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Clinical Utility of 10% Dextrose Solution as Analgesic after DPT Vaccination and it Comparison with Direct Breastfeeding

Authors

Yogesh Yadav[1], Kavita Yadav[2], Mahesh Chand Meena[3], Mehesh Kumar Goyal[4]

[1]Asst. Professor, Department of Paediatrics SMS Medical College Jaipur
[2]Senior Demonstrator, Department of Physiology SMS Medical College
[3]Senior Resident
[4]Medical Officer, Department of Pediatrics SMS Medical College
Corresponding Author
Yogesh Yadav
Assistant Professor, J K Lon Hospital Jaipur, Rajasthan ,India
Email: *yoge2501@gmail.com*

Objective: *To compare analgesic effect of 10% dextrose solution with direct breast feeding, and placebo after DPT vaccination to 6week- 3month old infants.*

Participants and study Design: *Infants coming for their DPT vaccination were randomized in to three groups of 50 each in a randomized, placebo controlled trial.*

Outcome Measures: *The primary outcome variable was the duration of cry after vaccination. Secondary outcome variables were Modified Facial Coding Score (MFCS) and latency of onset of cry.*

Results: *150 babies were equally in enrolled in breast feed group,10% dextrose fed group and distilled water fed group. Median duration of cry was significantly lower in direct breastfed 35.5(17-54)seconds and 10%dextrose fed babies52.5(31-67.5)seconds as compared to babies given distilled water 81.5(33.5-119.5) seconds ($P<0.05$).*

Conclusion: *Direct breasting and 10% dextrose act as analgesic in young infants undergoing DPT vaccination in young infants less than 3 months of age.*

Keywords: *10% dextrose, Breasting, Duration of cry, DPT vaccination, Management, Pain, Infant.*

Many new born babies undergo painful procedures like heel pricking, venepuncture and intramuscular injection for immunization. Such procedures inflict distinct physiological, behavioral, hormonal and metabolic changes [1]. Grunau and Caring have shown that first cry following pain Is most sensitive to noxious stimuli [1]. Great emphases is being laid in minimizing pain during these minor procedures in neonates. Duration of cry has been widely used in various studies as a maker of severity of pain [1-3]. Dextrose and sucrose in varying concentration have been shown to relive pain during venepuncture or intramuscular injection [4-8]. Evidence is emerging that breastfeed/breast milk has analgesic properties [9-13]. We planned a study with the objective to compare the efficacy of anti-nociceptive effect of breastfeeding and oral 10% dextrose, 2 minutes before DPT vaccination, using distilled water as placebo.

METHODS

The study was carried out in the immunization clinic of Department of Pediatrics, J K Lon Hospital Jaipur Rajasthan. Healthy term infants less than three months of postnatal ages, who were on exclusive or partial breastfeed and attended the immunization clinic for DPT vaccine were included. The following babies were excluded: infants who have required hospital admission for more than 48 hrs, perinatal asphyxia (5 min Apgar score <5) or delayed cry (> 5min) if born at home, intrauterine growth retardation (IUGR) (wt <10th centile for gestational age), preterm deliveries (<37 week of gestation), developmental delay (developmental age lags behind post-conceptional age by 1 months) and previous surgery. The subjects were randomized into three groups of 50 each through computers generated random numbers and put in serially numbered opaque sealed envelopes (SNOSE method). The person generating random numbers and placing them serially in sealed envelope was not involved in the study. The name, age, sex, weight, height, and head circumference were recorded in a pre-structured Performa. Babies were brought to the room where vaccination was to be done. At recruitment, one person opened the sealed envelope and administered the allotted intervention, as above, in all the babies. Breastfeed group: Babies in breastfeed group were breastfed throughout the intervention, starting 2 minutes prior to the vaccination; 10% dextrose group: 2 ml of 10%dextrose was given orally by a sterile syringe 2 minutes prior to intramuscular vaccination; Placebo group: 2 ml distilled water was given orally by a sterile syringe 2minutes prior to intramuscular vaccination. All the babies received the intervention from one investigator only; another two investigators would then come in the immunization room. One administered 0.5 ml of wDPT vaccine by a 2 mL syringe with 23 G 1" needle on anterolateral aspect of thigh (left/right) after cleaning the skin with spirit. The injection was given with the baby in the mother's lap, with thigh exposed, after calling a loud "in" when the needle was inserted, and "out" when the needle was removed. All events were recorded by the investigator on a digital video camera (model Sony CCDTRV238E)for total duration of five

minutes from the removal of the needle. A different investigator analyzed the outcome variables from the video recording in all our subjects. All the four investigators performed the same role in all the enrolled babies. Three investigators were blinded to the pharmacological intervention given to the baby; however, none was blinded to the intervention of "breastfeeding".

