The Effect of Virtual Reality on Pain and Anxiety During Colonoscopy: A Randomized Controlled Trial

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Cite this article as: Karaveli Çakır S, Evirgen S. The effect of virtual reality on pain and anxiety during colonoscopy: A randomized controlled trial. *Turk J Gastroenterol*. 2021; 32(5): 451-457.

ABSTRACT

Background: *The aim of the study is to evaluate the effect of virtual reality application during a colonoscopy on the pain and anxiety experienced by patients.*

Methods: *The study was conducted as experimental, randomized, controlled research. The study was carried out between October 15, 2017 and May 20, 2018 in the Endoscopy Unit of a Public Hospital in northern Turkey. The study sample consisted of 60 patients who underwent colonoscopy. The patients were divided into 2 groups by using simple randomization. The patients in the experimental group watched virtual reality applications during colonoscopy, whereas the patients in the control group underwent standard colonoscopy protocol. Colonoscopy was performed on patients in both groups by the same gastroenterologist without the use of anesthesia. The demographic data of both groups, pain levels during and after the procedure, before and after the procedure anxiety levels were evaluated.*

Results: *The mean age of the patients in the experimental group was 56.33 ± 11.81, the mean age of the patients in the control group was 56.20 ± 15.62. There was no statistically significant difference between the pre- and post-operative state anxiety score averages of the patients in the experimental and control groups. There was a statistically significant difference between the trait anxiety scores ($P < .000$) and pain scores ($P < .03$) during the procedure between both groups.*

Conclusion: *The virtual reality application was found to reduce patients' pain during the colonoscopy procedure. The virtual reality application, an easily available, inexpensive, and non-invasive method, can be used by nurses in pain management during colonoscopy.*

Keywords: *Nursing, virtual reality, pain, anxiety, colonoscopy*

INTRODUCTION

Colonoscopy is one of the endoscopic procedures used for the diagnostic and interventional procedures of the intestines.[1-3] Compared to other radiological imaging methods, the most important advantage of colonoscopy is that it can be used to evaluate symptoms and complaints as well as to obtain a biopsy when a differential diagnosis is needed.[3,4] In recent years, therefore, colonoscopy has been recognized as the gold standard for colon cancer screening.[5] Most patients consider colonoscopy a painful and uncomfortable procedure. Studies revealed that patients experience moderate anxiety during the colonoscopy procedure.[6-8] The reflex spasm resulting from stimulation of the colon in order to obtain a better image during colonoscopy, and acute distension resulting from flatulence may cause patients to experience pain during and after the procedure.[6,9] Studies have shown that patients experience pain and anxiety during the colonoscopy procedure.[6,8,10,11] The pain and anxiety that patients experience are not only related to the procedure, but also to the stress of the likelihood of getting cancer over time. Performing colonoscopy under sedation is widely used in clinical practice. However, sedation increases complications associated with colonoscopy and has potential risks, such as hypoxemia, hypoventilation, aspiration pneumonia, pulmonary embolism, and myocardial infarction.[5,7] Different drug regimens are used to manage pain during colonoscopy; however, the optimal regime is still debated.[12-14] In recent years, virtual reality has been widely used as a practice of distraction in clinical medical care to relieve pain. Virtual reality is a method of displaying computer images in order to isolate the individual from real life for a while. The virtual reality goggles, consisting of a head-mounted screen and a pair of glasses connected to a mobile phone, is a computer technology that creates a 3D environment.[15] The virtual reality application, originally designed for recreational purposes, has also been used in the medical field in line with the advances in computer technologies to reduce pain during invasive procedures. As an easily accessible,

