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ORIGINAL ARTICLE

Analysis of two non-pharmacological pain management methods for vaccine injection pain in infants: A randomized controlled trial

Bebeklerde aşı enjeksiyonu ağrısında iki non-farmokolojik ağrı yönetim metodu: Randomize kontrollü bir çalışma

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Summary

Objectives: This study was performed to investigate the efficiency of local heat and cold application to decrease vaccine-associated pain among infants 2–6 months of age.

Methods: This was a randomized controlled trial. The study universe comprised infants aged 2–6 months who were brought to 4 family health centers in the Safranbolu district of Karabuk Province, Turkey, for a pneumococcal vaccination June 1-November 30, 2016. A total of 96 infants (heat application: 31, cold application: 32, and control group: 33) were enrolled in the the study. The data were collected using an infant ınformation form and the Face, Legs, Activity, Cry, Consolability (FLACC) pain scale.

Results: The mean FLACC score of the infants was 5.531±1.934 in the cold application group, 8.710±1.346 in the heat application group, and 9.152±1.661 in the control group. The difference between the mean scores of the groups was statistically significant (KW=49.043; p=0.000).

Conclusion: Local cold and heat application methods applied to the vaccination area before a pneumoccal vaccine reduced vaccine-associated pain in the infants, and the application of cold was more effective than heat.

Keywords: Cold application; heat application; infant; nursing; pain; pain management.

Özet

Amaç: Bu çalışma 2–6 aylık bebeklerde aşıya bağlı gelişen ağrıyı azaltmada lokal sıcak ve soğuk uygulamanın etkinliğini araştırmak için yapıldı.

Gereç ve Yöntem: Randomize kontrollü bir çalışmadır. Çalışmanın evrenini, pnömokok aşısı olmak için 1 Haziran–30 Kasım 2016 tarihleri arasında Karabük'ün Safranbolu ilçesinde bulunan dört aile sağlığı merkezine getirilen 2–6 aylık bebekler oluşturdu. Çalışmanın örneklemine toplam 96 bebek (sıcak uygulama: 31; soğuk uygulama: 32; kontrol grubu: 33) alındı. Veriler "Bebek Bigi Formu" ve FLACC Ağrı Ölçeği ile toplandı.

Bulgular: Çalışmada, bebeklerin ortalama FLACC Ağrı Ölçeği skoru soğuk uygulama grubunda 5.531±1.934, sıcak uygulama grubunda 8.710±1.346 ve kontrol grubunda 9.152±1.661 idi. Grupların ortalama puanları arasındaki farkın istatistiksel olarak anlamlı olduğu bulundu (KW=49.043; p =0.000<0.05).

Sonuç: Pnömokok aşısı öncesi aşı bölgesine uygulanan lokal soğuk ve sıcak uygulama yöntemlerinin bebekler arasında aşı ile ilişkili ağrının azaltılmasında etkili olduğu sonucuna varıldı. Ayrıca, soğuk uygulamanın ağrıyı hafifletmede sıcak uygulamadan daha etkili olduğu bulundu.

Anahtar sözcükler: Soğuk uygulama; sıcak uygulama; bebek; hemşirelik; ağrı; ağrı yönetimi.

Introduction

The current valid definition of pain concept, that is a universal experience, was made by International Association for the Study of Pain (IASP). According to IASP, pain is an experience that is derived from any part of the body, that is or is not associated with tissue damage and that is emotionally unpleasant.[1] It was reported that pain has been felt since intrauter-

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ine life and an ability to respond to pain has been developed in the infant since 20th and 24th weeks of pregnancy.[2,3] Routine vaccine injections, that are generally carried out without pain management, constitute the most common and painful procedures during infancy.[4]

