Analgesic and Anxiolytic Effects of Virtual Reality During Minor Procedures in an Emergency Department: A Randomized Controlled Study



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Study objective: We aimed to assess the analgesic and anxiolytic efficacy of distraction, a nonpharmacologic intervention provided by 3-dimensional (3D) virtual reality (VR) compared with that provided by 2-dimensional (2D) VR during minor emergency department (ED) procedures.

Methods: This randomized controlled study conducted in the ED of a teaching hospital included patients aged more than or equal to 18 years undergoing minor procedures. The patients watched the same computer-generated VR world either in 3D in a head-mounted display (intervention) or in 2D on a laptop screen (control). Our main outcomes were pain and anxiety during the procedure, assessed on a 100-mm visual analog scale. Secondary outcomes included the impression of telepresence in the computer-generated world assessed using the Igroup Presence Questionnaire, and the prevalence and intensity of cybersickness measured on a 100-mm visual analog scale.

Results: The final analysis included 117 patients. The differences in median procedural pain and anxiety levels between the 2D and 3D VR groups were not significant: -3 mm (95% confidence interval [CI] -14 to 8) and -4 mm (95% CI -15 to 3), respectively; the difference in telepresence was 2.0 point (95% CI 0 to 2.0), and the proportion difference of cybersickness was -4% (95% CI -22 to 14), with an intensity difference of -5 mm (95% CI -9 to 3).

Conclusion: During minor procedures in adult patients in the ED, distraction by viewing a 3D virtual world in a head-mounted VR display did not result in lower average levels of procedural pain and anxiety than that by 2D viewing on a screen despite a higher sense of telepresence. There were no significant differences in the prevalence and intensity of cybersickness between the 2 groups. [Ann Emerg Med. 2023;81:84-94.]

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INTRODUCTION

Background

Pain is present in approximately 60% of patients on admission to the emergency department (ED); for approximately 50% of them, pain is their chief complaint.^{1,2} Furthermore, pain is frequently aggravated or caused by minor diagnostic or therapeutic medical procedures during an ED visit.^{3,4} In addition, anxiety is experienced by up to 75% of ED patients, triggered by the unexpected circumstances of their admission and the inherent uncertainty of care, which often includes the prospect of painful procedures.⁵⁻⁷ Pain and anxiety fuel each other because anxiety is associated with greater selfreported pain intensity, decreased pain tolerance, lower satisfaction with pain management, and pain-related catastrophism.^{5,8} Although ED pain management practices have improved over the years, effective and timely analgesia remains challenging.⁹ Notably, pharmacologic treatment is further complicated by the ongoing opioid crisis, and the use of nonpharmacologic analgesic modalities is encouraged.¹⁰ Thus, there is a need for new evidence-based nonpharmacologic management of anxiety and pain, with the latter having become a scorable element of performance for hospital accreditation by the Joint Commission since 2018.^{11,12} However, continued investigation has been encouraged to confirm the safety and effectiveness of nonpharmacologic interventions to reduce pain in the ED.^{10,13}

Editor's Capsule Summary

What is already known on this topic Distraction techniques can aid patient comfort during painful or anxiety-provoking procedures.

What question this study addressed

Which distraction device format best reduces pain and anxiety during minor emergency department procedures: 3-dimensional virtual reality or flatscreen?

What this study adds to our knowledge

In this randomized controlled trial of 117 adults, procedural pain and anxiety levels were similar between devices.

How this is relevant to clinical practice

Three-dimensional virtual reality may not enhance effective distraction relative to flat-screen interventions.

