Analgesic and Anxiolytic Effects of Virtual Reality and Classical Music Therapy on Tension-Type Headache: A Randomized Controlled Trial

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Study objective: Tension-type headache is the most common primary headache worldwide, significantly reducing individuals' quality of life. Although nonsteroidal anti-inflammatory drugs are commonly used for the pharmacologic treatment of tension-type headache, complementary and alternative treatment methods are gaining increasing importance. In this context, virtual reality technology stands out as a noninvasive option, particularly in pain management. This study investigates the analgesic effects and acute mood changes associated with virtual reality and classical music therapy in tension-type headache patients.

Methods: This randomized controlled trial involved 140 patients diagnosed with tension-type headache, divided into 2 groups. The control group received intravenous 25-mg dexketoprofen trometamol, whereas the intervention group was provided with virtual reality goggles to listen to classical music in a simulated forest environment in addition to this treatment. Pain intensity was assessed using the visual analog scale (VAS), whereas mood changes were measured using a 5-choice ordinal rating scale.

Results: The mean (SD) values for VAS-0, VAS-30, VAS-60, and VAS-120 in the control group were found to be 80.5 (11.2), 60.1 (17.0), 51.0 (18.0), and 45.9 (19.9), respectively, whereas the mean (SD) values for VAS-0, VAS-30, VAS-60, and VAS-120 in the intervention group were calculated as 79.8 (11.3), 40.35 (26.6), 21.9 (22.2), and 12.1 (15.7), respectively. Pain intensity was observed lower in the intervention group throughout the treatment than the control group. When ΔVAS-30, ΔVAS-60, and ΔVAS-120 values were examined, the values in the control group were 20.3 (13.4), 29.4 (15.9), and 34.5 (17.9), respectively, whereas in the intervention group, these values were 39.5 (22.5), 57.9 (20.1), and 67.7 (15.5), respectively. Regarding the ΔVAS%-30, ΔVAS%-60, and ΔVAS%-120 values, the control group had values of 25.5 (16.2), 36.8 (19.4), and 43.2 (21.9), respectively, whereas the intervention group had values of 50.9 (30.5), 73.6 (25.7), and 85.4 (18.4), respectively. At 120 minutes, the proportion of patients reporting a 5-choice ordinal rating scale score of 4 or 5 (indicating a positive mood) was significantly higher in the intervention group: 81.4% versus 31.4%, with a difference of 50% (95% confidence interval 35.8% to 64.2%).

Conclusion: The findings suggest that the combination of virtual reality and classical music effectively manages pain and improves mood in tension-type headache patients. This approach may reduce medication use and offers an innovative alternative for tension-type headache management, consistent with similar studies in the literature. [Ann Emerg Med. 2025;■:1-11.]

Please see page XX for the Editor's Capsule Summary of this article.

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INTRODUCTION

Tension-type headache is the most common type of primary headache, affecting one-fifth of the world population and occurring in all age groups. It is a recurrent type of headache, typically lasting an average of 4 to 6 hours, bilateral, and characterized by a pressing or tightening quality.[1] Diagnosis is made based on the history of headaches and the exclusion of alternative diagnoses. Although the biological foundations of tension-type headache are not fully understood, peripheral mechanisms are thought to play a significant role.[2] In addition, cognitive/mental stress, as well as nutritional, environmental, and genetic factors, has been suggested to contribute to the pathophysiology of tension-type headache.[1,3] It negatively affects the daily activities of most patients. Along with its high prevalence, tension-type headache poses a significant socioeconomic burden owing to its association with medical and psychiatric disorders.[4]

Nonsteroidal anti-inflammatory drugs (NSAIDs) are the first-line agents in the treatment of tension-type headache.[1,5] In addition to medication, methods such as psychotherapy, relaxation training, yoga, and massage have

Editor's Capsule Summary

What is already known on this topic

Virtual reality could aid analgesia by altering pain perception.

What questions this study addressed

In patients randomly receiving an intravenous NSAID, is adding virtual reality superior to routine care?

What this study adds to our knowledge

Virtual reality with NSAID reduced pain and improved mood more quickly than the NSAID alone.

How this is relevant to clinical practice

This can offer possible safe, easy intervention to help care.

Research we would like to see

Comparison work that better details the effect of drug and other therapies with added virtual reality.

been shown to be beneficial in the treatment of tension-type headache.[6]

In recent years, virtual reality technology has emerged as a method with significant potential in the field of health care. Virtual reality transports users away from the real world, providing them with the sensation of being in a different environment.[7] It has been suggested that virtual reality can influence pain perception through factors such as attention and concentration, and may reduce the pain experience by enhancing nonpainful neural signals.[8] In addition, by combining visual and auditory stimuli, a relaxing and positive experience can be created.[9,10] Research conducted during the coronavirus disease 19 pandemic on individuals who were distanced from nature has shown that virtual forest walks reduce negative emotions and stress while enhancing connection to nature and promoting positive emotions. These findings suggest that virtual reality is an effective tool for improving psychological well-being.[11]