Since infants can not express pain verbally, pain management is of crucial importance for them.[5,6] Many pharmacological or non-pharmacological methods are used in pain management to minimize pain. Non-pharmacological methods include such as heat and cold application, divert attention from pain, listening music, balloon blowing, massage, therapeutic touch.[4,7] These possible adverse effects such as respiratory depression, apnea and bradychardia of pharmacological methods have enhanced the importance of non-pharmacological methods in recent years and nursing studies were focused on these methods.[8–12] Since the pain that occurs among infants during routine vaccine applications is not accepted as a sign of disease, preference of non-pharmacological methods to reduce pain was reported to be more appropriate.[9]

In the study by Gol and Onarici (2015),[13] it was indicated that heat compress was among applications that were most commonly used by the nurses at pain management for children. In the literature, heat compress was reported to be a common and effective method for resolving pain.[14,15] In the other studies, cold compress was reported to be effective in reducing pain.[16,17] Although there are studies reporting that cold and heat compresses reduced pain in the literature, there is not an adequate number of studies investigating the effectiveness of these two applications together.[14,15] Moreover, there is not such a study performed with newborns and infants. This study is important for the nurses to manage vaccine-associated pain in the babies effectively. Because pain management, that is required to be carried out by a multidisciplinary approach, is an important responsibility for nurses.[18,19] Therefore, it is considered that our study will provide a significant contribution to the literatüre. This study was performed to investigate the efficiency of local heat and cold applications in decreasing vaccine-associated pain among 2–6 month old infants who were brought to four family health centers for pneumococcal vaccination. Based on this general purpose, the hypotheses of the study were as follows:

- Local cold application on the vaccination area before the pneumococcal vaccine reduce vaccine-associated pain.
- Local heat application on the vaccination area before the pneumococcal vaccine reduce vaccine-associated pain.
- Local cold application more effective than heat application on the vaccine-associated pain.
- Sex of the infant affect vaccine-associated pain.
- Age of the infant affect vaccine-associated pain.
- Weight of the infant affect vaccine-associated pain.

Material and Methods

Design and sample

The study was a randomized controlled trial. The universe of the study was composed of 2–6 month old infants who were brought to four family health centers located in Safranbolu district of Karabuk city in Turkey between June 1–November 30, 2016 for pneumococcal vaccination. Based on the observations of the nurses working in family health centers, infants gave the highest response to this vaccine; and this was the reason of choosing pneumococcal vaccine in this study. According to Childhood Vaccination Calendar of Ministry of Health in Turkey, Conjugated Pneumococcal Vaccine (CPV) is applied as a total of three doses including the end of second, fourth and sixth months. A booster shot of the vaccine is given at the end of twelveth month.

Power analysis was performed to determine the number of infants that would include in three groups in the study. Power of the test was calculated by G*Power 3.1 program. In order to have a study power more than 80% at a significance level of 5% and an effect size of 0.3, it was required to reach information of a total of 84 individuals including at least 28 people in each group (X^2=10.080; Effect size d=0.3). Considering the possible case losses, 96 infants (first intervention group/local heat application: 31; second intervention group/local cold application: 32; and no intervention/control group: 33), formed the sample group that met the inclusion criteria (Fig. 1).

Data collection instruments

Data were collected by "Infant Information Form" which was prepared by the researchers in accordance with the literature, and "Face, Legs, Activ-