Distraction is a nonpharmacologic strategy that is often applied during medical procedures to decrease pain and anxiety. The mechanisms underlying its effect seem to be multimodal, and theories include the voluntary redirection of attention to specific nonpainful stimuli, differential activation of cerebral areas associated with sensory and affective pain signal processing, and competition between the distracter and the pain signal for finite attentional resources allocated for nociception.^{14,15} According to the latter theory, distraction methods that provide a greater cognitive load or engage more of the patient's senses should provide greater relief from pain and anxiety.^{15,16} Virtual reality (VR), presented with a VR headset, provides a large cognitive load because it offers patients a more immersive 3-dimensional (3D) experience compared with that provided through 2-dimensional (2D) viewing as well as multisensorial stimulation (vision and sound).^{17,18} Patients feel virtually present in the 3D world, and this telepresence has been proposed to be vital to its effectiveness.¹⁹ The therapeutic effects of VR seem to be attributable to the differential activation of the cerebral and midbrain areas devoted to attentional processes, emotional processes, and pain modulation.²⁰ The evidence so far supports the use of VR to reduce procedural pain and anxiety during burn care or placement of venous access, mainly in children and adolescents.²¹⁻²⁴

However, it is uncertain whether these effects are specific to 3D VR and the telepresence mechanism or whether they could be achieved by simpler distraction methods, as suggested in previous comparative studies.²⁵ Moreover, 3D VR use for adult patients in the ED has not been the subject of much research to date.

Importance

³D VR may contribute in reducing the burden of unrelieved pain and reducing opioid use in the ED for adult patients undergoing common painful minor procedures.²⁶ However, a VR headset cannot be used for all ED patients and may be a source of nosocomial infections. In addition, although it is becoming a more affordable technology, a VR headset remains an expensive and fragile piece of equipment. Given these limitations, to be worthwhile, a VR-based approach would need to provide patients with greater analgesia and anxiolysis than what can be achieved by a projection of a virtual environment on a computer screen, a far simpler and cheaper distraction method.

Goals of This Investigation

The objective of this study was to investigate whether distraction by the diffusion of a computer-generated 3D environment through a VR headset would lead to lower levels of pain and anxiety than those observed with 2D diffusion of the same virtual environment during minor procedures in the ED. A secondary aim was to assess the acceptability of VR by patients and health care staff in this environment.

MATERIALS AND METHODS

Study Design and Setting

This was a parallel-design, randomized controlled trial conducted in a single ED of a 1,500-bed university hospital that serves as the primary care center for the city of Lausanne and a tertiary care center for the region and neighboring states. Our ED receives around 45,000 patient visits annually. The study was conducted between February 12, 2020, and September 23, 2020. It was approved by the Ethics Committee of the Canton of Vaud, Switzerland (protocol CER-VD N°2019-02276) and registered on the Clinicaltrials.gov website (study N° NCT04273958). Our study results are reported in accordance with the Consolidated Standards of Reporting Trials guidelines (Appendix E1 [part 1], available at http://www.annemergmed.com/).²⁷

Selection of Participants

Patients aged more than or equal to 18 years who were admitted to the ED were eligible if their management required any of the included minor procedures: suturing, wound exploration, casting, fracture reduction of joint dislocation or fracture, thoracotomy, paracentesis, or arterial blood gas measurement. Patients were recruited in the presence of the investigators from 8 AM to 6 PM. Patients were excluded if they were clinically unstable, were unable to understand French or the use of a visual analog scale (VAS), were hard of hearing or visually impaired, had a head injury that precluded the use of a VR headset, received procedural sedation, were incarcerated, or were previously enrolled in this study.

Interventions

The study was conducted at the bedside, either in an ED examination room or in a procedure room. Before the intervention, the patients received partial disclosure of the study design because they could not be blinded to their group assignment. Patients were informed of the general goal of the study (ie, to investigate the benefits of distraction) but not the specifics of the intervention. After obtaining verbal consent, patients were randomized in a 1:1 ratio between the 2 arms of the study, with a randomnumber table uploaded before the initiation of the study in the randomization module of RedCap, hosted at Lausanne University Hospital.²⁸ One of the investigators (T.E., L.B.) then set up the VR headset or presented the laptop screen to a patient. The displayed environment was a Zen garden developed by Healthy Mind for therapeutic use, incorporating audio elements of clinical hypnosis with suggestions regarding breathing promoting cardiac coherence, as well as relaxing music. The VR world was projected either in 3D using a VR headset or in 2D on a 14-inch laptop screen, with sound played through headphones with active noise reduction in both the groups. During the coronavirus disease 2019 pandemic, patients were fitted with disposable VR hygiene face masks, and headphones were protected by disposable headphone covers. Between each patient, the VR headset and headphones were thoroughly disinfected with antiviral wipes. The patients watched the virtual world video for a maximum of 5 minutes during preparation for the minor procedure, then during the whole procedure, and then for an additional 5 minutes after its completion. After data collection was complete, the patients were provided with a full description of the study and offered to sign the informed consent form.