A search on PubMed using the keywords "(virtual reality) AND (tension headache)" resulted in 4 articles. After reviewing these articles and tracking their references, no studies examining the effect of virtual reality on acute pain management in patients with tension-type headache were found. Some studies investigating the effectiveness of virtual reality on headaches have been identified, including those on postspinal anesthesia headaches, pediatric and adult chronic migraines, and pediatric chronic headaches. These studies have reported that virtual reality alleviates headaches.[12-15] This study was designed with the hypothesis that virtual reality could serve as an alternative treatment for tension-type headache, reduce the use of NSAIDs, and have positive effects on mood. The aim of the study is to investigate the effects of virtual reality and classical music therapies on pain and mood in patients with tension-type headache.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomized controlled study evaluated the effectiveness of integrating a simulated virtual environment using virtual reality glasses and classical music therapy as an adjunct or alternative method to standard NSAID treatment for tension-type headache. Patients presenting to the emergency department (ED) with tension-type headache were assessed according to eligibility criteria and included in the study, followed by a 2-hour observation period in the ED. Ethical oversight was provided by the Ethics Committee No. 2 of Ankara Bilkent City Hospital (approval date: 01/11/2023; ethics no: E2-23-5439). The study has also been registered at ClinicalTrials.gov (NCT06155669). The study was completed between December 15, 2023, and July 30, 2024, following the approval of the ethics committee.

The study was conducted in the ED of Ankara Bilkent City Hospital, a tertiary urban research and teaching hospital. Throughout the study, full time physicians at the levels of Assistant Professor and Associate Professor, proficient in both Turkish and English, were on duty 24 hours a day, 7 days a week.

Selection of Participants

Patients who described symptoms and history consistent with tension-type headache and met the diagnostic criteria for tension-type headache according to the third edition of the International Classification of Headache Disorders were included in the study.[16]

Diagnostic Criteria	Description
A. Headache frequency	At least 10 headache episodes, occurring less than once a month (<12 d/y), and meeting criteria B-D. Or at least 10 headache episodes, occurring between 1 and 14 days per month (for 3 months), and meeting criteria B-D.
B. Duration	The headache should last between 30 minutes and 7 days.
C. Two or more features	It should include at least 2 of the following 4 features: 1. Bilateral pain location. 2. Pain of a pressing or tightening (nonpulsating) quality. 3. Mild or moderate pain intensity. 4. Pain that does not worsen with routine physical activities such as walking or climbing stairs.
D. Other criteria	It must include both of the following features: 1. No nausea or vomiting. 2. Only one of photophobia or phonophobia may be present.
E. Absence of alternative diagnosis	The headache must not be better explained by another third edition of the International Classification of Headache Disorders diagnosis.

Participants were aged between 18 and 65 years. Pain severity was set at a threshold of 50 or higher on the visual analog scale (VAS), indicating moderate or severe pain. Patients were included in the study if they reported having experienced similar headaches previously. The duration of the headache—whether short or long—was not a factor for exclusion from the study.

Inclusion criteria.

- Patients aged between 18 and 65 years
- Patients meeting the criteria for tension-type headache in the third edition of the International Classification of Headache Disorders
- Patients willing to participate in the study
- Patients indicating a VAS score of 50 and above
- Patients without other suspected diagnoses
- Patients with no known history of adverse reactions to the active ingredients of the drugs to be used
- Conscious patients
- Patients who were oriented and cooperative

Exclusion criteria.

- Patients under the age of 18 and over the age of 65 years
- Patients who did not consent to participate in the study
- Patients with vital signs outside normal limits
- Patients with a history of adverse reactions to known NSAIDs
- Individuals unable to determine pain intensity on the VAS
- Patients with a VAS score of 50 mm and below
- Pregnant individuals
- Those with advanced systemic diseases
- Patients with malignancies
- Individuals with chronic liver and kidney diseases
- Those using sedative and analgesic neuropsychiatric drugs
- Individuals with a history of psychological and neurologic diseases
- Patients who used analgesics within 8 hours before the examination

Written and verbal informed consent was obtained from all patients who agreed to participate. In addition, approval and permission from the attending emergency physician were obtained before enrolling patients in the study.

Interventions

All patients included in the study (those meeting the inclusion criteria) were placed in single-person isolation rooms in the observation area where the study was conducted, ensuring they could not see each other. For both groups, regardless of the type of treatment, all patients were treated in single-person quiet and dark rooms.

