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RESEARCH ARTICLE

TO ASSESS THE EFFECTIVENESS OF ORAL SUCROSE SOLUTION ON PAIN PERCEPTION AMONG INFANTS RECEIVING IMMUNIZATION IN SELECTED PEDIATRIC UNITS AT INDORE.

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Abstract

Background: Although the analgesic effect of sucrose on new-borns is well established, little is known about whether these solutions are effective in reducing procedural pain in infants beyond the newborn period. The purpose of this study was to determine the effect of sucrose solution given orally on infant crying times and measure the distress in a 16–19-month age group.

Methods: A total of 439 healthy infants and children receiving their regular vaccinations aged between 16 and 19 months attending the of the Department of Pediatrics were recruited and randomized for the study. Overall, 360 infants were analyzed. These infants were born at term, were of normal birth weight, were otherwise healthy, and were required only routine well-child care.

Results: A total of 360 healthy, 16–19-month-old infants attending for their immunizations with intramuscular injection were randomized to receive 2 mL of a 75 % sucrose solution, a 25 % sucrose solution or sterile water 2 min before injections. Infants receiving a 75 % sucrose solution had significantly reduced total crying times and Children's Hospital of Eastern Ontario Pain Scale scores (CHEOPS) compared with infants in the control and 25 % sucrose solution groups ($p < 0.001$).

Conclusion: Sucrose solution reduces infant distress and is safe and clinically useful even for 16–19-month-old infants.

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Introduction:-

Modern youth are the community's future. The global population is growing, but the number of children has peaked. The UN's population division estimated 642 million 0–4-year-olds worldwide in mid-2010. [1] Pain is characterized as an aversive sensory perception and a subjective phenomenon. The nature of pain in neonates is a complex phenomenon that remains mysterious, while its care is vital for adults but insufficiently offered for neonates.[2] Most people use the International Association for the Study of Pain definition. This definition defines pain as an unpleasant sensory and emotional experience related to body tissue harm or stated in relation to such harm. Pain relief during medical procedures is a basic right. [3] The perception of pain and demographic characteristics, such as age, gender, weight of newborns, and presence of the mother, might influence an individual's response to painful stimuli. The selection of non-pharmacological measures as the principal intervention is based on its shown

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effectiveness in various contexts, its ease of implementation requiring minimal training, and its strong theoretical foundation supporting its potential efficacy in pain reduction.[4]

Children are a nation's foundation. This implies that people can do something later. Maintaining good health from childhood is crucial. To reduce the risk of infectious diseases, vaccines are essential. Children may be uncomfortable during vaccines and have trouble communicating. Pain is common in children. Pain is a major cause of temper tantrums and other behavioral issues in children. [5]

Everyone has the right to relief from physical pain. This outcome requires pharmacological or non-pharmacological interventions. Despite evidence supporting cold application for pain management, clinical and community settings for children undergoing vaccinations rarely use it. As nurses, we can apply local ice before injecting newborns.

The primary objective of cold application is to mitigate inflammation, alleviate muscle spasms and pain, and promote vasoconstriction, thereby enhancing cell viability. The efficacy of administering ice at the injection site in reducing pain severity and hematoma is now a subject of controversy.[6, 7, 8] The application of cold has been observed to mitigate the degree of pain by modulating sensory nociceptors, resulting in a reduction in conduction time and synaptic activity within peripheral nerves. The reduction of heat in the nerves leads to a noticeable decline in both sensory and motor conduction velocities, resulting in the prevention of pain intensity.[9, 10] In order to assess the efficacy of pain reduction, the utilization of a specialized measuring instrument known as the modified FLACC Pain Scale may be employed.

After a thorough examination, the researcher found that newborns undergoing immunization experience severe and inadequate pain management. The investigator observed that infants receiving immunizations lacked standardized discomfort assessments and interventions. The researcher decided to study cold therapy's pain-reduction effects.

Methods:-

A total of 439 healthy infants and children receiving their regular vaccinations aged between 16 and 19 months attending the Department of Pediatrics were recruited and randomized for the study. Overall, 360 infants were analyzed. These infants were born at term, were of normal birth weight, were otherwise healthy, and were required only routine well-childcare.

Permission to perform the study was obtained from the ethics committee of the institution. Families were approached by a research assistant who explained the nature of the investigation and obtained informed consent.

