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The effect of virtual reality in the treatment of migraine type headaches: A prospective, controlled, multicenter clinical study

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Abstract

Background & Objective: Migraine is the third most common disease and the second leading cause of neurological disability globally. Alternative treatments are needed due to the limitations of conventional medications. Virtual reality (VR) shows promise in pain management. This study evaluates the efficacy of VR technology combined with classical music as an adjunctive treatment for acute migraine in an emergency department (ED). *Methods:* In a prospective, non-randomized study, 140 patients with acute migraines at two urban EDs were divided into a control group receiving intravenous dexketoprofen and an intervention group receiving the same treatment plus VR exposure using Oculus Quest 2. Pain was measured with the Visual Analog Scale (VAS) at various intervals. Primary outcomes were changes in VAS scores and the need for rescue medication; secondary outcomes were side effects. *Results:* Of the 140 patients, 131 completed the study. The VR group exhibited significantly greater reductions in VAS scores at all time points compared to the control group ($p<0.001$). The need for rescue medication was also significantly lower in the VR group ($p<0.001$). Kaplan-Meier analysis indicated a more rapid and sustained pain relief in the VR group.
Conclusion: The addition of VR technology to standard pharmacological treatment significantly enhances pain relief in acute migraine attacks and reduces the need for rescue medication. This suggests that VR could be a valuable adjunctive tool in the ED for managing acute migraine pain.

Keywords: Migraine, virtual reality, visual analog scale, emergency department, pain

INTRODUCTION

According to the World Health Organization, migraine ranks as the world's third most prevalent ailment and the second most frequent neurological disorder causing disability. Its pathogenesis is not yet fully understood.[1] Stress. auditory stimuli, fatigue, hunger, and the menstrual cycle are the most commonly cited triggers for migraine attacks.[2] Symptoms of a migraine attack include severe headache, nausea, vomiting, hypersensitivity to light and sound, and intolerance to physical activity. Migraine accounts for 75–80% of emergency department (ED) visits for pain.[3,4] Traditionally, pharmacological treatments and lifestyle modifications have been recommended for managing migraine attacks.[5,6] New migraine treatment options are always welcome in view of the contraindications, adverse effects, and tolerability issues associated with many current migraine therapies.[7]

Research in the literature has posited that virtual reality (VR) technology has great potential in healthcare. VR, created with 3D graphics using information technology, allows individuals to experience an imaginary world as if it were real by transmitting sensory data to the brain. This enables users to feel as though they are in a different environment from the real world.[8] By providing this artificial reality experience, VR can influence the perception of pain through attention, concentration, and emotional changes. Additionally, it has been suggested that the immersive environment created by VR can enhance non-painful neural signals, thereby

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reducing the experience of pain.[9]

Given this background, a prospective controlled study was designed to explore the use of VR technology in combination with music as a novel approach to provide better treatment to acute migraine patients.

METHODS

Study design and setting

This study was a prospective, controlled clinical trial conducted across two centers aiming to assess the efficacy of incorporating a VR environment, utilizing VR headsets (Oculus Quest 2, Meta, USA) alongside or as an alternative to standard non-steroidal anti-inflammatory drug (NSAID) therapy in the management of acute migraine. Eligible patients presenting at the ED with acute migraine attacks were enrolled and underwent a two-hour observation period. Ethical approval was obtained from Ethics Committee No. 2 of the Ankara Bilkent City Hospital (06/09/2023-E2-23-4895). The study adhered to the principles outlined in the Declaration of Helsinki. Additionally, the trial was registered with ClinicalTrials.gov (NCT06061588).

The study was conducted in the emergency departments of two urban hospitals—Ankara Bilkent City Hospital and Ankara Etlik City Hospital—which receive approximately 400,000, and 600,000 adult patient visits per year, respectively. The study period was from September 15, 2023, to March 10, 2024.

Throughout the study period, full-time salaried physicians, including resident doctors, specialists, and associate professors, proficient in both Turkish and English, participated in the research. These physicians worked according to a 24-hour shift system seven days a week.