Measurements

The investigators recruited participants, explained the study to them, obtained their informed consent, instructed them on the study procedure, and collected data on a digital tablet.

Measurements of pain and anxiety were performed immediately before the beginning of the procedure (preprocedural pain and anxiety) and at the end of the video after the completion of the procedure (retrospective procedural and postprocedural pain and anxiety). The patients quantified their own pain and anxiety intensities on an electronic VAS ("how intense is your pain/anxiety?") by moving a marker on a 100-mm line displayed on a digital tablet, with VASs anchored with "No pain/Worst pain imaginable" and "Not at all anxious/Extremely anxious." The feeling of telepresence was measured with the Igroup Presence Questionnaire. The Igroup Presence Questionnaire is composed of 14 statements grouped into 4 categories: (1) spatial presence (the sense of being physically present in the virtual environment), (2) involvement (attention devoted to the virtual environment and experienced involvement), (3) experienced realism (the subjective experience of realism in the virtual environment), and (4) the general sense of being in the virtual environment. Each question is rated on a 7-point scale (0 to 6), with greater scores indicating a greater sense of presence. The patients answered the 14 questions directly on the digital tablet. The Igroup Presence Questionnaire has good internal consistency, with a Cronbach's α of 0.87 for the complete scale and approximately 0.75 for each subscore.²⁹ Cybersickness, a symptom similar to motion sickness that occurs with exposure to a virtual environment, and dissociation, defined as mental separation from the present environment, were assessed using 2 100-mm electronic VASs at the end of the procedure. The comfort and acceptability of these distraction technologies were evaluated by the patients on an electronic VAS ("How comfortable do you feel when using this technology?" ranging from not at all comfortable to completely comfortable and "How acceptable you find the use of this technology?" ranging from totally unacceptable to totally acceptable). Physicians' perceived utility of these distractions during the procedure was evaluated ("Did the technology help you during the procedure?," "Did the technology interfere with the procedure?" using categorical answers for both questions: yes, no, uncertain).

Outcomes

The main outcomes of this study were the patients' selfassessment of their maximal pain and anxiety intensity during the procedure. The secondary outcomes were the patients' evaluation of the feeling of telepresence, dissociation, and cybersickness immediately after the procedure; the association of these subjective measures with the intensity of pain or anxiety was also assessed.

Primary Data Analysis

We did not perform an intention-to-treat analysis because the main outcomes were missing in patients who did not complete the intervention; we only performed a per-protocol analysis.

Descriptive data are presented by medians and interquartile ranges for continuous variables, and proportions for categorical variables, as appropriate. The effect size between the groups was calculated as the difference between pseudomedians with nonparametric 95% confidence intervals using the Hodges–Lehmann method.^{30,31} The main outcome distribution between the randomized groups was also compared using the Wilcoxon-Mann-Whitney rank sum test for continuous variables. Missing data were not imputed. The statistician (P.T.) who conducted the analyses was blinded to the patients' group assignment.

Exploratory Analysis

Randomized clinical trials provide estimates of the average treatment effect but are less well suited for understanding the heterogeneity of treatment effect across individuals.³² We assessed a possible heterogeneous effect of the intervention (ie, 2D versus 3D VR) by conducting post hoc exploratory analyses using 2 different approaches: (1) risk-stratified analyses and (2) treatment-effect analyses.³³⁻³⁸

Briefly, in a risk-stratified analysis of treatment/ intervention, the effect is examined indirectly after having built risk strata without taking into account treatment allocation. On the other hand, in a treatment-effect analysis, effect modifiers (ie, interactions between treatment and potential effect modifiers) are introduced into the regression model to directly assess the heterogeneity of the effect. Risk-stratified analyses may be less subject to falsepositive findings than direct treatment-effect approaches. However, the latter may turn out to be more powerful than indirect ones.^{39,40} Here, we used both the approaches to assess a possible differential benefit of the distraction techniques (ie, 2D and 3D devices). Considering the 2D device as the reference, we referred to a heterogeneous intervention effect when patients in the 3D VR group responded differently from those in the 2D VR group. The details of these analyses are presented in Appendix E1 (parts 2 to 4).