Each patient received 25 mg of dexketoprofentrometamol (Arveles; Menarini Pharmaceuticals) intravenously, infused over 5 to 10 minutes in 150 mL of saline solution. Patients were randomly assigned in a 1:1 ratio to one of the following 2 groups:

1. Control group: Twenty-five-mg dexketoprofentrometamol administered intravenously over 5 to 10 minutes.
2. Intervention group: Twenty-five-mg dexketoprofentrometamol administered intravenously over 5 to 10 minutes, accompanied by a virtual reality experience using virtual reality goggles (OculusQuest 2; Meta) that simulated an environment with classical music playing. The simulated environment was preloaded on to the goggles (https://youtu.be/Kv5ap7VXjys?si=jNUqiw_oIJV1eU4d), and classical music was played in the background through an iPhone 15 Pro Max using YouTube at a moderate volume level (https://youtu.be/uk-DSogtQRo?si=1vA1y1RwY7eV-vze). The virtual reality

intervention consisted of a single simulated environment. This environment was described as a forest scene with a flowing river, a suspension bridge, and sunlight reflecting in a way that does not disturb the eyes. The classical music selection was derived from an arrangement featuring relaxing works by Camille Saint-Saëns, Johann Sebastian Bach, Jules Massenet, Wolfgang Amadeus Mozart, Claude Debussy, Astor Piazzolla, Pietro Mascagni, Pyotr Ilyich Tchaikovsky, Anton Arensky, Edvard Grieg, Joseph Haydn, Arcangelo Corelli, and Antonio Vivaldi.

Outcome Measures

Primary outcome measure. The ongoing relief of headache is defined according to international headache treatment criteria as the absence of or minimal pain within 2 hours and the maintenance of this level for 48 hours.[17] The main goal of our study was the achievement of a marked improvement in the pain within the first 120 minutes. The primary outcome was the comparison of changes in VAS scores from baseline and the differences between the 2 groups.

Secondary outcomes. The percentage changes in pain at 30, 60, and 120 minutes, the need for rescue medication, side effects observed after treatment, and the comparison of 5-choice ordinal rating scale scores at 120 minutes between the groups were evaluated as secondary outcomes. In the 5-choice ordinal rating scale scores at 120 minutes, categories 4 and 5 were considered as good outcomes, and the variable was dichotomized and analyzed accordingly.

Sample Size

To calculate the sample size, G*Power 3.1 software (for MacOS; Heinrich-Heine-Universitat Düsseldorf) was used. In a study conducted by Çetin et al,[18] the effect size was calculated as 0.62, with an α value of.05 and a β value of.20 anticipated. Power analysis indicated that at least 33 patients were needed in each group. However, considering potential data loss and to further reduce the β value, it was decided to enroll a total of 140 patients, with 70 patients in each group.

Randomization

The study employed a simple 1:1 randomization process through an online random number generated by the principal investigator. Treatments were sequentially numbered and sealed in envelopes according to the randomization sequence. When an eligible patient arrived, the attending physician, who had been informed in advance, opened the envelope and administered the assigned treatment to the patient. The attending physician completed the case report forms and submitted them to the principal or assistant researcher afterward. The study was conducted with blinded analysis, ensuring that the principal and assistant investigators were unaware of the treatments until the analysis was completed.

Allocation Concealment

The randomization process was implemented by concealing the assignment of treatment groups from the researchers. This was done to ensure that the group allocation process remained impartial and unbiased. Participants were randomly assigned to treatment groups without knowledge of their allocation, and researchers had no influence on the group assignment process.

Implementation

In the study, the diagnosis of tension-type headache was made by the researchers through medical history and physical examination, and other possible diagnoses were excluded. Daily reminders were provided to the assistant doctors at the triage point, and patients were identified in the triage room and reported to the researchers within 3 minutes. The patients were then taken from a location 1 minute away from the study area for registration. After the examination, the patient was included in the study, and this process took a total of 7 to 8 minutes, whereas the time from triage to inclusion was 12 to 13 minutes.

Blinding

In the study, the intervention group was not specified on the case report forms, and statistical analyses were conducted in a blinded manner. However, owing to the apparent differences in the interventions, blinding of the patients and the treating physicians could not be achieved.

Methods of Measurement

Preprepared case report forms were used to assess the patients. To evaluate pain levels, patients were asked to rate their pain using the VAS. On this scale, patients were instructed to mark their pain from 0 (no pain) to 100 mm (the worst pain they have ever experienced). The VAS scores at the time of admission to the ED (VAS-0) were recorded in the case report forms. Analgesic treatment was initiated for each patient within a maximum of 10 minutes.

All patients were positioned on a hospital bed with the head elevated at a 45- to 60-degree angle. Patients in the intervention group were relaxed using Oculus Quest 2 (Meta) virtual reality headsets, simulating a forest