Before beginning the study, the participating doctors were thoroughly briefed by the researchers on the use of the VR headset and the study details. Each researcher was given practical training on the use of the VR headset to ensure proficiency.

Selection of participants

The study enrolled patients with a confirmed diagnosis of migraine, presenting with symptoms consistent with the migraine diagnostic criteria outlined in the 3rd edition of the International Classification of Headache Disorders (ICHD-3) (10). Eligibility criteria included reporting a pain intensity of 50 mm or higher on the Visual Analog Scale (VAS) upon arrival at the ED, indicative of moderate to severe pain. The duration of the symptoms did not affect eligibility for participation.

Patients under age 18 or over age 65 who had secondary or organic headaches, who were hemodynamically unstable, had used analgesics in the past 12 hours, were allergic to NSAIDs or narcotics, were pregnant or suspected to be pregnant, had uncontrolled chronic heart failure, gastrointestinal bleeding, chronic renal or liver failure, epilepsy, peripheral or central vertigo, mental retardation, or were unable to respond to the VAS (e.g., due to visual impairment or language barriers) were excluded. Additionally, patients presenting between midnight and 8 am or who were unable to use the VR headset were also excluded.

The study was conducted on 140 patients who met the inclusion criteria and had provided informed consent. The patients included in the study were divided into two groups, an intervention (VR) group and a control group, according to their order of presentation. The first consecutive 70 patients enrolled were assigned to the intervention group. After reaching a total of 70 patients in the intervention group from both centers, the control group was formed by enrolling another 70 patients consecutively.

Interventions

All patients in the study had intravenous access established in the ED and were moved to a quiet, dark room and placed on a bed with the head raised 45-60°. Each patient received 50 mg of dexketoprofen (Arveles, Menarini Pharmaceuticals, Spain) in 150 ml saline over 5–10 minutes, administered by the attending physician. The patients remained in the room for 120 minutes. The attending physician measured their VAS scores at predefined intervals. The procedures performed for patients in both groups are outlined below.

Intervention Group: 50 mg of dexketoprofen was infused intravenously over a period of 5–10 minutes. Patients in this group were equipped with a VR headset that replicated a forest environment with tall pine trees, a flowing stream, and the sensation of advancing toward a waterfall, as depicted in https://youtu.be/Kv5ap7VXjys?si=SdvmvyOtEZ5G84v1). Classical music at medium volume (Beethoven's *Moonlight Sonata*, https://youtu.be/BxB9N1MmKOY?si=-OPmmBrAtV1uWldX) was played on an iPhone 14 Pro device positioned beside the patient's

right arm. The video and music were initiated concurrently with the commencement of the intravenous (IV) drug infusion. The duration of the video and music application was limited to a maximum of 60 minutes, after which the intervention was terminated. If the VAS score dropped below 50 mm at any of the scheduled measurement times within the 60-minute period, the VR application and classical music were discontinued before the 60th minute. All patients were monitored in a dark and quiet room for 120 minutes.

Control Group: 50 mg of dexketoprofen was infused intravenously over a period of 5–10 minutes. No additional procedures were performed. All control patients were monitored in a dark and quiet room for 120 minutes.

Patients were administered rescue treatment at the discretion of the treating physician if they requested additional treatment at the 120th minute or if their VAS scores remained > 50 mm. The rescue treatment consisted of IV fentanyl citrate (FENTANYL-PF, Polifarma Pharmaceuticals, Turkey) at a dose of 1 μg/kg administered in 500 ml normal saline over 30 minutes at the 120th minute.

Methods of measurement

Patient evaluations were conducted using pre-prepared case report forms. The VAS for pain assessment was administered to determine pain levels. On this incremental scale, patients were asked to mark their pain from 0 (no pain at all) to 100 mm (worst pain ever experienced).[11] VAS scores at the time of presentation to the emergency department (referred to as VAS-0) were recorded on the case report forms.

