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Is tablet-based interactive distraction effective on pain and anxiety during circumcision in children? A randomized controlled trial

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ABSTRACT

Objective: Distraction is a nonpharmacological method commonly used during painful procedures in children. However, there are a few studies investigating the effectiveness of active distraction on pain and anxiety in children during circumcision. The purpose of this study was to evaluate the effectiveness of tablet-based interactive distraction on pain and anxiety in children during circumcision.

Material and methods: To evaluate how tablet distraction could improve children's outcomes during circumcision, a single-center, nonblinded, randomized controlled, parallel group trial research design was employed. In this study, 35 children were included in tablet distraction group, which have a control group (n = 35). The primary outcome measure was the Numeric Rating Scale for pain. Secondary outcome measure was the State-Trait Anxiety Scale for Children, and other outcome variables were physiological parameters and satisfaction levels.

Results: During and after the surgical procedure, pain scores ($P < .001$, $P < .001$, respectively) and pulse rates ($P < .001$, $P < .001$, respectively) were significantly lower in the tablet distraction group, whereas O_2 saturation was higher than the control group ($P < .001$, $P < .001$, respectively). After the procedure, the anxiety scores were significantly lower in the tablet distraction group ($P < .001$), whereas the satisfaction scores were higher than control group ($P < .001$).

Conclusion: This study concluded that the use of tablet distraction during circumcision has a positive effect on children's pain, anxiety, satisfaction levels, and physiological parameters.

Keywords: Anxiety; nursing; pain; pediatrics; urology.

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Introduction

Circumcision is one of the oldest surgical procedures performed for social, cultural, and/or medical reasons worldwide.[1] Although circumcision is a very common elective surgical procedure in men, it has about 30% prevalence worldwide.[2] Circumcision is starting to become universal and is widely practiced in the Middle East, North and West Africa, Central Asia, Australia, Bangladesh, Canada, Indonesia, Pakistan, Philippines, Republic of Korea, the United States, and Turkey. Although circumcision has been practiced for years for nonreligious reasons, it is an integral part of transition to masculinity in some cultures and is closely related to masculinity, self-identity, and spirituality.[1]

Medical interventions that cause pain in infants and children are defined as painful procedures. Circumcision is one of the painful interventions performed under local or general anesthesia, which cause pain for children during or post-procedure. Which type of analgesia in children should be preferred is debatable and there is no gold standard, most male circumcision procedures can be performed under local anesthesia.[3] Due to the risk of complications of general anesthesia for circumcision, local anesthesia is recommended in newborns, infants, and compatible children

during the procedure. According to the American Academy of Pediatrics, circumcision is better tolerated when performed by experienced people under sterile conditions with appropriate pain management, and the possibility of complications is rare.[4]

Nonpharmacological methods, such as play therapy, music, distraction, directed imaging therapy, and pharmacological methods, such as local anesthetics or systemic analgesics, are used in pain management during painful procedures in children.[5–11] When the literature was examined, it has been found that there are limited studies using active distraction methods to reduce pain and anxiety during circumcision.[12–14] In line with these studies, it has been observed that nonpharmacological studies such as tablet distraction are needed to reduce pain and anxiety in children who will undergo circumcision under local anesthesia. In this study, it was aimed to evaluate the effects of tablet distraction (playing video games) on pain and anxiety during circumcision in children. Another aim of this study was to provide evidence about the effectiveness of tablet distraction used to reduce pain and anxiety during the circumcision and to contribute to nursing care in pain management.

Material and Methods

Study Design and Setting

This single center, open label study was planned as a parallel group randomized controlled trial. This study was conducted in the Department of Pediatric Surgery of a Training and Research Hospital in Ankara, Turkey between October 2018 and October 2019.

Participants and Randomization

The study of Hussein[9] was used for calculating the sample size of this study. When the Numerical Rating Scale (NRS) pain score mean was 4.44 ± 1.044 in the intervention group and 5.20 ± 0.816 in the control group, it was calculated that it would be sufficient to have at least 19 people in each group to achieve a 5% alpha error and 20% beta error. Considering possible losses in the study, each group consisted of 35 children.