Sample Size

Procedural pain intensity in the ED has been shown to vary according to the procedure, ranging from 25 mm to 65 mm.⁴ Therefore, we assumed that the mean procedural

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pain intensity would be 50 mm, with an SD of 25 mm. With this assumption and using a power of 0.8 and an α of 0.05, a sample of 60 patients per group was needed to demonstrate a clinically significant lower average pain level of more than or equal to 13 mm in the VR group.⁴¹ Assuming 10% attrition, the final sample size was 66 patients per group. All analyses were performed using Stata version 16 (StataCorp).

RESULTS

Patient Characteristics

Of the 253 screened patients, 131 were randomized, and 8 were excluded after randomization (Figure 1). Participants' baseline characteristics are presented in Table 1. Overall, the average age was 43.5 ± 17.2 years, with 64% of the patients being men. Most patients were admitted for a trauma-related cause, followed by surgicalrelated and medicine-related causes. The most common procedure was wound exploration and sutures, followed by fracture reduction and casting, and finally punctures. During wound exploration and suturing, local anesthesia was always delivered. Overall, 28% of the patients received systemic analgesics within 2 hours of their procedure. The percentage was 54% for those suffering from fractures/ dislocations, 24% for those undergoing suturing, and 18% for those undergoing puncturing. Analgesics were mostly acetaminophen or nonsteroidal anti-inflammatory drugs; 21% of patients were afraid of the planned procedure, and 54% of patients wanted to remain in verbal contact with the physician during the procedure. The preprocedural pain and anxiety intensity levels were mild. No rescue systemic analgesics were administered in either of the groups during the procedure. The main outcome was missing in 6 patients; hence, data from 117 patients were available for analysis, 62 in the 2D screen group and 55 in the VR group.

Outcomes

Pain and anxiety. There was no statistically significant difference between the groups for the maximal level of pain or anxiety during or after the procedure (Table 2 and Figure 2).

Cybersickness. Cybersickness affected 51% of the patients. It was of low intensity and without significant differences between the 2 groups. One patient in the 2D group had nausea but none did in the 3D VR group (P=.99). No patient vomited.

Presence/dissociation. Patients in the 3D VR group felt significantly more dissociated during the intervention than did those in the 2D group. Based on the Igroup Presence

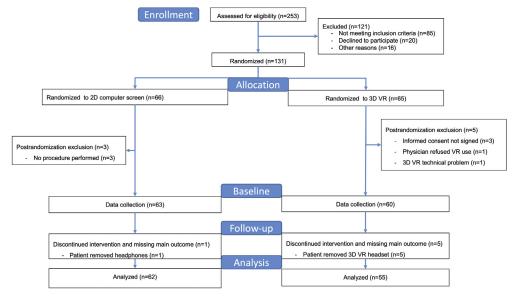


Figure 1. Consolidated Standards of Reporting Trials study flow diagram.

Questionnaire, the scores for the global impression of presence and sense of spatial presence in the virtual scenario were higher in the VR group, whereas experienced realism and involvement were not different between the groups.

Comfort and Acceptability

The patients rated both the distraction methods as very comfortable and acceptable. Nevertheless, in the 3D VR group, 5 (8.3%) patients took off the headset during the procedure, whereas (1.6%) patient interrupted the viewing in the 2D group (P=.11). Health care clinicians believed that either of the distraction types was of assistance in the majority of procedures. Although VR was reported as being helpful more often, this difference failed to reach statistical significance. A small and similar proportion of physicians believed that the distraction method interfered with the procedure.