The research team assessed patients' pain levels and additional complaints by asking them to mark their pain on the VAS at 15, 30, 60, and 120 minutes after initiation of treatment (VAS-1, VAS-2, VAS-3, and VAS-4, respectively). Decreased values at measurement times compared to VAS-0 were reported as delta-VAS (ΔVAS, that is, VAS-0–VAS-1 = ΔVAS-1). The percentage decrease in VAS scores (ΔVAS%) was calculated relative to VAS-0. For instance, the percentage decrease between VAS-0 and VAS-1 was calculated using the following formula: ΔVAS% –1 = (VAS-0 – VAS-1/VAS-0) × 100.

Side effects were documented at 15, 30, 60, and 120 minutes by asking patients as well as through clinical observation. In the group using the VR headset, non-specific symptoms such as expected dizziness and nausea were recorded by asking patients open-ended questions.

Outcome measures

Continuous relief of headache is defined, according to international criteria, as the absence of or mild headache within 2 hours of treatment, which is sustained for 48 hours (12). As the primary outcome, the main aim of the study was the rapid and effective relief of migraine pain, with no worsening and no requirement for rescue medication for 120 minutes. Failure of the method was defined as lack of improvement of pain within 120 minutes and requiring rescue medication.

The percentage reduction in pain scores at 15, 30, 60, and 120 minutes compared to baseline were also recorded as primary outcomes for comparisons between groups.

The emergence of side effects in either the intervention or the control group was also recorded as a secondary outcome.

Statistical analysis

The study data were recorded on preprepared case report forms and subsequently entered into IBM Statistics for MacOs, Version 28.0 (Armonk, NY: IBM Corp) software for blinded analysis.

The normality of continuous data was assessed using the Shapiro–Wilk test, Q–Q plots, and histograms. Normally distributed parameters were presented as means, standard deviations, and 95% confidence intervals, while non-normally distributed parameters were expressed as medians and interquartile ranges. The Mann-Whitney U test was used to compare medians for non-normally distributed parameters, while the t-test for independent samples was used to assess mean differences for normally distributed parameters. Pearson's chi-square (or Fisher exact) test was used to compare categorical data rates between the groups. Changes in pain within groups were illustrated using error bar graphs. Kaplan–Meier analysis was performed for patients whose pain decreased below 50 mm. A significance level of $p < 0.05$ was taken to indicate statistical significance. The sample size calculation was conducted using G*Power 3.1 software (for MacOS).

Sample size

Following a study by Çetin *et al*., an effect size of 0.62 was determined, with alpha set at 0.05 and beta at 0.20 (13). A power analysis indicated that a minimum of 33 patients per group would

be required. However, to account for potential data attrition and to further reduce the risk of type II errors, we decided to include a total of 140 patients, evenly distributed with 70 patients allocated to each group.

RESULTS

Patient variables

A total of 140 patients were included in the study. However, before obtaining VAS-1, -2, -3, and -4 data, 9 patients withdrew voluntarily from the study and were therefore not included in the intention-to-treat analysis. Consequently, the group using VR headsets consisted of 65 patients, while the group not using headsets consisted of 66 patients, totaling 131 patients who completed the study. The consort flowchart of the study is presented in Figure 1. The demographic characteristics of the participants, including age, gender, height, weight, BMI, monthly frequency of analgesic drug intake, vital signs, and accompanying symptoms, are listed in Table 1. Aside from average age ($p < 0.001$, CI: –11.59 to –3.60), no statistically significant differences were observed between the two groups ($p > 0.05$).

VAS discrepancies and the need for rescue therapy

The comparison of ΔVAS and ΔVAS% values calculated based on the VAS score at the initial visit and reflecting the primary endpoint of the study, is presented in Table 2. Results of the comparison of ΔVAS and ΔVAS% values between groups were statistically significant at all measurement points (for all parameters; $p < 0.001$; independent samples t-test). The 95% confidence interval (CI) values for the comparison of ΔVAS-1, -2, -3, and -4 between groups were as follows: –5.80–0.01, 27.62–40.3, 21.26–33.87, and 18.94–31.30, respectively. Additionally, the 95% CI values for the comparison of ΔVAS%-1,

