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Research Article / Araştırma Makalesi

The Comparative Effects of Ball Squeezing and Cartoon Watching in Pain Management in Children during İntramuscular İnjection: A Randomized Control Trial

Çocuklara Enjeksiyon Sırasında Stres Topu Verilmesinin ve Çizgi Film Seyrettirmenin Ağrıyı Azaltma Etkisi: Randomize Kontrollü Çalışma

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Abstract: This study was designed as a randomized controlled trial to investigate the comparative effect of ball squeezing and watching cartoons on pain management in children during intramuscular injection. The population of the study was comprised of 6-12 years old children who came to emergency for intramuscular injection. Power analysis was performed by G*Power program. Approximately 147 protocols completed with 6-12 years old children (each group 49 children). In the study, a questionnaire including child and socio-demographic characteristics their experiences of hospitalization data and Facial Pain Scale- Revised (FPS-R), Visual Analog Scale (VAS), and ball (for squeezing) were used. According to the results of the study, the FPS-R score during the procedure was the lowest in the stress ball group and was statistically significant ($p<0.05$). The lowest VAS scores during the procedure the lowest score was in the stress ball group and the differences between the relevant groups were statistically significant ($p<0.05$). It was determined that squeezing the ball and watching cartoons were effective in reducing pain during injection, however, the ball squeezing group had the lowest pain level. Among non-pharmacological methods, ball squeezing can be preferred as a practical and effective method, especially by pediatric nurses, in reducing pain during intramuscular injection in children.

Keywords: Pain management, Stress ball, Cartoon watched, Injection.

Öz: Bu çalışma, kas içi enjeksiyon sırasında çocuklarda ağrı yönetiminde top sıkma ve çizgi film izlemenin karşılaştırmalı etkisini araştırmak amacıyla randomize kontrollü bir çalışma olarak tasarlandı. Araştırmanın evrenini IM enjeksiyon için acile gelen 6-12 yaş arası çocuklar oluşturdu. Güç analizi G*Power programı ile yapıldı. 6-12 arası yaklaşık 147 çocukla (her grup 49 çocuk) protokol tamamlandı. Araştırmada çocukların sosyo-demografik özelliklerini ve hastaneye yatış deneyimlerini içeren bir anket, Yüz Ağrı Ölçeği Revize (FPS-R), Görsel Analog Skala (VAS) ve top (sıkma için) kullanıldı. Çalışma sonuçlarına göre işlem sırasındaki FPS-R puanı en düşük puan stres topu grubundaydı ve istatistiksel olarak anlamlıydı ($p<.05$). İşlem sırasında en düşük VAS skoru stres topu grubunda olup, gruplar arasındaki farklar istatistiksel olarak anlamlıydı ($p<0.05$). Topu sıkma ve çizgi film izleme uygulamasının enjeksiyon sırasında ağrıyı azaltmada etkili olduğu, bununla birlikte top sıkma grubunun en düşük ağrı düzeyine sahip olduğu belirlendi. Farmakolojik olmayan yöntemler içinde top sıkma, çocuklarda kas içi enjeksiyon sırasında ağrının azaltılmasında özellikle çocuk hemşireleri tarafından pratik ve etkili bir yöntem olarak tercih edilebilir.

Anahtar Kelimeler: Ağrı yönetimi, Stres topu, Çizgi film izleme, Enjeksiyon.

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Introduction

Pain is a universal condition experienced by all people (Bukola and Paula, 2017) and children, in particular (Şahiner and Türkmen, 2019; Semerci et al., 2020), being defined as an unpleasant emotional sensation of a person's past experiences but not due to tissue damage from a particular area of the body (International Association for the Study of Pain; IASP 2010). Considering the