Exploratory Analyses

The exploration of a potential heterogeneous impact of our intervention showed that 3D VR had differential analgesic and anxiolytic effects based on preprocedural anxiety. On one hand, compared with the 2D group, only the patients in the 3D VR group with no or very low preprocedural anxiety experienced lower procedural pain levels: in those with a preprocedural anxiety level of less than of equal to 12 mm, the procedural pain level was 22 mm lower in the treatment-effect analysis (Appendix E1 [part 3]; analyses on P10, 13 to 14; Figures on P13 and P15). On the other hand, the patients in the 3D VR group with very high preprocedural anxiety tended to have lower procedural anxiety levels. The procedural anxiety level was 18 mm lower, although this difference failed to reach significance (Appendix E1 [part 4]; analyses on P20 and P23, figures on P23 to 25).

LIMITATIONS

Our study presents several limitations. First, it was not possible to conduct a double-blinded study. Patients and investigators were aware of the assigned intervention arm. To minimize biases, patients received partial information regarding the intervention arms before their participation. Patients self-assessed their pain and anxiety levels digitally without interference from the investigators. In addition, the analyses were performed by a statistician (P.T.) blinded to group assignment. Second, our study sample size was moderate. However, the power was calculated conservatively, and, to the best of our knowledge, it is one of the largest VR randomized studies conducted in an ED and the only one including only adults. We did not reach the prespecified sample size because of postrandomization exclusions. Nevertheless, it is unlikely that the addition of the 3 missing patients would have led to different conclusions given the negligible between-group differences in the main outcomes. Third, when physicians needed to interact for the sake of the ongoing procedure with their patients in the 3D VR intervention group, the headset had to be removed, interrupting the viewing and potentially reducing the benefits of VR. Nevertheless, patients in the 3D VR group had higher telepresence and dissociation scores, suggesting successful absorption in the 3D VR virtual environment. In fact, this can be considered a

Table 1. Patient baseline characteristics.

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manipulation check: patients in the 3D VR group were more dissociated from the ED environment than those in the computer group. Fourth, we used only 1 video for all the patients (Zen garden), thus not giving them a choice. However, patients' choice of an environment that they like influences the efficacy of VR.¹⁷ Nevertheless, this limitation was identical in both groups. Fifth, the health care clinicians may have been influenced by the mode of distraction assigned to a patient and may have had different procedural, verbal, or nonverbal behaviors. We were unable to assess these potential differential performances and behaviors, which are likely to also be present outside the frame of the study and to affect VR efficacy more globally. Sixth, we included consecutive patients during the

Although this sampling method may have introduced a selection bias within eligible patients, its magnitude is probably small.⁴² Seventh, given that both our groups benefited from a type of distraction, it is impossible to know the magnitude of the effect of distraction on pain and anxiety. The study was designed to test the specificity of the effects of 3D VR (versus the effects of watching a movie on a 2D screen), and it appears that the magnitude of these effects is comparable. Eighth, we used a per-protocol instead of an intention-to-treat analysis, which could have overestimated the effect size of the 3D VR intervention. However, our study did not demonstrate lower levels of pain and anxiety in the 3D

investigators' presence, constituting a convenience sample.

Table 2.	Main an	d secondary	outcomes.
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Outcomes	Ν	2D Screen n=62	3D Virtual Reality $n = 55$	Difference (95% Cl
Main outcomes				
Procedural pain, [mm] median (IQR)	117	50 (40 to 61)	47 (33 to 60)	-3 (-14 to 8)
Procedural anxiety, [mm] median (IQR)	117	36 (15-62)	32 (7 to 51)	-4 (-15 to 3)
Secondary outcomes				
Postprocedural pain, [mm] median (IQR)	117	12 (2 to 36)	19 (4 to 49)	7 (-3 to 11)
Postprocedural anxiety, [mm] median (IQR)	117	10 (1 to 34)	11 (0 to 31)	1 (-3 to 5)
Cybersickness, n (%)	117	33 (53)	27 (49)	-4 (-22 to 14)
Cybersickness intensity, [mm] median (IQR)	60	14 (6 to 36)	9 (2 to 36)	-5 (-9 to 3)
Dissociation, [mm] median (IQR)	117	34 (10 to 61)	50 (22 to 68)	16 (0 to 22)
Igroup questionnaire scores, [points] median (IQR)	117			
Global impression of presence		2.0 (1.0 to 4.0)	4.0 (2.0 to 5.0)	2.0 (0 to 2.0)
Spatial presence		2.4 (1.2 to 3.4)	3.8 (2.6 to 4.2)	1.4 (0.6 to 1.6)
Experienced realism		2.4 (1.8 to 3.3)	3.0 (2.3 to 3.8)	0.6 (0 to 0.8)
Involvement		2.3 (1.3 to 3.3)	2.8 (2.0 to 3.5)	0.5 (0 to 0.8)
Patients' perception	117			
Comfort, [mm] median (IQR)		81 (66 to 92)	82 (70 to 96)	1 (-4 to 9)
Acceptability, [mm] median (IQR)		91 (69 to 100)	91 (77 to 100)	0 (-2 to 6)
Health care clinicians' perception	114			
Helpful for the procedure, n (%)				
Yes		35 (57)	38 (72)	15 (-3 to 30)
No		5 (8.2)	7 (13)	4.8 (-6 to 16)
Uncertain		21 (34)	8 (15)	-19 (-35 to -4)
Impediment for the procedure, n (%)				
Yes		3 (4.9)	2 (3.8)	-1.1 (-8.6 to 6.3)
No		51 (84)	46 (87)	3 (-10 to 16)
Uncertain		7 (11)	5 (9)	-2 (-13 to 9)

