

Implementation of virtual reality technology to decrease patients' pain and nervousness during colonoscopies: a prospective randomised controlled single-blinded trial

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ABSTRACT

Background

Improved patient satisfaction in endoscopy is worthy of study as it is an invasive and potentially uncomfortable procedure. There is growing literature on patient satisfaction assessment in endoscopy as part of improving quality assurance. This study aimed to determine whether virtual reality (VR) technology can decrease patients' pain and nervousness during colonoscopies.

Methods

Patients enrolled without sedation were randomly categorised into groups that watched VR (VR group; n=58) and those that did not watch VR (control group; n=59). The primary outcomes were pain score and skin conductance. Secondary endpoints included heart rate, systolic and diastolic arterial pressures, overall patient satisfaction, willingness to repeat the procedure, the difficulty of the procedure, the procedure duration, and bowel preparation.

Results

The median (interquartile range (IQR)) pain scores were 7 (6–8) and 5 (4–6) in the control and VR groups, respectively ($p<0.001$). The median (IQR) skin conductance values after colonoscope insertion were 0.660 (0.490–0.840) and 0.390 (0.280–0.600) in the control and VR groups, respectively ($p<0.001$). Overall, patient satisfaction was significantly improved with the use of VR, along with a significant reduction in the difficulty perceived by the endoscopist.

Conclusion

VR technology helped to reduce patients' pain and nervousness and to improve patients' satisfaction during colonoscopies.

KEYWORDS: colonoscopy, virtual reality, pain and satisfaction

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Introduction

Colonoscopy is a primary method for examining colorectal diseases. However, the procedure is uncomfortable for the patient due to abdominal discomfort among other factors.¹ Sedation is the routine choice to alleviate pain and discomfort around the globe. However, sedation colonoscopy requires longer wait times for appointments and accompaniment by family members in China. Therefore, many patients choose non-sedation colonoscopy.

Several methods have been incorporated to relieve patients' discomfort, including variable-stiffness colonoscope and music.² However, no method has been widely applied in clinical settings yet.

Virtual reality (VR) is a recent technology that has generated a multimedia technology application platform. A recent systematic review of randomised controlled trial studies on VR as pain relief in various medical settings has shown that VR is a helpful clinical tool for pain distraction.³ However, no relevant research has been reported on the use of VR to improve the acceptability of colonoscopy.

In our study, a randomised controlled single-blinded trial was conducted to examine the use of VR technology to determine whether it holds beneficial effects for patients' pain control, nervousness and satisfaction during outpatient colonoscopy without sedation.

Patients and methods

Ethics and trial registration

Our single-blinded randomised controlled trial was conducted between February 2019 and December 2019 and is reported following the CONSORT guidelines. All participants signed an informed consent form prior to participation in the study. The study protocol was approved by the local ethics committee of Shanghai Hospital. The study followed the guidelines issued by the International Council for Harmonisation (ICH). This study was registered at with Research Registry (ID: researchregistry5373).

Sample size, inclusion and exclusion criteria, and randomisation process

The sample size of the enrolled patients was estimated based on the Visual Analog Scale (VAS) pain scores (intervention group:

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5.1±2.5; control group: 7.0±2.4) as reported by Lee *et al.*⁴ With a $p=0.05$ and a power of 90%, the minimum sample size was calculated to be 42 in each group.

The inclusion criteria were a sedation-free colonoscopy and age between 20 and 75 years. The exclusion criteria were hearing and visual disorders; psychiatric illnesses; chronic pain disorders; Alzheimer's disease; a history of taking psychoactive drugs; and a history of taking beta blockers and Buscopan.

Patients were randomly categorised into two groups (VR group: watching VR; and control group: not watching VR) using the sequentially numbered opaque sealed envelopes technique (SNOSE). A doctor was responsible for the enrolled participants and assigned participants to interventions.

Procedure and intervention

Questionnaire investigation before colonoscopy

All patients received standard bowel preparation without any residue in stool before the colonoscopy. On the morning of the colonoscopy, all patients were admitted to the endoscopic unit and waited in a quiet area for about 30 minutes. All participants had been well informed about the purpose and procedure of the study. Prior to the examination, the questionnaire investigation involved questions about age, gender, marital status, educational background, previous abdominal surgeries, prior colonoscopy, habitual use of psychoactive drugs and anxiety score. The baseline anxiety score was measured based on the Depression Anxiety Stress Scale (DASS).⁵ Skin conductance, blood pressure and heart rate were monitored before the colonoscopy.

