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Original Research Article

Effect of expressed breast milk administration on pain response among newborns during heel lance procedure in a tertiary care hospital — A randomized controlled trial

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ABSTRACT

Newborn's pain is a great challenge to health professionals as well as to parents. Newborns are especially vulnerable to pain. The primary objective was to evaluate the effectiveness of expressed breast milk administration on pain response among newborns during heel lance procedure and the secondary objective was to find out association between selected sociodemographic variables and pain response among newborns during heel lance procedure. The research approach adopted was quantitative and the design was experimental - A randomized controlled trial. Sixty newborns after 48 to 72 hours of life who came to the Shalabham newborns screening unit for metabolic screening were selected according to the inclusion criteria. Samples were selected by using block randomization with fixed block size 4 and newborns divided into two groups, experimental and control group. Allocation concealment was done by using an opaque sealed envelope. The investigator, clinical data collected from the case record of the newborns and caregiver who came with newborns to Shalabham unit. After collecting clinical data, pain was measured by NIPS score 3 minutes before heel lance procedure for getting baseline data by an observer in both the groups by an observer. The investigator knows the newborns whether included in experimental or control group. Then for the experimental group, 5 ml expressed breast milk was given through gokarnam by the investigator and routine care was given by the staff nurse. For control group routine care given by staff nurse. After 1 minute performed heel lance procedure by a staff nurse who had adequate experience in neonatal care to minimize the variation in pain during the heel lance procedure, heel lance procedure was done using all sterile precautions and blood collected in the screening card and kept for drying process. The observer assessed the pain level of newborns by using NIPS score during heel lance procedure both experimental group and control group. After 30 minutes, pain level was reassessed by observer using NIPS score on experimental and control group and recorded. Results showed that the mean pain level was significantly improved in the experimental group ($p<0.00$) compared to the control group. Thus, it can be concluded that expressed breast milk administration is found to be effective in reducing pain during heel lance procedures.

1. Introduction

"A baby's laugh could simply be one of the most beautiful sounds in the world" A few decades back, it was thought that newborns could not experience pain and, analgesia was considered unnecessary. There was a paucity of appropriate tools for pain assessment in newborns and the risk of adverse effects of analgesics also augmented this practice.[1]

Newborns pain is a great challenge to health professionals as well as to parents. Newborns, are especially vulnerable to pain. In fact, at this age, babies

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are less able to control pain than at any other time of life. Fortunately, in the last ten years, there has been a growing interest in alleviating pain in newborns.[2] Pain relief is said to be cardinal principles of compassionate medicine, yet in practice, pain management is often an ignored aspect of care. Neonatal pain was continuous to receive limited attention and is treated less vigorously than in older newborns and adult.

A wide variety of pharmacological and non-pharmacological interventions for the management of pain in newborns like breastfeeding, non-nutritive sucking, swaddling, and sucrose administration.

1.1. Objectives of the study

1. To assess the effectiveness of expressed breast milk administration on pain response among newborns during heel lance procedure.
2. To find out association between selected sociodemographic variables and pain response among newborns during heel lance procedure.

2. Materials and Methods

The research approach adopted for this study is quantitative approach. Selection of the particular study approach is based on the purpose of the study and type of variables. Experimental — Randomised controlled trial was used for this study. Through this design the investigator was able to appraise the effect of expressed breast milk administration on pain response among newborns during heel lance procedure in a tertiary care hospital. The present study sample consisted of newborns in age group of 2-3 days coming for heel lance procedure in Shalabham, newborns screening unit of Sree Avittom Thirunal Hospital Thiruvananthapuram. In the present study, the sample who met the inclusion criteria was selected. Those who meet eligibility criteria and who are willing to participate in the study identified. Those who consented for the study were allocated. Those who are willing to participate allocate randomly to experimental and control group using block randomisation with a fixed size 4. Allocation concealment done by using an opaque sealed envelop.

Formal permission for data collection obtained from Institutional Research Committee, Institutional Ethics Committee, Clinical Trial Registry of India, Medical Superintendent Sree Avittom Thirunal hospital Thiruvananthapuram and head of the department, Neonatology. The period of data collection was from 1/3/2021 to 17/4/2021. The data collection from 60 newborns came to Shalabham newborns screening unit, who underwent the heel lance procedure for metabolic screening. Samples selected by using block randomization with fixed block size 4 and newborns divided into two groups, experimental and control group by another person who not involved in the present study. Allocation concealment done by using an opaque sealed envelope. Investigator selected the newborns in Shalabham, newborns screening unit who meet all the inclusion criteria of the study, after taking consent from their parents when the caregiver came to Shalabham for collecting the token number. The investigator introduced herself to caregiver who fulfilled the inclusion criteria. The purpose of the study was explained to caregiver and confidentiality was assured and informed consent was obtained. After getting consent from caregiver investigator has instructed caregiver to collect 5 ml of expressed breast milk in a clean container, both experimental and control group. Then the container labelled with newborns name. When the newborns came to the unit one envelope taken and opened by the investigator to know whether the newborns include experimental or control group.