VR group. Finally, our study was monocentric; hence, its external validity is limited.

DISCUSSION

Our study is one of the largest randomized trials to compare 2 methods of audiovisual distraction in order to reduce pain and anxiety during a painful procedure in adult patients in the ED, one involving 3D VR and the other a 2D screen. Both the technologies were considered suitable and comfortable by patients and had minor side effects, although 1 patient refused to wear the 3D VR headset and 4 removed it during the intervention. The health care team also considered both technologies to be helpful. VR induced a higher sense of telepresence and a greater degree of dissociation than the 2D screen. Contrary to our hypothesis, patients immersed in a virtual Zen garden by a 3D VR head-mounted display did not experience lower levels of procedural pain and anxiety compared with those in patients watching the same environment on a 2D laptop screen. However, these conclusions hold for the comparison of average effects. We, therefore, conducted post hoc analyses to investigate whether the effect of the intervention could have been heterogeneous. Interestingly, we found that patients in the 3D VR group with no or very little anxiety levels had lower levels of procedural pain.

Our study hypothesis was based on evidence from previous trials that compared 3D VR with a nodistraction control, in which 3D VR was a superior method of relieving pain.⁴³⁻⁴⁵ Our results suggest that projecting distracting materials through a VR headset may have additional benefits compared with a computer screen viewing regarding pain in specific subpopulations with no or very little preprocedural anxiety levels. The telepresence score represents a manipulation check: patients in the 3D VR group were more absorbed in the projected materials; however, this did not correlate with

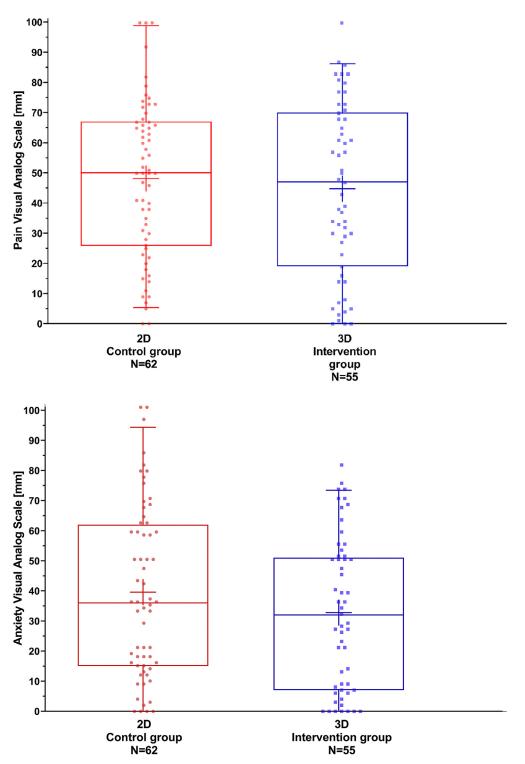


Figure 2. Individual procedural pain and anxiety levels by randomization arm. Top: Pain level; Bottom: Anxiety level; Box plot: the center line represents the median and the cross represents the mean; the box contains the 25th to 75th percentiles (interquartile range); the whiskers represent 95% confidence intervals. Each patient is represented by a point. Comparison of the distribution between groups with the Wilcoxon-Mann-Whitney rank sum test: P=.61 for pain, and P=.20 for anxiety.

lower pain levels. This finding speaks against a specific pain-alleviating effect of telepresence, at least at the level we were able to induce.