Main Points

- Circumcision can cause anxiety and pain for children.
- Tablet-based interactive distraction is a simple, reliable, and effective during painful procedures in children.
- This study demonstrates that using the tablet computer has a positive effect on pain, anxiety, satisfaction, and vital signs in children during circumcision.

The inclusion criteria consisted of several parameters: (1) between 8 and 12 years old; (2) male sex; (3) to undergo circumcision under local anesthesia; and (4) to agree to participate in the study. The exclusion criteria were (1) contraindications for the procedure (such as hemophilia, hypospadias, epispadias, bleeding, and urinary anatomical disorders); (2) to use any painkillers within 24 hours before the procedure; and (3) communication and mental disabilities.

A computer-based random number sequence generator was used by the researchers for the randomization method (www.random.org). The participants were enrolled the study by the principal researcher. The children were numbered in order of arrival and assigned to the tablet-based interactive distraction group or the control group according to the numbers on the randomization list by the researcher. Because of the feasibility and nature of the study, the principal researcher and participants were not blinded during allocation to groups, but evaluator was blinded to the groups of the participants. Participants were randomly assigned to two equal groups: (1) tablet-based interactive distraction group (n = 35) and (2) control group (n = 35). The assignment of the participants to the groups is showed in the CONSORT Flow Diagram (Figure 1).

Interventions

Standard surgical procedure was performed under local anesthesia to all children by the same surgeon in this study. The procedure was performed in the operating room under sterile conditions in approximately 10-15 minutes. Totally, a 5 mL, consisting of 2 mL lidocaine 2% with 0.0125 mg epinephrine and 3 mL bupivacaine 0.5%, was mixed and used for regional penil local anesthesia. Three milliliters of the mixture injected into penil clock 11 and 13 positions for deep penil nerve block and remaining 2 mL to 6^{o} clock position for scrotal nerve branches using a 5cc syringe with a 26G needle. Before injection, negative pressure was applied to the syringe to check if the needle was in the vein. Three minutes after the injection, local anesthesia was controlled by squeezing the preputium with a hemostatic clamp.

Tablet-Based Interactive Distraction Group

The children in the tablet-based interactive distraction group (n = 35) were given a tablet computer approximately 5-10 minutes before the surgical procedure by the researcher. Afterward, participants were informed about the tablet computer usage and game chosen by the same researcher. Three games for the age group 8-12 were installed on the tablet computer, and the children could choose the game they wanted. The children started to play their preferred video games on the tablet computer 5 minutes before the surgical procedure. At the