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relevant sources of the pain, blood collection, injection and vaccination are of the most common sources of procedural pain. Out of the pain sources of injections available, intramuscular injection (IM) is of the painful and most common experiments during medical procedures among hospitalized children (Yıldız et al., 2017), being chosen as the case of dense and irritating drugs uses. In this regard, the appropriate selection of the IM administration sites and muscles are of the substantial issues (Tuğrul and Denat, 2014; Yıldız et al., 2017). IM administrations are employed at areas, viz. Dorsogluteal, ventrogluteal, femoral, laterofemoral, and deltoid area. Of the relevant IM administration areas, even though dorsogluteal area is not recommended due to being rich in veins and close to sciatic nerve, the dorsogluteal region is clinically preferred area, as the case reported by Gülnar and Çalışkan (2014) indicating that 85.9% of the nurses used dorsogluteal area mostly, whilst 63.3% of nurses never used ventrogluteal area. Ventrogluteal area is regarded as the safest injection area for children 18 months and older (Kaya et al., 2015; Tuğrul and Denat, 2014; Yıldız et al., 2017). Concerning with muscles commonly used for IM, gluteal muscles (gluteus maximus, gluteus medius and gluteus minimus), deltoid muscle, rectus femoris and vastus lateralis muscles are of the most common muscles (Tuğrul and Denat, 2014).

Corresponding to the pain experienced during IM, substantial alterations in emotional and physical aspects of the children might be observed (SirtinTumakaka et al., 2020). Specifically, delaying or refusing future medical treatments are of the most observed attitudes among children (Semerci et al., 2020). In order to or minimize pain during IM, interventions by pediatric nurses are relatively significant (Şahiner and Bal 2016; Viggiano et al., 2015). In this context, pharmacological and non pharmacological approaches or attempts have been employed for children (Hogan et al., 2014; Kaheni et al., 2016). Although pharmacological methods such as opioid analgesics, non-opioid analgesics and local anesthetics are of the most commonly methods used for pain treatment (Laures et al., 2019), non-pharmacological methods including breastfeeding (Erkul and Efe, 2017), watching cartoon (Akgül et al., 2021; Inan and Inal, 2019) sucrose (Kassab et al., 2020), distraction (Şahiner and Türkmen, 2019), ball squeezing (Aydin et al., 2016; Abdolalizadeh et al., 2018), and massage/pressure (Hassan Ali et al., 2021) are also employed for the pain management (Hogan et al., 2014). Regarding non-pharmacological methods, these methods are applicable sequestered or together with pharmacological methods, being also preferred due to their simple practice, inexpensive and no side effects (Miller et al., 2016).

Out of the available common non-pharmacological pain management methods, distraction is considered to be effective methods for enhancing pain tolerance by changing the focal point (Bukola and Paula, 2017; Heidari Gorji et al., 2017; Inan and Inal 2019; Laures et al. 2019; Rezai et al., 2017; Viggiano et al., 2015), being classified as active and passive. Active distraction involves such as video games, controlled breathing, balloon inflation, bubble blowing foam, stress ball squeezing, relaxation and virtual reality goggles methods (Kaheni et al., 2016). On the other hand, passive distraction involves such as listening to music, irrelevant speech, watching television, cartoons, kaleidoscope and distraction cards. These methods are generally used a child needs to remain calm and quite during a procedure (Kaheni et al., 2016; Alemdar and Aktaş, 2019). In treatment and care practices, pain can be experienced as traumatic for the child and her family. Interventions applied by nurses in pain management can contribute to the positive results of these experiences. Comparative studies of different non-pharmacological applications and testing new methods will continue to be up-to-date in child health, which is an important part of today and the future. These methods will contribute to clinician nurses in the selection of the most appropriate approach, ease of application and time management. As deduced from the recent reports,

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the studies concerned with ball squeezing (Aydın et al., 2016; Sirtin Tumakaka et al., 2020) and cartoon watching (Heijden et al., 2019; İnangil et al., 2020) are available but the current study was designed to compare the effects of ball squeezing and cartoon watching in pain management in hospitalized children. The purpose of this study was to investigate the comparative effect of ball squeezing and cartoon watching in pain management in children during intramuscular injection.

Hypotheses

Hypothesis 0 (H0): There are no effects of giving a ball (for squeezing) and watching cartoons on reducing pain during injection.

Hypothesis 1 (H1): Children who are given ball (for squeezing) during injection have less pain than children who are not given pain-relieving interventions.