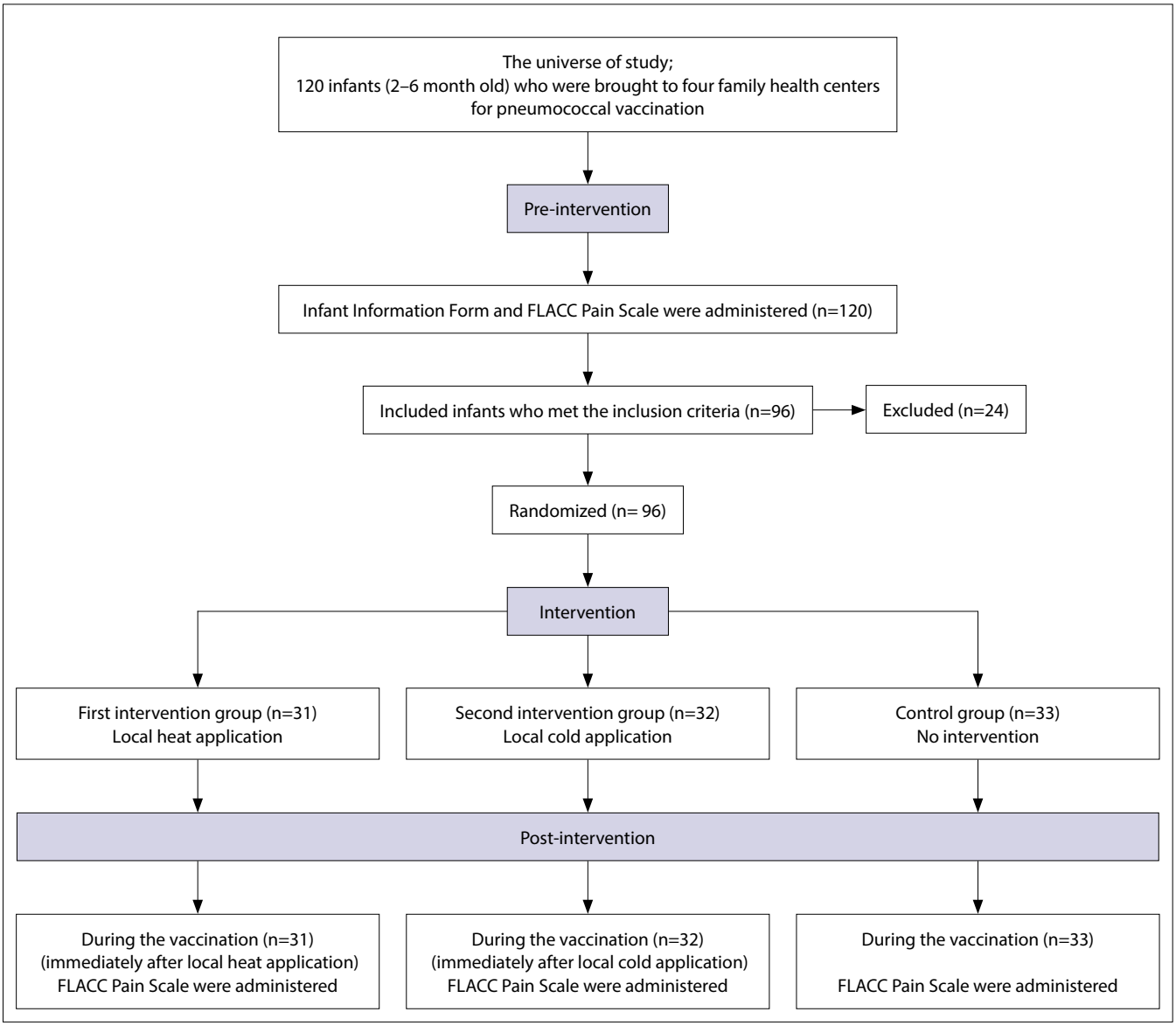

Figure 1. Intervention phases of the study.

ity, Cry, Consolability Pain Scale" (FLACC Pain Scale) which was used to evaluate pain in infants.

Infant Information Form. This was a form that was prepared to obtain information about the babies. There were 7 questions in the form examining the information such as birth date, gestational age, sex, anthropometric measurements, nutrition type and deliver type of the babies.

FLACC Pain Scale. This scale was developed by Merkel et al.[20] (1997) in order to use for the evaluation of pain among the children who were aged between 2 months and 7 years and who had a limited verbal communication. Measurement was made by the evaluation of five behavioral categories in the scale. Facial expression of the children, position of their legs, their activity, cry and consolability were graded between 0–2 points. The score that could be taken from the scale ranged between 0–10. The increase in the score of the scale meant that pain increased, and a decrease in the score corresponded to a decrease in the pain. In the study by Senayli et al.[21] (2006), postoperative pain of children between 1 month–9 years old was evaluated by FLACC Pain Scale. It was reported that Turkish version of FLACC pain scale could be used with this study. In our study, general reliability of FLACC pain scale was found to be high as 0.86.

