

The Effect of the Use of Black and White Flashcards on Acute Pain Levels in Infants*

Siyah Beyaz Dikkati Başka Yöne Çekme Kartlarının Bebeklerin Hissedilen Akut Ağrı Düzeyine Etkisi

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Citation/Atf: Yılmaz D, Canbulat Sahiner N, Erçelik ZE. The effect of the use of black and white flashcards on acute pain levels in infants. Çocuk Dergisi - Journal of Child 2023;23(3):285-291. <https://doi.org/10.26650/jchild.2023.1327823>

ABSTRACT

Objective: Vaccination practices are one of the most painful procedures in infancy, creating anxiety and distress for both infants and their parents. This study was planned to determine the effect of black and white flashcards on the level of acute pain infants feel during vaccination applications.

Materials and Methods: The sample of this prospective randomized controlled trial comprised 119 infants who were brought to the family health center for the 2nd and 3rd dose of the combined 5-vaccine and who met the inclusion criteria. The data were obtained using the information form, which included descriptive characteristics of the baby and family, and the FLACC pain assessment tool.

Results: The mean pain scores of the infants (2.76 ± 2.06) in the black and white flashcard group were significantly lower than those of the control group (4.61 ± 2.00) ($p < 0.01$). Additionally, there was statistically no significant difference between the total durations of crying and the periods of the infants between initial crying and calming down in both the experimental and control groups ($p > 0.05$).

Conclusion: We concluded that the use of black and white flashcards during the vaccination practices was efficient. In line with these results, we recommend that nurses use black and white flashcards, an easily applicable method, to decrease the pain sensitivity of infants during vaccine applications.

Keywords: pain, vaccination, distraction

ÖZ

Amaç: Aşı uygulamaları, bebeklik dönemindeki ağrı ve en acı verici prosedürlerden biri olup hem bebekler hem de ebeveynleri için endişe ve sıkıntı yaratıcı durumdur. Araştırma; aşı uygulamaları sırasında kullanılan siyah beyaz dikkati başka yöne çekme kartlarının bebeklerde hissedilen akut ağrı düzeyine etkisini belirlemek amacı ile planlandı.

Gereç ve Yöntem: Randomize kontrollü araştırmanın örneklemini aile sağlığı merkezine 5'li karma aşının 2. veya 3. dozu için başvuran vaka seçim kriterlerine uyan toplam 119 (dikkati başka yöne çekme grubu ($n=60$), kontrol grubu ($n=59$)) bebek oluşturdu. Veriler bebek ve ailenin tanıtıcı özelliklerini içeren bilgi formu ve FLACC ağrı değerlendirme ölçeği kullanılarak elde edildi.

Bulgular: Dikkati başka yöne çekme yönteminin uygulandığı grupta yer alan yenidoğanların (2.76 ± 2.06) işlemsel ağrı puan ortalamaları kontrol grubuna (4.61 ± 2.00) göre anlamlı derecede düşüktü ($p < 0.01$). Hem deney hem de kontrol grubunda yer alan yenidoğanların toplam ağlama süreleri ile ilk sakinleşme süreleri arasında istatistiksel yönden anlamlılık bulunmadı ($p > 0.05$).

Sonuç: Sonuç olarak, aşı uygulamaları sırasında hissedilen ağrıyı azaltmada dikkati başka yöne çekme kartlarının etkili olduğu belirlendi. Bu sonuçlar doğrultusunda; bebeklerin aşı uygulamaları sırasında ağrıya hassasiyetini azaltmak için kolay uygulanabilir bir yöntem olarak dikkati başka yöne çekme kartlarının hemşireler tarafından kullanımı önerilmektedir.

Anahtar Kelimeler: ağrı, aşılama, dikkati başka yöne çekme

*This study was funded by Bandırma Onyedil Eylül University Scientific Research Projects Coordination Unit, Bandırma, Türkiye (grant number: BAP-19-1004-003).