Outcome variables: Primary outcome variable was the duration of cry (in seconds) after vaccination. It was defined as duration of continuous distressed vocalization (cry) after needle insertion to the period of silence of more than 5 second, excluding these 5 seconds. As video recording was done only for 5 minutes, the babies who were still crying even after 5 minutes, the duration of cry was noted as 3000 seconds only. Secondary outcome variables were the latency of onset of cry and Modified Neonatal Facial Coding Score (MFCS) [9]. Latency of onset of cry (in seconds) was defined as the period between insertion of needle, marked by the sound "in" and the onset of vocalization, in form of cry. The MFCS was calculated immediately and after 1 and 3 minutes of needle insertion. This was a composite score obtained from the sum of the following: brow bulge, eye squeeze, nasolabial furrow, open mouth, chin quiver, and trunk movement. Each parameter was scored "0" if absent and"1" if present and the total score was obtained. One observer was responsible for giving the scores in all the babies. During breastfeeding, only one half of the face was visible; thus, all facial parameters were based on the facial side which observer could see. We included only healthy term infants without any neurological deficits ,movements and facial expression of the face in these babies will be symmetrical, unless facial nerve palsy is present. However, if for some reason, any parameter could not be seen on both sides, a zero score was given to that parameter. In order to avoid confounding by other pain relieving methods, the following steps were ensured. All enrolled babies had been fed within 3 hours prior to the interventions but had not received a feed in the previous 45 minutes. All babies were held in their mother's lap during vaccination. The mothers were allowed to hold ,talk to, or rock the baby during the procedure in all the groups. Since the state of wakefulness could have modified the response, the procedure was done in awake babies. If baby was sleeping, he was gently awakened; if he cried, he was soothed to quite wakefulness before the procedure. Non-nutritive sucking was not done during the procedure. All the tests were performed between 9am to2 pm to avoid diurnal variation in pain response. Written informed consent was taken from the parents and the ethical clearance was taken from Ethical Committee of the College. Duration of cry was the primary outcome variable and sample size was calculated for this variable. 50 cases in each group were required to attain a power of 90% with test significance of 0.05. Results were analyzed using STATA 9.1 software. Analysis of continuous data with normal distribution was done by one-way ANOVA test followed by Bonferroni correction for multiple analyses of data, and non-normally distributed data by Kruskal-Wallis test.

Categorical data was be analyzed by Chisquare test.

Results

A total of 188 eligible babies were approached, of which38 were excluded (25, not meeting exclusion criteria; 12, refusal to participate). 150 babies were randomized into 3groups of 50 babies each. The postnatal age, number of prior injections, sex ratio, time to last feed, and duration of needle insertion was comparable in all three groups **(Table I).**

Median (inter quartile range) of duration of cry was significantly lower in direct breast fed 35.5 $^{(17-54)}$seconds and 10% dextrose fed babies 52.5 (31-67.5)seconds as compared to babies given distilled water 81.5(33.5-119.5) seconds (P<0.05). Significantly fewer babies had duration of cry in 0-60 seconds range in the two interventions groups as compared to placebo group**(Table II).**

The difference in latency of cry in the breast fed, dextrose and placebo groups were 2.1 (1.2) seconds, 2.2(1.2) seconds and 1.8 (0.75) seconds (P>0.05)

Table I Baseline Demographic Characteristics of the Study Subjects, Mean (SD)

Parameter	**Direct breast feeding (n=50)**	**10% Dextrose (n=50)**	**Distilled water (n=50)**
Age (wks)	10.3 (2.4)	10.2 (2.2)	10.1
Weight (kg)	4.5 (0.5)	4.4 (0.4)	4.4 (0.4)
Time since last feed (min)	45 (8.2)	39 (4.3)	47 (9.2)
Duration of needle insertion (s)	3.0 (0.5)	3.0 (0.5)	2.8 (0.4)

Table II Duration Cry in the Three Groups After DPT Vaccination

Cry duration (s)	**Direct breast feeding**	**10% dextrose solution**	**distilled water**	**P value**
0-60	40	35	18	<0.001
61-120	7	12	22	<0.05
121-180	3	2	6	>0.05
>180	0	1	4	>0.05
Median	35.5	52.5	81.5	<0.05
(IQR)	(17-54)	(31.67.5)	(33.5-119.5)	

Cry at 1 min and 3 min was significantly lower in direct breast fed and dextrose fed babies. There was no statistically significant difference in MFCS immediately after needle insertion **(Fig. 1)**.

