

## Comparative Study of Efficacy of Breast Milk and Oral Sucrose for Pain Relief During Minor Procedures in Infants

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### Abstract:

**Background:** Infants may also experience pain during procedures like simple physical examination, bladder catheterization, phlebotomy, intravenous line placement, central venous line, chest tube placement and circumcision. Data on managing pain in infants in low and middle-income countries is scarce. In view of the high incidence of procedural pain and less available data, the current study was taken up to check for better management options. Our objective is to compare the efficacy of oral sucrose versus breastmilk in reducing procedural pain among infants.

**Materials and Methods:** This interventional comparative study was done at a tertiary care centre among 200 infants who underwent certain minor procedures in the department of paediatrics at Fathima Institute of Medical Sciences, Andhra Pradesh, from March 2022 to September 2022. Infants with perinatal asphyxia, congenital malformations, neurological problems and who need repeated pricks for blood collection were excluded. 100 infants belonged to the breastmilk group and 100 infants belonged to the oral sucrose group. Age, gender, level of pain etc were assessed and compared between both groups.

**Results:** There is no significant difference in the mean age of infants in both groups. There is no significant difference in the type of painful procedure, and duration of procedure between both groups. There is a significant reduction in pain in the sucrose group compared to the breastmilk group. Duration of crying is significantly more in the breastmilk group. There were no side effects seen in both groups.

**Conclusion:** Oral sucrose provided effective pain relief among infants who underwent minor procedures. We recommend using oral sucrose for all infants 10 min before the scheduled painful procedure.

**Key Words:** Breast milk, Oral sucrose, Procedural pain, Infants, Non-pharmacological interventions

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### I. Introduction

Infants routinely experience acute pain during skin-breaking procedures, or after surgery, and due to necrotizing enterocolitis or meningitis. They may also experience pain during procedures like simple physical examination, lavage tube placement, physical examination bladder catheterization, phlebotomy, intravenous line placement, central venous line, chest tube placement and circumcision. Though surgical and procedural pain management in infants is effective, they are not much used in minor procedures and nursing care. Painful procedures can impact psycho-social development of infants<sup>1</sup>. Various physiological, and behavioral measures during the interventions can help to assess pain among infants, which include heart rate (HR), blood pressure (BP), respiratory rate (RR), saturation of oxygen (Spo<sub>2</sub>), hormonal changes apart from motor patterns, mimicry, and crying.

Many pharmacological and non-pharmacological strategies help to provide pain relief. Mild to moderate pain can be managed with the help of a pacifier, sucrose, glucose, breast milk, kangaroo care, massage, and by using topical anaesthetic gels<sup>2</sup>. Dextrose and topical anesthetics are not easily available and they are expensive. Sucrose is commonly available and inexpensive. Oral glucose may be used for treating mild to moderate pain or as an adjunct to severe pain.<sup>3</sup>

Data on managing pain in infants in low and middle-income countries are scant<sup>4</sup> Previous studies show that pain is experienced by around 1/4<sup>th</sup> to 1/3<sup>rd</sup> of children<sup>5-8</sup> of which 1 in 20 experience moderate to severe levels of pain and related disability. In view of the high incidence of procedural pain, the current study was taken up to check for better management options.

### Objective:

To compare the efficacy of oral sucrose and breast milk in relieving pain during procedures among infants.

## II. Materials And Methods

**Source of data and type of study:** This interventional comparative study was done on infants who underwent painful procedures in the department of pediatrics, at a tertiary center named Fathima Institute of Medical Sciences, Kadapa, Andhra Pradesh.

**Study Design:** Interventional comparative study.

**Study Location:** This study was done at a tertiary care teaching hospital in the Department of Pediatrics at Fathima Institute of Medical Sciences, Kadapa, Andhra Pradesh.

**Study Duration:** The study was done for 6 months from March 2022 to September 2022.

**Sample size:** 200 infants

**Sample size calculation:**

Sample size calculation: As per the study done by Carbajal et al.<sup>9</sup> 18.2% of infants who experienced painful procedures underwent non-pharmacological interventions. In our study also, we used non-pharmacological interventions only. Considering the prevalence as 18.2%, the sample size is estimated as follows:

$$N = Z^2 PQ / E^2$$

N=Sample size

P=Prevalence

Q=1-P

N=163

Confidence levels -90%(power)

Error-5%

163 is the minimum sample size. So, we included 200 infants in our study, considering few losses to follow up and incomplete data.

**Subjects and selection method:** Group D: 100 infants received oral sucrose- given 10min before the scheduled painful procedure

Group B: 100 infants received expressed breast milk orally given 10 min before the scheduled painful procedure.