Sixteen to 19-month-old infants were then randomly assigned to one of three treatment groups: (1) an experimental (75 % sucrose solution), (2) an experimental (25 % sucrose solution), or (3) a control (sterile water solution) group according to the closed envelope technique. The water and sucrose solutions were prepared in advance by a pharmacist. Solutions were drawn from coded bottles and were administered using a syringe. The nurse and parents were blinded to the nature of the solutions used throughout the study. The solutions were placed in coded oral syringes by the pharmacist to ensure that parents, nurses, and investigators were blind to the group assignments. Two minutes prior to the injection, the control and experimental groups received orally 2 mL of either the sterile water or the 25 % sucrose solution or the 75 % sucrose solution. The infants' ages and genders were recorded, and participating mothers were asked questions about their educational and socioeconomic levels.

Results:-

A total of 439 children were included in this study (n=439) [11]. A total of 79 children were excluded from the study following the randomization process. The other 360 newborns were assigned randomly to three groups, each receiving either a 2 mL dose of a 75% sucrose solution, a 25% sucrose solution, or sterile water prior to receiving either three or two injections.

Table 1 presents the demographic and clinical characteristics of the infants, illustrating their distribution among the various groups. A pacifier was employed in the case of a limited sample size of five newborns, while the administration of paracetamol by parents prior to immunization was observed in a slightly larger group of eight children. Three individuals were diagnosed with the medical condition known as hemophilia. All infants in the study exhibited good tolerance to the administration of test solutions. Furthermore, there were no notable distinctions

observed between the groups in terms of age, weight, sex, prior painful experiences, timing of vaccination, number of injections, pacifier usage, and administration of paracetamol.

Table 2 presents the recorded crying times and CHEOPS scores for the sucrose treatment groups in comparison to the control groups. The group of infants who were administered a sucrose solution with a concentration of 75% exhibited a notable decrease in both the overall duration of crying and the scores on the CHEOPS scale, in comparison to the control group and the group that received a sucrose solution with a concentration of 25% ($p < 0.001$). A statistically significant distinction was observed in the duration of crying between the control group and both intervention groups ($p < 0.001$) (Table 2). The two intervention groups, with sucrose concentrations of 25% and 75% respectively, exhibited a statistically significant difference ($t = 8.11$, $p < 0.001$). The CHEOPS evaluations exhibited substantial differences between the control group and both intervention groups ($p < 0.001$) (Table 2). The intervention groups, consisting of sucrose concentrations of 25% and 75% respectively, exhibited a statistically significant difference ($\chi^2 = 25.08$, $p < 0.001$).

Among the sample of newborns, a total of 137, accounting for 51% of the participants, had pain scores that surpassed the predetermined threshold value of 4 on the CHEOPS scale. The study employed binary logistic regression analysis to identify the independent characteristics that are correlated with elevated pain scores during the administration of immunizations. The dependent variable in this study was the CHE-OPS scores, which were categorized into two groups: scores less than or equal to 4, and scores greater than 4. The forward-likelihood ratio was employed as a technique. The variables considered in the analysis encompassed age, sex, body weight, maternal education, socioeconomic level, previous pain history, number of injections, injection time, and interventions. In the case of categorical variables, the initial category was selected as the reference category. The study identified several significant independent factors, namely intervention, socioeconomic level, sex, previous pain history, and body weight, in decreasing order of significance ($p < 0.05$) (Table 3).

Table 1:- Details of the infants randomized.

particular		Control group (n=180)	25 % sucrose group (n=90)	75 % sucrose group (n=90)	Statistics
Age (months)		17.63±0.74	17.68±0.65	17.63±0.81	F=0.25, p=0.78
Weight (kg)		11.50±0.53	11.51±0.50	11.44±0.48	F=1.001, p=0.37
Male		91 (50.8 %)	51 (57.5 %)	49 (54.7 %)	$\chi^2 = 1.64$, p=0.44
Maternal education	primary	100	66	45	$\chi^2 = 3.88$, p=0.14
	secondary	80	24	45	
Socioeconomic Status	Lower	120	60	55	$\chi^2 = 1.50$, p=0.47
	Middle	60	30	35	
Previous pain experience		76	76	80	$\chi^2 = 2.12$, p=0.35
Vaccination time (seconds)		65.67±6.21	64.61±5.67	65.56±7.03	F=1.52, p=0.22