DISCUSSION

Our study demonstrated that babies who were directly breastfed or given 10% dextrose had significantly shorter duration of cry, and lower pain score at 1min and 3minafter needle insertion, as compared to placebo.

Numerous non-pharmalogical intervention have been tried to reduce pain of vaccination and minor procedures. Ingestion of sucrose decreases pain in term and preterm infants [4-8]. A systematic review reported that10%sucrose was effective in alleviating minor procedural pain in neonates [5]. Upadhyay, et al. [9] and Uyan, et al. [10] have earlier demonstrated that expressed breast milk given 2 minutes prior to venepuncture significantly reduced pain in term infants. Osinaike, et al. [11]. Have demonstrated that breastfeeding reduces pain in neonates during venepuncture. Singh, et al. [12] have shown that exclusively breastfed babies perceive lesser pain during intramuscular injection than partially or non breastfed babies, even without any physiological or medical intervention during vaccination. This is probably because babies who are exclusively breast fed are better developed neurologically and physically. They probably can tolerate noxious stimuli better as compared to top fed infants. Uga, et al. have evaluated analgesic effect of breastfeeding during heel puncture in newborn [13].Others have demonstrated analgesic effects of skin-to skin contact in procedural pain in healthy term neonates[17,18]. Efe and Ozer hypothesized that following mechanisms could be attenuating the pain response while direct breastfeeding the baby during the painful procedure[19]. Firstly, suckling at the breast stimulates the infant's oropharyngeal tactile and mechanoreceptor rand focuses attention on the mouth, reducing outside influences. Secondly, the sweet flavor of milk stimulates the release of opioids in midbrain of infant which act on receptor that decrease the perception of pain. Thirdly, breastfeeding involves maternal skin to skin contact which stabilizes blood glucose level, body temperature and respiratory rate and reduces release of stress hormone [20]. Finally, breastfeeding involves intimate social interaction between mother and child and may release anti stress hormone, oxytocin [21]. The mechanism of relaxation and analgesia probable works synergistically [22, 23]. During breastfeeding, only half of face is visible but facial scores can be interpreted due to symmetry of facial response.

Breastfeeding during and before intramuscular DPT injection is as good as 10% dextrose as an analgesic in infants younger than three months. Previous studies have demonstrated pain relief with dextrose in varying concentrations, but no other previous study has directly compared analgesic effect of breastfeeding and dextrose. Skogsdal, et al. [14] reported reduction in crying time by 75% in babies receiving 30%glucose compared to no treatment group. Ramenghi, et al. [15] found hydrogenated glucose solution as effective as 25% or50% sucrose in reducing crying time and duration of first cry. A recent Cochrane review has also concluded that if available, breastfeeding or breast milk should be used to alleviate procedural pain in neonates

undergoing a single painful procedure compared to placebo, positioning or no intervention [23].

One of the limitations of our trial design is the lack of blinding. In breastfeeding studies, it is not possible to "blind" subjects as it is quite evident during video recording. In this case, a potential bias in the pain score evaluation could be introduced. Other limitation is that we have not taken physiological parameter of pain assessment (heart rate, respiratory rate, oxygen saturation) into account. However, previous studies have also used pure behavioral scales in older children. We avoided use of physiological parameters because pulseoxymeters often do not give readings in crying and vigorous baby and attaching chest leads to healthy babies in immunization rooms can be intimidating and stressful the parents.

Though MFCS has been reported to be used only in neonatal age group, we extrapolated its use in early infancy, as the physiological characteristics of babies in this age group are similar. However, it should have been validated for ages beyond neonatal period. We also used other parameters of pain assessment (duration of cry),which showed correlation to the MFCS.

CONCLUSION

Direct breastfeeding and oral dextrose have antinociceptive effect during intramuscular whole cell DPT vaccination. This effect is probably more for direct breastfeeding during vaccination than oral feeding of10% dextrose 2 minutes before vaccination.

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