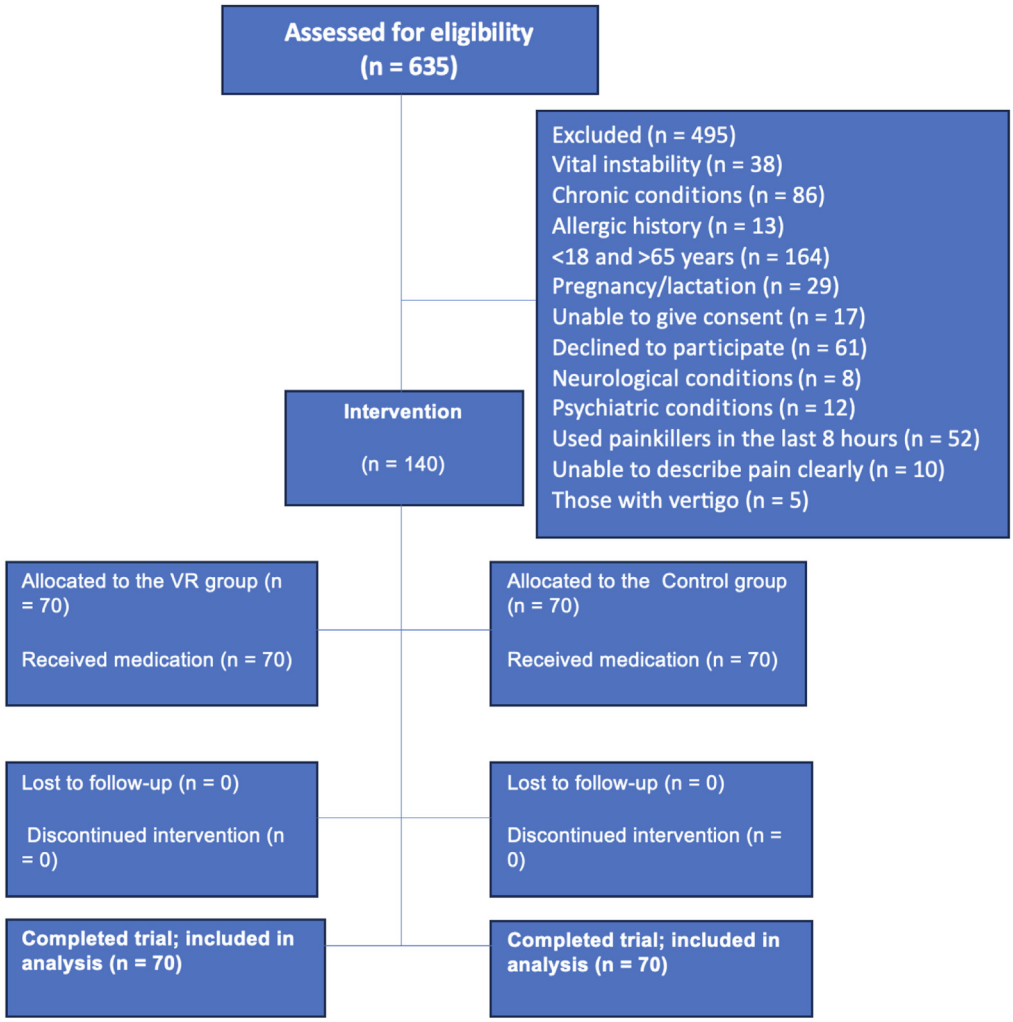

Figure 1. Flow diagram of participant selection and randomization.

environment accompanied by classical music. The control group, on the other hand, rested in a quiet, dark, and calm room without additional interventions.

The research staff approached patients at 30, 60, and 120 minutes to assess their pain levels and any additional complaints, asking them to mark their pain on the VAS. The differences between VAS scores at baseline (VAS-0) and subsequent time points were recorded as delta VAS (ΔVAS). For the calculation of ΔVAS, the following formula was used: for ΔVAS-30, ΔVAS-30=VAS-0-VAS-30, and for ΔVAS-60, ΔVAS-60=VAS-0-VAS-60. The percentage decrease in VAS scores (ΔVAS%) was also calculated relative to VAS-0. For example, the percentage reduction between VAS-0 and VAS-30 was calculated as follows: ΔVAS %-30=([VAS-0-VAS-30]/VAS-0)×100.

For patients whose VAS scores remained >50 mm at the 120th minute, rescue treatment was provided based on the treating physician's discretion and on patient request. Rescue treatment options included either an additional intravenous infusion of 25-mg dexketoprofen or 1 μg/kg of intravenous fentanyl citrate (FENTANYL-PF; Polifarma Pharmaceuticals) administered in 500 mL of normal saline solution over 30 minutes, as recorded.

The patients' moods related to their headaches were assessed using a 5-choice ordinal rating scale. The responsible investigator asked an open-ended question and requested the patient to select one of the following responses: "Very Poor – Poor – Normal – Good – Excellent" (1=very poor, 2=poor, 3=normal, 4=good, and 5=excellent). Mood was assessed at baseline (0 minutes) and again at 120 minutes using the same 5-choice ordinal rating scale.

Side effects were recorded by asking patients and observing them at 30, 60, and 120 minutes. In the group using virtual reality goggles, expected nonspecific symptoms such as dizziness and nausea were recorded by asking open-ended questions to the patients.

Table 1. Baseline characteristics of the study participants.