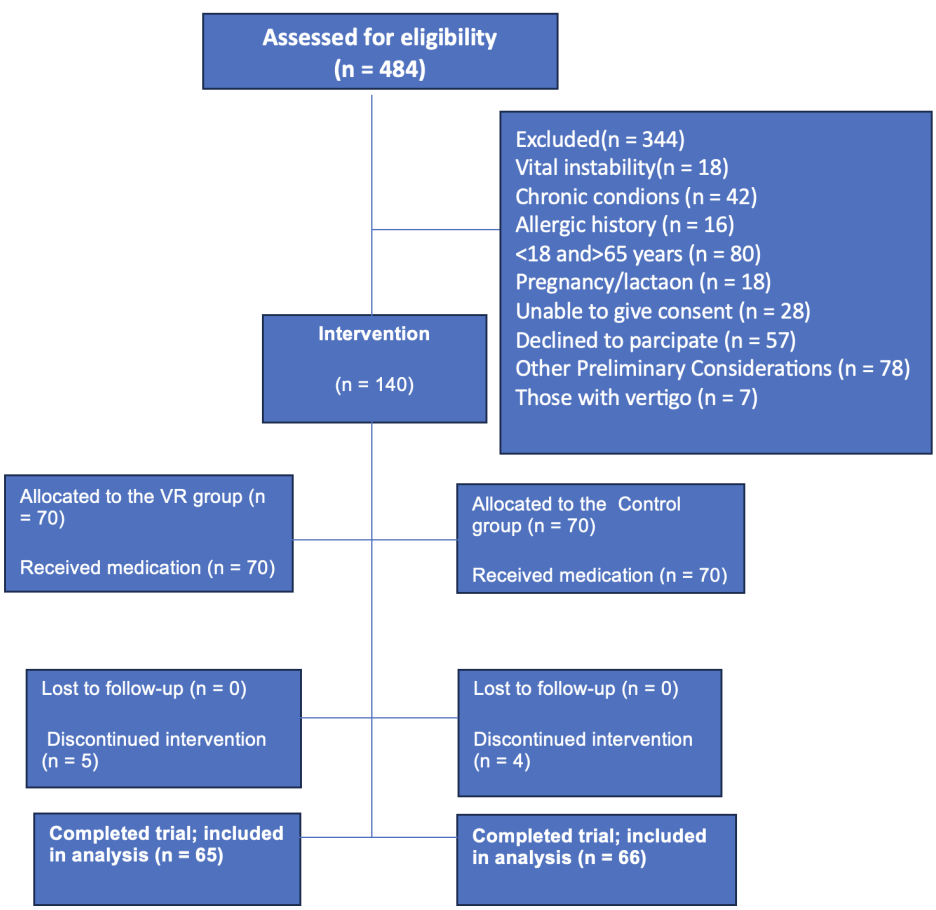

Figure 1. Consort flow diagram

Table 1: Demographic, symptom, and background characteristics in the treatment groups

Variables		Treatment group			p-value
		VR	Control	Diff- 95% CI	
Gender, n (%)	Male	28 (43.1)	19 (28.8)	-0.02- 0.33	0.088*
	Female	37 (56.9)	47 (71.2)		
Age, mean ± SD		37.9 ± 9.8	43.1 ± 11.1	-8.78 - -1.51	0.003†
Height, mean ± SD		168.3 ± 9.6	166.6 ± 8.3	-1.43 - 4.77	0.288†
Weight, mean ± SD		74.3 ± 13.8	73.6 ± 12.4	-3.87 - 5.21	0.770†
BMI, mean ± SD		26.22±4.38	26.56±4.28	-1.84-1.15	0.325†
Analgesic usage frequency per month, med (25-75%)		3 (2-5)	3 (2-4)		0.800‡
TA systolic, mean ± SD		125.5 ± 13.7	125.5 ± 11.9	-4.51 - 4.37	0.976 †
TA diastolic, med (25-75%)		80 (70-80)	80 (70-81.25)		0.778‡
Pulse/minute, mean ± SD		85.4 ± 14.8	85.7 ± 12.2	-4.98 - 4.41	0.906†
Saturation-%, mean ± SD		97.3 ± 1.1	97.3 ± 1.2	-0.46 - 0.34	0.778†
Respiratory rate/minute, med (25-75%)		17 (16-18)	17 (16-18)		0.193‡
Photophobia, n (%)		43 (66.2)	39 (59.1)	-0.10 - 0.25	0.404*
Phonophobia, n (%)		22 (33.8)	15 (22.7)	-0.05 - 0.32	0.158*
Nausea, n (%)		35 (53.8)	35 (53)	-0.16 - 0.18	0.925*

