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ORIGINAL ARTICLE

The Effect of Using Musical and Lighted Baby Crib Mobile on Newborns' Pain and Stress During Blood Draw; Randomized Controlled Trial

Işıklı Müzikli Dönencenin Yenidoğanlarda Kan Alma Sırasında Oluşan Ağrı ve Strese Olan Etkisi; Randomize Kontrollü Bir Çalışma

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Abstract

Objective: Newborns may experience pain and stress during blood draw procedures, and when these adverse reactions are not managed, they can lead to both physiological and psychological consequences. To evaluate the effect of using musical and lighted baby crib mobile on newborns' pain and stress during blood draw.

Method: A parallel-group and randomized controlled methodology was employed in this research. The study involved 60 newborns and their caregivers. Data were collected through the "newborn information form" and the "ALPS-neo pain and stress assessment scale".

Results: There is no statistically significant difference between the average pain and stress scores stated by parents and nurses for newborns (p>0.05) during the blood draw (intervention group=9.20±1.94; control group=9.33±2.17) and after the blood draw (intervention group=9.18±2.01; control group=9.10±). The average pain and stress scores stated by the parents and the nurse for the newborns in the intervention and control groups were compatible with each other (p>0.05).

Conclusion: It was revealed that the musical and lighted baby crib mobile was not effective in reducing newborn's pain and stress during blood draw. A scientifically grounded clinical investigation is advised to ascertain the impact of newborn crib mobiles on newborns' pain and stress levels.

Keywords: Pain, crib mobile, nursing management, needle intervention, stress, non-pharmacological intervention

Öz

Amaç: Yenidoğanlar, kan alma işlemi sırasında ağrı ve stresle karşılaşabilirler, bu olumsuz tepkiler yönetilemediğinde hem fizyolojik hem de psikolojik sonuçlara neden olabilmektedir. Işıklı ve müzikli dönencenin yenidoğanlarda kan alma işlemi sırasında oluşan ağrı ve strese olan etkisini incelemektir.

Yöntem: Bu çalışma paralel grup ve randomize kontrollü tasarımda gerçekleştirilmiştir. Araştırma 60 yenidoğan ve ebeveyn ile yürütüldü. Veriler "bilgi formu" ve "ALPS-neo ağrı ve stres değerlendirme ölçeği" kullanılarak toplandı.

Bulgular: Kan alımı sırasında (müdahale grubu=9,20±1,94; kontrol grubu=9,33±2,17) ve kan alımı sonrasında (müdahale grubu=9,18±2,01; kontrol grubu=9,10±) ebeveynlerin ve hemşirenin yenidoğanlar için belirttiği ağrı ve stress puan ortalamaları arasında istatistiksel olarak anlamlı bir fark yoktur (p>0,05). Müdahale ve kontrol grubundaki ebeveynlerin ve hemşirenin yenidoğanlar için belirttiği ağrı ve stress puan ortalamaları birbiri ile uyumlu idi (p>0,05).

Sonuç: Müzikli ve ışıklı dönencenin yenidoğanlarda kan alma sırasındaki ağrı ve stresi azaltmada etkili olmadığı ortaya çıktı. Dönencenin yenidoğanlardaki ağrı ve stres üzerindeki etkisini belirlemek için kanıta dayalı klinik çalışmaların yapılması önerilmektedir.

Anahtar Kelimeler: Ağrı, dönence, hemşirelik yönetimi, iğneli işlem, stres, non-farmakolojik girişim

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Introduction

Newborns are exposed to needle procedures after birth, such as vitamin K injection, hepatitis B vaccine, screenings, and routine immunization (1). During the process, it may be necessary to repeat the procedures and take a blood sample according to the baby's condition (2). These are painful procedures for the newborn and cause stress for the baby during the procedure; they can also cause neurocognitive, physiological, metabolic, and behavioral problems (3-6). Experienced pain can negatively affect the newborn's future painful reaction (7). Therefore, poor pain management during procedures causes the newborn to suffer pain and to be exposed to short-term and long-term adverse effects (8).

The International Neuropsychiatric Pain Group and the American Academy of Pediatrics strongly recommend minimizing pain in newborns during procedures and prioritizes the use of non-pharmacological methods as the initial approach for pain management (9-11). Non-pharmacological methods aiming to provide analgesic effects during painful procedures by creating a relaxing environment are important because they do not have side effects (5,12,13). Breastfeeding (14), skin-to-skin contact (15), swaddling, music therapy, oral glucose (5), and pacifier use (16) are some of the non-pharmacological methods with proven pain-reducing effects in newborns.