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Submitted/Başvuru: 15.07.2023 • Accepted/Kabul: 08.09.2023 • Published Online/Online Yayın: 24.10.2023



INTRODUCTION

The vaccine is one of the most effective inventions concerning its positive impact on human health, and immunization is considered an effective method of protection in the fight against infectious diseases (1,2). Vaccines are the most common source of iatrogenic pain in early childhood, which is also an important pain source for the children, who are being exposed to this procedure, their parents, and people responsible for the vaccination process (3). Vaccination practice is one of the most painful procedures in infancy, and it creates anxiety not only for the infants but also for their parents (4,5). Pain is a complex and multidimensional situation, which is personally perceived at different levels. Pain, according to the Taxonomy Committee of the International Association for the Study of Pain, is a biochemical or sensational situation or behavior that originates from a particular region of the body. It results from actual or potential tissue damage, is affected by the experience of the person, and is displayed in an attempt to avoid an unpleasant and unwanted situation (3,6,7).

Two-thirds of children experience a fear of vaccination in childhood due to painful experiences that even continue in adulthood (4). The fear of injection experienced due to vaccination practices in early childhood may lead to refusal of treatment, and refusal or detention of certain necessary examinations (4,8,9). In the literature, it is reported that, according to the Centers for Disease Control and Prevention (CDC), syncope cases in adolescents emerge in response to the anxiety and fear of pain associated with immunization (4). It has also been noted that relieving pain during vaccination is an important strategy against vaccine hesitancy today (WHO, 2016) (10). Additionally, it was reported that some factors during vaccination practices affect the behavioral and vocal responses of infants to painful stimuli, therefore, it is necessary to control the factors to minimize pain (11). Infants depend on their parents for consolation and reassurance. Similarly, parents are uncomfortable with the thought of causing their children to suffer while they are administered vaccines. Consequently, if parents are anxious, frightened, or reluctant, babies' ability to regulate their emotions is compromised and eventually the pain becomes more severe.

Treating pain during vaccination is part of pediatric primary care services around the world and is stated to be a fundamental human right (4). Therefore, up until today, various pain relief methods have been applied to prevent/reduce vaccination pain from the infancy period onwards. Pain management in the newborn is usually based on the "3-P" approach, which involves pharmacological, physical, and psychological strategies (12). In many studies, non-pharmacological methods are effective in coping with pain (3,4,5,13-15). Non-pharmacological methods can be used in pain control alone or together with pharmacological methods. Non-pharmacological methods are among the preferred methods in recent years as they are non-invasive, inexpensive, reliable, have no side effects, and constitute the independent practice of nurses (7).

Non-pharmacological methods used in pain control in infants and children are collected in the following three main groups: supportive methods, cognitive/behavioral methods, and physical methods. While supportive methods comprise techniques such as watching videos, reading books, and ensuring that the family stays with the child during the painful procedure, physical methods consist of techniques such as touching, positioning, massage, skin stimulation, and heat and cold application (8,16,17,18). On the other hand, cognitive/behavioral methods which consist of methods such as relaxation and distraction are based on the argument that pain has a perceptual, sensory, and behavioral dimension (9,17). As stated in Sıktaş and Uysal (17), the use of distraction cards reduces injection-related pain.

It has been reported that distraction cards used during interventions such as phlebotomy, intramuscular injection, and skin prick tests in children are effective in reducing the pain and anxiety levels of children in different age groups. In the literature, there are studies, although limited in number, in which the effectiveness of the use of musical mobile, a method of distraction which is one of the cognitive/behavioral methods used to reduce pain in infants during vaccination applications is indicated (19). In recent years, black and white cards have been used as a popular example of neuroscience and neuro-parenting. In the literature, it is stated that black and white are the first colors that attract babies' attention due to their strong contrasts and that they are effective in stimulating babies (20). Our search for randomized controlled studies conducted on the use of black and white flashcards during vaccination applications revealed a gap in the literature. Thus, we thought that there was a need for studies to be conducted on this topic.

The present study is significant in that it can be a response to whether the use of black and white flashcards for infants, one of the distraction methods to be applied during vaccination practices, is an accurate and effective method. We expect that it will reveal the best distraction method to be used during vaccination through an evidence-based approach.

In light of this information, the study was planned to determine the effect of the use of black and white flashcards on the acute pain level and crying status of infants during vaccine administration.

