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Is audio a mandatory component of multimedia distraction for reduction of pain and anxiety of pediatric dental patients? A split-mouth crossover randomized controlled clinical trial

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ABSTRACT

Background: Control of pain, fear, and anxiety of pediatric dental patients is a common concern for the parents and dental clinicians. This study aimed to compare the efficacy of audiovisual distraction (AVD) and mute-video distraction (MVD) for reduction of pain and anxiety of pediatric dental patients.

Materials and Methods: This randomized split-mouth crossover clinical trial evaluated 60 systemically healthy children between 4 and 7 years requiring bilateral pulpotomy of primary maxillary first molars. The samples were randomly divided into 6 groups based on the distraction technique and sequence of its receipt: (I) control-AVD, (II) AVD-control, (III) control-MVD, (IV) MVD-control, (V) AVD-MVD, and (VI) MVD-AVD and were treated. The severity of pain and anxiety of patients during anesthetic injection was measured using physiological (pulse rate [PR]), sound, eyes, and motor (SEM) and faces pain rating (FPR) scales. Data were compared between Groups 1 and 2, 3 and 4, and 5 and 6 using crossover clinical trial analysis ($P = 0.05$).

Results: The increase in PR and the mean FPR and SEM scales during anesthetic injection was significantly smaller in AVD than MVD ($P < 0.05$). No significant difference was noted between MVD and control technique regarding PR and mean FPR or SEM ($P = 1.00$).

Conclusion: It appears that MVD has no significant efficacy for reduction of pain and anxiety of pediatric dental patients. AVD, however, can effectively decrease the pain and anxiety of pediatric dental patients during anesthetic injection.

Key Words: Audiovisual media, behavior control, dental anxiety, distraction, pain perception, pediatric dentistry

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INTRODUCTION

Control of pain, fear, and anxiety of pediatric dental patients is a common concern for the parents and dental clinicians and can lead to reduction in dental care utilization and the quality of dental services.[1-3] The stage of growth and development of the child, inability to cope with the environment, previous adverse medical and/or dental experiences, unfamiliar sounds in dental office, and the injection needle are the main causes of dental fear and poor cooperation of children in dental office setting.[3-5]

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A wide range of pharmaceutical and nonpharmaceutical (behavioral control) strategies is available for the management of anxious and fearful pediatric dental patients.[6,7] The nonpharmaceutical behavioral control techniques (such as the tell-show-do, verbal communication, positive reinforcement, voice control, and distraction techniques) mainly aim to decrease the need for excessive use of medications with potential side effects.[8] At present, both parents and dental clinicians prefer to use less invasive behavioral control techniques such as the tell-show-do and distraction techniques.[9]

The distraction techniques aim to decrease the patients' attention to the source of anxiety (such as the unfamiliar sounds of dental equipment) by distraction. The advantages of distraction techniques for reduction of anxiety in adults and especially children in medical settings have been previously confirmed.[9,10] The efficacy of distraction techniques for reduction of pain and anxiety of children has been extensively studied. However, well-designed studies in this field are limited, and the available ones have reported controversial results.[1,2]

Due to the noisy dental environment, it is often difficult for pediatric patients to well hear the sound of displayed videos without using a headset or earphones. On the other hand, many dental clinicians believe that audiovisual media with loud sound are destructive and have an adverse effect on the professional clinical performance of the staff and efficient verbal communication with pediatric patients. Thus, they either do no use the distraction technique or use visual media in mute mode. Since no previous study has compared the efficacy of mute-video distraction (MVD) with audiovisual distraction (AVD) for reduction of pain and anxiety of children, this study aimed to compare the efficacy of MVD and AVD for reduction of pain and anxiety of pediatric dental patients during anesthetic injection. The null hypothesis was that no significant difference would be found in the efficacy of MVD and AVD for reduction of pain and anxiety of pediatric dental patients during anesthetic injection.

MATERIALS AND METHODS

The clinical trial study was approved by the ethics committee of Arak University of Medical Sciences (IR.ARAKMU. REC.1397.259) and registered in the Iranian Registry of Clinical Trials (IRCT2019022404282DN1). All participants and their parents were briefed about the study and the parents willingly signed informed consent forms.

