

THE EFFECTIVENESS OF ORAL SUCROSE IN MANAGING INFANTS' PAIN DURING IMMUNIZATION

Gad R F¹, Abusaad FE², Dowling DA³,
Bassiouny MR⁴, Abd El Aziz MA⁵.

¹Faculty of Nursing, Mansoura University

²Faculty of Nursing, Mansoura University

³Frances Payne Bolton School of Nursing, Case Western Reserve University

⁴Faculty of Medicine, Mansoura University

⁵Faculty of Nursing, Mansoura University

Email of the corresponding author: drrashafawzy@mans.edu.eg

Abstract

Treating pain during vaccination should be a part of pediatric primary health care around the world, as untreated pain in children has short and long-term consequences. Few studies of pharmacologic and non-pharmacologic methods of pain relief during immunization have been conducted in low-and-middle-income countries. Finding a cheap and effective pain intervention would improve primary health care. The current study aimed to evaluate the effectiveness of oral sucrose as a method of pain management during immunization among infants through six months of age. A randomized controlled experimental design was used. The study sample included 80 infants distributed into sucrose and control groups. Data were collected in an Egyptian primary health center. Outcome measures, including pain, as measured by the FLACC pain scale, crying time, and heart rate, were measured at three time points (before, during, and after injection). There were statistically significant differences during and after immunization ($p < .001$) reflecting lower: scores of pain, crying duration, and rising in heart rate for the sucrose group compared to the control group. The study supports the effectiveness of oral sucrose in managing infants' immunization pain and recommends for providing clinical setting with safe resources and education for proper administration of oral sucrose in pain management.

Keywords: Immunization, Oral sucrose, pain management

1. Background and Significance

Immunization is considered an essential component of primary health care as a preventive health measure that occurs frequently in childhood. Immunization produces immune-resistance to infectious diseases and it saves up to 3 million children each year (1). Intramuscular injection is the commonly route used during immunization. According to the Egyptian obligatory immunization schedule, most of injections are given during the first 6 months of life (2). Research evidence indicates that Immunization is one of the most painful procedures in infancy (3,4). This causes distress for the infants, parents, and providers. The most important

complication is fear of injections for infants and their parents which leads to non or incomplete –adherence to immunization schedules. Negative experiences with injections lead to the development of needle fears in some children. These consequences are sometimes neglected or inappropriately treated in the infant population (5).

To ensure infant safety and prevent long-lasting consequences related to immunization procedures, methods to manage infants' pain should be provided. Interventions for pediatric procedure-related pain in primary care include pharmacological and non-pharmacological methods. Concerning pharmacological

methods, analgesia is not routinely used for infants under 6 months of age during painful procedures such as immunization, heel lance, and venipuncture (6). Although topical anesthetic [EMLA] such as lidocaine and prilocaine have been proved to be effective in decreasing vaccination needle-related pain in various studies, it has to be applied for 20 to 60 minutes before painful procedure according to which commercial preparation is being used. This pre-application time is not always available especially in a busy clinical area like vaccination clinics (7). Other pharmacological methods like vapocoolant sprays and ethyl chloride which not only provide immediate onset of action and approximately 20 seconds of dermal and epidermal anesthetic duration but also produce unpleasant anxious cold sensation particularly in children who perceive it as a painful sensation (8). Delayed onset of action, cost, and inconvenience of Pharmacological methods have resulted in outweighing of non-pharmacological ones regarding acute pain management (9).

Non-pharmacological methods have been shown to be effective, costless, and convenient in reducing procedure-related pain. Administration of sweet-tasting solutions, mainly sucrose, has been found to have a pain relieving effect in both term and pre-term newborns(10). Releasing an endogenous opioid activated by the sweet taste is the mechanism in which oral sucrose reduces pain, (11). There are a large number of studies and evidence demonstrating analgesic effects of sweet solution in neonatal population but, studies with older infants especially those who live in Middle Eastern countries are lacking (12).

Examining the use of non-pharmacological methods for reducing immunization pain is necessary. The aim of this study is to evaluate the effectiveness of oral sucrose in managing

infants' pain during Immunization. The study addressed the hypothesis of "Oral sucrose will decrease the infants' painful experience during immunization".

2. Methods

2.1 Study design and setting

A randomized controlled experimental study was conducted in Child Primary Health Care Center (Reayt Tefl Awal), located in Mansoura city, Dakahlia Governate, Egypt.

2.2 Sampling

The study population included infants aged two, four or six months who were attending the immunization clinic to undergo routine immunizations. Healthy breastfed infants who came to the clinic with their mothers are included in the sample. Infant exclusion criteria included infant unable to tolerate oral fluids, or had received paracetamol in the day prior to immunization. The sample size was determined by using a power = .80 and a medium effect size (.5). The total sample size was 80 infants, 40 infants in each group of the two (sucrose & control) groups.