*Pearson Chi-square test
†Student-t test
‡Mann Whitney-U
VR: Virtual Reality Enhanced Group, Diff: Difference, CI: Confidence interval, SD: Standard deviation, med: median, BMI: Body max Index, TA: Tension arterial

-2, -3, and -4 between groups were calculated as follows: 30.23–43.73, 35.77–51.47, 28.68–43.63, and 26.25–40.58, respectively. A comparison of only the VAS values within each group is presented as an error bar graph in Figure 2. Upon examining the graph, it can be observed that in the VR group, there was a decrease of over 50% in pain at the 15th minute.

Another primary endpoint, the need for rescue medication, is provided in Table 2. As shown, the difference between groups was statistically significant ($p < 0.001$; Pearson's chi-square test; 95% CI: –0.059 to –0.24).

The frequency distribution of patients whose

Table 2: Comparison of VAS differences and rescue medication usage between groups

Variables	Treatment group			p-value
	VR Mean ± SD	Control Mean ± SD	Diff- 95% CI	
VAS-0	80.89 ± 8.46	83.79±8.38	-5.80 - 0.01	0.51*
ΔVAS-1	48.46±18.12	19.42±12.95	23.48 – 34.40	<0.001*
ΔVAS-2	66.21±17.17	32.22±19.53	27.62 – 40.35	<0.001*
ΔVAS-3	74.47±14.75	46.90±21.17	21.26 – 33.87	<0.001*
ΔVAS-4	77.21±13.53	52.09±21.35	18.94 – 31.30	<0.001*
ΔVAS%-1	60.56 ± 22.68	23.57±15.61	30.23- 43.73	<0.001*
ΔVAS%-2	82.55 ± 21.58	38.93±23.75	35.77 – 51.47	<0.001*
ΔVAS%-3	92.50 ± 16.81	56.33±25.54	28.68 – 43.63	<0.001*
ΔVAS%-4	95.79 ± 14.63	62.37±25.40	26.25 – 40.58	<0.001*
Rescue drug use, n (%)	3 (4.6)	18 (27.3)	-0.059 - -0.24	<0.001†

*Independent samples-t test
†Pearson Chi Square
VR: Virtual Reality Enhanced Group, SD: Standard deviation, Diff: Difference, CI: Confidence interval, VAS: Visual analog scale

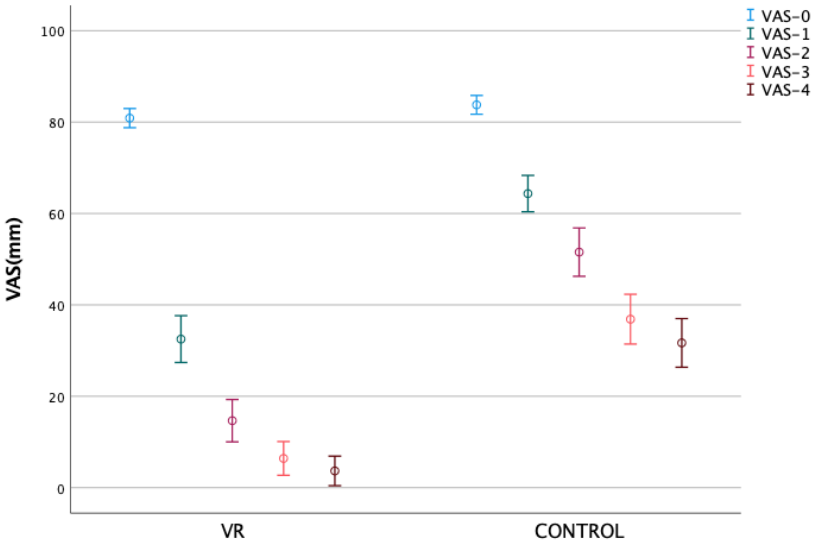

Figure 2. Changes in VAS values over measurement points for each group: Error bar analysis

pain levels dropped below 50 mm is presented using Kaplan–Meier analysis (Figure 3). The results showed that at 15 minutes, there was a dramatic improvement of over 80% in the VR group compared to the control group. In the control group, clinical significance appeared at the 60th minute. Similarly, in other measurements, the rate of improvement in the VR group was significantly higher than in the control group.