Study design

This split-moth crossover randomized clinical trial was conducted on 60 patients. The patients were randomly divided into 6 groups (n = 10) based on the type of distraction technique and sequence of its receipt [Figure 1]. Each patient received both distraction techniques. The first technique was applied when treating one quadrant of the maxilla and the second technique was applied when treating the other quadrant in the next treatment session.

Participants, eligibility criteria, and settings

The patients were selected among 4–7-year-old children presenting to a pediatric dentistry private office in Arak city, Iran, between July 2019 and December 2019 using convenience sampling. The eligibility criteria were as follows:

Inclusion criteria: (a) Genetically and systemically healthy children between 4 and 7 years, (b) absence of any dental history or hospitalization, (c) patients with positive or definitely positive behavior according to the Frankl behavior rating scale, (d) children requiring pulpotomy of bilateral primary maxillary first molars.

Exclusion criteria: (a) Mental or cognitive disability and (b) visual or auditory deficits.

Interventions

The study was carried out during four sessions. The first session (T1) included precise clinical dental examination of children and prescription of radiography, if required. In the second session (T2), dental treatment plan was designed and all patients received dental prophylaxis. The tell-show-do technique was also used for all patients regarding air and water spray, saliva ejector, and low-speed handpiece. After ensuring that the patients met the eligibility criteria, they were divided into 6 groups based on the type of distraction (AVD, MVD, and control) and sequence of receipt by simple randomization [Table 1].

The procedure was performed as split mouth in the third (T3) and fourth (T4) sessions. For this purpose, in T3, one of the two teeth requiring pulpotomy (right or left) was randomly selected by "envelope technique " and underwent pulpotomy along with the allocated distraction technique. The contralateral tooth underwent pulpotomy in the next session (T4) using

Table 1: Classification of study groups based on the type of distraction (audiovisual distraction, mute-video distraction, and control) and sequence of receipt in the third (T3) and fourth (T4) sessions

Group	T3	T4
1 (C-AVD)	Control	Audiovisual
2 (AVD-C)	Audiovisual	Control
3 (C-MVD)	Control	Mute-video
4 (MVD-C)	Mute-video	Control
5 (AVD-MVD)	Audiovisual	Mute-video
6 (MVD-AVD)	Mute-video	Audiovisual

AVD: Audiovisual distraction; MVD: Mute-video distraction

the other distraction technique (in the same group). The fourth session (T4) was scheduled 2 weeks after the third session (T3) to consider a washout period.

In this study, the Tom and Jerry Show 2014 (Hollywood company) was used as the selected media for distraction in both AVD and MVD techniques and was displayed on a 17-inch monitor installed on the dental unit with approximately 150 cm distance from the children's eyes. The animation was started right after the child sat on the dental chair. In the MVD technique, the monitor was muted, and the video was played with no sound. In the AVD technique, the sound volume was set at 50% and the child used wired earphones (C100SI In-ear headphones, JBL, South Korea) in his/her left ear only. The right earbud was not used so that the dental staff could communicate with the child. In the control distraction technique, the monitor was off.

Outcomes

The primary outcome of this study was to determine the level of pain and anxiety of children during dental anesthetic injection using different distraction techniques, which was measured using the following three scales:

- Pulse rate (PR) as a physiological scale
- The sound, eyes, and motor (SEM) pain scale as an objective scale
- Faces pain rating (FPR) scale as a subjective scale.

Pulse rate

To assess the PR as the physiological scale of anxiety, the probe of digital pulse meter (Oxy 300; Microlife AG, Widnau, Switzerland) was connected to the index finger of the left hand, and in each treatment session, the PR of patient was measured twice and recorded by a dental assistant: (I) 1 min after starting the distraction method at the onset of treatment session (T3a and T4a) and (II) during local infiltration anesthesia of the maxilla (maximum PR was recorded during anesthetic injection) (T3b and T4b). The mean difference in PR between a and b was calculated.

