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# Effects of Breastfeeding and Sensorial Saturation on Physiological Parameters of Infants after Administration of Pentavalent Vaccine at Four and Six Months of Age: A Field Trial

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#### Abstract

**Background:** Vaccination is the most common painful procedure throughout infancy. Therefore, vaccination pain management in infants may prevent short-term and long-term physical and mental consequences in them. As a result, this study aimed to determine and investigate the effect of breastfeeding and sensorial saturation on physiological parameters of infants after administration of pentavalent vaccine at four and six months of age.

Materials and Methods: This randomized controlled field trial was conducted on 171 four-month-old infants. The infants were randomized into three groups. The first group was breastfed for two minutes before vaccination (Breastfeeding group =55 infants). In the second group, the five senses of the infants were stimulated for two minutes before vaccination (Sensorial Saturation group =57 infants). The third group did not receive any intervention (Control group = 59 infants). In all groups, physiological parameters of the infants at four and six months of age were measured and recorded one minute after the vaccination. Data was analyzed using descriptive and inferential statistics in SPSS version 21.0 software.

**Results:** Results showed no significant difference was observed in demographic variables of research samples including gender and weight at four and six months of age, and statistically significant between groups difference in three physiological parameters (respiratory rate, heart rate, and peripheral oxygen saturation) of the infants at four and six months of age (p=0.001). Although sensorial saturation was more effective than breastfeeding, this difference was not statistically significant; whereas, these interventions were significantly more effective than the control.

**Conclusion:** Both breastfeeding and sensorial saturation practices resulted in the stability of physiological parameters of the infants after vaccination at four and six months of age; however, no significant within-group difference was observed after vaccination at four and six months of age in these two groups and both methods had identical effects.

**Key Words:** Breastfeeding, Sensorial Saturation, Pain, Infant, Vaccination.

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#### 1- INTRODUCTION

Vaccination is the main part of every healthcare system and the most effective and reasonable means to reduce the rate of diseases and disease-induced mortality (1-3), and a proven means to control and eradicate diseases, which cause three million child deaths per year (4-8). Pentavalent, as a combined vaccine with five individual vaccines conjugated into one, is among the important achievements of the past 30 years after the initiation of the Expanded Program on Immunization (EPI) in Iran. This vaccine reduced the number of shots and protects the infants against 5 life-threatening diseases, namely diphtheria, pertussis, tetanus, hepatitis B and Haemophilus influenzae type b (9). According World to the Health Organization (WHO), many immunization programs have sustained high vaccine coverage levels without addressing pain during the procedure, while reducing pain could be considered a good immunization practice worldwide (10).

Despite the key role of vaccination in maintaining public health, many people postpone or reject it (4). According to Taddio et al. approximately 25% adhere children do not the recommended vaccination schedule (11). principal the causes nonadherence, and postponing or rejecting immunization schedule by parents are fear of pain, anxiety, and distress from vaccination (12). More than 90% children show severe distress during vaccination (13). Parents are dissatisfied of the existing pain relief methods, and negative experience from this insufficient pain management results in rejection of recommended infant vaccination schedule (14). Infants respond to harmful stimulants through physiological parameters (increased heart rate and blood pressure, variability in heart rate and intracranial pressure, and decreases in peripheral oxygen saturation (SpO2), and skin blood

flow, and behavioral reactions (muscle crying, rigidity, facial expression, withdrawal and sleeplessness) (15). In response to a negative stimulus, the neurological and neurological-hormonal pathways under the hypothalamus control, is activated, resulting in increased heart rate (HR), blood pressure (BP), ventilation, etc. (16). Pain from painful procedures can be decreased through pharmacological and nonpharmacological practices (17).Distraction is an effective nonpharmacological pain management technique (18, 19). It is an intervention used to change children's sensorial stimuli during the procedure aiming at shifting their attention from the pain stimuli towards the distracting factor (20). Sensorial saturation is another distraction method, by which the senses of touch, smell, hearing, taste and vision are stimulated at the same time (21). Bellieni et al. approved the positive effects of saturation on infant pain sensorial reduction during the heel stick blood sampling (22); however, the effects of this method on infant vaccination pain have not been investigated.