Side effects

Finally, the differences observed in terms of adverse effects are provided in Table 3. The results indicated no statistically significant variance in adverse effects.

DISCUSSION

In this study, our primary objective was to evaluate the analgesic efficacy of a simulated environment using a VR headset and classical music in patients with acute migraine attacks in the emergency department. Our findings revealed that adding a VR headset application to standard analgesic treatment significantly reduced pain

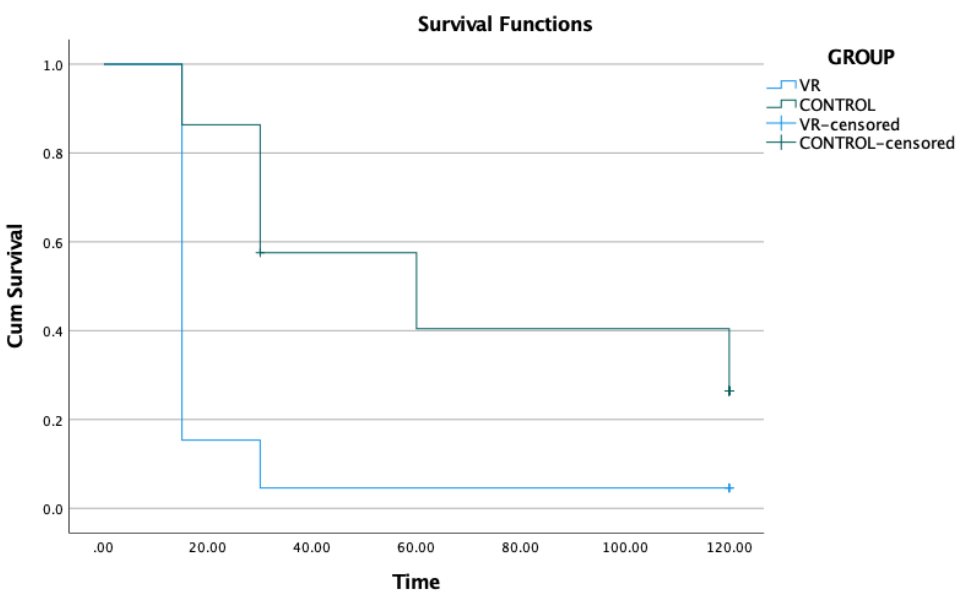

Figure 3. Pain recovery times according to VAS score: Kaplan-Meier analysis

Table 3: Side effects

Variables	Treatment Group			p-value
	VR	Control	Diff- 95% CI	
	n (%)	n (%)		
Nausea	2 (3.1)	1 (2.3)	-0.36 – 0.71	0.619*
Dizziness	1 (1.5)	2 (3.1)	-0.71 – 0.37	1,000*
Other side effects	0 (0)	0 (0)		-

*Fisher exact test
VR: Virtual Reality Enhanced Group, Diff: Difference, CI: Confidence interval

scores compared to the standard treatment group. Additionally, the VR group had a significantly lower need for rescue analgesia and a shorter recovery time.