The VR and control groups

The patients in the VR group wore a head-mounted VR display (Nibiru 3.50.005, Nanjing, China) during colonoscopy (Fig 1a and 1b). The E4 wristband (Empatica, Milan, Italy), which can assess the patient's nervousness according to the shrinkage of pores, was attached to the wrist to monitor skin conductance (Fig 1a and 1c). The video and music content that was visualised on the VR hardware consisted of several short clips (with a total length 30 minutes) featuring tropical islands and forests with soothing music: 'With an orchid' by Yanni (based on suggestions from specialists working in the Department of Psychology, Naval Medical University, Shanghai, China). The patients in the VR group could choose their favourite videos and sound, which included options of symphonies, concerts and landscapes. These patients were exposed to approximately 30 minutes of VR therapy broadcasting before and during the procedure. Video and sound were provided via the VR machine and headphones. In the control group, the VR and headphones were worn without any videos or sounds. Headphones were connected to the VR machine to ensure that others did not hear the sound, and endoscopists could remain blinded to the group assignments.

Colonoscopy

The procedure was performed by the same experienced endoscopist who had at least 5 years of experience for all patients. A flexible video colonoscope (CV-290, Olympus, Tokyo, Japan) was used combined with carbon dioxide (CO₂) insufflations. The

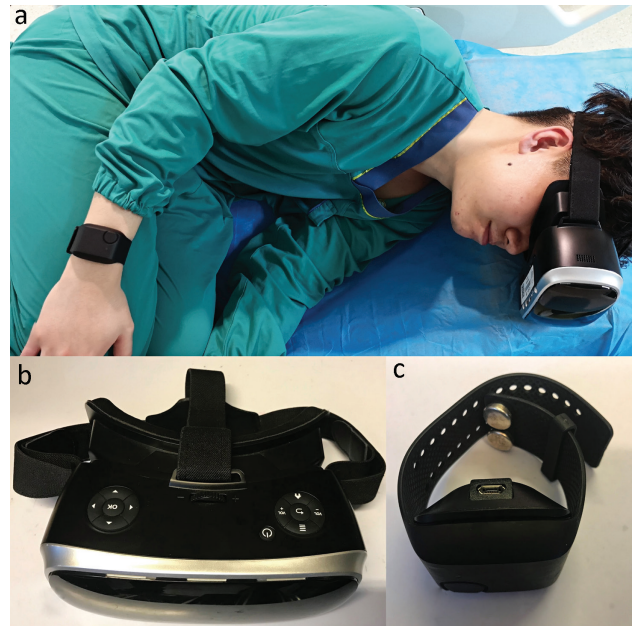


Fig 1. a) Head-mounted VR display and E4 wristband worn during colonoscopy. b) The head-mounted VR display (Nibiru 3.50.005, Nanjing, China) showed video and music content consisting of several short clips. c) The E4 wristband (Empatica, Milan, Italy) can assess the patient's nervousness from the shrinkage of pores attached to the wrist to monitor skin conductance.

heart rate, blood pressure and skin conductance were monitored throughout the procedure.

Outcome measures

The primary outcomes of this study were the patients' pain score and skin conductance. The pain intensity was measured according to the VAS.⁶ Skin conductance was recorded 5 minutes after the insertion of the colonoscope and prior to the beginning of the colonoscopy (this was baseline) using the E4 wristband to observe the patients' nervousness.

The secondary outcomes included patient satisfaction rating (not at all, very low, moderately and completely satisfied); willingness to repeat colonoscopy (not at all, very low, moderately and completely willing); difficulty of colonoscopy examination from the perspective of the endoscopist (not at all, very low, moderately and very difficult); bowel preparation (Boston Bowel Prep Scale: 8–9 points, 7 points, ≤6 points); procedure duration; heart rate; systolic arterial pressure; and diastolic arterial pressure. The heart rates along with systolic and diastolic arterial pressures were recorded 5 minutes after the start of the VR administration and prior to the insertion of the colonoscope.