MATERIALS AND METHODS

Design

The present study conducted to assess the effect of the use of black and white flashcards on the level of acute pain felt by infants was planned as a randomized controlled experimental study. The study was approved by the non-interventional clinical research ethics committee (IRB number 04-14, March 28, 2018), and from the relevant institution where the study would be conducted. Before the study, verbal and written consent was obtained from the parents of all the infants with the Informed Consent Form after they were informed about what the purpose of the study was, how it would be performed,

and how the data would be used. They were also told that they could withdraw from the study at any time without having to explain their excuses.

Setting and Participants

The population of the present study comprised infants aged 1-12 months who were registered with a family health center in Bandırma, a city in northwestern Türkiye, for medical follow-up between July 2018 and July 2019. The sample of the study comprised infants aged 4-6 months who were brought to the center for the 2nd and 3rd doses of the combined 5-vaccine as specified in the Ministry of Health's vaccine calendar, who met the research inclusion criteria, and who were selected through the randomized controlled method. The inclusion criteria of the study for the infants and their families were as follows: volunteering to participate in the study, being a 4-6-month-old, term, and healthy infant, having no health problems after birth, and having taken no analgesic medication in the last 3 hours before the vaccination process.

Randomization

In Power analysis based on the literature (13,21), the sample size was determined as 120 (reliability level: 90%; α : 0.05. The infants in the sample were randomly assigned to the control group and distraction cards group. To determine which case would be included in which group, numbers were randomly distributed to the two groups through a computer program without repetition of numbers. Because one of the parents wanted to withdraw from the study, her baby was not included in the study. Therefore, the number of participants included in the study was 60 in the experimental group with the black and white flashcards and 59 in the control group (Fig. 1).

Procedures

The vaccine application and data collection processes were carried out in the Family Health Center vaccination room. Before the procedure, it was ensured that the vaccination room was calm, warm, and well-lit, and all the infants were awake, fed and their diapers were changed. To ensure the reliability of the study results, the vaccine injection was administered by the same nurse who had 10 years of professional experience. The pain behaviors and crying status/durations of all the infants were observed by the same researcher. In both groups, the infants were laid in a supine position on the examination couch, and their parents were allowed to stay with the infants during the vaccination (To eliminate the parental factor, parents didn't hold their babies)

At the onset of the study, the infants' parents who were satisfied with the experimental and control group selection criteria were informed about the purpose, method, and implementation of the study and were asked whether they wanted to participate in the study. Using the Child Information Form, the following data on what the socio-demographic characteristics of the infants and parents were, whether the child had an intramuscular injection before, and whether the infant had previously been subjected to a painful intervention,

etc. were obtained from the parents who agreed to participate in the study. Before the vaccine administration, weights, heights, and head circumferences of all the infants in the experimental and control groups were measured. Before the vaccination, a video camera was placed in the vaccination room to videotape the infants. Each infant was recorded by the researcher for 1 min before the procedure, 2 min during the vaccination, and 2 min after the procedure. Using the FLACC Scale, the researcher assessed pain scores before and after the vaccination as well as the total duration of crying, and the total time which elapsed between the start of crying and calming down. The researcher started the stopwatch as soon as the baby started crying during the vaccine administration and stopped it as soon as the baby stopped crying. Then, she recorded the time which elapsed.

Black and White Flashcard Group: The cards used during the vaccination were designed in a simple way to stimulate the baby and support its visual development. Black and white flashcards were shown in front of the faces of infants in the experimental group by the researcher during and one minute after the procedure. During vaccination, parents are allowed to be together in the examination chair without touching their baby. If a baby cried more than a minute after the procedure, the baby's parent was allowed to comfort the baby owing to the ethical principles.

Control group: The infants in this group underwent no intervention to reduce their pain during vaccination. During vaccination, parents are allowed to be together in the examination chair without touching their baby.

Measures

The study data were obtained using the Child Information Form, Pain Assessment Tool – FLACC, black and white flashcards, and a video camera.

Child Information Form: This data collection form consisted of 18 items questioning what the socio-demographic characteristics of the child and the parents were, whether the child was previously subjected to an intramuscular injection, whether the child was previously exposed to a painful intervention, how long the duration of crying during the vaccination was, and how much time elapsed between the start of crying and calming down.