Hypothesis 2 (H2): Children who are watched cartoon during injection have less pain than children who are not given pain-relieving interventions.

Hypothesis 3 (H3): There is a difference between children who are given a ball (for squeezing) during injection and children who are watched cartoons.

Materials and Methods

The study was designed as a randomized controlled experimental study. It was carried out with 6-12 years old children at injection unit of emergency of the University Training and Research Hospital between August-October 2019. The relevant interventions were implemeted by a nurse. The experiments were finalized by the same nurse. This study was conducted using the single-blind method. Regarding the experimental set up, inclusion criteria of the study were as follows: (a) first injection for current treatment (b) aged between 6-12 years old (c) without any mental disorder (d) without any vision, audition and conversation problems (e) consent with the families regarding participation. Exclusion criteria of the study were as follows a) former injection experience b) aged lower than 6 and higher than 12 years old) with any mental, vision, hearing and conversation problems, d) nonconsent regarding family participation. Along with the experiments, same generation antibiotics, analgesics and others (antiemetic, antihistaminic etc.) were grouped for drugs of injection.

Sample Size and Randomization

For the sample size of the study, power analysis was performed using G*Power (v3.1.9.7) program. Power of study is expressed as a 1-β (β = Type II error) and is usually considered to be 80% power. According to Cohen's f (effect size) factors; assuming that the evaluations made between three independent groups will have the effect size (f=0.4).Power analysis for the present study was based on the study by Mutlu and Balcı (2015) which performed the study with at least 129 children, 43 children in each group (with 95% confidence interval and 5% alpha (two tailed). Herein, the present study was performed with a total of 147 children corresponding to 49 children for each experimental group (It was assumed that could be lost cases during the study). Randomization was achieved by means of the computer program (https://www.randomizer.org) indicating the total number of children, groups and children groups and the children divided into control and experimental groups.The research CONSORT flow diagram is given Figure 1.

Data Collection Instruments

For data collection, a questionnaire including child's age, gender, diagnosis, previous hospitalization, pain experience, painful procedure exposure and current medication characteristics (Antibiotic, Analgesic and Blood sample)and Facial Pain Scale- Revised (FPS-R) and Visual Analog Scale (VAS) were used. Also, 'ball (ball squeezing)' and 'Reader tablet' were used for the study. Prior to the study, verbal and written

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consent were obtained for each child's parents after the purpose of the study was explained.

Questionnaire on Socio-Demographic and Experiences

A questionnaire was prepared by the researchers according to the reports by Mutlu and Balcı (2015) and Inan and Inal (2019). The relevant questionnaire included child's age, gender, diagnosis, previous hospitalization, pain experience, painful procedure exposure and current medication characteristics (antibiotic, analgesic and blood sample).

Facial Pain Scale-Revised (FPS-R)

The scale is used as a valid and reliable scale for the evaluation of acute pain for children aged 4-16 years (Drendel et al., 2011). In school-aged children between 4–12 years old, the FPS-R is considered to be the most valid and reliable measure of acute pain since an comprehensible of words or numerical values is not necessaries (Drendel et al., 2011).