Music therapy, a non-pharmacological method widely used in newborns, is a popular distraction method that reduces the perception of pain (17). In the study of Tang et al. (18) with premature newborns, it was found that the application of music therapy during central venous catheter placement reduced physiological and behavioral reactions. The study conducted by Ozdemir and Tüfekci (19) with 120 healthy newborns found that the presence of musical baby crib mobile in the vaccination rooms reduces newborns' pain levels and crying times. Similarly, different studies report positive results of listening/singing lullabies to babies during painful procedures (20,21). Although all these methods are simple, effective, and applicable (2,22), it is known that the rate of use of non-pharmacological methods in neonatal pain management is low in the world and our country (1,2,23,24). Nurses are responsible for managing pain by using various methods and preventing its negative effects on newborns (2,25).

Radesky and Christakis (26) stated that toys with sounds, lights, and different features effectively direct newborns' attention. For this reason, it is predicted that the baby crib mobile, which combines these three features that will attract the attention of newborns, can be used as a distraction during needle interventions and can be effective in reducing pain and stress. There is, however, a gap in the available research on this subject. The purpose of this study was to address current limitations and provide practical knowledge for nursing care. The primary objective was to investigate the effect of using a musical and lighted baby crib mobile on babies' pain and stress during blood draws.

Main Points

- Blood draw procedure is a painful and stressful intervention for newborns.
- Distraction methods are an effective technic to increase physiological and psychological well-being.
- Musical and lighted baby crib mobile is distracted newborns with sound and light
- This study findings showed that musical and lighted baby crib mobile not effective to reduce newborn's pain and stress.

Material and Methods

Study Hypotheses

Hypothesis 1 (H1): During the blood draw, the musical and lighted baby crib mobile groups was effective in decreasing newborns' pain level.

Hypothesis 2 (H2): During the blood draw, the musical and lighted baby crib mobile groups was effective in decreasing newborns' stress level.

Study Design

The research utilized a parallel group design, involving an intervention group and a control group, and followed a randomized controlled experimental approach. The study's design and implementation adhered to the guidelines and principles specified in the consolidated standards of reporting trials checklist, as illustrated in Figure 1.

Study Sample

The study population comprised term newborns aged 0-28 days and their parents who applied the blood collection unit at a university hospital between January 2022 and July 2022.

No previous research has been identified that specifically examines the impact of utilizing a musical and lighted baby crib mobile on pain and stress experienced by newborns during blood draws. Therefore, aiming for a medium effect size (d: 0.60), a power of 80% (1-β error), and a confidence level of 95% (α error), the sample size for each group was determined to be 36 newborns using G*Power 3.1.9.4. The sample size was increased by 10% to account for potential dropouts. Thus, the objective was to include a total of 80 newborns, with 40 newborns allocated to each group.

Inclusion criteria: Born between 38-42 weeks, being 0-28 days, absence of visual and auditory problems, not using any pain reliever or sedative medication in the last four hours, parents' willingness to participate in the study, parents' knowledge of Turkish, and parents' ability to read and write.

Exclusion criteria: Having a preterm birth, having a disease that causes chronic pain, having visual or auditory problems, and using any pain or sedative medication in the last four hours.