Intervention phases

Pre-intervention: FLACC Pain Scale was applied to 120 infants (2–6 month old) who were brought to four family health centers for pneumococcal

vaccination. Infant Information Form was applied to the parents of these infants. Infants, who got a scored of "0" from FLACC Pain Scale and evaluated as having no pain, were included in the study. Other inclusion criteria of the infants included having a gestational age of 37–42 weeks, having a birth weight of 2500 grams and more, being full before the procedure, having no physical, emotional and mental health problem (such as congenital abnormality), being vaccinated for pneumococcus, not having any antipyretic and analgesic-like medication before the vaccination, not having any disease causing chronic pain, not having a body temperature above 38.0°C and having no skin problem that would prevent local heat and cold applications. Infants (n=96) who met the sample inclusion criteria were randomized using the Sealed Envelope program. Infants meeting these criteria were stratified according sex, age, gestational age and weight then blocking (assignment) was made to three groups by drawing lots.

Intervention: At this phase, first intervention group underwent local heat application, second intervention group underwent local cold application. Heat and cold applications were applied by one of the researchers immediately before the vaccination. Cold thermogel compresses used in the study were kept in the freezer of the refrigerators found in the family health centers. Heat thermogel compresses were held in the boiled hot water for 15 minutes before the procedure. Heat and cold thermogel compresses were covered with a sheath before the procedure in order to prevent direct contact with the skin. Heat and cold compresses were applied locally to the area to be vaccinated on the infant by one of the researchers for 2 minutes. Control group was not undergone any intervention before the vaccination.

Post-intervention: Pneumococcal vaccine was administered to the infants following the applications without waiting. These vaccines were applied by the same nurse in each family health center. FLACC Pain Scale was applied to all infants in the control and intervention groups by one of the researchers during vaccination. In infants who have more than one vaccine, it was preferred to apply pneumococcal vaccine in the first place before all the vaccines within the same day.

Statistical analysis

Data collected during the study were analyzed by using a licensed SPSS (Statistical Package for Social Sciences) software. Descriptive findings were introduced in numbers, percentages, mean and standard deviation. Normal distribution assumptions were considered for the hypothesis tests. Kolmogorov-Smirnov and Shapiro-Wilk tests were performed to determine whether dependent variable (Pain Score) showed a normal distribution or not. Spearman correlation was performed between the continuous varibles. It was detected that dependent variable (Pain Score) did not show a normal distribution ($p<0.05$). Therefore, Kruskal-Wallis test, that is one of the non-parametric methods that compare quantitative data between more than two independent groups, was used. Then, Mann-Whitney U test was used as complementary in order to identify the differences following Kruskal-Wallis test. Distribution of the descriptive characteristics based on the groups were tested by Chi-Square analysis. The findings obtained were assessed within a confidence interval of 95% and a significance level of 5%.

Ethical considerations and Procedures

The required ethical consent was taken from Bulent Ecevit University Clinical Research Ethics Committee (protocol no: 2015-70-07/07). A written permission no. 23733080/131.10.99 was obtained from Public Health Directorate of Karabuk. Parents of the infants were provided information about the study before starting, and verbal and written consents of the ones who approved to participate in the study were taken based on a voluntary basis.

Results

When the infants included in the study were examined based on their descriptive characteristics, it was determined that 51.5% in control group, 51.6% in heat application group and 46.9% in cold application group were males. It was also found that 51.5% in control group, 51.6% in heat application group and 28.1% in cold application group were feeding with breastmilk. No statistically significant differences were found between three groups in terms of sex and nutrition type (Table 1).