2.3 Instruments

Two instruments were used in this study. The first is the Demographic Characteristics instrument, which was developed for the purposes of the study. It includes the infant's name, ID number, gender, age, weight, pre-injection state, time since last feeding, and randomized group (A, B, or C). It was developed by the researcher and revised by pediatric nursing experts.

The FLACC scale was used to measure pain before, during, and after the immunization injection. The FLACC scale, developed by (13), measures pain based on observations in five categories: facial expression, position of legs, activity, cry, and consolability, scored 0-2 for each. Total scores range from zero to ten; 0-4 indicates mild pain, 5-6 indicates moderate

pain, while 7-10 indicates severe pain. Interrater reliability is high 0.94 (14). Additionally, crying time and heart rate changes were measured as indirect measures of pain. The infant's crying duration in response to the needle-related procedure was measured in seconds using the android application stopwatch (G Stop) offered in Google play store (15). Crying was measured up to 2 minutes after injection.

Procedure.

After the approval of the Research Ethics Committee of Faculty of Nursing, Mansoura University, the official permission for conducting the study was obtained from Agency of Egyptian Ministry of Health and health administration office in Dakahlia Governate. The research team consisted of the researcher and three research assistants (RA) who were associate degree nurses working in the study setting.

The first RA determined if the mother met the inclusion criteria and obtained a written consent.

Eighty cards marked A or B were arranged in a small box; where the first RA nurse asked the eligible infant's mother to choose a card from the cards box that indicated the assigned group: sucrose (Group A) or control group (Group B). In the vaccination room, the second RA assisted the mothers to be seated in a chair and in holding the baby in a right-sided, cradled position then she counted the infant's heart rate for one full minute. After the researcher assessed the FLACC pain score, the second RA gave the infant 2ml of [25% sucrose (A) or sterile water (B) according to the chosen card] one minute before injection.

During injection, the third RA intramuscularly injected the (DPT+HBV+HIB) vaccine in the left thigh vastuslateralis muscle using nonpyrogenic syringe 23G X 1" and 0.6 X 25 mm needle. The researcher measured infant's

crying time in response to injection up to 2 minutes then she assessed the FLACC pain score.

After injection, the researcher reassessed the FLACC pain score while the second RA counted the infant's heart rate for one full minute.

The timing of the interventions before injection was based on the determination of a systematic review (16) that found that to be effective sweet solutions used for infants beyond the neonatal period needed to be given not more than one minute before the painful procedure for sustainability of the analgesic effect. After finishing the study session, the RA gave the infant the oral polio vaccine to complete the infant's required vaccinations.

3. Data collection

Data collection was carried out weekly over 7 weeks in the spring season of 2015. The number of participants ranged from 15-20 every day. Each infant spent 4 to 6 minutes in the vaccination room.

4. Statistical analysis

Data were analyzed with SPSS version 21. Discrete data were described using number and percent. Association between categorical variables was tested using Chi-square test. Data of the study were meeting the criteria of parametric data using Shapiro-Wilk Test of Normality. Continuous variables were presented as mean \pm SD (standard deviation) and compared with Student t test. All statistical tests were done at fixed values significance ($p \leq .05$).

5. Results

No statistically significant differences were found between the study groups in either infants' sex ($p=.502$), age ($p=.845$), weight ($p=.761$), the time since the last feeding ($p=.239$), or pre-intervention state ($p=.314$). The majority of infants in the study sample were nonexclusively breastfed and were calm and awake before the injection as shown in Table 1.

Concerning pain scores, there were no significant differences between the study groups in pain scores before injection ($p=.794$). During and after injection, the means of pain scores in sucrose group (5.40 ± 1.11 & 3.15 ± 1.56) were significantly ($p<.001$) lower when compared to control group (9.65 ± 0.70 & 8.93 ± 1.1) respectively as illustrated in Table 2.

Regarding crying time, the mean of crying time measured in seconds was significantly ($p<.001$) lower in sucrose (18.18 ± 15.17) group compared to control group (89.18 ± 26.56) as shown in Table 3. Change in heart rate is the difference between heart rate before and heart rate after injection. The means of change in heart rates in sucrose group was significantly lower when compared to control group ($p=.009$ & $p=.036$) as illustrated in Table 4.

6. Discussion

Absence of statistically significant differences between the study groups in infants' characteristics proportions related to sex, age, and weight or means related to the time since the last feeding precludes any chance for these factors to influence the study outcomes particularly pain scores through perception or threshold.

Pain Scores Outcomes

The means of pain scores were measured by FLACC pain scale before, during, and after injection. The study revealed that there were no significant differences in the mean FLACC scores between the study groups before injection. This precludes also any difference in baseline pain scores accounting for subsequent differences.

The present study demonstrated that the pain scores in sucrose group was significantly lower when compared to those in control group during and after injection as illustrated from Table 2.