Individuals experiencing headaches due to acute migraine attacks often present to EDs, constituting one of the commonest reasons for such visits.[1] The primary goal in EDs is to alleviate pain as quickly as possible and to minimize the need for rescue medication.[1,14] While there is no standardized treatment for pain management, the efficacy of analgesic therapies varies. Non-specific treatments are generally used for managing migraine-related headaches.[1] NSAIDs are widely used in the symptomatic treatment of migraines. Dexketoprofen, a member of the NSAID group, is actively used for various acute and chronic pain complaints.[15] It is one of the NSAID drugs shown to be effective in migraine treatment. Although many pharmacological agents are used, the treatment of acute pain in migraines remains a challenging issue in EDs. Therefore, alternative and complementary therapies are fruitful areas of investigation.[15,16]

VR technology, emerging as an alternative treatment, has gained traction in medical applications. Initially constrained by high costs, VR systems have become more adaptable and accessible for analgesic purposes thanks to the widespread use of high-resolution mobile phones.[17,18] In a review involving patients with spinal cord injuries, eight of nine studies reported the significant efficacy of VR technology in alleviating pain.[19] Furthermore, it has been shown to provide significant relief in chronic pain.[20] In a study by Frey *et al*., using VR technology to simulate an underwater environment with relaxing music was found to significantly alleviate pain during childbirth.[17] In four studies involving patients undergoing various types of surgical procedures, VR technology was evaluated for its analgesic efficacy in perioperative pain control, and significant relief was reported in all but one study.[21-24] To the best of our knowledge, no studies have tested this tool for analgesia in migraine cases; however, when considered alongside studies on pain related to other conditions, the overall findings of our study are in line with published literature.

Another primary endpoint of our study was the requirement for rescue medication. In a previous study involving migraine patients, the rate of rescue medication required in the dexketoprofen group was 22.3%.[16] Similarly, another migraine study reported that 24% of patients included in the dexketoprofen group required rescue medication.[25] The rescue rate of 18% in our patient group receiving only IV dexketoprofen at this point is consistent with the literature. However, it is noteworthy that only 3 patients (4.6%) in the VR headset group required rescue medication.

Among the significant additional contributions of this study is the effectiveness of a VR headset combined with dexketoprofen in rapidly relieving pain compared to dexketoprofen alone. In our study, 55 patients (84.6%) using VR therapy experienced a decrease in pain scores to below 50 mm within 15 minutes. This percentage was only 13.6% in the dexketoprofen-only group. The maximal efficacy of the medication in the control group, however, was observed after 60 minutes. In other studies involving dexketoprofen use in migraine patients, a similar trend was observed, with a reduction in VAS score within the first 15 minutes, but with effectiveness beginning after 30 minutes.[26] Our results indicate that analgesia can be achieved much more rapidly with the concomitant use of VR headsets. Additionally, VR headset use may enable early discharge of patients.

Prior studies on dexketoprofen for migraine treatment have shown either no or rare side effects.[16,27] Given consistent dosing in both arms of our study, the observed side effects were minimal and align with the literature. In a VR study, headache and dizziness were notably higher in the VR group.[28] Another review noted minor side effects in 6 studies, not reaching statistical

significance.[29] Our study's side-effect profiles show both parallels and contrasts with existing literature.

The strengths of the study include the VR group having received standard treatments alongside VR, a large sample size, and participants from two hospitals. Additionally, there was prolonged follow-up in the ED for up to 120 minutes, despite early relief. However, a significant limitation is the lack of blinding of researchers, patients, and clinicians evaluating VAS scores. The study design did not permit a standard placebo-controlled trial. Our randomization methodology, based on consecutive allocation, may have introduced time- or situation-related biases. The first 70 participants were assigned to the intervention group, and the subsequent 70 participants were allocated to the control group. This approach, implemented due to operational constraints, may have contributed to the observed demographic differences between the groups. Future studies should consider alternative methods, such as block or stratified randomization, to ensure a balanced demographic distribution.

Demographic differences between the intervention and control groups, particularly the trend of more males in the VR group and the significantly lower average age, despite not being statistically significant, represent limitations of our study. Younger individuals, especially males, may be more familiar with VR technology and may exhibit greater comfort and participation during the intervention.

In conclusion, this study assessed the efficacy of VR technology and music in managing migraine pain in an emergency room setting. The VR group showed significantly greater pain reduction and lower rescue analgesic use compared to the control group. Patients with VR experienced faster pain relief without notable differences in side effects, indicating VR's potential in acute migraine treatment. Given the importance of acute migraine management in emergency care, VR headsets could be valuable tools for further exploration of treatment approaches.

DISCLOSURE

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Conflicts of interest: None

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