Statistical analysis

For statistical analysis, SPSS version 21.0 (IBM, Armonk, USA) was applied. The variables were described for the VR group and control group separately. Pearson's chi-squared test and Fisher's exact test were used for analysing categorical variables. A t-test or Mann–Whitney *U* test was used to analyse differences in continuous variables based on the normality of

distribution. The results were considered to be significant if $p < 0.05$ (two-sided).

Results

Initially, a total of 156 patients participated in this study. Among these, 36 patients were excluded as 13 did not meet the inclusion criteria and 23 refused to participate due to the development of vertigo caused by VR. The remaining 120 patients were included in the study, with 60 patients randomised to each group. Two patients in the VR group and one patient in the control group were excluded after the randomisation process. A total of 58 patients in the VR group and 59 patients in the control group were included in the final analysis. A flow chart outlining the study design is presented in Fig 2. No significant differences in baseline characteristics were observed between the two groups (supplementary material S1).

The procedure did not involve any side effects. The median times for completing colonoscopy were 15 minutes and 16 minutes for the VR and control groups, respectively.

The major outcomes are listed in supplementary material S2. The median (interquartile range (IQR)) pain score was significantly reduced by VR from 7 (6–8) to 5 (4–6), $p < 0.001$ (Fig 3a). The skin conductance values were 0.660 (0.490–0.840) and 0.390 (0.280–0.600) in the control and VR groups, respectively ($p < 0.001$; Fig 3b). The difficulty and duration of the procedure were significantly reduced by VR ($p < 0.05$). Further, overall satisfaction correspondingly increased with VR ($p = 0.001$). At the baseline, 5 minutes prior to the colonoscope's insertion, the heart rate and the systolic and diastolic blood pressures were not significantly different between the two groups. After the insertion of the colonoscope, the heart rate was lower in the VR group than in the control group ($p < 0.001$), even though the systolic and diastolic blood pressures were not significantly lower ($p > 0.05$).

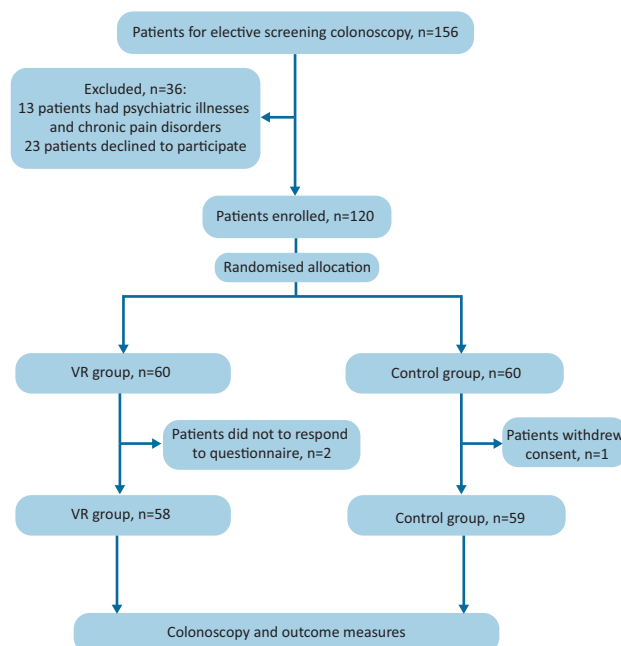


Fig 2. Study design for VR trial.