Variables	Treatment Group		
	Control	Virtual Reality	Diff - 95% CI
Sex, n (%) MaleFemale			−4.8% to 28.9%
Male	31 (44.3)	23 (32.9)	
Female	39 (55.7)	47 (67.1)	
Age (y), mean (SD)	37.8 (13.0)	39.4 (13.0)	−5.98 to 2.73
Height (cm), mean (SD)	168.5 (8.3)	166.7 (8.7)	−1.01 to 4.72
Weight (kg), mean (SD)	74.2 (12.3)	72.3 (14.0)	−2.52 to 6.32
Analgesic usage frequency per mo, median (25%-75%)	3 (1 - 5)	3 (1.75 - 5)	
SBP, mean (SD)	124.4 (10.3)	121.2 (10.6)	−0.34 to 6.68
DBP, mean (SD)	76.8 (10.1)	76.9 (7.7)	−3.06 to 3.00
Pulse (beats/min), mean (SD)	85.5 (10.3)	82.7 (7.9)	−0.25 to 5.88
Saturation %, mean (SD)	97.7 (1.1)	97.6 (1.1)	−0.31 to 0.45
Respiratory rate (breaths/min), median (25%-75%)	17 (16 - 18)	17 (16 - 18)	
VAS-0, mean (SD)	80.5 (11.2)	79.8 (11.3)	−3.14 to 4.40
LIKERT-0, median (25%-75%)	2 (1-2)	2 (1 - 2)	

Pearson χ^2 test, Student's *t* test, and Mann-Whitney *U* test were used for statistical analysis.
DBP, diastolic blood pressure; *Diff*, difference; *SBP*, systolic blood pressure.

Primary Data Analysis

Study data were recorded in preprepared case report forms and subsequently entered into IBM Statistics for MacOS, Version 28.0 (IBM Corp) and Jamovi (MacOS version, open-source software) for analysis. The normal distribution of continuous data was assessed using the Shapiro-Wilk test, Q-Q plots, and histograms. Parameters with a normal distribution were expressed as mean, SD, and 95% confidence interval (CI) for the difference; nonnormally distributed parameters were expressed as median and interquartile range. The Mann-Whitney *U* test was used to compare medians between nonnormally distributed parameters, whereas the independent samples *t* test was employed to evaluate mean differences among normally distributed parameters. Pearson χ^2 (or Fisher exact) test was used for comparing the proportions of categorical data between primary groups. Box plot graphs were used to present the means for VAS, whereas a stacked bar chart was used to show the percentage distribution of 5-choice ordinal rating scale scores at baseline (0 minutes) and at 120 minutes in the control and virtual reality groups.

Table 2. Comparison of VAS, ΔVAS, ΔVAS%, Likert-120 scores, and rescue medication needs between groups.

Variables	Treatment Group		
	Control	Virtual Reality	Diff - 95% CI
VAS-30, mean (SD)	60.1 (17.0)	40.4 (26.6)	12.34-27.30
VAS-60, mean (SD)	51.0 (18.0)	21.9 (22.2)	22.32-35.84
VAS-120, mean (SD)	45.9 (19.9)	12.1 (15.7)	27.81-39.80
ΔVAS-30, mean (SD)	20.3 (13.4)	39.5 (22.5)	−25.42 to −12.97
ΔVAS-60, mean (SD)	29.4 (15.9)	57.9 (20.1)	−34.51 to −22.39
ΔVAS-120, mean (SD)	34.5 (17.9)	67.7 (15.5)	−38.79 to −27.57
ΔVAS%-30, mean (SD)	25.5 (16.2)	50.9 (30.5)	−33.61 to −17.21
ΔVAS%-60, mean (SD)	36.8 (19.4)	73.6 (25.7)	−44.45 to −29.17
ΔVAS%-120, mean (SD)	43.2 (21.9)	85.4 (18.4)	−49.03 to −35.48
LIKERT-120 (4 and 5), n (%)	22 (31.4)	57 (81.4)	35.8%-64.2% (50.0%*)
Rescue drug use, n (%)	32 (45.7)	2 (2.9)	30.6%-55.2% (42.9%*)

Independent samples *t* test and Pearson χ^2 test were used for statistical analysis. Likert-120 scores indicate the patients' moods related to their headaches in the 120th minute.
*Difference in proportions with continuity correction applied.