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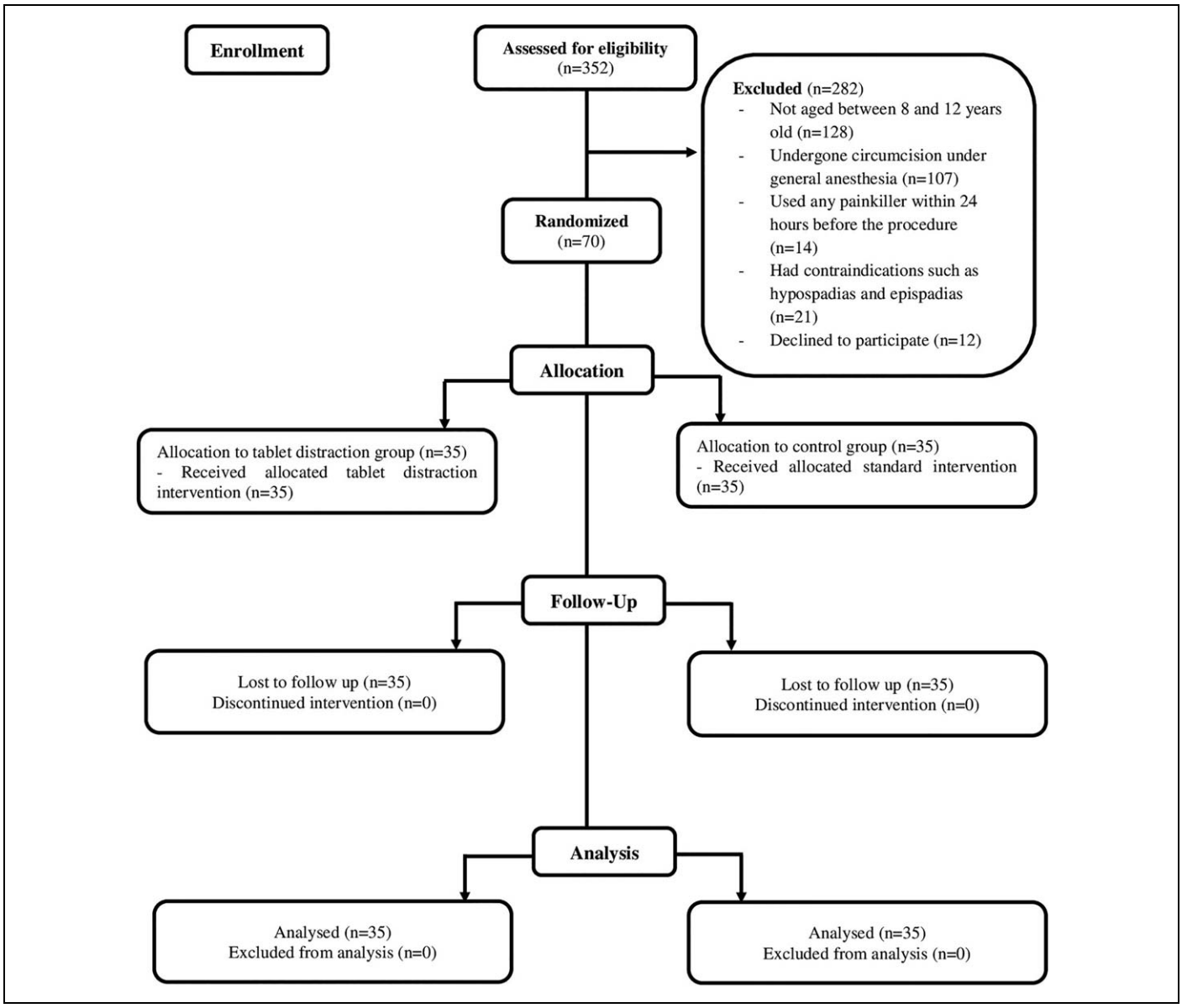

Figure 1. CONSORT flow diagram.

end of the procedure, the distraction intervention was ended. The pulse and O_2 saturation of the children were measured approximately 5 minutes before and after the circumcision and during the circumcision of the preputium.

Control Group

The children in control group (n = 35) did not have any distraction technique before and during surgical procedure. The pulse and O_2 saturation were measured approximately 5 minutes before the circumcision, during the circumcision of the preputium and 5 minutes after the procedure.

Outcome Measures

The descriptive characteristics were obtained from the children with the data collection form approximately 10-15 minutes before the procedure. The NRS, State-Trait Anxiety Inventory for Children, and physiological parameters were used as the outcome measures of this study.

The primary outcome was the change in pain severity based on the NRS as reported by the participants at the end of the circumcision procedure compared with the baseline. The NRS is a one-dimensional scale commonly used to measure the severity

of pain in school-age children. This scale, which provides numerical assessment of pain intensity, is rated between 0 and 10 points. One end of the scale indicates the absence of pain (0), and the other end indicates unbearable pain (10). As the numerical value obtained from the scale increases, the severity of pain increases.[9] Pain levels of the children were evaluated by the NRS 10-15 minutes before the circumcision, during the cutting of the prepicium and 5 minutes after the procedure ended.