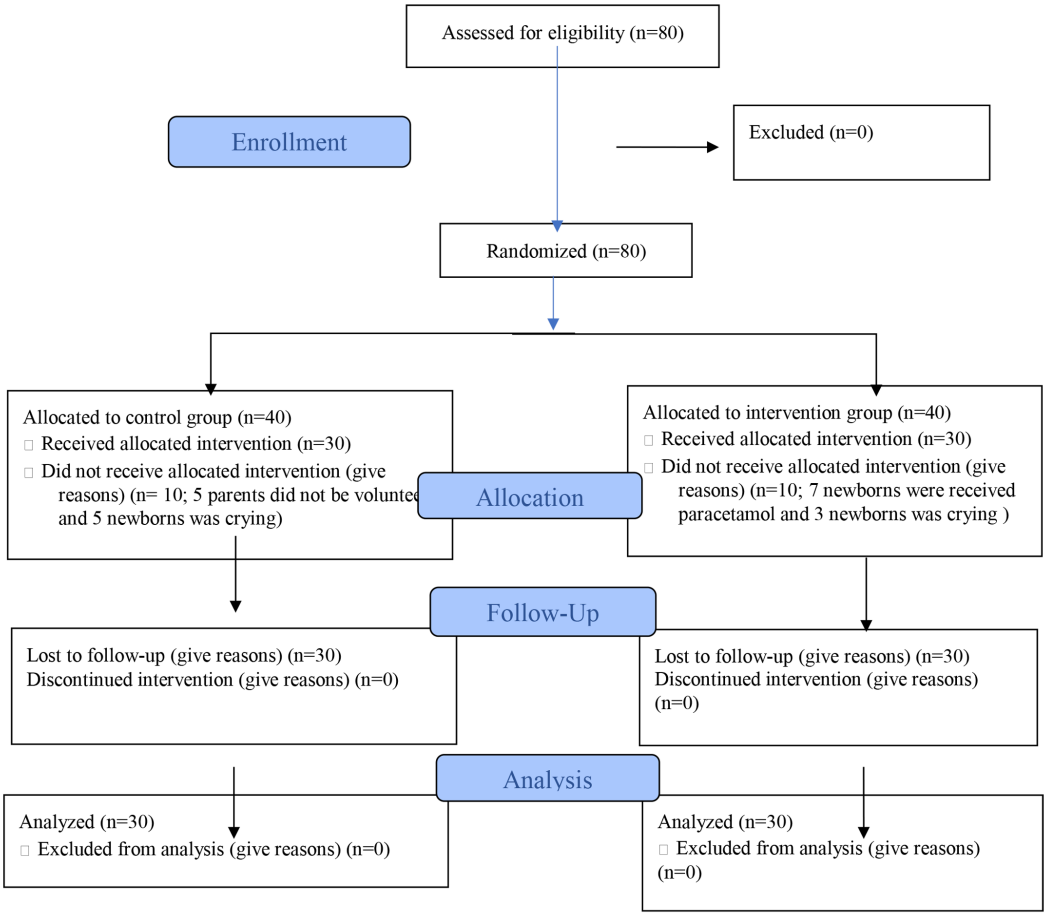

Figure 1.
CONSORT flowchart

Randomization

Newborns were assigned randomly to either the musical and lighted baby crib mobile (intervention) group, consisting of 40 newborns, or the control group, also comprising 40 newborns. The random assignment was conducted using a computer program (www.randomizer.org). Newborns whose parents did not meet the study criteria or declined to participate in the randomization process were not included in the study. Both parents and researchers were aware of the group assignments and therefore could not be blinded. The inclusion of newborns in the study was based on their adherence to the predefined inclusion criteria, following the sequential order of their admission to the hospital. However, 10 children from the control group (5 parents did not volunteer, and 5 newborns were crying) and 10 children from the intervention group (7 newborns received paracetamol, and 3 newborns were crying) were excluded from the study. Consequently, the research was completed with a total of 60 newborns. A post-hoc analysis was conducted, revealing an effect size of d=0.06, an alpha error probability (α err prob) of 0.05, and a sample size that achieved 80% power.

Data Collection Tools

The data collection process involved the utilization of two instruments: The "newborn information form" and the "ALPS-Neo pain and stress assessment scale". These tools were employed to gather relevant data during the study.

Newborn information form: The "newborn information form" was specifically developed by the researchers and comprised seven questions (16-18). These questions aimed to gather descriptive characteristics of the newborns, including their age, gender, prior experience with needle attempts, and the number of needle attempts they had undergone. The form served to collect pertinent information regarding the participants' background and experiences related to the study.

ALPS-neo pain and stress assessment scale: The scale was originally developed to assess the levels of pain and stress experienced by newborns, including both premature and full-term newborns (27). A validity and reliability study of the scale specifically for the Turkish population was subsequently conducted by Ceylan and Bolışık (28). The scale employs a 3-point Likert-type format and consists of

five items: Newborn's facial expression, breathing pattern, tone of extremities, hand and foot activities, and activity level. Observational assessments are used to evaluate these items. Increased scores on the scale reflect elevated levels of stress and pain perceived by the newborns. According to the scale, scores ranging from 3 to 5 indicate mild pain and stress, while scores above 5 indicate severe pain and stress. The scale is used as a standardized tool to assess and quantify the newborns' pain and stress levels during the study. Cronbach's alpha coefficient was between 0.70-0.81. In this study Cronbach's alpha coefficient was between 0.90-0.95.