The sweet taste of the solutions (sucrose, glucose, and dextrose) induces releasing endogenous opioids that mitigates the

intensity of pain experienced by infants during needle injection. In accordance with this finding, there are many studies support the effectiveness of oral sweet solution particularly sucrose in terms of reducing pain scores during different painful procedures including vaccination for either newborns (17) or infants up to 6-12 months (19,21). 75% oral sucrose reduced pain scores even for 16-19-month-old infants (22). However, there were no significant difference in reducing pain scores when 33% oral sucrose (23) or 24% oral sucrose (24) were used for toddlers and young children immunization. This paradox proposes a hypothesis that higher concentrated sucrose could be more effective in managing vaccination pain for toddler and young children.

Crying Time Outcomes

The current study revealed that the crying time was significantly lower in sucrose and breastfeeding groups when compared to the control group. Regarding lower crying time in sucrose compared to control, this finding is in accordance with (25,26) where sucrose was given to infants 2, 4, and 6 month 2 minutes before the injection. In contrary to the study finding, sucrose did not reduce the crying time when used to manage toddler and young children's vaccination pain (23).

Heart rate outcomes

The current study revealed that the infants' heart rates significantly increased after injection secondary to stress and pain. Infants' heart rates in sucrose groups after injection were significantly lower when compared to their peers in control group. This is similar to previous studies that demonstrated the effectiveness of sucrose regarding physiological recovery (18) were all supporting the analgesic effect of sucrose in preventing the rise in heart rate pain response for neonates and infants in different minor painful procedures.

Limitations

Some limitations were encountered in this study, including methodological limitations inherent in the non-blinding design. There were some limitations related to data collection. Uncontrolled consoling acts considered one of the limitations where the number and the type of the used consoling acts varied between one or more of shushing, distracting words, cuddling, rocking, and upright position with rubbing back or rubbing buttocks. The third limitation regarding data collection was manual assessment of heart rate. The final limitation was that the mothers were asked to recall or estimate the time since the last feeding of their infants. This limit the accuracy of data as mothers may not remember the exact time and time estimation may differ from person to another.

7. Conclusion

In the current study, oral sucrose was effective in reducing the painful experience of the infant during immunization by lowering: pain scores, crying duration, and rising in heart rate. So when it is available and safe oral sucrose should be given to infants to manage their immunization related pain.

Recommendations

- Providing safe water and resources to safely make oral sucrose solution
- Well trained staff capable of constituting oral sucrose in an appropriate percentage, and recognizing safe administration.
- Educational programs for parents and staff about managing pain during immunization and how to use oral sucrose.

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Table 1: Infants’ Characteristics Data of the Study Groups

Items	Sucrose Group 40		Control Group 40		Test of sig.	p-value
	n	%	n	%		
Sex						
Male	19	47.5	22	55.0	$\chi^2=.45$.502
Female	21	52.5	18	45.0		
Age in months						
2 month	16	40.0	19	47.5	$\chi^2=.336$.845
4 months	12	30.0	8	20.0		
6 months	12	30.0	13	32.5		
Type of feeding						
Exclusive	15	37.5	11	27.5	$\chi^2=.912$.340
Nonexclusive	25	62.5	29	72.5		
Pre-intervention state						
Quiet sleep	11	27.5	7	17.5	$\chi^2=3.56$.314
Calm awake	26	65.0	26	65.0		
Active awake	1	2.5	5	12.5		
Crying	2	5.0	2	5.0		
Infant weight						
Mean ± SD	7102.50±1709.62		6982.50±1798.84		t= 0.306	.761
Min-Max	4300-10200		4000-11000			
Time since last feeding in hours						
Mean ± SD	1.37± 0.7		1.21± 0.47		t= 1.19	.239
Min-Max	0.50-2.5		0.50-2			

Note.n= number; %= percentile; χ^2 = chi square. t= student t test * $p < .05$. ** $p < .01$.

Table 2: Pain Scores before, during, and after injection

FLACC Pain Score	Sucrose Group	Control Group	t	p-value
	Mean ± SD	Mean ± SD		
Before injection	0.28 ± 0.93	0.33±0.76	0.26	.794
During injection	5.40 ±1.11	9.65±0.70	20.55	<.001***
After injection	3.15 ±1.56	8.93±1.1	19.15	<.001***

Note.n= number, %= percentile, t= student t test ***p < .001.

Table 3: Infants' Crying duration in seconds

Crying time	Sucrose Group	Control Group	t	p-value
Mean ± SD	18.18±15.17	89.18±26.56	14.68	<.001**
Min-Max	2-57	53-120		*

Note.n= number, %= percentile, t= student t test ***p < .001.

Table 4: Change in Heart Rate

Change in HR	Sucrose Group	Control Group	t	p-value
Mean ± SD	4.70±3.24	17.13±5.98	11.56	<.001***
Note.n= number, %= percentile, t= student t test			***p < .001.	