The secondary outcome was the change in anxiety level in State-Trait Anxiety Scale for Children (STAI) reported by the participants at the end of the circumcision procedure compared with the baseline. The STAI was developed by Spielberger[15] to assess emotions related to state anxiety in children. The Turkish validity and reliability study of this scale was conducted by Özusta[16] in 1995. The scale in a triple-Likert type format consists of a total of 20 items. The lowest score obtained from the State Anxiety Inventory is 20, and the highest possible score is 60. As the score obtained from this scale increases, the level of anxiety also increases.[14] Anxiety levels for children were assessed by the State Anxiety Inventory 10-15 minutes before circumcision and 5 minutes after the procedure.

Other outcome measures were physiological parameters and satisfaction levels. A Creative PC 60D (Made in China) brand, finger-type, calibrated pulse oximeter was used for pulse rate and O_2 saturation. Changes in two physiological parameters (pulse and O_2 saturation) at the end of circumcision procedure were compared with baseline values. Another outcome was the difference between two groups in terms of the numerical rating scale satisfaction levels at the end of circumcision. Physiological parameters were measured by the nurse researcher. All other outcome measures were obtained from patients by the nurse researcher.

Statistical Analysis

The data of the study were analyzed using the Statistical Package for the Social Sciences (SPSS) version 22 (IBM SPSS Corp.; Armonk, NY, USA). Descriptive data were presented as number, percentage, mean, standard deviation, median, minimum, and maximum. The Shapiro–Wilk test was used to assess suitability for normal distribution. The chi-squared test was used to compare categorical variables. The difference between the two groups not normally distributed was compared with the Mann–Whitney U test. The Friedman test was used to compare the difference between more than two measurements not normally distributed, while the Wilcoxon test was used for the difference between the two measurements. The Bonferroni corrected Wilcoxon test was used as a post-hoc test ($\alpha/3 = 0.0167$). $P < .05$ was considered statistically significant.

Ethical Consideration

In order to conduct this study, permission was obtained from the Ankara Numune SUAM Clinical Research Ethics Committee of the University of Health Sciences in Ankara, Turkey, and ethics committee approval was obtained (number: 2018-123, date: September 7, 2018). This study was registered at ClinicalTrials.gov, number NCT04220346. The design and writing of the study were carried out in accordance with Consolidated Standards of Reporting Trials (CONSORT). Before data were collected, the participants and their families were informed about the purpose of the study, and data were collected from those who agreed to participate in the study. Written and verbal consent of participants/their families were obtained, and they were informed that they could leave the study at any time.

Results

The Comparison of the Participants' Descriptive Characteristics

In this study, a total of 352 children were evaluated, and 282 of them were excluded from the study. One hundred and twenty-eight children who were not between 8 and 12 years old, 107 children who were circumcised under general anesthesia, 14 children who used any painkiller within 24 hours before the procedure, 21 children with contraindications such as hypospadias and epispadias, and 12 children who declined to participate in the study were excluded from the study. This study was conducted with a total of 70 children who have the inclusion criteria. None of the participants withdrew from the study. The comparison of the participants' descriptive characteristics is shown in Table 1. No significant difference was found between the groups in terms of age ($P = .692$), family income ($P = .759$), and duration of the surgical procedure ($P = .976$).

The Comparison of Physiological Parameters of the Groups

Table 2 shows the comparison of physiological parameters between the groups. While there was no significant difference between the two groups in terms of pulse ($P = .942$) and O_2 saturation levels ($P = .839$) before the procedure, there was a significant difference between both the groups in terms of pulse rates ($P < .001$, $P < .001$, respectively) and O_2 saturation levels ($P < .001$, $P < .001$, respectively) during and after the procedure. Compared to the control group, pulse rates were significantly lower in the tablet distraction group during and after the procedure, while O_2 saturation was significantly higher. A statistically significant difference was found among before, during, and after the procedure in terms of "pulse rates" ($P < .001$) and "O_2 saturation levels" ($P < .001$) in the tablet distraction group. Also, it was found to be a statistically significant difference among before, during, and after the procedure in terms of "pulse rates" ($P < .001$) and "O_2 saturation levels" ($P < .001$) in the control group.