The musical and lighted baby crib mobile: It measures 43.5x33x9.5 cm and is made of plastic. It is recommended for use in newborns 0-12 months. It has music that makes it easier for babies to fall asleep by reducing stress. This baby mobile has a projection and music function. In addition, the mobile has a 360° flexible swivel bracket that can be adjusted as desired. The surface of the apparatus of the mobile, which is designed to be environmentally and baby friendly, is smooth. There are four rattles on the mobile (Figure 2).

Study Protocol

Standard blood draws procedure: In the blood collection unit where the research took place, healthcare professionals do not regularly employ pharmacological or non-pharmacological methods to alleviate the discomfort and anxiety arising from needle procedures in newborns. Instead, they rely on customary practices such as having family members present and providing positive encouragement. The nurse (H) in charge of the blood collection unit informs the parents about the procedure and then performs the needle interventions.

Intervention group: Prior to the procedure, the researcher (R) provided detailed information about the study procedure and its purpose to the parents of the newborns assigned to the musical and lighted baby crib mobile group. To prevent any contamination or potential harm to the newborns, the mobile was securely positioned 60 cm above the newborn's eye level. Once the parents were informed and had given their written consent, a face-to-face interview was conducted to collect data using the "newborn information form". Subsequently, the musical and lighted baby crib mobile was activated. Exactly one minute after the activation of the mobile, a nurse (H) proceeded with the blood draw. Both parents and nurses were instructed to closely observe the newborn's behavior throughout the procedure and immediately afterward, aiming to assess the level of pain and stress experienced by the child. Right after the completion of the procedure (after the needle was removed from the vein and a tampon was placed to stop bleeding, approximately one minute after the procedure), the nurse and parents were asked to mark the highest level of pain and stress observed in the baby using the "ALPS-Neo pain and stress rating scale".

Control group: The newborns in the control group received standard care from the unit. No pharmacological or non-pharmacological pain-reducing methods were utilized, except for allowing the presence of parents with the newborns. Both parents and nurses were instructed to closely observe the newborn's behavior during and immediately after the procedure to assess the levels of pain and stress experienced by the child. After the procedure, the nurse and parents were requested to identify the peak levels of pain and stress observed in the baby during and immediately after the procedure. This assessment was made specifically after removing the needle from the vein and applying a tampon to stop bleeding, which occurred approximately one minute after the procedure. This assessment was done using the "ALPS-Neo pain and stress rating scale".

Statistical Analysis

The data analysis was performed using the IBM SPSS software, a licensed package for Windows, specifically designed for statistical analysis (IBM 28). Various statistical measures were employed to analyze the descriptive data, including mean, standard deviation,

Figure 2.
The musical and lighted baby crib mobile

frequency, and percentage distributions. These statistics provided a comprehensive understanding of the data's central tendency, variability, and distribution. The normal distribution of the mean scores obtained from the ALPS-neo pain and stress assessment scale was assessed using the Shapiro-Wilk-W test. The Pearson chi-square test and Mann-Whitney U test were employed to compare the socio-demographic characteristics of the newborns in the two groups. The Mann-Whitney U test and Wilcoxon signed-rank test were used to compare the mean scores on the ALPS-neo pain and stress assessment scale between the two groups. The significance level was set at $p<0.05$, and the results were evaluated at a 95% confidence interval.

Results

Table 1 presents the distribution of descriptive characteristics among the newborns based on the groups. The distribution of newborns' age, weight, height, gender, previous experiences of needle intervention, number of needle interventions experienced, and the presence of chronic diseases were homogeneous across the intervention and control group ($p>0.05$).

The distribution of the ALPS-neo pain and stress assessment scale scores, as reported by both parents and nurses, is presented in Table 2. Based on the parent's report during the blood draw intervention, the mean ALPS-neo pain and stress assessment scale score for the intervention group was 9.20±1.94, while for the control group, it was 9.33±2.17. However, according to the parent's report, the two groups had no statistical difference (t=422.500, p=0.491). Similarly, based on the nurse's report, the mean ALPS-neo pain and stress assessment scale score for the intervention group was 9.18±2.01, whereas for the control group, it was 9.10±2.31. Additionally, there was no statistical difference between the intervention and control groups according to the nurse's report (t=449.500, p=0.991). Furthermore, a comparison between the nurse's and parent's reports did not reveal a significant difference. The nurse's and parent's reports were similar ($p>0.05$), indicating agreement between the two assessment sources.