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Received: **December 30, 2019** *Accepted:* **August 26, 2020** *Available Online Date:* **June 25, 2021**
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DOI: **10.5152/tjg.2021.191081**

non-invasive, and inexpensive method, it is preferred in clinical practice.[16] The virtual reality application is considered an effective tool for distraction during pain. The effect of virtual reality practice in reducing pain is associated with the limited attention capacity of the people. Pain requires attention, and if some of this attention can be redirected, the patient will respond more slowly to the pain signals. The virtual reality application does not block the pain signals, but interferes with signaling directly and indirectly, through pain perception, attention, emotion, concentration, memory, and other senses.[16-19] There are studies showing its effectiveness in the management of pain and anxiety in operations, such as burn debridement, wound care, endoscopy, acute and chronic pain, and chemotherapy applications.[7,18,20-22] There were studies in the literature that carry out pain and anxiety assessment using a virtual reality application during the colonoscopy procedure.[6,7,10,11,23] The audiovisual distraction method was not tested alone during the colonoscopy procedure performed without sedation in these studies. And also there is no such study on patients undergoing colonoscopy in Turkey. The aim of this study is to evaluate the effect of virtual reality applications during a colonoscopy on the pain and anxiety experienced by patients.

METHODS

The study was conducted an experimental, randomized, controlled research. The study was carried out between October 15, 2017 and May 20, 2018 in the Endoscopy Unit of a Public Hospital in northern Turkey. The study sample consisted of patients who underwent colonoscopy and met the research inclusion criteria (Patients who volunteered to participate in the study with written and verbal consent, who were over 18 years of age, who did not have any psychiatric illness, who did not have vision, hearing and cognitive problems, who were literate, who underwent colonoscopy by the same doctor without anesthesia). Patients who underwent gastroscopy were not included in the study (gastroscopy was performed on a different day in patients with iron deficiency anemia and in patients with hidden blood (+) in the gaita. Patients who were admitted to the endoscopy unit for a colonoscopy appointment were informed about the research. A total of 70 patients applied to colonoscopy appointments. Sixty patients (10 patients did not agree to participate in the study) were included in the study. After explaining the purpose of the research patients were randomly allocated into 2 groups by drawing lots using closed envelopes with numbers from 1 to 2. Those who selected number 1 were allocated to the control group, and those with number 2 formed the experimental group. Colonoscopy is done twice a week (Tuesday and Friday) in the endoscopy unit**.** In order to prevent the 2 groups from being affected by each other colonoscopy, appointments were scheduled on Friday for the patients in the experimental group and on Tuesday for the patients in the control group. The sample of the study consisted of 60 patients, who underwent colonoscopy by the same physician (Gastroenterology specialist who performs about 600 colonoscopy per year) in the Endoscopy Unit, who met the research inclusion criteria, patients with latent blood positive in gaita, according to KETEM (Cancer Early Diagnosis, Screening and Training Center) screening, patients with a family history of colon cancer, >50 years of age, and patients with iron deficiency anemia diagnosed in the internal medicine outpatient clinic and patients who underwent colonoscopy for screening purposes and who agreed to participate in the study. Only 9 patients had polyps (5 in the control group, 4 in the experimental group). All polyps were dimunitive polyps and each patient had 1 polyp. They were removed piecemeally. None of the polyps extended the duration of the procedure. Of the patients, 30 patients who watched images through the virtual reality application were included in the experimental group, and 30 patients who undergo the standard protocol were included in the control group. The study plan is shown in Figure 1.

Statistical Analysis

The sample size was determined through power analysis. The study power analysis in G* Power, version 3.1 (Heinrich-Heine University of Dusseldorf, Germany) computer program was deployed to determine the sample size. For repeated-measures analysis of variance, the effect size was calculated as $f=0.55$. For the 95% CI ($P=.05$) and 0.90 power (1-β), the total number of samples reached was calculated as 30 patients in both groups. The results of the study were analyzed in the Statistical Package for Social Sciences (SPSS) Statistics 23.0 (IBM Corp., Armonk, NY, USA) package program. Descriptive statistical methods (number, percentage, average, standard deviation) were used in the comparison of demographic variables and other qualitative and quantitative data between the experimental and control groups, the suitability of the data to the normal distribution was investigated by visual (histograms) and analytical methods (Kolmogrov–Simirnov/Shapiro–Wilk tests). Paired group comparisons of numerical variables were performed with the Student's *t*-test. The Mann–Whitney *U* test was used to compare groups for non-normal data distribution. In all results, $P < .05$ was considered statistically significant.