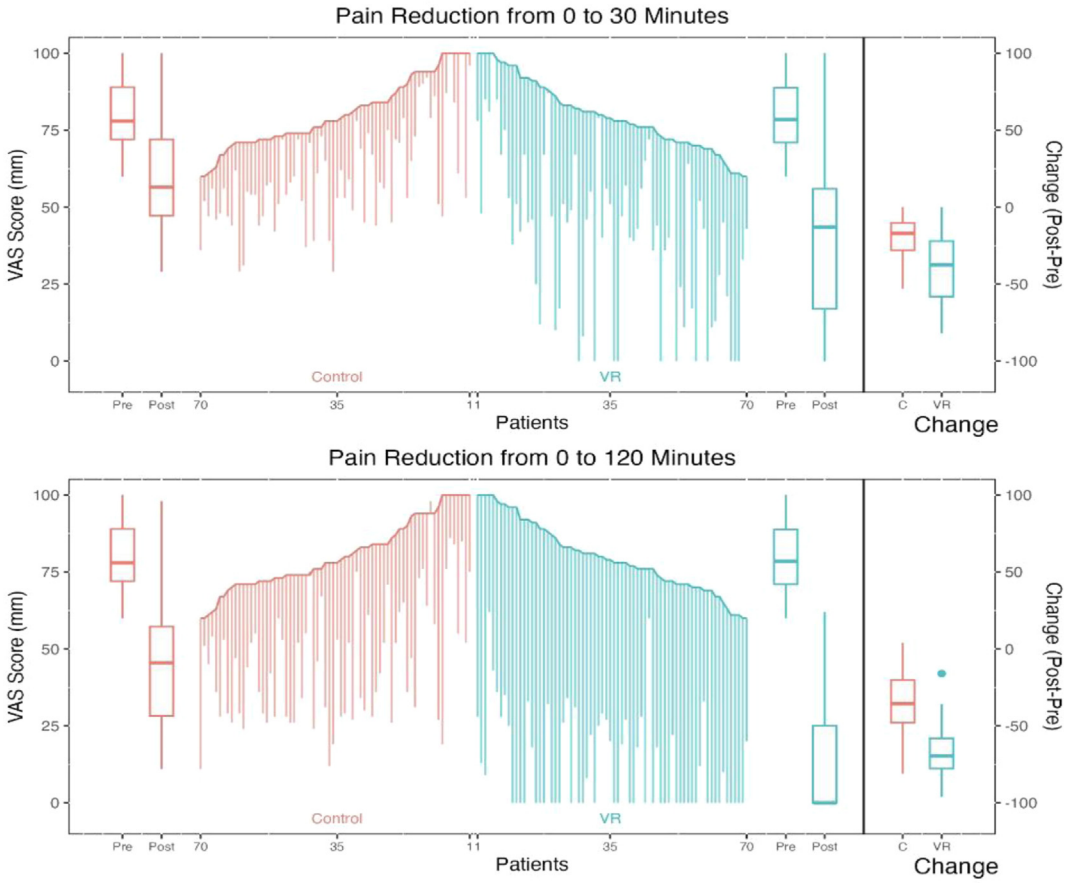

Figure 2. Changes in VAS scores over time by group.

RESULTS

Patient Variables

A total of 635 patients were assessed for eligibility, and 201 patients met the inclusion criteria; however, 140 patients agreed to participate in the study. Seventy patients were randomized to the control group, whereas the other 70 were assigned to the intervention group. No patients had missing data or withdrew from the study after inclusion. Thus, the study was completed with 140 patients (Figure 1).

Baseline characteristics of the participants, including age, sex, height, weight, frequency of monthly analgesic use, vital signs, VAS-0, and 5-choice ordinal rating scale scores at baseline, were found to be similar between groups (Table 1). In addition, because the pain onset times for included patients did not exceed 120 minutes, no further analyses were conducted.

VAS Differences

The VAS values obtained at 30, 60, and 120 minutes, along with ΔVAS and ΔVAS% values, and their intergroup comparisons for the patients included in the study are presented in Table 2. In addition, the intergroup comparisons of VAS and ΔVAS values are also illustrated in Figure 2. Graphs for other time periods are provided as supplementary files (Figures E1 and E2, available at http://www.annemergmed.com).

At 30 minutes, virtual reality group was lower than the control group—difference 19.7 points (95% CI 12.34 to 27.30). At 60 minutes, the virtual reality group was lower than the control group—difference 29.1 points (95% CI 22.32 to 35.84). At 120 minutes, the virtual reality group was lower than the control group—difference 33.8 points (95% CI 27.81 to 39.84).

In terms of absolute change from baseline (ΔVAS), the virtual reality group was higher than the control group at 30 minutes—difference 19.2 points (95% CI −25.42 to −12.97); at 60 minutes, the virtual reality group was higher than the control group—difference 28.5 points (95% CI −34.51 to −22.39); at 120 minutes, the virtual reality group was higher than the control group—difference 33.2 points (95% CI −38.79 to −27.57).

Regarding percentage changes (ΔVAS%), the virtual reality group was higher than the control group at 30