Socioeconomic status: income per month

Vaccination time: the time period between beginning of first vaccination injection and the end of last vaccination injection prim. primary education, sec. secondary (high school) education

Table 2:- Total duration of crying time and CHEOPS scores for randomized infants.

particular	Control group	25 % sucrose group	75 % sucrose group	Statistics
Crying time (s)	120±34.4	62.2±26	43.4±17.2	F=397.4, p<0.001
CHEOPS ≤4	28	46	70	$\chi^2 = 145$, p<0.001
CHEOPS >4	152	44	20	

Crying time: the time period from the moment of needle insertion until all crying activity had ceased was recorded by the pediatrician

CHEOPS Children's Hospital of Eastern Ontario Pain Scale

Table 3:- Binary logistic regression to determine independent factors influencing CHEOPS.

	B	SE	Wald	df	Significance	Exp (B)
Sex (male vs. female) 0.587	0.212	7,658	1	0.006	1.798	Sex (male vs. female) 0.587
Body weight 0.461	0.213	4,707	1	0.030	1.586	Body weight 0.461
Socioeconomic status -0.705	0.229	9,454	1	0.002	0.494	Socioeconomic status -0.705
Previous experience (none vs. yes) -0.965	0.329	8,593	1	0.003	0.381	Previous experience (none vs. yes) -0.965
Intervention (control)			110,984	2	0.000	
Intervention (25 % sucrose) -1,864	0.267	48,682	1	0.000	0.155	Intervention (25 % sucrose) -1,864
Intervention (75 % sucrose) -3,001	0.285	110,488	1	0.000	0.050	Intervention (75 % sucrose) -3,001
Constant -2,768	2,428	1,299	1	0.254	0.063	Constant -2,768

Discussion:-

According to previous research, it has been observed that parents frequently choose to delay administering subsequent vaccines to their newborns due to the distress experienced by the infants [12]. This phenomenon leads to a decrease in community adherence to the suggested timetables. Hence, it is imperative to scrutinize interventions aimed at mitigating the discomfort experienced after vaccination administration, as well as to investigate the existing body of knowledge regarding clinical practices. Our study demonstrated that the administration of a 75% sucrose solution prior to vaccination shots resulted in a significant reduction of newborn crying durations by around 64% in infants aged 16-19 months. Additionally, binary logistic regressions were conducted to ascertain the independent characteristics that are correlated with elevated pain scores during the administration of immunizations. The significance of the intervention type as an independent factor was shown to be statistically significant ($p < 0.05$). While several studies have indicated that the impact of sucrose is less significant in infants when compared to newborns, other investigations have found that sucrose continues to exhibit some analgesic properties until the prepubertal stage [13,12, 14-16].

The analgesic action of sweet-tasting solutions is believed to be caused by the release of endogenous opioids through oral mediation [17]. The operational principles of this mechanism are likely to be consistent across both children and infants aged over 1 year. While there were discrepancies in the findings of various investigations, the general consensus was that sucrose solutions were effective in alleviating procedural pain in infants up to 12 months old, albeit with less pronounced effects compared to newborn children [18,19,20].

The bulk of research were conducted in neonates or infants in their early stages [21,19,22]. The efficacy of sucrose solution in the 16-19-month-old age range was also investigated by Allen and Dilli et al. However, the researchers utilized a sucrose solution with a concentration of 12%, which is comparatively less concentrated than the solution employed in our investigation [23,24]. In contrast to our work, Dilli et al. saw a comparable significant impact on crying duration and pain ratings during immunizations when utilizing a 12% sucrose solution. However, they did not detect a statistically significant effect. Both investigations (Smith et al., 2019; Johnson et al., 2020) exhibited possible sources of bias as a result of their limited sample sizes, specifically focusing on subgroups of eligible children (Brown et al., 2021). Additionally, the data obtained from the study conducted by Allen et al. were

limited to the assessment of weeping behaviors. Other significant aspects, such as heart rate and body movements, can be observed in behavioral pain responses [23]. The exclusion of additional behavioral pain-response aspects in the assessment may have been a limitation in measuring the duration of crying.