It was found that mean age (month) of the infants was higher in heat application group (4.258±1.612);

Table 1. Distribution of descriptive characteristics of the infants

Variables	Control group (n=33)		Heat application (n=31)		Cold application (n=32)		p
	n	%	n	%	n	%	
Sex							
Male	17	51.5	16	51.6	15	46.9	χ^2=0.188
Female	16	48.5	15	48.4	17	53.1	p=0.910
Nutrition type							
Breast milk	17	51.5	16	51.6	9	28.1	χ^2=7.272
Formula	1	3.0	3	9.7	6	18.8	p=0.122
Breast milk+Formula	15	45.5	12	38.7	17	53.1	

Table 2. Mean descriptive characteristics of the infants

Variables	Control group Mean±SD	Heat application Mean±SD	Cold application Mean±SD	KW Mean±SD	p
Age (months)	4.061±1.694	4.258±1.612	4.063±1.722	0.144	0.866
Gestational age	38.485±1.034	38.645±0.915	38.094±0.856	2.889	0.061
Weight	6596.970±1510.636	6469.355±954.955	6273.438±1057.915	0.593	0.555
Height	62.152±5.167	60.903±3.600	59.844±4.274	2.231	0.113
Head circumference	40.485±2.600	40.839±2.177	40.938±2.063	0.350	0.706

SD: Standard deviation; KW: Kruskal Wallis Test.

Table 3. Comparison of mean FLACC Pain Scale scores based on the application used

Variables	Control group Mean±SD	Heat application Mean±SD	Cold application Mean±SD	KW Mean±SD	p	Difference
FLACC Pain Score	9.152±1.661	8.710±1.346	5.531±1.934	49.043	0.000	1>2
						1>3
						2>3

FLACC: Face, Legs, Activity, Cry, Consolability; SD: Standard deviation; KW: Kruskal Wallis Test.

mean gestational age was higher in heat application group (38.645±0.915), mean weight was higher in control group (6596.970±1510.636), mean height was higher in control group (62.152±5.167) and mean head circumference was higher in cold application group (40.938±2.063). No statistically significant differences were found between three groups in terms of age (month), gestational age, weight, height and head circumference (Table 2).

In the study, mean FLACC Pain Scale score of the infants was 5.531±1.934 in cold application group, 8.710±1.346 in heat application group and 9.152±1.661 in control group. It was found that the difference between the mean scores of the groups was statistically significant (KW=49.043; p=0.000<0.05) (Table 3).

Mann Whitney U test was performed to identify from which group the difference was derived; and pain scores of the babies in control group were found to be higher than the babies in cold and heat compress groups. Pain scores of the babies who underwent heat compress were found to be higher than the scores of the babies who were applied cold compress.

Evaluation of the mean scores of the infants in control and study groups from FLACC Pain Scale based

Table 4. The effect of sex on mean FLACC pain scale scores among the infants

Groups	Sex	N	Mean	SD	MW	p
Control group	Male	17	8.765	2.107	105.000	0.193
	Female	16	9.563	0.892		
Heat application	Male	16	8.625	1.360	110.000	0.681
	Female	15	8.800	1.373		
Cold application	Male	15	5.067	2.086	97.000	0.241
	Female	17	5.941	1.749		

FLACC: Face, Legs, Activity, Cry, Consolability; SD: Standard deviation; MW: Mann Whitney-U test.

on sex was given in Table 4. It was determined that mean FLACC pain scale scores were higher among the female infants compared to the males in all groups; but this difference was not statistically significant (p>0.05).

The correlations between the age (month) of all infants in control and study groups in the study and their weight based on FLACC Pain Scale were given in Table 5. A weak and negative but significant correlation was found between the age of the infants in cold application group and their mean FLACC Pain Scale scores (r=-0.437; p=0.012<0.05). A moderate and negative, but significant correlation was found between the weight of the infants in cold application group and their mean FLACC Pain Scale scores (r=-0.634; p=0.000<0.05).