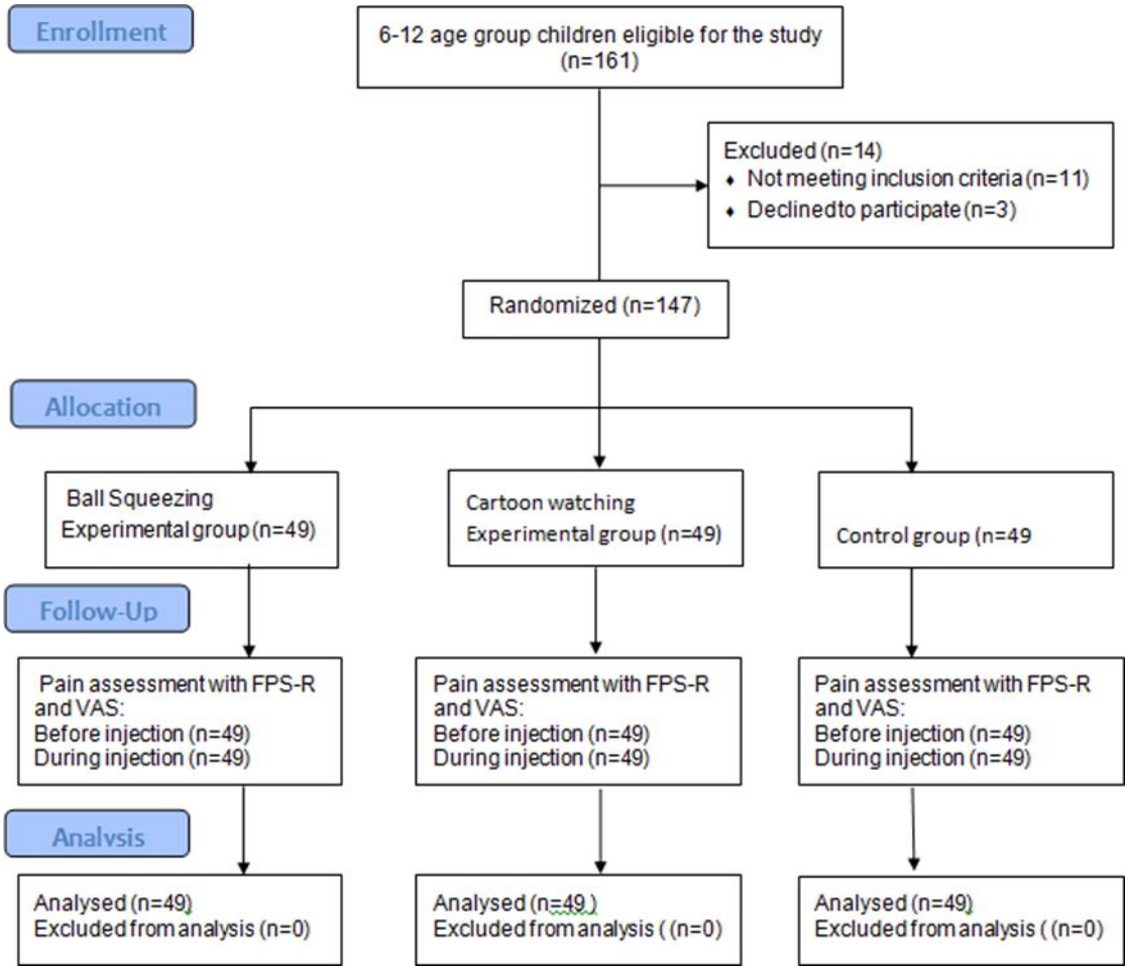

Figure 1. CONSORT flow diagram

Schulz KF, Altman DG, Moher D. CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomized trials. PLoS Med. 2010; 7(3): e1000251. doi:10.1371/journal.pmed.1000251 Published March 24, 2010.

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The FPS-R consists of six facial expressions that evaluate the degree of pain, on a scale of 0–10 (Conlon, 2009). It is expressed that '0' is no pain, '10' is severe pain (Okyay and Ayoğlu, 2018). In the evaluation of the scores obtained from the scale, the scores are considered as dull (1-3), reasonable pain (4-6) and severe pain (7-10) (Drendel et al., 2011; Mutlu and Balcı, 2015). FPS-R is considered to be advantageous when compared to other facial expression scales because it commonly uses scores (0-10) and has a certain 0 score indicating not starting with smiley expression and no crying facial expression at the end (Mutlu and Balcı, 2015).

Visual Analog Scale (VAS)

The scale consist of a horizontal line 100 mm in length, with the end point 'No pain' and 'worst imagination pain' placed at each end of the line. It is a reliable and valid scale for the children aged between 3-18 years old (Bakır, 2017). The children are asked to mark the severity of the pain on the line and starting from point 0, the marking is measured and the severity of pain is determined (Okyay and Ayağlu, 2018).

Ball

The ball is 6 cm in diameter with a smiley face and suitable for over 3 years old. The ball is soft and odorless.