Following the blood draw intervention, according to the parent's report, the mean ALPS-neo pain and stress assessment scale score for the intervention group was 8.57±2.11, whereas for the control group it was 8.26±2.65. However, the two groups had no statistical difference based on the parent's report (t=413.500, p=0.546). Similarly, based on the nurse's report, the mean ALPS-neo pain and stress assessment scale score for the intervention group was 8.53±2.04, while for the control group it was 8.07±2.69. Again, there was no statistically difference among intervention and control groups according to the nurse's report (t=408.000, p=0.496). Furthermore, when comparing the nurse's and parent's reports, no significant difference was found. The nurse's and parent's reports were similar ($p>0.05$), indicating agreement between the two assessment sources.

Table 1.
The Descriptive Characteristics of the Newborns by Groups

Variables	**Intervention group n=30**		**Control group n=30**		**Test**	**p**
	Mean ± SD		**Mean ± SD**			
Age	17.67±8.20		16.17±7.64		407.000	0.524**
Weight	3171.50±713.64		3492.33±568.32		336.000	0.092**
Height	50.13±2.09		50.83±2.39		328.500	0.068**
Gender	**n**	**%**	**n**	**%**	1.067	0.302*
Girl	13	43.3	17	56.7		
Boys	17	56.7	13	43.3		
Experiences of the needle intervention						
Yes	29	96.7	26	86.7	1.964	0.161*
No	1	3.3	4	13.3		
Number of needle intervention experiences						
1 time	1	3.3	3	10.0	1.667	0.435*
2 times	4	13.3	2	6.7		
3 times and more	25	83.3	25	83.3		
Status of chronic diseases						
Yes	1	3.3	2	6.7	3.018	0.221*
No	29	96.7	28	93.3		

**=chi-square test, **=Mann-Whitney U test, SD=standard deviation*

Discussion

The distraction strategy is a valuable treatment approach often employed by nurses to modify the environment and promote overall health and well-being (17). Within the realm of distraction techniques, music therapy stands out as a particularly promising avenue. Research suggests that music therapy can yield notable improvements in both behavioral and physiological indicators. These improvements include reductions in heart rate, respiration rate, blood pressure, oxygen levels, and muscle tension (29). The American Music Therapy Association defines music therapy as the evidence-based utilization of music interventions within a therapeutic relationship, aimed at addressing individualized goals. This therapeutic approach encompasses various modalities, including vocals and instruments, to address a wide range of physical and psychological conditions (30). The primary objective of this study was to explore the potential benefits of utilizing a musical and lighted baby crib mobile in alleviating pain and stress experienced by newborns during blood draws. However, the study's findings yielded unexpected results, as they did not support the effectiveness of the musical and lighted baby crib mobile in reducing pain and stress in newborns during blood draws. Consequently, our study hypotheses were ultimately rejected. These findings provide valuable insights into the limitations of this specific intervention and underscore the need for further research and development in this area.

In our current study, both parental and nursing assessments of pain and stress experienced by newborns did not show significant differences between the intervention and control groups. These results contrast with the findings of previous research that have demonstrated the positive impact of various interventions on neonatal pain and stress. Bekar and Efe (20) conducted a well-designed randomized controlled study to investigate the effects of mother-sung lullabies on pain experienced by newborns during vaccination, as well as maternal anxiety levels. Their study yielded compelling results, showing that the use of mother-sung lullabies effectively reduced both the pain experienced by newborns during vaccination and maternal anxiety levels. Similarly, Tang et al. (18) conducted a study with a focus on investigating the effects of music interventions on pain responses in premature newborns. Their findings were noteworthy, revealing that musical intervention during the insertion of peripheral central venous catheters led to significant reductions in stress hormone levels, physiological parameters, and behavioral responses associated with pain. In another study by Ozdemir and Tüfekci (19), the efficacy of using musical mobiles to alleviate pain during newborn vaccinations was investigated. Their findings demonstrated that newborns exposed to musical mobiles exhibited lower pain scores both during and after vaccination, as well as reduced crying duration compared to the control group. Despite the consistently positive outcomes reported in studies related to the effects of music and similar interventions on the physical and emotional well-being of newborns (17-20), our current study did not find a positive effect associated with the use of the baby mobile crib on neonates. It is important to acknowledge that a potential explanation for this disparity may lie in the duration of use and the distance at which the baby mobile crib was held during the intervention. However, it is crucial to highlight that there is currently no existing evidence or clinical recommendations supporting the use of baby mobile cribs in neonatal care. Moving forward, future research endeavors should prioritize investigating the impact of the duration for which baby crib mobiles are used, as well as exploring other potential factors that may influence their effectiveness in improving the comfort and well-being of newborns. Future research endeavors should prioritize investigating the impact of the duration for which baby crib mobiles are used, as well as exploring other potential factors that may influence their effectiveness in improving the comfort and well-being of newborns.