**Inclusion criteria:**

- Infants scheduled for some kind of painful procedure
- Infants of any gender, for whom consent was taken from legally accepted representatives.
- Breastfed infants for group B

**Exclusion criteria:**

- Infants with acute illnesses
- Infants with perinatal asphyxia
- Infants with congenital malformations.
- Infants on analgesics, sedatives in the last 24 hours
- Infants who need repeated pricks for blood sampling
- Infants with neurological problems
- If mothers had any problem that avoided them from giving breast milk.
- Infants who required repeated pricks

**Parameters assessed:**

- Age
- Gender
- Infant's current weight
- Type of procedure
- Duration of procedure
- Level of pain
- Duration of cry

**Pain assessment was done using the neonatal infant pain scale (NIPS):**<sup>10</sup>

It is recommended for children aged below 1 year.

A score of 3 -indicates the presence of pain.

Score of 0 to 2: No pain

3 to 4: Mild pain to moderate pain

5 and above: Severe pain

**Ethical considerations:** Ethical committee approval was taken before conducting the study. The informed consent form was taken from every parent of infants who participated in the study.

**Statistical analysis:**

Data analysis was done using Epi Info software version 7.2.5. The results were expressed as mean ± S.D, percentages, and all parameters were compared between two groups using students T test or chi-square test. P value < 0.05 was considered significant.

**III. Results**

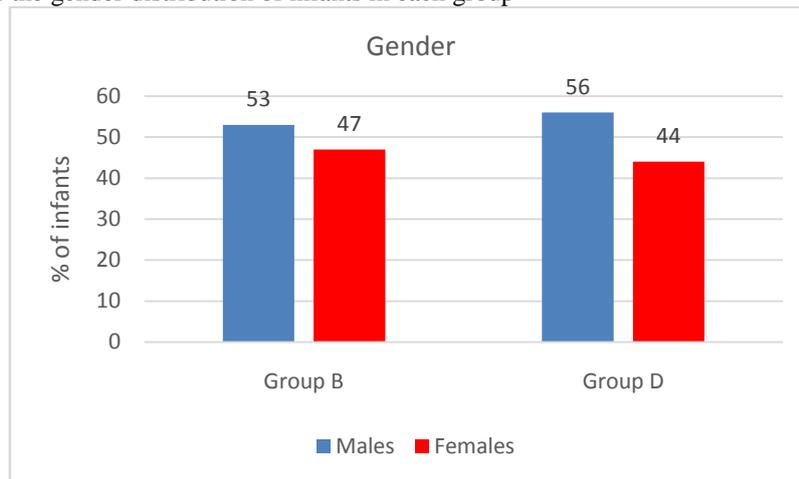
**Age:** The mean age of infants in group B was 9.2±1.2 months and the mean age of infants in group D was 8.9±2.0 months. There is no significant difference in age between both groups as per T-test.

Table 1 illustrates mean age of infants of both groups

Groups	Mean age	P value
Group B	9.2±1.2	0.19 T value: 1.2
Group D	8.9±2.0	

**Gender:** Most of the infants were males.

Graph 2 illustrates the gender distribution of infants in each group



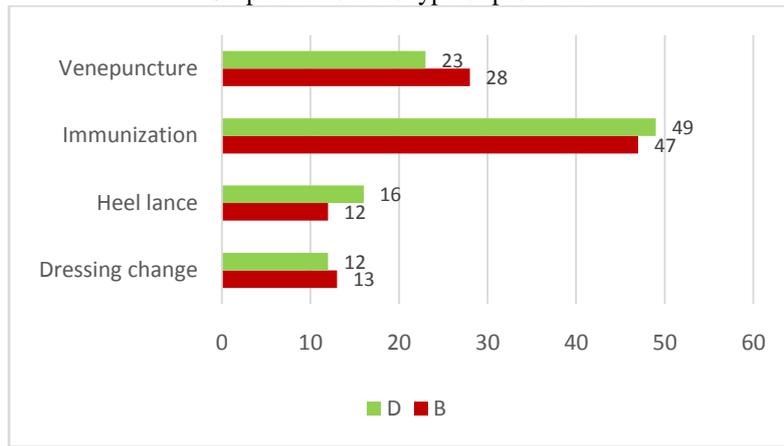
**Current weight:** There is no significant difference in the current weight of infants in both groups, as per T test. Hence the comparison is justifiable.

Table 2 illustrates mean current weight of neonates of both groups.

Groups	Mean weight	P value
Group B	8.4±1.3	0.09 T value:1.69
Group D	8.7±1.2	

**Type of procedure:**28 infants underwent heel lance. 96 infants underwent immunization. There was no significant variation in the type of procedure undergone by infants belonging to two groups, as per the chi-square analysis(p=0.76).

Graph 2 illustrates type of procedure



**Duration of procedure:**

There is no significant difference in duration of procedure between two groups.