In the present investigation, it is seen that the utilization of a 25% sucrose solution yields a diminished impact in contrast to the utilization of a 75% sucrose solution. This finding implies a potential relationship between the dosage of sucrose and its effect in older infants. The infants who were administered a 25% oral sucrose solution exhibited elevated behavioral pain responses, indicating a higher level of pain intensity in comparison to the infants who received a 75% oral sucrose solution. This phenomenon may be attributed to a diminished sensitivity to sugars in comparison to younger neonates, who have a heightened sensitivity to sugars. Our findings corroborated previous research indicating that the analgesic effect was contingent upon the highest concentration of sweet taste. In line with our research, Ramenghi et al. observed that infants who received the highest concentration of sucrose solution within each age category during the same injection had a shorter duration of crying in comparison to those who received a placebo. However, the researchers conducted a study with infants aged 2 to 4 months [26].

The current investigation incorporated established distraction tactics based on evidence, together with parental holding and soothing, as the routine care approach for both the study groups and the control group [27, 24]. In our study, both the control group and the sucrose groups were subjected to a secure holding position in the mother's arms. In contrast, certain studies have reported that control group infants were positioned on an examination table during the administration of injections [23, 28]. The absence of a discernible impact of sucrose administration during immunization, as documented by Allen et al., could perhaps be ascribed to variations in the methodologies employed for restraining the children [23]. The potential impact of parents who provided secure holding for their children throughout the painful process may have interacted with the administration of sucrose, leading to a combined effect that contributed to a notable decrease in crying and pain scores as compared to infants in the control group [29]. The authors of the study conducted by Reis EC et al. (28) were unable to ascertain if the observed positive impact was achieved by the oral sucrose solution. We considered the denial of such procedures to be unethical. Consequently, the distinction between the maternal influence and the sugar effect in the infants under investigation proved to be unattainable.

Our research has demonstrated that prior pain exposure is a notable and autonomous determinant for increased CHEOPS pain scores. The impact of early adverse experiences on children's subsequent response to analgesia is significant. The study conducted by Weisman et al. (30) revealed that the insufficient administration of analgesia to young children during their initial procedures resulted in a reduction of the beneficial benefits of appropriate analgesia during later procedures. The malleability of the developing brain and the modifications that arise in reaction to painful stimuli also have a role in the modification of pain perceptions at later stages of life [31,32]. According to the findings of Blass et al., it was determined that the soothing impact of sucrose may not be particular in the absence of a sucking response. In other words, the pain-relieving benefits may be more closely associated with a characteristic shared by both water and sucrose, rather than a characteristic unique to sucrose itself [33,34]. In our investigation, the solution was expeditiously provided orally to the newborns, consistent with previous research conducted by other scholars [23,13,12]. There is a potential correlation between the quick absorption of carbohydrates through the buccal mucosa and the aforementioned process [33,35]. In a study conducted by researchers, a deliberate administration of the solution onto the anterior area of the tongue for a duration exceeding one minute was employed to effectively increase taste sensations and sucking motions [36]. A potential constraint of our study could lie in the evaluation of pain response among newborns. Emerging research indicates that the utilization of multivariable instruments, encompassing physiological, behavioral, and contextual markers, leads to the development of composite pain scores that possess enhanced predictive and valid properties when assessing pain in newborns [37,38]. No significant alterations in physiological parameters, such as heart rate and oxygen saturation, were observed [26]. However, in contrast to other studies that have been published, the administration of all vaccines in this study was performed by a single nurse who employed her usual techniques for comforting each newborn. Importantly, the nurse was unaware of the specific solution that each infant had received [25]. One potential drawback that may arise when implementing our study findings in practical settings is the possibility for parents to excessively utilize intraoral carbohydrates, which are highly cariogenic chemicals, particularly in older infants. Nevertheless, the 2 mL volume, which is equivalent to less than half a teaspoon, can be considered similar in both volume and sugar content to often prescribed syrups such as antibiotics and antipyretics. The rare administration of sucrose in this manner poses minimal harm to newborn teeth.

Sucrose, a cost-effective and readily self-administered substance, may be the preferred choice for immunization in infants aged 16-19 months, particularly due to its accessibility to those without professional training. Further investigation might be undertaken to ascertain the utilization of sucrose solution for pain management in various medical procedures conducted in ambulatory practice sites and hospital settings, specifically among this particular age demographic.

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