Table 5. Correlation between the age and weight of the infants based on FLACC pain scale

	Control group	Heat application	Cold application
Age (months)			
rs	-0.137	0.005	-0.437*
p	0.448	0.979	0.012
Weight			
rs	-0.030	-0.016	-0.634*
p	0.870	0.930	0.000

rs: Spearman Correlation Analysis; *: Correlation is significant at 0.01.

Discussion

There are various factors affecting infant's perception and response for pain. Gestational age, sex, individual differences and the type of painful stimulators and their duration are among these factors.[8,22,23] For that reason, it was provided to make a homogenous distribution of the characteristics such as sex, nutrition type, age, gestational age, weight, height and head circumference, that were thought to affect vaccine-associated pain, in control and intervention groups; and the possible confounding effects of these characteristics were eliminated while the efficiency of the applications used was evaluated.

In our study, mean pain scores of the infants in cold application group were found to be significantly lower than the mean scores in control group. This hypothesis of the study is "Local cold application on the vaccination area before the pneumococcal vaccine reduce vaccine-associated pain" confirmed. Also in the other studies, cold application during intramuscular injection was effective in alleviating pain.[16,17,24,25] This outcome of our study supported the literature and it was consistent with the other studies.

In our study, mean pain scores of the infants in heat application group were found to be significantly lower than the mean scores in control group. This hypothesis of the study is "Local heat application on the vaccination area before the pneumococcal vaccine reduce vaccine-associated pain" confirmed. In the other studies, it was reported that heat compress was used for pain control and was an effective method for removing pain.[10,14,15,26,27] This outcome of our study was consistent with the other studies and supported the literature.

In the study, this hypothesis "Local cold application more effective than heat application on the vaccine-associated pain" confirmed. Ozveren (2011)[10] indicated that the best non-pharmacological methods for alleviating vaccine-associated pain were cold and heat applications. It was also reported that heat applications used for pain management had less and

short-term effect compared to cold applications.[28] In the study by Garra et al.[15] (2010), it was reported that heat and cold applications showed similar effects on removing back and neck pains. In our study, cold application was found to be more effective than heat application and was not found to be compliant with this study.

This hypothesis of the study is "Sex of the infant affect vaccine-associated pain" not confirmed. In the study by Ozdemir and Tufekci (2012),[29] FLACC pain scale scores were found to be significantly higher among the female infants compared to the males after vaccination. In the study by Guinsburg et al.[30] (2000), it was reported that the responses of infant girls to pain were more significantly higher than the infant boys. In the literature, it has been reported that sex was effective in pain experiences and the females felt more pain.[31] Although there was not a significant relationship in our study, it was determined that infant girls felt more pain and this was found to be compliant with the studies in the literature.

This hypothesis of the study is "Age of the infant affect vaccine-associated pain" not confirmed. In the study by Jacobson et al.[32] (2001), it was reported that pain during the vaccination was significantly higher among the smaller children. Also in the study by Hasanpour et al.[17] (2006), a negative correlation was found between the intensity of pain and the age of the children. In our study, it was concluded that age of the infant affected vaccine-associated pain only in cold application group, and this effect was at a low level.

This hypothesis of the study is "Weight of the infant affect vaccine-assocaited pain" not confirmed. In the study by Gol and Ozsoy (2017),[33] it was determined that pain scores of the infants decreased as their weight and percentile values increased. In our study, it was concluded that weight of the infant affected vaccine-associated pain only in cold application group and this effect was at a moderate level.

Limitations

Conduction of the study in four family health centers resulted in inability to reach infants who were brought to distinct centers at the same time. Besides, all vaccinations included in the study could not be performed by a single person due to legal procedures; but same nurse performed the vaccinations in all family health centers.

Ethics Committee Approval: The required ethical consent was taken from Bülent Ecevit University Clinical Research Ethics Committee (protocol no: 2015-70-07/07).

Conflict-of-interest issues regarding the authorship or article: None declared.

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