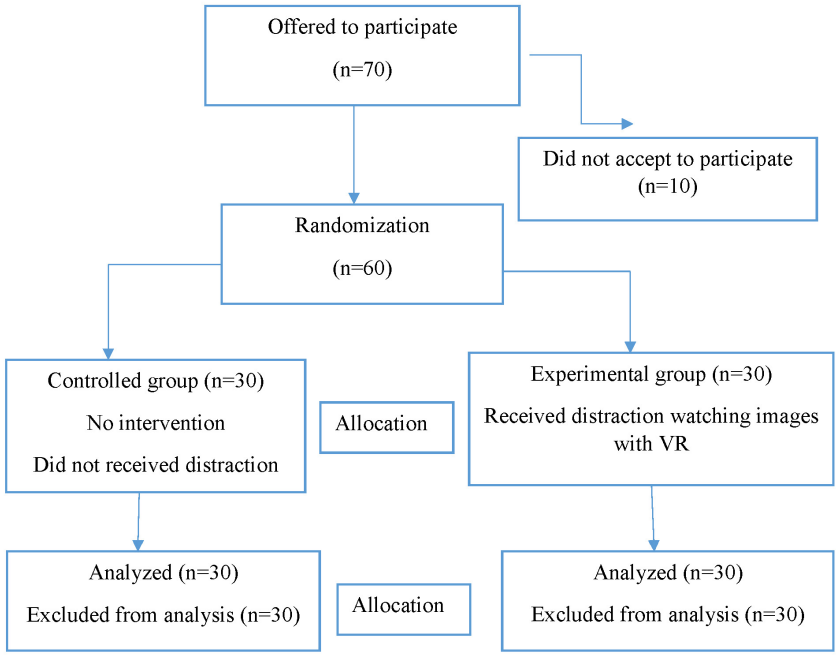

Figure 1. Study flowchart.

Data Collection Tools

Individual Identification Form

It was prepared by the researcher on the basis of the related literature and contains items about the introductory characteristics of patients.[5-7,10,11,23] This form includes questions about the patient's gender, age, education, marital status, and working status, and a previous colonoscopy status.

The Visual Analog Scale (VAS)

A 10-cm vertical VAS was used to assess the severity of pain experienced by patients during and after the procedure.[24] Pain intensity is scored between 0 and 10, absence of pain is "0" point, whereas the most severe pain is scored "10". Patients were informed about the use of the VAS for pain prior to the procedure. Patients were asked to evaluate the pain experienced during the procedure as soon as the procedure finishes. Patients were asked to evaluate the pain they experienced after the procedure before being discharged.

The State-Trait Anxiety Inventory (STAI)

The STAI scale was used to assess state and trait anxiety levels.[25] It was adapted to the Turkish Language by making validity in Turkey in 1983.[26] It includes 2 subscales with 20 items each that assess state and trait anxiety. The State Anxiety Scale (STAI-S) requires individuals to described their feelings at a specific moment under specific circumstances, while the Trait Anxiety Scale (STAI-T) requires them to describe the way they feel in general. The feelings and behaviors that are expressed by the items of the State Anxiety Scale are indicated by selecting 1 of 4 options: none (1), somewhat (2), highly (3), and completely (4) based on the degree of severity of these experiences. The feelings and behaviors that are expressed in the items of the Trait Anxiety Scale are selected from almost never (1), sometimes (2), very often (3), and almost always (4) based on how frequently they occur. Higher scores on each subscale indicate higher levels of anxiety. Scores on the entire scale range from 20 to 80, with higher scores indicating higher anxiety levels.