Then the investigator, collected clinical data from the case record of the newborns and caregiver who was came with newborns to Shalabham unit. After collecting clinical data, for experimental and control group assessed pain using NIPS score 3 minutes before heel lance procedure for getting baseline data by an observer. Then instructed to the caregiver to wait outside of the unit. The investigator knows the newborns whether included in experimental or control group. Then for experimental group 5 ml expressed breast milk given through gokarnam by investigator and routine care (comfort positioning and general assessment) given by staff nurse, but the observer can't saw whether newborns got expressed breast milk or not. For control group routine care (comfort positioning and general assessment) given by staff nurse.

After 1 minute performed heel lance procedure by a staff nurse who had adequate experience in neonatal care to minimize the variation in pain during heel lance procedure, heel lance procedure done using all sterile precautions and blood collected in screening card and kept for drying process. The observer assessed pain level of newborns by using NIPS score during heel lance procedure both experimental group and control group. Then instructed the caregiver to wait for 30 minutes outside the unit with the newborns. After 30 minutes, pain level was reassessed by observer using NIPS score on experimental and control group and recorded. After that collected expressed breast milk given to control group since its collected for both groups.

The data obtained from the clinical data sheet and pain scale were analysed on the basis of objectives by descriptive and inferential statics. Statistical analysis was done using frequency, percentage, Chi square test and Repeated measures ANOVA.

3. Result

Result shows that majority of the newborns in experimental group (60%) and control group (53.3%) were males. It was clear that majority of newborns birth weight were 2.5 to 2.99 kg in the experimental (66.7%) and control group (53.3%). It was clear that 96.7% of newborns in control group and 83.3% of the newborns in experimental group the mode of feeding was breast feeding and 3.3% of newborns in the control group and 16.7% of newborns in experimental group the mode of feeding was expressed breast milk / formula feed. It clear that 56.7% of newborns in control group and 43.3% of the newborns in experimental group born through normal vaginal delivery and 43.3% of newborns in the control group and 56.7% of newborns in experimental group born through LSCS. The finding shows that most of the newborns in the control group (53.3%) and experimental group (56.7%) had previous experience with heel lance procedure. It was evident that, majority of newborns getting breast milk in the control group (96.7%) and experimental group (83.3%).

Table 1: Effect of expressed breast milk administration on pain response in control and experimental group

Category	Mean	SD	F	p
Experimental group	1.10	0.47	93.48	.000
Control Group	3.40	1.81		

It was evident that pain level mean score among experimental group was 1.10 ± 0.47 and that of control group was 3.40 ± 1.81 and the calculated p value was = 0.00 and F value (93.48, p = 0.01). Hence, it was statistically significant and therefore the null hypothesis was rejected and the alternate hypothesis was accepted. Thus, it can be concluded that expressed breast milk administration was found to be effective in reducing pain during heel lance procedure.

In this study there was no significant association between pain level during heel lance procedure and selected clinical variables of newborns ($p<0.05$). Hence, it was statistically not significant and therefore the null hypothesis was accepted and the alternate hypothesis was rejected. Thus, it can be concluded that there was no association between selected sociodemographic variables and pain response among newborns during heel lance procedure.

4. Discussion

The present study used quantitative design to evaluate the effect of expressed breast milk administration on pain response during heel lance procedure.

The study conducted by Tharun C Varghese, Anna Susan Paul on expressed breast milk for the pain relief of newborns shows that the total number of male neonates in experimental and control were 60.4% and 70.3% respectively whereas female neonates in experimental and control were 39.6% and 29.7% respectively,[3] the review study congruent with present study. The study conducted by Singh RK, Simalti AK, Singh D on breast feeding as analgesia: randomised controlled trial shows that 50% of newborns in control and experimental group delivered through normal vaginal delivery and 50% of newborns in the control and experimental group delivered through LSCS,[4] the review study congruent with present study. It is revealed from the study 56.7% of newborns in control group and 43.3% of the newborns in experimental group born through normal vaginal delivery and 43.3% of newborns in the control group and 56.7% of newborns in experimental group born through LSCS. A prospective double blinded randomised controlled study conducted by Sujatha S et al. on effect of expressed breast milk administration on neonatal pain shows that, the neonates born through spontaneous vaginal delivery i.e. 32 (61%) and remaining 26 (39%) born through assisted type of delivery like forceps and vacuum delivery and none born through caesarean section.[5]

The study conducted by Sujatha S et al. on effect of expressed breast milk administration on neonatal pain response — randomised experimental study shows that pain level mean score among experimental group was 58.64 ± 3.42 and that of control group was 70.73 ± 3.06 and the calculated p value was = 0.00. The pain management intervention used should be simple, practicable, cost effective and safe. Administration of breast milk as a study intervention could be easily adopted from the perspectives of health care providers and parents[5] the review study congruent with present study. In this present study there was no significant association between pain level during heel lance procedure and selected clinical variables of newborns ($p<0.05$). This finding was supported by another study conducted by Denise Harrison on Breast feeding for procedural pain in newborns beyond the neonatal period — A systematic review shows that there was no significant association between pain level during heel lance procedure and selected clinical variables of newborns.[6]

5. Conclusion

In the light of the above finding of the study the following conclusions were drawn: Expressed breast milk administration decrease pain response among newborns during heel lance procedure. So, it can be used as an intervention in Shalabham screening unit. So, the research hypothesis was accepted and the study concluded that expressed breast milk administration had a significant effect on the pain response.

6. Source of Funding

None.

7. Conflict of Interest

The author declares that there is no Conflict of interest.

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