Music therapy for neonates is a professional adaption of planned music activities such as singing, playing, and listening to evidence-based music. It is intended to address the sensory, physical, and emotional demands of neonates and their parents and support the attachment

Table 2.
The Distribution of the ALPS-Neo Pain and Stress Assessment Scale According to the Parent's and Nurse's Report

	Intervention group n=30	**Control group n=30**	**Test**	**p**	**Effect size**
	Mean ± SD	Mean ± SD			
During intervention					
Parent's report	9.20±1.94	9.33±2.17	422.500	0.491*	0.07
Nurse's report	9.18±2.01	9.10±2.31	449.500	0.991*	0.04
Test, p	t=0.994; p=0.998**	t=-0.447; p=0.655**			
After intervention					
Parent's report	8.57±2.11	8.26±2.65	413.500	0.546*	0.13
Nurse's report	8.53±2.04	8.07±2.69	408.000	0.496*	0.19
Test, p	t=-0.342; p=0.180**	t=-1.342; p=0.180**			

**=Mann-Whitney U test, **=Wilcoxon signed-rank test, SD=standard deviation*

process (30). Although music interventions have a positive effect on the metabolic, physical, and emotional outcomes of babies, the results of this study show that more studies are needed on the use of baby crib mobile, which is one music intervention. Music therapy for neonates represents a specialized approach involving carefully planned musical activities like singing, playing instruments and listening to evidence-based music. Its primary goal is to cater to the sensory, physical, and emotional needs of neonates and their parents while fostering the attachment process (31). While existing research indicates the positive impact of music interventions on various aspects of neonatal care, such as metabolic, physical, and emotional outcomes, the findings of our study underscore the need for further investigations specifically concerning the use of baby crib mobiles as a music-based intervention.

Study Limitations

The results of this study highlight the importance of expanding our understanding of the potential benefits and limitations associated with baby crib mobiles in neonatal care. As a music intervention, baby crib mobiles may offer a unique avenue for providing comfort and stimulation to neonates. However, our study did not yield the anticipated positive effects, prompting the recognition that more comprehensive research is necessary to discern the precise circumstances under which baby crib mobiles may be most effective. In conclusion, while music therapy has demonstrated its value in neonatal care, the specific role of baby crib mobiles as a music intervention remains a topic that warrants further investigation. Future studies should aim to provide a more comprehensive understanding of the use of baby crib mobiles in neonatal care settings and their potential impact on neonatal health and well-being.

Conclusion

Although music therapy is widely used for newborns, in this study, it was found that playing music with a baby crib mobile did not affect pain and stress outcomes in newborns. However, while there are many publications on the effective results of music therapy, it would not be acceptable to state that it is not effective only according to the results of the present study. The small sample size of this study and the similar assessment for pain and stress by the same measurement tool may have affected the results. Future studies focus on reaching conclusive results regarding the impact of music on newborn physiology, research design and data collection should be reliable, as well as have adequate power to identify intervention effects.

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Ethics Committee Approval: This study was conducted in accordance with the principles outlined in the Declaration of Helsinki. Approval was granted by the Ethics Committee of Trakya University, Faculty of Medicine Scientific Research Ethics Committee for the implementation of the study (number: 01/05, dated: 03/02/2022), and written permission was obtained from Trakya University Health Research and Application Center, Department of Child Health and Diseases.

Informed Consent: Written consent was obtained from parents. It was informed that the data obtained from the study will only be used for this scientific research.

Author Contributions: Surgical and Medical Practices – R.S., H.E., E.H.S.; Conception – R.S.; Design – R.S.; Data Collection and/or Processing – R.S., H.E.; Analysis and/or Interpretation – R.S., E.H.S.; Literature Review – R.S., H.E.; Writing – R.S., E.H.S.

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