Objective scale

The SEM pain scale was recorded by a trained dental assistant at the time of anesthetic injection (T3b and T4b) [Table 2]. The SEM pain scale scores the slightest manifestation of the eyes, sound, or motion of patients during anesthetic injection.[11]

Subjective pain scale

The self-reported FPR scale was used during anesthetic injection (T3b and T4b), and the score selected by the child was recorded.[12]

The treatment process was the same in both treatment sessions in all 6 groups. Lidocaine (2% E – 80, Daroupakhsh, Tehran, Iran) was used as anesthetic agent for all patients, which was injected with a 30-gauge short (16 mm) injection needle (C-K Dental, Gyeonggi-do, South Korea) through the conventional infiltration technique within 1 min by an experienced pedodontist.

Sample size calculation

Sample size was calculated to be 9 in each group according to a study by Ghadimi *et al*.,[9] assuming 0.5-unit level of significance for the FPR scale, 95% confidence interval, 80% study power, and alpha = 0.05. To increase the study power, ten patients were enrolled in each group.

Randomization

SPSS, version 16.0 software (SPSS Inc., Chicago, IL) was used for random allocation of patients to 6 groups. To select the right or left quadrant of the maxilla for treatment in the third session, the envelope technique was used. For this purpose, 60 envelopes were prepared; half of them contained a piece of paper with the code 0 and the other half contained a piece of paper with the code 1. Code 0 indicated the left quadrant and Code 1 indicated the right quadrant. In the third session, patients randomly selected an envelope and based on its content, the quadrant to be treated was selected. The other quadrant was treated in the next session.

Blinding

This was a single-blind study. The patients and the operator were not blinded to the group assignments because it was not possible. However, the statistician was blinded to the type of intervention performed for each group.

Table 2: The sound, eyes, and Motor Pain Scale

Score	Designation	Sound	Eyes	Motor
0	Comfort	No sound indicating pain	No eye signs of discomfort	Hands relaxed, no apparent body tenseness
1	Mild discomfort	Nonspecific possible pain indication	Eyes wide show of discomfort	Hands show some tension
2	Moderately painful	Specific verbal complaint e.g., ow! voice raised	Watery eyes	Random movement of arms/body grimace, twitch
3	Painful	Verbal complaint indicates intense pain	Crying tears running down the face	Movement of hands to make aggressive physical contact, pulling head away punching

Statistical analysis

The collected data were analyzed using SPSS version 23 through the crossover clinical trial analysis according to the method suggested by Reed (AB/BA crossover model).[13] This model includes the following measurements:

Y_{AB1} = General mean + period effect$_1$ + effect of treatment$_A$

Y_{AB2} = General mean + period effect$_2$ + effect of treatment$_B$ + carryover effect $_{AB}$

Y_{BA1} = General mean + period effect$_1$ + effect of treatment$_B$

Y_{BA2} = General mean + period effect$_2$ + effect of treatment$_A$ + carryover effect $_{BA}$

The data of Groups 1 and 2, 3 and 4, and 5 and 6 were compared pairwise, and the treatment effect, period effect, and sequence effect on all three scales were measured. The means, differences, and sums of PR, SEM, and FPR scales in all groups were calculated in the third and fourth treatment sessions using independent student *t*-test. $P < 0.05$ was considered statistically significant.

RESULTS

The mean age of patients was 5.7 ± 0.55 years, and all groups were similar in terms of age and gender distribution. No data or participant missed in this study. Pairwise comparisons of the groups (Groups 1 and 2, Groups 3 and 4, and Groups 5 and 6) regarding the mean difference in PR, SEM, and FPR scales are presented in Tables 3-5. As shown, the carryover effect was insignificant in all pairwise comparisons regarding all three scales of PR, SEM, and FPR ($P > 0.05$).

Harms

No patient was harmed during this study.

DISCUSSION

Dental anxiety is the main cause of not seeking dental care.[2] Behavioral control of children and encouraging them to cooperate are among the main topics in pediatric dentistry. Thus, dental clinicians are attempting to find strategies to improve the cooperation of children. Furthermore, old behavioral control methods such as the use of physical restraints, sedation with nitrous oxide, and hand-over-mouth technique are no longer accepted by the majority of parents.[14]

Table 3: Difference in pulse rate, sound, eyes, and motor and faces pain rating between the control-audiovisual distraction and audiovisual distraction-control groups (mean±standard deviation)

