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Effect of the Local Heat on the Pain of Vitamin K Injection in the Infants

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Abstract

Background

The absence of pain relief in infants can lead to harmful effects; so, this study aimed to investigate the effect of local heat on the pain of vitamin K injection in the infants.

Materials and Methods

This randomized clinical trial was conducted on 80 healthy infants. For the control group, 1 mg vitamin K was injected into the vastus lateralis muscle by a nurse. In the 3 intervention groups, respectively 5, 10 and 15 minutes before the injection, hot-water bag at 37 °C was placed on the quadriceps muscle and then injection was done with the same condition as in the control group. Immediately after the injection, the Neonatal Infant Pain Scale (NIPS) was completed. Data analysis was done using SPSS version 21.0 software.

Results

41(51.25%) girls and 39 (48.75%) boys were participated. First-minute Apgar of all samples were 8.64±0.557. Birth weight was 3335.37±339.51 grams and the minimum gestational age 36.37±1.01 weeks. The mean pain score in the first minute in the control group was 3.6± 2.136, which was 3.3± 1.976 in the 5-minute warm-up group, and this amount was reached to 1.6± 1.569 in 10-minute warm up group, and 0.6± 0.821 in 15 minute warm-up group (P=0.008). The mean pain scores in the control group for the second minute was 1.0±1.835, which was reduced to 0.25± 0.716 in the 10-minute and 15-minute warm-up group (P=0.023).

Conclusion

Local heating before the injection procedure can be effective in reducing pain in infants and the pain will reduce by increasing the local heating time (15 minutes).

Key Words: Hot Temperature, Infant, Injections, Pain.

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1- INTRODUCTION

Every newborn baby is frequently undergone painful procedures in several situations, like the need for screening, diagnosis, and treatment (1). Evidence suggests that babies are feeling the pain and they may be more sensitive to pain and long-term effects, even greater than older children (2), and they may actually have a 30% to 50% lower pain threshold than adult (3). Babies are able to interpret the pain from 24-28 weeks of pregnancy (4). Until the late 1970s, it was believed that babies are not able to feel the pain due to insufficient myelinated sensory nerves and prematurity of the pain receptors, so surgeries on babies and children were done without the use of anesthesia and analgesics (5). But researches have shown that every infant is able to understand, experience and remember the pain, and also babies due to the lack of descending control system, which is effective in modulating pain, are more sensitive than adults and more prone to receive the effects of pain (6). Also, the absence of pain relief can lead to short and long-term harmful effects (7).

Much evidence suggested that early and prolonged exposure to painful stimuli before the development of the nervous system, can lead to permanent behavior changes (8). In addition to the various problems, experiencing the pain in infants can be associated with an increased risk of various complications; pain is one of the multiple causes of ventricles bleeding in newborns (9). The release of stress hormones due to the absence of pain control, can also lead to delayed wound healing, infection, increased hospitalization and even death in newborns (10). Long-term effects of pain include anxiety, more sensitivity to pain, emotional problems, hyperactivity and inattention (11). Pain can cause physiological changes such as increased heart rate and breathing, sweating, skin redness, decreased oxygen saturation, dilated pupils, restlessness and hypertension that if not controlled, they will have numerous effects on different body systems and life of babies including, cardiovascular, pulmonary, gastrointestinal and immune system problems, or cause restlessness, loss of appetite, incontinence, restlessness, insomnia, nutritional problems, hypoxia, metabolic changes, nocturnal panic, a delay in recovery , long period of hospitalization, worsening the child's illness or even death. Moreover, its psychological effects can also be impaired learning and memory, and psychological diseases that occur in the future (12).

It is obvious that effective pain management is an important indicator of the quality of care provided to neonates, not only from an ethical standpoint, but also in terms of protecting the long-term outcome. Neonates cannot express their pain and protect themselves like adults. Moreover, medical treatment initially has a strong focus on saving their lives, accepting that well-being is only secondary. Inadequate pain management in neonatal life impairs the neurodevelopment outcome. It alters pain thresholds, pain and stress-related behavior, and physiologic responses in later life (13).