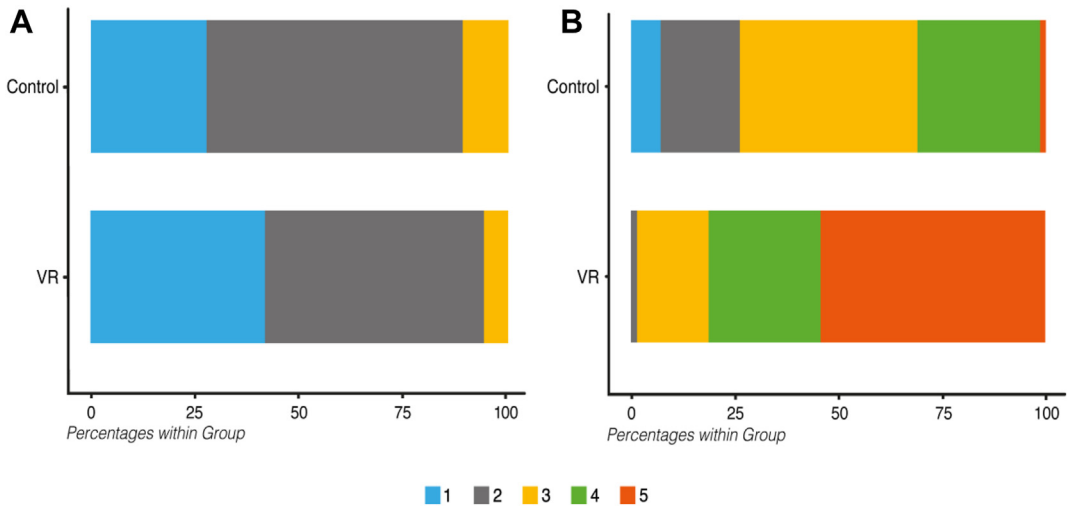

Figure 3. A 5-choice ordinal rating scale in terms of patients' moods (1: very poor; 2: poor; 3: normal; 4: good; 5: excellent). *A*, mood at baseline; *B*, mood at 120 minutes.

minutes—difference 25.4% (95% CI −33.61% to −17.21%); at 60 minutes, the virtual reality group was higher than the control group—difference 36.8% (95% CI −44.45% to −29.17%); and at 120 minutes, the virtual reality group was higher than the control group—difference 42.2% (95% CI −49.03% to −35.48%). Because all 95% CIs excluded 0, these differences were statistically significant.

Acute Mood Change

One of the secondary outcome measures of the study was the patient's mood at the time of pain. This 5-choice ordinal rating scale was administered by the principal or assisting investigators. The initial 5-choice ordinal rating scale scores at baseline did not show a statistically significant difference between groups (Table 1). The percentage of patients with a 5-choice ordinal rating scale score of 4 or 5 at the 120th minute was higher in the virtual reality group than in the control group—difference 50.0% (95% CI 35.8% to 64.2%), as shown in Table 2. In addition, the virtual reality group showed higher 5-choice ordinal rating scale scores at 120 minutes compared with the control group (Figure 3), suggesting a positive effect of the virtual reality intervention.

Rescue Medication Needs and Side Effects

The comparison of rescue medication requirements, presented in Table 2, shows that the virtual reality group was better than the control group—difference 42.8% (95% CI 30.6% to 55.2%). Aside from mild dizziness observed in one patient in the intervention group, no other side effects were noted in either group, and thus, these were not included in the statistical analysis.

To assess symptoms of cybersickness, participants were asked open-ended questions such as "Did you experience any discomfort during the treatment process" or "Did you experience nausea, dizziness, or any other unusual sensations?" However, no such effects were observed in any of the patients.

In addition, nausea, vomiting, dizziness, allergic reactions, and other side effects were investigated in all other patients. However, no such effects were observed in the control group, except for mild dizziness in one patient.

The raw statistical output that includes more models and diagnostics can be found at https://osf.io/rwshd/?view_only=0aabc22c20694e978d871f3d21491370.

LIMITATIONS

This study was conducted at a single center with a relatively limited patient population, which might have restricted the generalizability of the findings. The forest environment simulated with virtual reality glasses and the classical music used were not customized according to the personal preferences of the patients, which might lead to a less than optimal experience for some individuals. Furthermore, the 120-minute follow-up period used in the study was insufficient for assessing the long-term effects of pain management. Because patients and health care providers were not blinded to the intervention, there is a potential risk of bias in assigning the 5-choice ordinal rating scale for mood assessment. Another limitation is that, considering the high crowding in EDs, providing a quiet space for a prolonged period to administer the virtual reality intervention could pose a significant challenge.

In our study, we did not include a "sham" virtual reality intervention in the control group owing to practical and

methodological concerns. Designing a truly ineffective virtual reality experience is challenging, because even minimal visual or auditory stimulation could have unintended effects on patients. In addition, the use of sham virtual reality glasses might create misleading expectations, potentially influencing pain perception and study outcomes. Given these limitations, we opted for a standard control group. However, because patients and health care providers were not blinded to the intervention, the risk of bias remained a consideration.

In terms of strengths, the use of noninvasive and innovative approaches such as virtual reality and classical music therapy offers a modern perspective on pain management. Virtual reality therapy can be considered a low-risk intervention for patients, making the study safer and more applicable. In addition, the randomized design allows for comparisons between treatment groups and more reliable evaluation of the findings. The multidimensional assessment tools employed in the study (VAS, 5-choice ordinal rating scale) enabled the examination of significant clinical parameters such as pain, stress, and anxiety both subjectively and quantitatively, providing a comprehensive assessment of the treatment's physical and psychological effects.

DISCUSSION

Tension-type headache is the most common primary headache type in adults and, when chronic, can lead to decreased work performance, social isolation, and a reduction in quality of life.[19,20] This study examined the analgesic efficacy of a simulated virtual environment using virtual reality goggles and classical music, as well as their effects on mood in patients presenting to the ED owing to tension-type headache. In the intervention group, pain scores significantly decreased compared with the control group, mood was positively affected, and the need for rescue medication was lower.