Reeder M8 Plus Tablet

The tablet is equipped with Android 7.0 operating system, 8 screen sizes, a resolution of 1280*800 IPS, 213.5*123.6*8.9 mm dimension, weight 351 gram. The tablet used for the group consider as cartoon watching group.

Implementation of The Study

Data of the study was collected by researchers on Monday and Tuesday of the week due to intensive days regarding injection implementations. Children who met the sample selection criteria were evaluated by the researcher on the application days. Child who has including criteria was assigned to the experimental and control groups according to the randomization table. Injection procedure in all groups was implemented by the same experienced nurse. In this study, the nurse at the injection room preferred the ventrogluteal area for injection in children 6 years and older. Only three of the children were injected from the laterofemoral area due to their weakness and anatomical structure.

All groups fulfilled the questionnaire including socio-demographic and experiences. Children were informed for Facial Pain Scale- Revised (FPS-R) and Visual Analog Scale (VAS). Herein, the children in the experimental group were asked to mark the expected pain on FPS-R and VAS to determine the level of pain before injection.

Group 1: The children in this group were given a ball (ball squeezing) at the beginning of the procedure and it was explained that child could squeeze the ball during injection. Different ball was used for each child. After a short time of injection, the children were asked to mark the experienced pain on FPS-R and VAS.

Group 2: The tablet was loaded with 10 cartoons suitable for children's age and was asked to choose one of them. Cartoons were selected according to the age groups proposed by the official channels such as TRT child (Turkish radio television), Minika child and Minika GO. For children aged between 6-8 years, cartoons such as Rafadan Crew (RafadanTayfa), Explore with Jet (Jet ileKeşfet), My Little Pony, Master Bob (Bob Usta) and StrawberryGirl (ÇilekKız) were chosen. For the children aged between 9-12 years, Bizarre team (Tuhaf İşler Takımı) Puzzle Tower (BulmacaKulesi), Thunderbirds Are Go, New Adventures of Peter Pan (Peter Pan'ınYeni Maceraları) and Guards of Istanbul (İstanbul Muhafızları) were chosen. During injection, the children were asked to mark the experienced pain on FPS-R and VAS.

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Group 3: Routine care was employed during the injection. During injection, the children were asked to mark the experienced pain on FPS-R and VAS.

Data Analysis

Data were analysed using SPSS (Statistical Package for the Social Sciences) 24 version (IBM SPSS). Numerical variables were expressed as mean, standard deviation, frequencies, and percentages. The chi-square test, within the groups paired sample t-test and compare the groups one-way ANOVA followed by Tukey HSD multiple range test and the differences between individual averages were considered to be statistically important at p-values <0.05.

Ethical Approval for the Research

Prior to the study, written permission from faculty administration and ethics committee approval (IRB Number: OOO) were received from a University Medical Faculty Clinical Research Ethics Committee.

Results

Table 1 shows demographic characteristics of the sample. When children were compared based on gender (p=0.702) and age (p=0.945) of distribution, diagnosis (p=0.245), medicines given (p=0.064), hospitalization (p=0.891), if yes, number of hospitalizations? (p=0.451), has the painful procedure been performed before? (p=0.773), if yes, which painful procedure? (p=0.615), no statistically differences were determined between the groups. All groups showed similarity in terms of descriptive characteristics (Table 1).

Table 2 shows the comparison of FPS-R and VAS scores before and during the procedure. Accordingly, the lowest FPS-R score before the implementation was found in the control groups, while the highest score was determined in the group that watched cartoons. The differences between the relevant groups were statistically significant (p<0.05). As deduced from statistical analysis, control group was cause of differences. During the procedure the lowest score was in the stress ball group and statistically significant (p<0.05). When these scores were evaluated within the group, it was detected that the differences before and during procedure were statistically significant, and the significance in the control group was negative (p<0.05).

