different phases of heel lance procedure while receiving standard care (Glucose 25%) and Dextrose Gel 40%. Dextrose Gel has been recommended for the management of neonatal hypoglycemia (12) and there are other reports of improvement in blood glucose concentration after Dextrose Gel absorption via the bucal

mucosa.(13,14) Dextrose Gel treatment for neonatal hypoglycemia has various advantages including ease of administration and low cost. Babies tolerated both the administration of the Gel and gel itself. Both staff and researchers reported gel treatment to be acceptable and simple to administer.(15) Considering the consequence of pain in newborns, pain relief should be offered for all painful procedures.

Despite the contributions of this study, it had some limitation and one of these is the fact that we included in our sample only term healthy newborn babies, without any other previous painful procedures in contrast with previous reports who included, for example term and preterm infants who received more than 10 painful procedures during the first 24 hours of life.(16,17) Other study also suggests that newborns who had received six painful stimuli before the targeted interventions studied had significant lower pain score than those with fewer prior pain experience.(18)

CONCLUSIONS

Pain caused by heel lance procedure in healthy term infants was lower after administering oral Dextrose Gel 40% than that after routine care sucrose 25%. Dextrose Gel 40% is an efficacious pain management tool, brief as less than two minutes procedures, enhancing infants' physiological stability and recovery after the procedure. Clinicians should incorporate Dextrose Gel 40% into pain management of healthy newborn babies during brief painful procedures because is efficacious, low cost and ease to administer.

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