Pain Assessment Tool (Face, Legs, Activity, Cry, Consolability - FLACC): The FLACC scale, which was developed by Merkel et al. (22), in 1997, is used to assess five behavioral parameters. Each of the five parameters (the baby's facial expression, leg movements, activity, crying, and Consolability) is scored as 0, 1, or 2 and the total score is between 0 and 10. While "0" points indicate that the baby has no pain, "1-3" points indicate mild pain, "4-6" points indicate moderate pain, and "7-10" points indicate severe pain. This scale is used in the postoperative period in children between 2 months and 7 years of age who cannot express their pain and cannot communicate. It was determined that, in later years, the FLACC scale could be used

for pain assessment in all age groups of children and adults after necessary reliability and validity tests were conducted (22).

Black and white flashcards: These flashcards are created for babies aged between 0 and 1 year and include contrasting colors (black, and white). The size of each card is 15*15 cm (23) (Fig. 2). The retina of a baby is not fully developed at birth; therefore, a newborn’s retina can only distinguish between light and dark, or the contrast between black and white. In the literature, it was reported that high-contrast, black-and-white images with sharp outlines make it much easier for the baby to see in the first few months of its life while its vision is still developing. Therefore, it is reported that everything with a clear contrast such as black-white edges and lines is the most appropriate stimulus, supporting the development of the baby in the first months. The flashcards used during the application were designed in a simple way to stimulate the infant and support its visual development.

Video camera: To videotape the vaccine administration process, a rechargeable battery-powered video camera with 30x optical zoom (SONY-HDR-PJ410) was used. Each infant was recorded by the researcher for 1 min before the procedure, 2 min during the vaccination, and 2 min after the procedure. The videotaped footage was recorded on an external hard drive.

Data analysis

The IBM SPSS Statistics 22 package program was utilized in the statistical analyses of the data obtained in the study. Whether the parameters were suitable for normal distribution was evaluated through the Shapiro-Wilks test. In addition to the descriptive statistical methods (arithmetic mean, standard deviation, frequency), the Student-t test was used for the comparison of the quantitative data between two groups demonstrating normal distribution. The Chi-Square test was used to compare qualitative data. The significance level was accepted as $p < 0.05$.

RESULTS

Comparison of the groups in terms of some variables

In the study, 59 baby girls and 60 baby boys were included. The mean age of the children was $4.78 \pm .98$ (min: 4, max:6) months.

The children included in the study were randomly divided into the following two groups: the black and white flashcards group (n=60) and the control group (59). Characteristics of the children are given in Table 1. Accordingly, some variables such as age (month), sex, and total duration of the process were similar in both groups.

Comparison of the groups in terms of the pain levels, durations of crying, and time which elapsed between the start of crying and calming down.

Comparisons of the two groups in terms of the pain levels, duration of crying, and time that elapsed between the start of crying and calming down are presented in Table 2. As is seen in Table 2, the pain levels of children in the control group were higher than those of the children in the black and white flashcards group, and the difference was statistically significant ($p = .003$).

The duration of the crying and the time that elapsed between the start of crying and calming down were similar in both groups, and the difference was not statistically significant ($p > .05$).

DISCUSSION

Considering that the first pain experience of healthy infants is vaccination, pain management in vaccine applications is of vital importance (9). Many pharmacological and non-pharmacological methods are applied to control pain while children are vaccinated (3,9). The method to be used in vaccine applications to reduce pain should be effective easy, fast, unprepared, and tolerable by infants/children (9,10).

Cognitive-behavioral non-pharmacological methods involving distraction have been experimentally supported in acute pediatric pain management (9,24). Distraction is a method to increase pain tolerance by diverting attention away from the painful stimulus. This method is used as a powerful anxiety and pain management tool in children’s pain. It is a suitable method for infants as it does not require advanced cognitive skills. Moreover, in the literature, it is stated that distraction is the most effective method among non-pharmacological pain relief methods in pediatric vaccine applications in the first 7 years of life (9,17,20,25).