Several factors could explain this lack of superiority of 3D VR for all patients. First, many early studies in the VR literature failed to include a control condition or were not

randomized, which could have led to an overestimation or misattribution of the effect. In fact, our results confirmed, in an adult ED population, the earlier findings reviewed in a meta-analysis that suggested that 3D VR was not superior to other cognitive distractions, such as watching a video on a television set or playing a videogame.⁴⁶⁻⁴⁹ Furthermore, a recent Cochrane review found insufficient high-quality evidence demonstrating the effectiveness of 3D VR distraction compared with other non-VR distraction techniques in reducing acute pain intensity, at least in children in any health care setting.⁵⁰

On the other hand, our study may have failed to detect a difference in average effect in favor of VR because of the specificities of its design. Many prior studies have been conducted on children and adolescents, whereas ours included only adults. Children are more distractible, and age has been negatively associated with the sense of telepresence.⁵¹⁻⁵³ Nevertheless, despite this lower sense of telepresence or VR realness, older patients may still benefit from similar pain reduction in certain circumstances, such as during physical therapy.⁵² Our study used a passive VR digital world. Active VR, in which patients interact with the virtual environment, may be more effective for reducing pain and situational anxiety.⁵⁴ Furthermore, the ED is a chaotic and noisy environment that may not be an ideal setting for VR or any distraction technique to be effective.^{17,55} Finally, patients were submitted to procedures during which they often wanted to stay in contact with the physician; however, self-rated scores of absorption do not support a significant interference with 3D VR.

Nevertheless, our exploratory analyses suggest that the analgesic and anxiolytic effects of 3D VR vary across patients. This heterogeneity may be related to the preprocedural anxiety level. As shown by others, the anxiety level is positively associated with a heightened perception of acute experimental pain and higher pain levels during minor procedures, such as wound dressing or intramuscular injection.⁵⁶⁻⁵⁸ High levels of anxiety and fear of pain toward an upcoming procedure are also associated with selective attention to pain. As fewer cognitive resources are allocated to distraction, this may counteract the analgesic effect of VR.⁵⁹⁻⁶² Our results would, thus, extend to a clinical ED setting experimental findings from studies conducted in pain-free volunteers, in whom tolerable pain stimuli were applied without a threat to their health or physical integrity. If additional studies confirm that preprocedural anxiety hinders VR distraction, it may become a target to potentiate the benefits of VR.

In summary, distraction by the projection of the same virtual world in a head-mounted 3D VR display did not result in lower average levels of procedural pain and anxiety than those achieved by a simple projection on a laptop screen during painful procedures in adult patients in the ED. Additional research is needed to confirm, first, that distraction is superior to the absence of distraction to relieve pain and anxiety and, second, to test whether more immersive and interactive 3D VR programs lead to the superiority of 3D VR over a simple 2D screen. Nevertheless, on the basis of these results, if clinicians want to use visual distraction as a nonpharmacologic method to reduce procedural pain in adult patients in the ED, the simpler projection method should be used given the costs and limitations associated with the 3D VR technology.

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Author contributions: LB and TE contributed equally to this work. LB, TE, CB, and OH conceived the study and designed the trial. DCB, TC and OH supervised the performance of the trial and the data collection. LB and TE recruited patients and managed the data, including quality control. OH and PT provided statistical advice on study design and analyzed the data. LB, TE, CB, TC and OH drafted the manuscript, and all authors contributed substantially to its revision. OH takes responsibility for the paper as a whole.

All authors attest to meeting the four ICMJE.org authorship criteria: (1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND (2) Drafting the work or revising it critically for important intellectual content; AND (3) Final approval of the version to be published; AND (4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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