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Table 1. The Comparison of the Descriptive Characteristics of the Participants (n = 70)

Characteristics	Tablet Group (n = 35)	Control Group (n = 35)	*P* Value
Age (years)			
Mean (SD) Med (min – max)	8.11 (0.32) 8 (8-9)	8.08 (0.28) 8 (8-9)	.692*
Family income status, n (%)			
Income is less than expenses	6 (17.1)	7 (20.0)	.759†
Income is equal to expenses	29 (82.9)	28 (80.0)	
Duration of the procedure			
Mean (SD) Med (min – max)	14.60 (2.59) 15 (10-20)	14.57 (2.60) 15 (10-20)	.976*

*Mann–Whitney U test.

†Chi-square test.

Table 2. The Comparison of Physiological Parameters between the Two Groups (n = 70)

Physiological Parameters	Tablet Group (n = 35) Med (Min – Max)	Control Group (n = 35) Med (Min – Max)	*P* Value
Pulse			
Before[1]	104 (101-111)	104 (101-112)	.942*
During[2]	100 (96-107)	118 (96-119)	<.001*
After[3]	98 (95-102)	111 (94-118)	<.001*
P value	<.001†	<.001†	
Post-hoc‡	1 > 2 (*P* < .001) 2 > 3 (*P* < .001) 1 > 3 (*P* < .001)	2 > 1 (*P* < .001) 2 > 3 (*P* < .001) 3 > 1 (*P* < .001)	
O_2 saturation			
Before[1]	98 (97-99)	98 (97-99)	.839*
During[2]	99 (98-100)	97 (96-98)	<.001*
After[3]	98 (97-100)	97 (96-98)	<.001*
P value	<.001†	<.001†	
Post-hoc‡	2 > 1 (*P* < .001) 2 > 3 (*P* = .006) 3 > 1 (*P* = .012)	1 > 2 (*P* < .001) 1 > 3 (*P* = .005) 3 > 2 (*P* < .001)	

*Mann–Whitney U test.

†Friedman test.

‡Bonferroni corrected Wilcoxon test ($\alpha/3 = 0.0167$).

The Comparison of Pain, Anxiety, and Satisfaction Scores of the Groups

The comparison of pain, anxiety, and satisfaction scores of the groups is shown in Table 3. The children had no pain before the operation. A significant difference was found between both groups in terms of pain scores during ($P < .001$) and after the procedure ($P < .001$). Pain scores of the tablet distraction group were significantly lower during and after the circumcision. A significant difference was found between during and after the procedure in terms of "pain scores" in the tablet

Table 3. The Comparison of Pain, Anxiety, and Satisfaction Scores between the Two Groups (n = 70)

Measures	Tablet Group (n = 35) Med (Min – Max)	Control Group (n = 35) Med (Min – Max)	*P* Value
Pain			
During	2 (1-3)	6 (2-8)	<.001*
After	0 (0-1)	0 (0-7)	<.001*
P value	<.001†	<.001†	
Anxiety			
Before	48 (36-56)	50 (29-54)	.171*
After	30 (20-55)	50 (31-54)	<.001*
P value	<.001†	.166†	
Satisfaction	8 (7-10)	4 (1-6)	<.001*

*Mann–Whitney U test.

†Wilcoxon test.

distraction group ($P < .001$) and control group ($P < .001$). While no significant difference was found between anxiety scores of the two groups before the procedure ($P = .171$), the difference after the procedure was significant ($P < .001$). A statistically significant difference was found between anxiety scores of the tablet distraction group before and after the procedure ($P < .001$), and anxiety scores after the procedure were significantly reduced compared to before. After the procedure, satisfaction scores of the tablet distraction group were higher compared to the control group ($P < .001$).