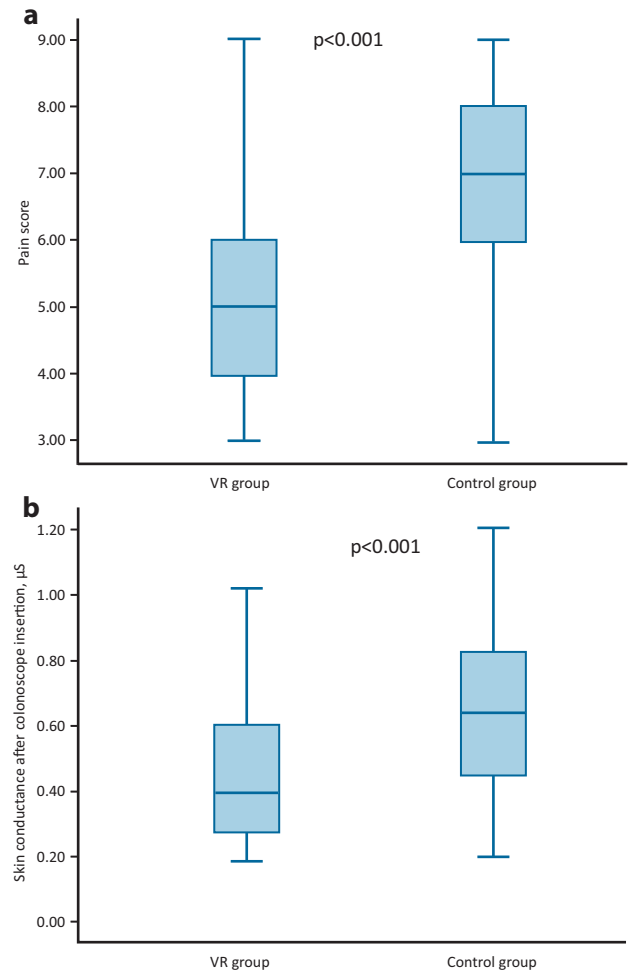


Fig 3. Comparison between the control group and the virtual reality group. a) Pain score. b) Skin conductance. VR = virtual reality.

Discussion

Colonoscopy is the most common method for gastrointestinal examination.⁷ Anaesthesia technology has been applied to colonoscopy, which has significantly improved the acceptance of colonoscopy examination.⁸ However, due to the long waiting time for appointments in China, most patients choose non-sedation colonoscopy. Blokzijl *et al* reported that, overall, 25.7% of patients were willing to start with VR instead of sedation, suggesting that VR may increase the percentage of patients who choose non-sedation colonoscopy.⁹ In our study, we evaluated the effect of VR technology on patients undergoing non-sedation colonoscopy.

The literature has shown that VR is advantageous as an attention diverter to relieve pain during medical processes.^{10,11} Chirico *et al* reported that VR and music could alleviate anxiety in breast cancer patients undergoing chemotherapy.¹² Moreover, VR has been found to be more effective than music alone in relieving anxiety, depression and fatigue. So far, only one pilot study has reported the application of VR in colonoscopy.¹⁰ Therefore, our study is the first randomised controlled trial to investigate the influence of VR on patients' pain and nervousness during

non-sedation colonoscopy. In our study, the pain was significantly lower in the VR group than the control group ($p < 0.001$).

The pain due to colonoscopy is often attributed to the spasm of smooth muscles. By choosing a favourable scenario, the patient can relax during colonoscopy. The results indicate that pain can be reduced through VR technology. Compared with the control group, the patients in the VR group enjoyed a significantly higher level of satisfaction in terms of pain control ($p = 0.001$). The difficulty of the procedure as perceived by the physician also was significantly reduced ($p = 0.011$). Further, VR technology also decreased the duration of the procedure ($p = 0.038$).

The beneficial effects of VR were confirmed through objective measures. A significant reduction in heart rate was observed 5 minutes after the insertion of the colonoscope. This is in accordance with the result that VR technology may decrease patients' nervousness, based on the observation on skin conductance ($p < 0.001$). Because VR acts as a consciousness distracter, it can shift the patient's attention, eliminate negativity and instil positive thoughts.¹³

Our study also has some limitations. First, silence in the headphones along with a missing video in the VR viewer could have a negative psychological impact on patients in the control group, thus increasing the discomfort of these patients. Second, we recruited patients both with and without prior experience with wearing VR; this might bias the subjective outcome measures. Third, we enrolled patients with pre-existing anxiety. And patients with previous history of trauma, particularly sexual abuse and fear of underlying cancer, were not excluded in this study; this may affect the results. In future studies, sub-group analysis will be done including the patients with anxiety. In addition, there is no analysis of what the assisting nursing team thought about the patient's tolerance/experience.

In conclusion, the results of our study reveal that VR technology improves patients' satisfaction and reduces their pain during colonoscopy. Therefore, routine application of VR is recommended for the patients undergoing non-sedated colonoscopy, although more research is required to confirm our findings. ■

Supplementary material

Additional supplementary material may be found in the online version of this article at www.rcpjournals.org/clinmedicine:

S1 – Baseline characteristics of participants in the VR and control groups.

S2 – Summary of primary and secondary outcomes for the VR and control groups.

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