According to groups, the lowest VAS scores before the implementation was found in the control groups, otherwise the highest score was stated in the group that watched the cartoons. The differences were not statistically significant (p>0.05). During the procedure the lowest score was in the stress ball group and the differences between the relevant groups were statistically significant (p<0.05). As deduced from statistical analysis, trial groups were cause of differences. When VAS scores were evaluated within the groups, it was detected that the difference before and during procedure were statistically significant, and the significance in the control group was negative group (p<0.05) (Table 2). In order to determine the differences, paired sample t-test was performed (Table2). Furthermore, the changes were displayed using box-plot graph (Figures 2-3).

Discussion

During the life span of the children, pain experience is of the crucial issues while injection, resulting from blood collection, injection and vaccination from interventional procedures (Şahiner and Türkmen, 2019; Çakır and Yıldırım, 2020; Semerci et al., 2020). The former reports have revealed that the relevant pain experience brought about vital alterations in attitudes of the children (Bukola and Paula, 2017). Regarding pain management by nurses, various attempts have been done such as cartoon watching (Akgül et al., 2021; Inan and Inal, 2019), ball squeezing (Abdolalizadeh et al., 2018; Aydin et al., 2016), breastfeeding (Erkul and Efe, 2017), sucrose (Kassab et al., 2020), distraction (Şahiner and Türkmen, 2019), and massage/pressure (Hassan

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Ali et al., 2021). Considering the importance and researches, as deduced from the cited studies herein, those non-pharmacological attempts have been employed in a quite number of studies for children but the health-care and pain management among children remain incomplete, deserving to be investigated. In addition, to compare the relevant attempts is also great interest, in this regard. For that reason, we designed the current study in order to compare the efficiency of ball squeezing and cartoon watching in pain management in children during intramuscular injection using FPS-R and VAS scales. The reasons of methods employed for pain management for the current study were due to the non-time consuming and non-long term intervention (Inan and Inal, 2019).

Table 1. Demographic characteristics of the sample

	Ball Squeezing (*n*=49)	**Cartoon watching (*n*=49)**	**Control (*n*=49)**		***p***
	Mean±SD(Min-Max)				
Age	8.95±2.11 (6-12)	8.85±2.17 (6-12)	8.87±2.00 (6-12)	0.32	0.968
	n%	n%	n%		
Gender of children					
Girls	22(31.00)	26(36.60)	23(32.40)	0.708	0.702
Boys	27(35.50)	23(34.20)	26(34.20)		
Diagnosis					
Respiratory tract diseases	33(31.10)	39(36.80)	34(32.10)	5.44	0.245
Gastrointestinal diseases	11(47.80)	3(13.00)	9(39.10)		
Other	5(27.80)	7(38.90)	6(33.30)		
Medicines given					
Antibiotics	32(29.10)	37(33.60)	41(37.30)	8.899	0.064
Analgesic	5(45.50)	6(54.50)	0(0.00)		
Other	12(46.20)	6(23.10)	8(30.80)		
Hospitalization					
Yes	20(35.70)	18(32.10)	18(32.10)	0.231	0.891
No	29(31.90)	31(34.10)	31(34.10)		
If yes, number of hospitalizations?					
First	10(41.70)	6(25.00)	8(33.30)	9.885	0.451
2-4 times	10(40.46)	12(38.63)	8(20.90)		
4 and higher	1(25.00)	0(0.00)	2(75.00)		
Has the painful procedure been performed before?					
Yes	29(32.20)	29(32.20)	32(35.60)	0.516	0.773
No	20(35.10)	20(35.10)	17(29.80)		
If yes, which painful procedure?					
Intravenous (medication, serum, etc.)	9(33.30)	9(33.30)	9(33.30)	4.456	0.615
Intra muscular	6(23.10)	8(30.80)	12(46.20)		

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Taking a blood sample	14(37.83)	12(32.43)	11(29.72)

χ2: Chi square * p<0.05

Table 2. Comparison of the FPS-R and VAS scores during and after procedure according to groups