Table 1: Group Comparison of the Demographic Characteristics of the Infants

		Total	Group		Test Value
			Black and White Flashcard Group (n=60)	Control Group (n=59)	
Sex n (%)	Girls	59 (49.6)	30 (50.0)	29 (49.2)	0.009
	Boys	60 (50.4)	30 (50.0)	30 (50.8)	[†] 0.926*
			Black and White Flashcard Group (n=60)	Control Group (n=59)	
Age (Month)	Min-Max (Median)	4-6 (4)	4-6 (4)	4-6 (4)	-0.859
	Mean ± SD		4.86±0.99	4.71±0.96	[†] 0.392*
Duration of Procedure			3.26±0.82	3.50±1.16	1.311 [†] 0.193*

[†]Pearson Chi-Square Test; [†]t Test; * $p > 0.01$

Table 2: Comparison of the groups in terms of the mean FLACC Pain Scores of the infants

		Total	Black and White Flashcard Group (n= 60)	Control Group (n= 59)	t / p
Mean FLACC score during the procedure	Min-Max (Median)	0-8 (5)	0-8 (4)	1-7 (6)	2.989
	Mean \pm SD	4.54 \pm 1.75	4.08 \pm 1.81	5.01 \pm 1.58	.003*

Data are represented as mean \pm standard deviation. FLACC, a pain assessment tool; t=t Test; *p<0.01

Table 3: Group Comparison of the Infants Concerning the Total Durations of Crying and Time Periods Between the Start of Crying and Calming Down

		Total	Black and White Flashcard Group (n= 60)	Control Group (n= 59)	t / p
Total duration of crying (sec)	Min-Max (Median)	0-45 (6)	0-45 (5)	0-22 (8)	1.016
	Mean \pm SD	7.52 \pm 6.00	6.96 \pm 7,24	8.08 \pm 4.39	.312*
Time which elapsed between the start of crying and calming down (sec)	Min-Max (Median)	0-60 (5)	0-60 (5)	0-24 (7)	1.329
	Mean \pm SD	7.23 \pm 6.93	6.40 \pm 8.42	8.08 \pm 4.92	.186*

t=t Test; *p>0.05

The distraction method is used to reduce pain during many invasive interventions in childhood. In this regard, in the literature, there are numerous previous studies in which the distraction methods such as watching cartoons, inflating balloons, creating foam bubbles, speaking things irrelevant to the intervention, virtual reality glasses, listening to music, using kaleidoscope, etc. are investigated during vaccine applications in various age groups (9,26-28). It was determined that there were no previous studies in which distraction methods with black and white flashcards were used during vaccine applications in infants.

Bekar and Efe (28) reported that lullabies sung by the mother while their 2-month-old babies are vaccinated were effective in reducing vaccine-induced pain. Şıktaş, and Uysal (17), stated that the pain levels of the 12-month-old babies who were administered the measles, mumps, and rubella vaccine were lower in the Buzzy group than in the control group. Vaziri et al. (29) reported that inhaling low-concentration lavender oil during vaccine applications has a pain-relieving and sedative effect on infants. In a study conducted by Gedam et al. (30), it was reported that luminous toys, sound-producing toys, and cartoons are effective in reducing pain during vaccine applications. In their study, Shahid et al. (15) noted that the distraction technique of using an iPad during vaccination practices in children aged 2-6 years was effective in reducing pain levels and increasing satisfaction. In our study, the mean FLACC pain score of the infants in the experimental group, in which black and white flashcards were used, was significantly lower than that of the infants in the control group (p= .000). The results of the present study in which black and white flashcards were used in infants were consistent with the results of several studies in the literature in terms of reducing pain with a distraction method (17,28,29).

Crying behavior is described as the most obvious and traceable behavioral reaction displayed by infants against pain (5,30). In

our study, the total duration of crying, and time that elapsed between the start of the crying and calming down were similar in both groups, and the difference between the groups was not statistically significant (p>0.05). In the literature, there are various studies in which the effect of different methods applied during vaccine applications on durations of crying was investigated. Vaziri et al. (29), determined that the duration of crying was shorter in the infants in the lavender-oil-inhaling group than it was in the infants in the control group. In their study conducted with 4-6-month-old infants who were administered DTaP-IPV/Hib vaccine, a 5-in-1 combination vaccine Göl and Altuğ Özsoy (31), investigated the effect of 10-second manual pressure on the vaccination point before the procedure and non-aspirated rapid injection technique on crying time determined that the duration of crying (in seconds) of the infants in the experimental group during and after the procedure was shorter than was that of the infants in the control group (p=0.001). Koç and Gözen (20) determined that there was a significant difference between the control and experimental groups of infants who were administered the reflexology method before the vaccination process in terms of the mean durations of crying (p< 0.05). Karakuş Türker (32) who investigated the effect of breastfeeding and kangaroo methods during vaccination practices determined that the infants in the breastfeeding group cried for a shorter time than did those in the kangaroo group, though the difference was not statistically significant. The results of our study, which were consistent with the results in the literature, indicated that the total crying period of the infants in the experimental group was shorter than that of the infants in the control group, though the difference was not statistically significant. Our study results are consistent with the result of Karakuş Türker's (32) study in that there is statistically no significant difference between the durations of crying. It is thought that the difference between the studies in terms of the duration of crying of infants is due to the use of non-pharmacological methods through different

distraction practices and in different age groups.