Outcomes	C-AVD Group (*n*=10)	AVD-C-Group (*n*=10)
PR mean difference (n/min)		
First visit	5.83± 3.37	0.83±1.32
Second visit	1.16± 1.21	6.16±2.48
Treatment effect: *P*=0.000*, Period effect: *P*=0.475, Sequence effect: *P*=0.817, Carryover effect=0.29		
SEM Scale		
First visit	1±0.63	0±0
Second visit	0.16±0.40	1.13±0.51
Treatment effect: *P*=0.000*, Period effect: *P*=0.209, Sequence effect: *P*=0.664, Carryover effect=0.33		
FPR Scale		
First visit	1.16±0.75	0.83±0.4
Second visit	1.16±1.16	2.66±1.03
Treatment effect: *P*=0.007*, Period effect: *P*=0.007, Sequence effect: *P*=0.210, Carryover effect=0.24		

*Significant. AVD-C group: Audiovisual distraction in the first visit, no distraction in the second visit; C-AVD group: No distraction in the first visit and audiovisual distraction in the second visit; SEM: Sound eyes and motor; FPR: Faces pain rating; PR: Pulse rate; AVD-C: Audiovisual distraction-control

It appears that visual media in mute mode are commonly used in most dental clinics and schools of dentistry for distraction of pediatric dental patients because the environmental noise does not often allow hearing the audio of the media.[9] One strength of the current study was that no previous study has assessed the effect of MVD on the level of pain and anxiety of children during a dental visit in comparison with AVD. The crossover split-mouth design was another strength of this study since this design eliminates the effect of variability between samples on the results

Table 4: Difference in pulse rate, sound, eyes, and motor and faces pain rating scales between the two groups of control -mute-video distraction and mute-video distraction-control (mean±standard deviation)

Outcomes	C-MVD Group (*n*=10)	MVD-C-Group (*n*=10)
PR mean difference (n/min)		
First visit	3±0.89	4±1.89
Second visit	2.66±1.75	3.66±2.5
Treatment effect: *P*=1.00, Period effect: *P*=0.612, Sequence effect: *P*=0.271, Carryover effect=0.36		
SEM Scale		
First visit	0.5±0.54	0.83±0.40
Second visit	0.33±0.51	0.66±0.51
Treatment effect: *P*=1.00, Period effect: *P*=0.187, Sequence effect: *P*=0.234, Carryover effect=0.18		
FPR Scale		
First visit	1.16±1.16	1.33±0.81
Second visit	1±0.63	1.16±0.75
Treatment effect: *P*=1.00, Period effect: *P*=0.460, Sequence effect: *P*=0.719, Carryover effect=0.41		

*Significant. MVD-C group: Mute-video distraction in the first visit, no distraction in the second visit, C-MVD group, no distraction in the first visit mute-video distraction in the second visit. SEM: Sound, eyes and motor; FPR: Faces pain rating; PR: Pulse rate; MVD-C: Mute-video distraction-control

Table 5: Difference in pulse rate, sound, eyes, and motor and faces pain rating between audiovisual distraction - mute-video distraction and mute-video distraction - audiovisual distraction groups (mean±standard deviation)

Outcomes	MVD-AVD Group (*n*=10)	AVD-MVD Group (*n*=10)
Pulse rate mean difference (n/min)		
First visit	2.66±4.36	0.33±1.5
Second visit	0.66±0.51	2.77±2.34
Treatment effect: *P*=0.048, Period effect: *P*=0.869, Sequence effect: *P*=0.885, Carryover effect=0.53		
SEM Scale		
First visit	1±0.63	0.5±0.54
Second visit	0.33±0.51	0.66±0.51
Treatment effect: *P*=0.049, Period effect: *P*=0.209, Sequence effect: *P*=0.756, Carryover effect=0.85		
FPR Scale		
First visit	1.16±0.40	1±0.63
Second visit	0.5±0.54	1.13±0.51
Treatment effect: *P*=0.007, Period effect: *P*=0.289, Sequence effect: *P*=0.243, Carryover effect=0.68		

*Significant. AVD-MVD group: Audiovisual distraction in the first visit, mute-video distraction in the second visit. MVD-AVD group: Mute-video distraction in the first visit audiovisual distraction in the second visit; SEM: Sound, eyes, and motor; FPR: Faces pain rating; AVD: Audiovisual distraction; MVD: Mute-video distraction

and is different from the parallel design of most similar studies.[15] Moreover, to increase the validity and reliability of the results, the level of pain and anxiety of patients was measured using three different scales, namely the physiological, objective, and subjective (self-reported) scales.