Babies show physiological and behavioral reactions in response to pain that accordingly the appropriate tools are designed to assess their pain such as, premature infant pain profile (PIPP), Neonatal Facial Coding System (NFCS), Neonatal Infant Pain Scale (NIPS), and Crying, Required Increased Oxygen, Increased Vital Sign, Expression, Sleepless (CRIES). Most of these tools consider a combination of behavioral and physiological reactions in the baby's body (14). Given the importance of pain control, pharmacological and non-pharmacological methods are introduced for pain control in infants, including environmental and

behavioral interventions, separately or in combination with medication in infants which are very applicable. Since there are concerns about side effects, non-pharmacological interventions have been recently established to relieve the pain of different procedures (15). Non-pharmacological methods of pain relief include heat, changing position, swaddle, limiting movement, hugging, shaking, music, reduction of environmental stimuli, skin contact and non-nutritive sucking (16, 17). Skin to skin contact in kangaroo mother care (KMC) reduces the energy consumption by transferring natural heat, and has an important role directly or indirectly in pain relief (16). It also has been shown in a clinical trial that in KMC, the average temperature in the baby within an hour after skin contact was more than the group with no contact (18). Mechanisms of heat effects on pain relief are due to breaking muscle spasms and the resulting pain relief or increasing the flexibility of connective tissue (19).

Since the infants receive the vitamin K injection in bed after their first breast feeding, so putting them under a radiant heating does not routinely perform to warm up the baby in order to reduce injection pain. Few studies have been conducted to examine the local heating effect on pain relief in infants; so this study aimed to investigate the effect of local heating provided by a hot water bag in bed baby on the vitamin K injection pain in infants.

2- MATERIALS AND METHODS

This randomized clinical trial (RCT) was carried out in January 2016 during 4 months and it is registered at www.IRCT.ir under the code of IRCT2015092624210N1. All infants participated in this study were born in Ayatollah Rouhani hospital of Babol (Educational referral hospital), and had required specifications. The samples were randomly enrolled in one of the intervention or control groups. This study was conducted on the first day after birth and by intramuscular injection of 1 mg vitamin K (0.5 ml) that is routinely given to all newborn infants. The babies had a gestational age of 37 to 42 weeks after the first breastfeeding during the first 4 hours after birth. In order to unify the groups and to minimize the delivery stress, all infants were chosen from elective cesarean deliveries. They were classified randomly into 4 groups, including 3 intervention groups and a control group. According to the confirmation of a pediatrician, theses neonate were well babies and with no sign of disease or congenital abnormalities. Their birth weight was between 2,500 to 4,040 grams and did not receive any medication. Exclusion criteria included addicted mothers, infants with a history of injection, infants with heart and lung disease, and infants who were crying or sleeping. The babies were in a comfortable condition before injecting. Before intervention, the registration form was completed, including infant information (gender, gestational age, birth weight and Apgar score at birth).

To determine the effect of localized heat and duration of heat on pain of newborns, samples were randomly divided into 4 groups. For the control group, according to the hospital routine, 1 mg (0.5 ml) vitamin K was injected into the middle third area of vastus lateralis muscle by an experienced nurse using an insulin syringe while the baby was dressed in a cut. In the 3 intervention groups, respectively 5, 10 and 15 minutes before the injection, hot-water bottle at 37 °C was placed on the quadriceps muscle and then injection was done by a nurse with the same condition as in the control group. One ml insulin syringes with needles size 30, made in Iran Avapezeshk Co. were used for all samples. Immediately after the injection, the Neonatal Infant Pain Scale (NIPS) was

completed by an independent observer, who was unaware of the case group, in the first, second and third minutes after the injection. Neonatal Infant Pain Scale (NIPS) is a combination of the face, gestures and voice changes in babies (20). The scale for measuring pain in infants can be used up to six weeks after delivery. This scale examines the crying, facial expressions, breathing pattern, movements of hands and legs, and the baby's level of consciousness. In this scale, crying option has zero, one and two scores (zero: quiet, one: whining, two: severe crying), facial expression option has zero and one scores (zero: quiet, one: scowl); breathing pattern has zero and one scores (zero: normal, one: a change in the normal breathing pattern), movements of hands and legs have zero and one scores (zero: normal, one: sagittal); level of consciousness has zero and one scores (zero: sleeping or awake, one: screaming), in which the total score ranges between zero and seven (4).

The validity and reliability of this scale were confirmed by Suraseranivongse et al. (2006) in a study to compare the validity and reliability of 3 pain scales (CHIPPS, CRIES, NIPS) in infants (21). Asadi Noghabi and Kashani Niya were also determined the face and content validity of this tool with the opinion of more than a dozen faculty members of Tehran University and Tarbiat Modarres University; so that to achieve inter-rater reliability, questionnaires were completed for 20 subjects and Cronbach's alpha coefficient was 0.75 (22).