Discussion

This study examined the effects of playing video games with tablet on pain and anxiety during circumcision in school-age children. After acute pain, children's pulse, respiratory rates, and blood pressure increase, while oxygen saturation may decrease.[17,18] In this study, before the circumcision procedure, pulse rates and oxygen saturation averages of the tablet and control groups were similar. However, the pulse rates were found to be significantly lower in the group playing video games on the tablet compared to the control group during and after the circumcision procedure, while O_2 saturation was higher. Similarly, in the study of Karakaya and Gozen,[19] which was conducted to determine the effect of distraction (looking through a kaleidoscope), a nonpharmacological method, on minimizing pain in school-age children during venipuncture, oxygen saturation, and pulse rates before venipuncture were compared among the children in both experimental and control groups; no significant difference was found. In this study, the oxygen saturation was higher, and the pulse rate was lower of the children in the tablet group during and after the procedure compared to the control group. This is thought to be because playing games on the tablet distracts the child and makes him relax. In a study examining the effect of virtual reality on mothers' anxiety during children's circumcision, the pulse and respiratory rates were found to be significantly lower in the virtual reality group than the control group.[13] In the study of Joyce et al,[20] the effect of eutectic mixture of local anesthetic (EMLA) cream and music on the pain responses of circumcised newborns was investigated. Pulse rates were found to be significantly lower for the EMLA group, while these rates remained constant in the music group. Oxygen saturation was found to be significantly higher at the end of the procedure in the music group compared to the nonmusic group. According to studies in the literature, the effect of distraction methods used in children during invasive procedures on physiological parameters varies.

In the present study, the severity of pain was found significantly lower in children who played video games on tablet during and after circumcision. In a study examining the effects of virtual reality on children's anxiety, fear, and pain levels before circumcision, the post-operative pain score was significantly lower in the virtual reality group than in the control group.[12] Similarly, in the study of Suzan et al,[14] the pain score during and after the circumcision was significantly lower in the children in the puppet show group compared to the control group. In a study conducted in neonates undergoing circumcision, the pain response was significantly lower in the music group at the end of the procedure compared to the nonmusic group.[18] These studies show that distraction methods used

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during invasive procedures in children had a positive effect on pain.

In this study, anxiety was found to be significantly lower in the group playing games on the tablet compared to the control group after the circumcision procedure. After the procedure, satisfaction level was found higher in the tablet group compared to the control group. In the study of Buyuk et al,[12] anxiety and fear scores were found to be significantly lower in the children in the virtual reality group compared to the control group before and after circumcision. In the study of Liguori et al,[11] the video app showing two clown physicians giving a comical and informative tour of the operation room was effective in reducing preoperative anxiety in children. In the study of Yesilot et al,[13] there was no significant difference between the virtual reality group and the control group in terms of state anxiety levels of the mothers of the children circumcised. However, anxiety score according to their facile expressions was significantly lower in the mothers used the virtual reality compared to the control group after the intervention. In another study, the anxiety levels of children in the puppet show group during and after circumcision significantly decreased compared to the before procedure.[14] In line with these studies, playing video game, which is one of the active distraction methods during painful medical procedures, is thought to decrease children's anxiety levels and increase their satisfaction levels.

This study has several limitations. The results obtained from the study could not be generalized to male children who undergo circumcision with local anesthesia. Since pain is subjective, it is very difficult to evaluate an individual's pain level objectively. In addition, the limited evaluation of children's socio-economic background is a limitation for this study. The final limitation of the study was also that it was not blinded to the participants and researchers due to the design of the study.

According to the results of this study, the use of tablets during circumcision decreases the pain and anxiety levels of children and increases their satisfaction levels. Tablet distraction used during circumcision also has a positive effect on pulse rates and O_2 saturation of children. In addition, more randomized controlled studies are needed to prove the effectiveness of distraction methods during circumcision.

Ethics Committee Approval: Ethical committee approval was received from the Ankara Numune SUAM Clinical Research Ethics Committee of the University of Health Sciences in Ankara, Turkey (number: 2018-123, date: September 7, 2018).

Informed Consent: Written and verbal informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - E.G., D.S.; Design - E.G., D.S., M.B.C.; Supervision - E.G., D.S.; Materials - E.G.; Data Collection and/or Processing - D.S., M.B.C.; Analysis and/or Interpretation - E.G.; Literature Search - E.G.; Writing Manuscript - E.G., D.S.; Critical Review - E.G., D.S.

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Conflict of Interest: The authors have no conflicts of interest to declare.

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