Scales		**Ball Squeezing (n=49)[a]**	**Cartoon (n=49)[b]**	**Control (n=49)[c]**	**F**	**p**
		Mean±SD				
FPS-R (Facial Pain Scale-Revised)	Before	5.79±2.45	5.91±2.34	4.69±2.25	4.02	**0.020* c<a;b**
	During	3.18±1.99	4.28±2.41	6.20±2.16	20.38	**0.000** a<b<c**
	t	11.88	9.50	-6.01		
	p	**0.000**	**0.000**	**0.000**		
VAS (Visual Analog Scale)	Before	5.02±2.52	5.46±2.06	4.75±1.79	1.385	0.254
	During	2.69±1.99	4.14±2.11	6.04±1.97	33.561	**0.000** a<b<c**
	t	12,25	14,84	-6,88		
	p	**0.000**	**0.000**	**0.000**		

F: Anova F test a-b-c: Tukey HSD t: Paired Sample Test * p<0.05 **p<0.001).

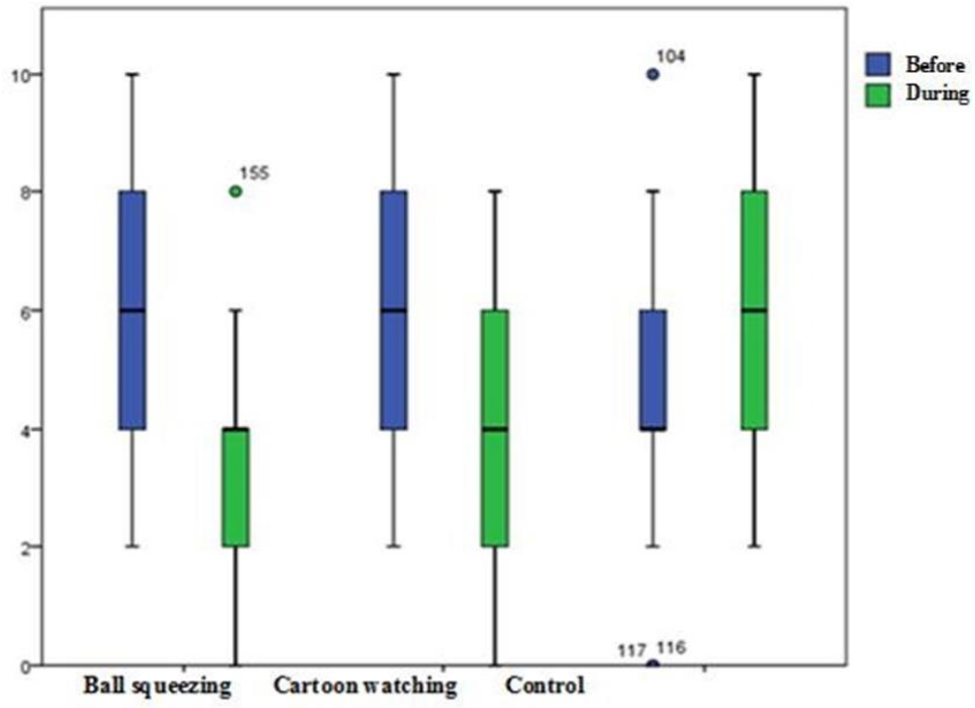

Figure 2. Changes in groups for FPS-R scores

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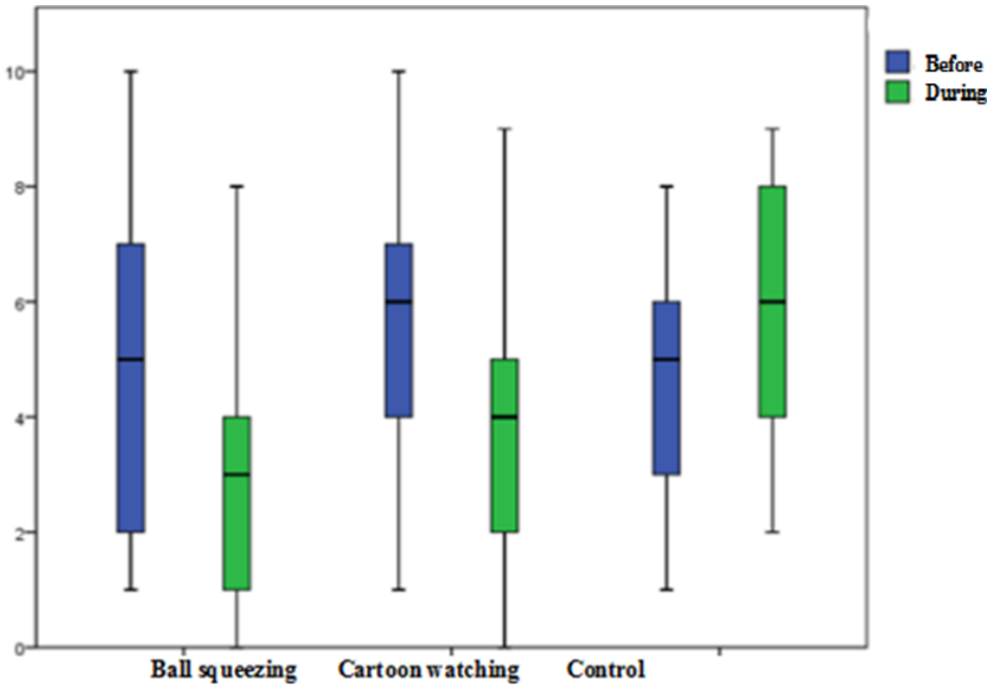

Figure 3. Changes in groups for VAS scores

Regarding injection types, IM are common but the relevant interventions are often addressed on vaccination (Bergomi et al., 2018; Robabi et al., (2016) for watching cartoon), phlebotomy=venipuncture (Aydin et al. (2016); Girgin and Göl (2020) for ball squeezing), venous catheterization (SirtinTumakaka et al. (2020) for ball squeezing), intramuscular injection (Çelik and Khorshid, 2015; Yilmaz and Alemdar, 2019). However, nonpharmacological interventions employed during IM are rare. In this regard, we compared the two different distraction methods in pain management during IM. Accordingly, the findings of the current study revealed that significant differences between ball squeezing and cartoon watching were observed. Those groups exhibited lower pain scores in relative control group as expected and similar to the previous reports [Akgül et al., (2021); İnangil et al. (2020); Inan and Inal (2019); Kuo et al., (2018) for cartoon watching; Aydin et al., (2016); Abdolalizadeh et al., (2018) for ball squeezing]. However, corresponding to the comparison of the relevant groups, ball squeezing was more effective in reduction of pain during injection among children. The higher efficiency of the ball squeezing might be attributed to the cognitive engagement of the children with the distracting stimulus (Hussein, 2015), suggesting that the distraction techniques applied during lumbar puncture are