Breastfeeding is another effective, natural, accessible, reasonable, complication free, and pleasant nonpharmacological method during painful procedures; however, results from different studies measuring the palliative effect of breastfeeding during painful procedures are contradictory (23-29). Due to following reasons, researchers intended to specify compare the effect of breastfeeding and sensorial saturation on physiological parameters of infants after receiving pentavalent at four and six months of age:

(1) The beneficial effects of breastfeeding in reducing vaccination pain, (2) Contradictory results regarding the effectiveness of this nonpharmacological pain-relief method, (3) The lack of assessment of effectiveness of sensorial saturation in reducing pain from injection of pentavalent, and (4) The lack of study in Iran on the degree of pain from administration of pentavalent (at four and six months of age).

#### 2- MATERIALS AND METHODS

# 2-1. Study design and population

This randomized controlled field trial was conducted on 171 four-month-old infants, visiting Shahid Dastgheib Health Center in Yasuj city, Kohgiluyeh and Boyerahmad province-Iran, for inoculation pentavalent vaccine in 2016. In the beginning of the study, 194 infants were enrolled; out of which 14 were removed because they did not meet the inclusion criteria. Finally, the remaining 180 infants, aged four months, were randomized into the three study groups. Due to the sample loss (one sample because of withdrawal of guardian, because legal one of immigration, one because of hospitalization due to having fever in the two-month interval between the two intervention stages, one because of bloody developing diarrhea and hospitalization, and five samples because of not referring for routine vaccinations at months of age according immunization schedule) during the next two months (at six months of age), data of remaining 171 infants was ultimately analyzed (55 infants in the Breastfeeding group, 57 in the Sensorial Saturation group, and 59 in the Control group).

# 2-2. Measuring tools: validity and reliability

The checklist of physiological parameters of infants included respiratory rate per minute, heart rate per minute and peripheral oxygen saturation. The number of breaths for one minute was counted by the researcher. To assess the reliability of respiratory rate counting by the researcher, the inter observer method was employed. The heart rate (per second) and peripheral oxygen saturation (percent) were measured

using a pulse oximeter (Zyklus med Model CONTEC08A, China), which had been compared with pulse oximeter Masimo Set Rainbow (Pooyandegan Rah Saadat Co., Iran) in terms of accuracy and precision.

# 2-3. Intervention

In the Breastfeeding group, breastfeeding was performed for two minutes and then the infant vaccination was administered immediately after the breastfeeding was stopped. In the Sensorial Saturation group, following stages were done by the researcher two minutes before giving vaccination: Infant was placed lateral on the vaccination bed and his/her legs and arms were flexed but free to move. Only the movement of the vaccinated organ was limited. Then, 2 ml of dextrose solution 50% was slowly dropped on the infant's tongue with a needle-free syringe. To stimulate the sense of smell, two drops of lavender extract (Zardband Company; approved by the Ministry of Health, Treatment and Medical Education of Iran, licensed for supplement products under the registration code 70069006810002 and factory standard 65.81.00001), poured onto sterile gas pieces and placed 30 cm away from the infant's head. The senses of sight, hearing, and touch of the infant were stimulated by keeping eye contact, speaking softly and continuously with the infant, and giving face and back massage, respectively (22). In the Control group, the routine protocol of the health center was administered, based on which the mother kept the infant's leg firm during the injection. In all three groups, the infants were laid down on the vaccination bed and injection was done by a vaccinator. After the injection, the infant was returned to mother's arms, and his/her physiological parameters (respiratory rate, heart rate. and peripheral saturation) were measured and recorded by the researcher during the first minute after the injection. In all groups, administration of pentavalent vaccine 0.5 ml was carried out into the anterolateral half of vastus lateralis muscle of the left side under the same conditions in terms of temperature, injected solution, temperature of the injected solution, light, noise. injections were performed by the same vaccinator in the health center using autosyringes (30-32). After two disable months, the administration of pentavalent vaccine was repeated for the same infants at six months of age under similar study conditions. and their physiological parameters were measured and recorded, too.

#### 2-4. Ethical consideration

Before initiating the interventions. research objectives were explained to the legal guardians of the infants and their written informed consent was obtained. They were assured that the collected information would only be used for the purposes of this research. This study was approved bv the Research **Ethics** Committee of Yasui University of Medical Sciences with the ID code IR.YUMS.REC.1395.20. It was also registered in the Iranian Registry of Clinical Trials under the code IRCT.2016051527916N1 (32).