Emotions are an important part of human psychology, and therefore, studying emotions can be challenging. The Likert scale is considered an effective method for recalling emotional experiences. In one study, there was no significant difference between the 4-point Likert scale, the 7-point scale, and VAS in mood assessments. This suggests that inexperienced individuals tend to prefer Likert scale with fewer response options.[21] In addition, the 5-response alternative Likert scale provides more reliable results, especially for inexperienced individuals or children.[22,23]

Research shows that exposure to nature has positive effects on mood and stress.[24,25] A meta-analysis conducted by McMahan and Estes[25] found that exposure to nature moderately increases positive emotions and has a smaller yet significant effect on negative emotions. In addition, virtual reality technologies are becoming increasingly accessible, providing a practical solution for enhancing well-being during challenging times. One study examined the effects of virtual nature on young adults and the elderly, reporting that walks in virtual natural environments improved emotional states.[11] In both groups, clinical psychological relief was primarily observed in the quiet, dark room we provided, with this relief positively correlating with pain reduction. Furthermore, the simulation of a flowing stream and birdsong in a forested area, combined with classical music therapy in the intervention group, yielded significantly better clinical and statistical outcomes compared with the control group.

A review showed that dexketoprofen 25 mg demonstrated efficacy across various pain types. In dental pain, it was superior to dipyrone 575 mg, whereas in postoperative pain, it was equivalent to tramadol 50 mg, diclofenac 50 mg, and a paracetamol-codeine combination. Compared with ketoprofen 50 mg, results were mixed, with some studies showing ketoprofen as less effective. In acute pain, dexketoprofen consistently provided greater pain relief, although not statistically significant. For renal colic, 25-mg and 50-mg dexketoprofen showed similar efficacy to dipyrone 2,000 mg. It was also as effective as ketoprofen 50 mg in dysmenorrhea and superior to diclofenac 50 mg in lower extremity injuries.[26] Another study found dexketoprofen 25 mg and ibuprofen 400 mg equally effective after third molar extraction.[27] In our study, a single NSAID choice and low dose were preferred to better assess virtual reality+NSAID efficacy, ensuring regional standard alignment.

Virtual reality is potentially a powerful tool for alleviating pain by enhancing psychological well-being. It can provide users with 3-dimensional environments and multiple sensory stimuli. Virtual reality can generate therapeutically beneficial scenarios and facilitate appropriate usage.[28] A recent systematic review reported that virtual reality effectively provides analgesia for various types of pain, including phantom limb pain, chronic headaches, chronic neck pain, and chronic back pain.[29] In another systematic review focused on wound care, procedure-related pain, physical or occupational therapy, dental treatment, and generalized acute pain, most studies demonstrated analgesic superiority for virtual reality.[30] Frey et al[31] also simulated an underwater environment accompanied by relaxing music to alleviate childbirth pain, finding that virtual reality technology significantly reduced and relieved pain. The results of our study align with the

literature, demonstrating analgesic effectiveness across different types of pain.

The need for rescue medication in the control group in this study was 45%, which is considerably higher than a report in the literature on the use of NSAIDs that included dexketoprofen for tension headache.[32] However, the dose of dexketoprofen used in that study was twice the dosage given in our study. In a separate study involving migraine patients, the rate of rescue medication required in the 50-mg intravenous dexketoprofen group was reported to be 22.3%.[33] The requirement for rescue medication in our control group appears inconsistent with findings in the literature, which may be attributed to the 25-mg dose of dexketoprofen used in our study. The observation that only 2 patients in the intervention group required rescue medication suggests that virtual reality and classical music therapy effectively reduce pain and the need for additional analgesics.

In examining the side effect profile, previous studies involving dexketoprofen for the treatment of migraines and tension-type headache have reported either no side effects or rare occurrences.[32-34] Because dexketoprofen was administered at the same dose and duration in both arms of our study, the observed side effects were minimal and consistent with the literature. This may also be attributed to our use of a 25-mg dose of dexketoprofen. A study usng virtual reality reported significantly higher incidences of symptoms such as headache and dizziness in the virtual reality group.[35] However, another systematic review indicated that minor side effects were observed in 6 studies, but these did not reach statistical significance.[36] In this context, when comparing side effect profiles with the literature, our study noted mild dizziness in one patient, with no other side effects reported.

This study highlights the analgesic and psychological effects of virtual reality and classical music therapies in the treatment of tension-type headache. The significant reduction in pain scores, improvement in emotional well-being, and decreased need for rescue medication in the intervention group suggest that the combined use of virtual reality and classical music may serve as an effective complementary treatment method. The intravenous dose of 25-mg dexketoprofen appears to offer a more effective and safer alternative compared with higher doses of NSAIDs. These findings support the potential benefits of virtual reality and classical music therapy in pain management and well-being, indicating that these approaches should be considered in clinical practice. Future studies may explore innovative strategies for tension-type headache treatment using these modalities with lower doses or solely virtual reality applications.

In conclusion, this study demonstrates that a nature environment simulated with virtual reality glasses, combined with classical music therapy, can be an effective method for pain control in patients with tension-type headache in addition to intravenous dexketoprofen treatment. Patients in the intervention group experienced a significant reduction in pain levels and improvements in their mood states.

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