effective in pain management (Heidari Gorji et al., 2017). Also, Aydin et al., (2016) compared ball squeezing with balloon inflating and distraction cards and reported that ball squeezing was less effective in comparison with the other relevant groups during venipuncture. Girgin and Göl (2020) also revealed that ball squeezing was less efficient in relative to the coughing but more effective than balloon inflating during venipuncture. However, it is worth to note that active engagement methods should be convenient and compatible with age and state of development and include several sensory components of the children (Laures et al., 2019; Rezai et al., 2017). As deduced from the methods applied for the injection types, the relevant methods also should be convenient with the injection types.

Limitation of Study

A limitation of the study was that no preliminary preparation or intervention was made before

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watching cartoons and applying the ball (for squeezing). However, it is important as it is the first study to use ball squeezing, which is one of the non-pharmacological methods used to reduce pain during intramuscular injection. In the period of the study, the cartoons shown to the determined age groups are limited to the selected ones.

Conclusion

According to this study outcome; ball squeezing and cartoon watching implementation were revealed to be effective in alleviating the pain during the injection. Ball squeezing and watching cartoons should be expanded to manage pain in children during IM injections in emergency departments and other units. In this case, it is thought that the application times of invasive procedures will be shortened and the health personnel will benefit in terms of time and ease of application. The implementations employed, the ball squeezing group had the lowest pain level in comparison to the cartoon watching and control groups. In future studies, it is recommended to repeat the methods with IM pain-reducing effects in children comparatively, to include these methods more in clinical applications, and to conduct more clinical studies to determine the best method.

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