# 2-5. Inclusion and exclusion criteria

The inclusion criteria were infants who were healthy, without a chronic disease, with history hospitalization, of chronological age between 4 months and 4 months and 29 days, exclusively breastfed, not fed for 30 minutes before vaccination. awake, and calm; in addition, infants and their mothers should not have been given analgesics within 48 h before vaccination, and their guardians' consent should be obtained. Exclusion criteria included withdrawal of the legal guardian from participation, infants with chronic disease or hospitalization within 2-month interval between two intervention stages, and incidence of pertussis-pertinent complications after administration of pentavalent vaccine at four months of age.

# 2-6. Data Analyses

To compare the groups in terms of demographic variables, the Chi-square and one-way analysis of variance were used. First, normal distribution of the scores of physiological parameters was determined with Kolmogorov-Smirnov test. Since these scores were not normally distributed, nonparametric statistics such as Kruskal-Wallis, Median, and Wilcoxon tests were used. In addition, the Mann-Whitney U test was used for making comparisons between every two groups. Results from statistical tests were analyzed considering the confidence level of 95%. Significance level throughout this study was considered at p<0.05. Data was analyzed in SPSS version 21.0.

#### **3-RESULTS**

This study was conducted to specify and compare the effect of breastfeeding and sensorial saturation on physiological parameters of infants after administration of pentavalent vaccine at four and six months of age. In total, 53.8% of infants were boys and 46.2% were girls. The Chisquare tests did not show any statistically significant difference between the three groups in terms of gender (p=0.3).

In addition, there was not any significant difference between the three groups in terms of weight at four and six months of age (p>0.05); whereas, a statistically significant between-group difference was observed between the last breastfeeding and administration of the vaccine (p<0.05) (Table.1). According to the results from the Kruskal-Wallis and Median tests, there significant between-groups difference in the mean rank and median of all physiological parameters at four and six months of age (p=0.001). In this study, all groups were compared pairwise with Mann-Whitney U test. In terms of

physiological parameters, there was no significant difference between Breastfeeding group and Sensorial Saturation group; whereas, the differences the between Control group intervention groups were statistically significant. Regarding the significant between-group difference in physiological parameters, the post hoc test was conducted using the Tukey's test. Results showed that the interventions (sensorial saturation and breastfeeding) significantly more effective than the control. Although the sensorial saturation reported more effective breastfeeding, this difference was not statistically significant (Table.2).

There was no statistically significant within-group difference in physiological parameters of the infants after vaccination at four and six months of age in the Breastfeeding group and Sensorial Saturation group (p>0.05).

Although a statistically significant difference was observed in the peripheral oxygen saturation after the vaccination at four versus six months of age in the Sensorial Saturation group, this difference was not clinically significant (since the normal level of peripheral oxygen saturation is 95-98%).

**Table-1**: Demographic characteristics of infants in Breastfeeding group, Sensorial Saturation group, and Control group

Outcomes		Breastfeeding group (n=55)	Sensorial Saturation group (n=57)	Control group (n=59)	P-value	
Gender,	Female	29 (52.7)	27 (47.4)	23 (39)	0.3	
Number (%)	Male	26 (47.3)	30(52.6)	36 (61)	0.5	
Weight (kg), Mean ± SD	Four months	6.7±0.8	6.8±0.6	6.8±0.7	0.8	
	Six months	7.4±0.9	7.5±0.6	7.5±0.7	0.6	
Time since last feed (min), Mean ± SD	Four months	63.3±30.4	51.3±13.7	57.4±22.7	0.03	
	Six months	84.3±42.5	64.5±17.9	72±26.3	0.03	

**Table- 2**: Physiological parameters at four and six months of age in Breastfeeding group, Sensorial Saturation group, and Control group

Outcomes		Breastfeeding group (n= 55)	Sensorial Saturation group (n=57)	Control group (n=59)	P-value
		Mean ± SD	$Mean \pm SD$	$Mean \pm SD$	
Respiratory rate	Four months	36±3	35.8±3	44.7±4.7	0.001
	Six months	36±4.1	35.4±2.9	46.8±5.7	0.001
Heart rate	Four months	139.3±5.1	137.6±3.1	153.3±8.5	0.001
	Six months	138.4±7.4	137.6±4.9	157±9.7	0.001
Peripheral oxygen saturation	Four months	95.3±2.1	96.9±1.2	91±2	0.001
	Six months	95.5±1.7	96.3±1.8	90.2±1.6	0.001

SD: Standard deviation.