Registration form information included the type of delivery, gender, gestational age, birth weight, and the fifth minute Apgar score. After collecting the information, the four groups were compared. Data analysis was done by SPSS version 21.0 software. For normal birth weight, the ANOVA was used to determine the significance, and the Kruskal Wallis test was used to determine the significance of gestational age. Also, Kruskal Wallis and Mann-Whitney tests were used to evaluate pain scores in groups. P-value <0.05 was considered significant in all tests.

3- RESULTS

A total number of 80 infants, 41(51.25%) girls and 39 (48.75%) boys were participated. All infants were born by caesarean section. First minute Apgar scores of newborns was 8.64±0.557. Their birth weight ranged from 2,900 to 4,040 grams. All babies were healthy and were tested on the first day after birth. Apgar score of all babies was considered based on the Inclusion criteria and in the normal range of 7 to10.

Gender distribution in the control and intervention groups is shown in **Table.1**. Four groups had no statistically significant difference in terms of gender (P = 0.795). The minimum gestational age was ranged from 37 to 41 weeks (mean: 36.37±1.01 weeks), the Kruskal Wallis test showed that the groups were not significantly different in terms of gestational age (P=0. 098) (**Table.1**). The birth weight was ranged from 2500 to 4040 grams (mean: 3335.37±339.51 grams). ANOVA test showed that both groups had no statistically significant difference in weight (P=0.063) (**Table.1**).

Based on Kruskal Wallis test, pain scores had a significant difference between the groups. The four groups were compared pairwise using the Mann-Whitney test in terms of pain score in the first, second and third minutes after injection; the obtained results are shown in **Table.2**.

The mean score in the first minute in infants of the control group was 3.6 ± 2.137, this amount in 10 minutes warm up group was reached to 1.6 ± 1.569 (P = 0.005), and in the 15 minutes warm-up group was 0.6 ± 0.821 (P = 0.000), which was a significant difference. The pain score in the first minute in the 5 minutes

local heat group was 3.3 ± 1.976, this amount in 10 minutes local heat group was 1.6 ± 1.569 (P = 0.01), and in the 15 minute warm-up group was 0.6 ± 0.821 (P = 0.000), which indicated a statistically significant difference. The result of comparing the pain score in the first minute of the 10 minute and 15 minute warm-up groups was also significant, so that the pain score was ranged from 1.6 ± 1.569 to 0.6 ± 0.821 (P = 0.042). In terms of pain score in the second minute, the mean pain score in the control group was 1.00 ± 1.835, this amount in the 10 minutes and 15 minutes warm up groups was 0.25 ± 0.716 (P = 0.042), which showed a statistically significant difference. Also, the pain score in the second minute in the 5 minute local heat was 1.5 ± 2.09, this amount in the 10-minute and 15-minute local heat was reduced to 0.25 ± 0.716 (P = 0.007). The pain score in the third minute showed no significant difference in any of the groups.

Table-1: Comparison by gender and gestational age and birth weight in one control group and 3 intervention groups

Variables	Groups				P-value
	15 min local heating	10 min local heating	5 min local heating	Control group	
Girls	8	14	9	10	0.795
Boys	12	6	11	10	
Gestational age, weeks; (Mean ± SD)	0.098	38.10±0.788	38.15±1.137	38.80±0.951	38.04±1.046
Birth weight, gram (Mean ± SD)	0.063	3239.0±265.526	3233.50±357.584	3466.25±409.926	3402.75±263.331

Table-2: Comparison of pain scores in the first, second and third minutes after injection in one control group and three intervention groups*

Neonatal Infant Pain Scale	Groups				P- value**
	Control group	5 min local heating	10 min local heating	15 min local heating	
The pain score in the first minute	3.6±2.137[a] (3.00)	3.30±1.976[a] (3.00)	1.6±1.569[b] (1.50)	0.6±0.821[b] (.00)	0.008
The pain score in the second minute	1.00±1.835[ab] (.00)	1.50±2.090[a] (1.00)	0.25±0.716[b] (.00)	0.25±0.716[b] (.00)	0.023
The pain score in the third minute	0.7±1.867 (.00)	0.5±1.395 (.00)	0.6±0.224 (.00)	0.2±0.696 (.00)	0.334

* Values are presented as Mean ± standard deviation; ** Kruskal-Wallis Test; Similar letters in each row indicated not significant difference between two groups based on Mann Whitney test.