The results of crossover analysis in this study showed that the sequence effect and period effect were insignificant in all pairwise comparisons, which indicated that the sequence of receipt of the distraction technique (AB or BA) and time of their provision (1 or 2) had no effect on the results.

Comparison of AVD with the control technique for reduction of pain and anxiety of pediatric dental patients (Group 1 vs. Group 2):

According to the results of Table 3, the mean difference in PR between T3b and T3a and between T4b and T4a in AVD technique was significantly lower than that in the control technique, which indicates the positive effect of AVD on anxiety of patients during anesthetic injection compared with the control technique (P = 0.000). Furthermore, significant differences were noted in SEM and FPR scales between the AVD and control techniques. It appears that AVD can significantly decrease pain during local anesthetic injection. Since audiovisual media have two components of audio and video to distract the children, they can effectively confront the signals generating anxiety and can decrease the level of pain and anxiety experienced by children during anesthetic injection.

Kaur *et al*.[16] in their study in 2015 in India compared the efficacy of audio and AVD for the management of anxious children. The patients were assigned to three groups of control, audio distraction, and AVD and were evaluated during three dental visits. The level of anxiety of children was measured at each dental visit using a combination of parameters for anxiety assessment such as the PR. They reported significantly lower level of anxiety in AVD group compared with the control and audio distraction groups. Their results were in line with our findings. Prabhakar *et al*.[17] in 2007 in India compared AVD and audio distraction for the management of anxious pediatric dental patients. They measured the anxiety level of children by four methods of Venham picture test, PR, blood oxygen saturation rate, and Venham's clinical anxiety rating scale. They reported that AVD was more effective than audio distraction for the management of anxious children. Their results supported our findings regarding the superiority of AVD to other distraction techniques. Jafarzadeh *et al*.[1] in 2011 evaluated the effect of AVD on the level of anxiety of pediatric