Study Limitations

Flashcard study is a new method. This study determined the effect of only one method in relieving pain caused by vaccine administration.

Clinical Implications

One of the most important purposes of nursing care is reducing or eliminating pain. Since one of the first pain experiences of healthy babies is the vaccine application, the significance of pain management becomes apparent. It is thought that this method to be used in reducing pain during vaccine applications may be preferred by nurses in a greater number of clinics because they are practical, cheap, and easy to use. In addition, it is thought that it will contribute to nursing practices because it is a new and alternative method that can be used in infants to reduce pain during vaccination practices. Using black and white flashcards can help reduce pain during vaccine injections and increase the comfort of both infants and parents.

CONCLUSIONS

In conclusion, we determined that the black and white flashcards shown during vaccine applications were effective in reducing the pain level of infants, that the use of black and white flashcards did not create a significant difference between the infants concerning the duration of crying, but that we observed a decrease in the duration of crying in infants.

In line with these results, black-and-white information cards, which are an easy-to-apply method to reduce infants' pain sensitivity during vaccine administration, can be used by nurses. However, most other relevant studies were conducted with children aged 2 to 18 years. In the present study, the applicability and effectiveness of black and white flashcards in the treatment of pain in 4-6-month-old babies without any complications were demonstrated. Therefore, we expect that our study might contribute to the literature on the use of black and white flashcards in pain management in infants. According to the results obtained in the present study, we recommend that further studies should be conducted in which larger sample groups are compared by using different distraction methods.

Ethics Committee Approval: This study was approved by the Karamanoğlu Mehmetbey University non-interventional clinical research ethics committee (IRB number 04–14, March 28, 2018)

Informed Consent: Written consent was obtained from the participants.

Peer Review: Externally peer-reviewed.

Author Contributions: Conception/Design of Study- D.Y., N.C.S., Z.E.E.; Data Acquisition- D.Y., Z.E.E.; Data Analysis/Interpretation- N.C.S.; Drafting Manuscript- D.Y., N.C.S., Z.E.E. ; Critical Revision of Manuscript- D.Y., N.C.S., Z.E.E.; Final Approval and Accountability- D.Y., N.C.S., Z.E.E.

Conflict of Interest: Authors declared no conflict of interest.

Financial Disclosure: This study was funded by Bandırma Onyedi Eylül University Scientific Research Projects Coordination Unit, Bandırma, Türkiye (grant number: BAP-19-1004-003)

Etik Komite Onayı: Bu çalışma, Karamanoğlu Mehmetbey Üniversitesi girişimsel olmayan klinik araştırma etik kurulu tarafından onaylandı (IRB numarası 04–14, 28 Mart 2018)

Bilgilendirilmiş Onam: Katılımcılardan bilgilendirilmiş onam alınmıştır.

Hakem Değerlendirmesi: Dış bağımsız.

Yazar Katkıları: Çalışma Konsepti/Tasarım- D.Y., N.C.S., Z.E.E.; Veri Toplama- D.Y., Z.E.E.; Veri Analizi/Yorumlama- N.C.S.; Yazı Taslağı- D.Y., N.C.S., Z.E.E.; İçeriğin Eleştirel İncelemesi- D.Y., N.C.S., Z.E.E.; Son Onay ve Sorumluluk- D.Y., N.C.S., Z.E.E.

Çıkar Çatışması: Yazarlar çıkar çatışması beyan etmemişlerdir.

Finansal Destek: Bu çalışma Bandırma Onyedi Eylül Üniversitesi Bilimsel Araştırma Projeleri Koordinasyon Birimi tarafından finanse edilmiştir, Bandırma, Türkiye (hibe numarası: BAP-19-1004-003)

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