4- DISCUSSION

The results showed that the use of local heating before small painful procedures such as intramuscular injection of vitamin K in infants can be effective in reducing pain. Infants in this study who received 10 minutes of hot-water bag had less pain than those who did not receive hot water bag. Moreover, the pain score reduced in infants who received hot-water bag in longer duration, so that the infants with 15 minutes intervention had less pain than 10 minutes and 5 minutes hot-water bag (P=0.008). These findings are consistent with similar studies in this area previously. Gray, Larry et al. conducted in 2015 on the effect of sucrose and heating on analgesia for babies, it was revealed that the simultaneous administration of 1 ml of 25% sucrose and exposure to warmer two minutes before the vaccination can reduce the infant pain better than using sucrose alone (23).

In 2015, a clinical trial conducted by Lee and Shu et al. entitled "Effects of swaddle and heating the heel on pain responses using Lancet in heel of infants" in Taiwan showed that both methods of swaddle and heating the heel reduced the pain responses during using a lancet on their heel; heating the heel also can lead to less pain responses than only swaddle the baby (24). In another relevant study Gray et al. in 2012, in a clinical trial showed that heating babies under warmers before performing the painful procedure can reduce the crying time in babies (17). Assadi Noghabi et al. (2011) showed that the infants who had skin contact with their mother before performing intramuscular injection experienced less pain than infants who were in bed with their mother (22). Also Cignacco et al. in their study on the impact of non- pharmaceutical interventions to painful procedures in preterm and term infants concluded that factors such as gestational age, or health status of infants had no effect on non- pharmaceutical interventions; they also showed that non-pharmaceutical interventions are somewhat useful for infants under painful procedures (18), which is consistent with the results of this study.

Behmanesh et al in 2008 conducted a study entitled "The effect of heat therapy on the pain severity and outcome of labor in nulliparous women at the affiliated hospitals of Babol University of Medical Sciences"; in this study, 64 nulliparous women were randomly divided into two heat therapy and usual care groups. The usual care group received common delivery care, and the heat therapy group also received additional local heat on their lower back and in the second stage in the perineal area. Labor pain level was measured using the McGill pain ruler and duration of the three stages of labor was determined in the two groups using digital clock. The obtained data showed that the heat therapy with hot water bag is effective on the pain severity in the first and second stages of delivery, and on the duration of the first and third stage of delivery; it had no adverse effect on the baby or mother (25). Besides, Golianu (2007), in a study on the effects of non-pharmaceutical interventions on reducing pain reported that although non-pharmacological methods are effective in reducing acute and moderate pain in infants, but using analgesic medication is necessary to reduce severe pain in babies (26).

It seems that the heating mechanism of pain relief is more with non-opioid skin to skin contact mechanisms (15). Despite the analgesic effect of the heat on infants in the 10 and 15 minute intervention group, pain score in the second minute for infants of 5-minute local heat has increased compared with a pain score in the second minute in the control group; so that the average pain score has reached from 1.00 to 3.30. This result was not justified by the assumptions of the study.

4-1. Limitations of the study

This study had no certain limitation during the research process.

5- CONCLUSION

It seems that local heating before the injection procedure is effective in reducing pain for infants and by increasing the warm-up time (15 minutes), the pain will be less; also, the pain scores for all groups in the second minutes after the injection were reduced (except the pain score in the second minute of 5-minute local heat). In neonatal intensive care units and public neonatal nursery sector that painful procedures are performed repeatedly for babies, it seems necessary to keep the babies calm and reduce stress and pain, in which the use of local heating can be performed without any damage or threat and no need to spend a lot of time as well as equipment for all the infants at the birth time during injection of vitamin K, which is one of the first painful procedures that infants experience, and ultimately improves the quality of care associated with pain. It is suggested that future studies try to investigate the effect of simultaneous administration of local heating and oral sucrose compared with sucrose only or try to compare the effect of the heating warmer and local heating effect in pain relief for infants.

6- CONFLICT OF INTEREST

The authors declare that there are no competing interests regarding the publication of this paper.

7- ACKNOWLEDGMENT

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