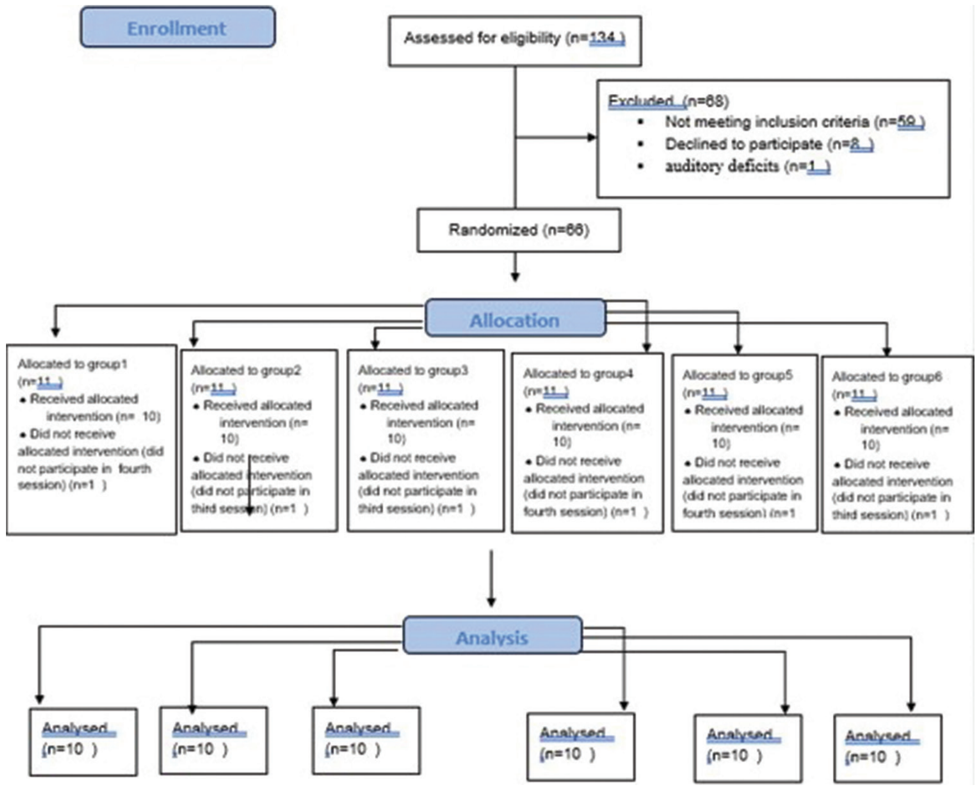

Figure 1: CONSORT flow diagram of study procedure

patients during occlusal restoration of primary molars. They measured the salivary cortisol level and PR per minute to determine the level of anxiety of children. They reported that AVD by video glasses during dental treatment had no significant effect on the anxiety of children. Their results were different from our findings, which may be attributed to the different study design, use of different audiovisual equipment (wired earphones and LCD in our study), assessment of anxiety level during a more invasive procedure (pulpotomy of primary molars in our study), and different scales for assessment of anxiety.

Comparison of the effect of MVD and control technique on the level of pain and anxiety of pediatric dental patients (Group 3 vs. Group 4):

According to the results [Table 4], the mean difference in PR between T3b and T3a and between T4b and T4a was not significantly different between the control and MVD groups, which indicates no significant effect of MVD on the level of anxiety of patients during anesthetic injection (P = 0.594). Furthermore, the mean of SEM and FPR scales was not significantly different between the control and MVD groups, which indicates no significant effect of MVD on the level of pain experienced during anesthetic injection.

It appears that MVD cannot provide sufficient distraction to decrease pain and anxiety during anesthetic injection. However, this technique may be effective in other aspects. In other words, the current results showed that the use or no use of MVD would not make any difference in the level of pain and anxiety experienced by patients during anesthetic injection.

Ghadimi *et al.*[9] displayed an animation with no sound (due to the presence of masking sounds in the environment) for distraction of children. Unlike our study, they concluded that MVD effectively decreased the anxiety level of children during dental treatment. Difference between their results and ours may be attributed to the different time of measurement of PR in the two studies since PR was measured during anesthetic injection in our study while they measured the PR at the onset and at the end of treatment session.

Comparison of the efficacy of MVD and AVD for reduction of pain and anxiety in pediatric dental patients (Group 5 vs. Group 6):

According to the results [Table 5], difference in PR between T3b and T3a and also between T4b and T4a in AVD was significantly smaller than that in the MVD technique, which highlights the optimal efficacy of AVD for reduction of anxiety during anesthetic injection ($P = 0.048$). Furthermore, a significant difference existed in the frequency of SEM and FPR scales between the MVD and AVD techniques. These results support the superiority of AVD for reduction of pain during anesthetic injection, compared with MVD.

In total, the results of the present study indicated that audiovisual media are significantly more effective for reduction of pain and anxiety of children during anesthetic injection, compared with watching the same content in mute mode. It appears that mute animations cannot cause sufficient distraction to decrease the pain and anxiety of children during anesthetic injection. The audio factor is important in distracting the children. Accordingly, Adler *et al*.[18] in their systematic review in 2016 confirmed that audio-only media distracted the children and decreased their level of pain and anxiety during dental treatment. Thus, it may be concluded that audio component is more important than video component for distraction of children because it has been previously confirmed that audio distraction alone can decrease the anxiety and pain of children during dental treatment while our study showed that MVD was not effective for reduction of anxiety and pain of children during anesthetic injection. On the other hand, AVD involves both vision and hearing sense of children and effectively distracts them, leading to significant reduction in pain and anxiety during anesthetic injection. Since many dental clinicians turn down or mute the TV and visual media, further studies are required to find the ideal combination of audio and visual media for maximum reduction in pain and anxiety. The effect of sound volume, type of audio media, use of earphones, and the environmental noise on multimedia distraction should also be investigated in future studies.

CONCLUSION

I. Anesthetic injection can increase the level of anxiety of children even despite the use of distraction methods
II. AVD can significantly decrease the level of pain and anxiety of pediatric patients during local anesthetic injection while MVD is not effective for this purpose.

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All authors met the standard authorship criteria.

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Conflicts of interest
The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or non-financial in this article.

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