Table 3 illustrates the mean duration of procedure among infants of both groups

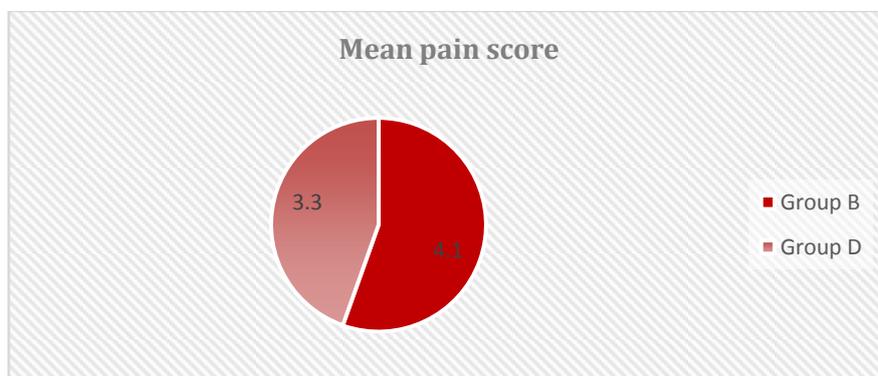
Groups	Mean pain score	P value
Group B	45.4±9.8 seconds	P =0.29 T=1.05
Group D	44.1±7.5 seconds	

**Level of Pain as per NIPS:**

There is significant difference in level of pain between both groups, as per T test.

Table 4: Level of pain as per NIPS in both groups

Groups	Mean pain score	P value
Group B	4.1±2.1	0.001 T value:3.16
Group D	3.3±1.4	



Graph 3 illustrates mean pain score

**Mean duration of cry:**

There is a significant difference in the mean duration of crying among infants between two groups after painful procedure.

Table 5: Mean duration of crying among both groups

Groups	Mean duration of cry	P value
Group B	1.3±0.5 min	P =0.001 T=3.93
Group D	1.1±0.09 min	

#### IV. Discussion

The current study included 200 infants. There is no significant difference in the mean age of infants between groups B and D. Hence the comparison is justifiable between groups with no age bias. Our study has slightly more male infants compared to female infants. This was in contrast to the study of **Lan et al.**<sup>11</sup> who included 120 full-term babies. Among them, 50.8% were females and 49.2% were males. In the study done by **Abhinaya S et al.**<sup>12</sup> among 80 babies included, 42 were males and 38 were females. Male preponderance was similar to the current study. There is no significant difference in the type of procedures underwent by infants between groups. Most of infants underwent vaccination. Other procedures include heel lance, venepuncture and change of dressing for wounds. In the study of **Goswami**<sup>13</sup>, only neonates who were scheduled for DPT vaccination were included. In some other studies, only venepuncture was included.<sup>14-15</sup> There is no significant difference in the mean duration of procedure between two groups in our study. In the study of **Goswami**,<sup>13</sup> mean duration of the procedure was around 2.8 minutes. The mean duration was more compared to our study, as their study assessed only 1<sup>st</sup> DPT vaccination. Preparation for vaccination might have taken more duration of time. There was no difference in the mean duration of painful procedures of neonates of all the groups, similar to our study. There is a significant difference in pain score as assessed by NIPS between the two groups in our study. In the study done by **Lalitha et al.**<sup>16</sup> premature infant pain profile (PIPP) scores were used. Children in the breastmilk group had lower PIPP scores than the control group. The mean score in the breastmilk group was 12.7. The mean score in the control group was 15.5 ± 1.78. Beneficial effects were seen at 1 min and 5 min in both groups after the procedure. At 1 min, babies of the control group had severe pain, but it was reduced to moderate pain in the breastmilk group. At 5 min after the procedure, the neonates of control group experienced moderate pain but breastmilk group babies had only mild pain. 20 babies required resuscitation in their study. Among them, 12 belonged to the breastmilk group. **Tarun C**<sup>17</sup> used dextrose and we used sucrose in our study. In the study of **Varghese Tarun C**<sup>17</sup>, results showed that there was a significantly lower pain score in dextrose group after venipunctures. The mean NIPS score was 4.67 in dextrose group. The mean NIPS score in breast milk group was 6.62. There was no significant variation in heart rate and desaturation between both groups. Previously many associations suggested proper pain management guidelines.<sup>18-22</sup> Effective implementation of these guidelines helps in reducing pain among neonates and infants.

The strength of this study was we provided effective intervention to reduce the incidence of pain among infants during painful procedures.

The main limitation is the small sample size.

We recommend studies on the comparison of sucrose with sucrose and glucose, and studies on relieving pain among preterm neonates.

#### V. Conclusion

In the current study, we tested the efficacy of oral sucrose with oral expressed breast milk among 200 infants scheduled for painful procedures. Results showed that there was significant relief in pain among infants who were given oral sucrose. There were no side effects with these two non-pharmacological interventions. Hence, we recommend using oral sucrose 10 min before the scheduled painful procedure for any infant. If there is no oral sucrose available, we recommend giving breast milk.

There were no conflicts of interest.

The study is self-sponsored.

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