#### 4- DISCUSSION

breastfeeding Both and sensorial saturation techniques were effective in stabilizing physiological parameters of the after the administration infants pentavalent vaccine at four and six months of age and both methods had identical effects. The age of infants and instruments employed in Kheirkha et al.'s study (34), mean weight of the infants Haddadimoghadam et al.'s study (35), and interval between the mean last breastfeeding and vaccination in Gupta et al.'s (36) were similar to the current study. Cong et al. (37) and Cheraghi et al. (38) showed the effectiveness of kangaroo care in stabilizing physiological parameters of during painful infants procedures. Kangaroo care causes peace and painrelief in infants through skin-to-skin contact, exclusive breastfeeding, and support mother-infant (39).The breastfeeding method and results of these studies were consistent the current study. Rafati et al.'s findings were also consistent with the current study (40). Massage in their study was equated to the stimulation of the sense of touch in the Sensorial Saturation group in the current study. Stimulation through giving massage and touch inhibits the release of substance P (neurotransmitters) and blocks out the pain by affecting the central nervous system and release of analgesics, such as betaendorphin and enkephalin (41).

On the other hand, results from the Efe and Özer's study were inconsistent with those study. their of current In study, physiological parameters of the Breastfeeding group, and control were similar at the time of injection (42). this difference Therefore, may attributed to the length of breastfeeding. In Efe and Özer's study, vaccination was administered 30-60 seconds after the breastfeeding; however, according to different studies, breast milk can act as an endogenous opioid, like sweet solutions

(43), if it is given at least two minutes to become operative (31). In the current study, breastfeeding lasted for two minutes. Results from Golchin et al.'s study are inconsistent with those of the current study (44). Impregnating a pacifier with adequate dose of sucrose, along with non-nutritive sucking could increase the serum level of beta-endorphin, as an endogenous analgesic, through stimulating the taste receptors of the tongue by operating pre-absorption mechanism within two minutes. This phenomenon stability increases the of cardiacrespiratory indices during procedures (31). There was no statistically significant within-group difference in physiological parameters of the infants after vaccination at four and six months of age in the Breastfeeding group and Sensorial Saturation group. According to Hockenberry and Wilson, the normal heart rate for children aged 3 months to 2 years is 80-150 bpm; in addition, the normal respiratory rate in infants aged 1 month to 11 months is 30 breaths per minute. They did not distinguish the heart rate and respiratory rate at four versus six months of age (15).

According to Miller et al., the normal respiratory rate for newborns is 40-60 breaths per minute and for six-month-old infants are 25-35 breaths per minute. They also did not distinguish the infants at two, four, and six months of age in this regard (45). The lack of significant clinical difference in the effect of breastfeeding and sensorial saturation on physiological parameters of infants after administration of pentavalent vaccine at four and six months of age can be attributed to the short interval between these two times and similarity of physiological parameters at these ages. Despite a broad literature review within our scope of information, we did not find a similar study in terms of the interval between two stages of the study. Gao et al. compared the heart rate and the length of crying for premature infants one minute before the intervention, during the intervention, and two minutes after the heel stick blood sampling (with four repetitions) in the kangaroo care and control groups (46). This study reported the effectiveness of repetition of kangaroo care procedure on anesthesia in infants during a repetitive painful procedure.

# 4-1. Limitations of the study

Among research limitations was the anxiety in infants from being in an unfamiliar environment, which was out of the researcher's control. Another limitation was in generalizability of the results to unhealthy children. In addition, given the research methodology, blinding could not be imposed.

#### 5- CONCLUSION

According results, to the the breastfeeding and sensorial saturation stabilized physiological parameters of infants after vaccination; however, no within-group difference was observed in these parameters after the administration of pentavalent vaccine at four and six months of age in the Breastfeeding group and Sensorial Saturation group. Given the importance of early control and treatment of pain in infants to prevent short- and long-term physical and mental consequences of pain, the use of breastfeeding and sensorial saturation is recommended during painful procedures.

# 6- AUTHORS CONTRIBUTIONS

- ZK, NKK, EM and AA participated in the study design.
- NKK participated in data acquisition.
- NKK drafted the manuscript modified by ZK, EM and AA. All authors read and approved the final manuscript.

# 7- CONFLICT OF INTEREST: None.

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