Data Collection

The patients in the experimental group allowed to watch a licensed virtual reality application, "A walk on the beach," through an Android mobile phone placed in Cardboard Super Flex Goggles, started 1 min before the colonoscopy process, which lasted 5-12 min on average; and, standard colonoscopy was performed on the patients in the control group, without any additional intervention. Colonoscopy was performed on patients in both groups by the same gastroenterologist without the use of anesthesia. After positioning the patients in the left lateral position for the colonoscopy procedure, and vemcain local anesthetic

and vaseline were applied to the anal area before starting colonoscopy using a Fujinon flexible colonoscope. The blood pressure of patients with abnormal heart rate before the procedure was measured at regular intervals during the procedure. During the procedure, the patients' oxygen saturation and heart rate were monitored. During the colonoscopy procedure, cecum was accessed in all patients, and ileum was intubated. The start and end times of the colonoscopy procedures were recorded. The demographic data of the 2 groups were collected before the procedure, and pre- and post-procedure state-trait anxiety levels, and pain levels of the groups during and after the procedure were evaluated.

Ethical Considerations

In order to carry out the research, approval was obtained from the Non-Interventional Clinical Research Ethics Committee of the University (number 2017/7-3), the permission of the Provincial Directorate of Health was obtained (Decision No 710.03), and verbal and written consents of the patients included in the study were obtained by informing them about the research.

RESULTS

The study was conducted with 60 patients (experimental group $n=30$, control group $n=30$). The patients were in the 23-85 age group, and the mean age was 56.33 ± 11.7. There was no statistical difference between the age, gender, marital status, educational status, and previous colonoscopy status of patients in the experimental and control groups ($P > .05$). The introductory characteristics of the patients included in the study are presented in Table 1. There was a statistically significant difference between the pain scores, during the procedure, of the patients in the experimental and control groups ($P < .03$) (Table 2). There was no statistically significant difference between the pre- and post-operative state anxiety scores of the patients in the experimental and control groups ($P > .05$). There was a statistically significant difference between the trait anxiety scores between both groups ($P < .000$) (Table 2). The findings suggest that virtual reality application has an effect on pain experienced during the colonoscopy. There was no statistically significant difference between the groups in terms of the duration of colonoscopy and heart rate during the colonoscopy (Table 3).

DISCUSSION

Colonoscopy is a procedure that causes patients to experience pain and anxiety.[6,7,10,11,23] The American Pain Association recommends optimal control of pain before and during painful procedures.[5,27,28] Pharmacological and nonpharmacological methods can be used in pain management.[29] The virtual reality application, developed with the advancement of technology, is a practice that reduces the perception of pain and anxiety by utilizing cognitive and attentive processes in individuals. In this study, the effect of virtual reality application on the pain and anxiety experienced by patients during colonoscopy was investigated.

Table 1. Distribution of Identifying Characteristics of Groups

	Experimental Group ($n=30$)	Control Group ($n=30$)	*P*
Age (mean)	56.33 ± 11.81	56.20 ± 15.62	.426*
Sex [n (%)]			.78**
Female	11 (36.7)	10 (33.3)	
Male	19 (63.3)	20 (66.7)	
Marital status [n (%)]			1.000**
Single	28 (93.3)	28 (93.3)	
Married	2 (6.7)	2 (6.7)	
Educational status [n (%)]			.37**
High school diploma or less	24 (80)	21 (70)	
More than diploma	6 (20)	9 (30)	
Number of colonoscopy [n (%)]			.595**
First time	20 (66.7)	18 (60)	
Two and more	10 (33.3)	12 (40)	

*Student's *t*-test.
**Mann–Whitney *U*-test.

Table 2. Distribution of Pain Score and Anxiety of Experimental and Control Groups

	Experimental Group ($n=30$)	Control Group ($n=30$)	*P*
Trait anxiety	39.73 ± 3.14	46.70 ± 5.97	.000
State anxiety			
Pre-procedural	47.70 ± 3.55	48.28 ± 5.26	.647
Post-procedural	46.83 ± 10.94	49.66 ± 2.83	.175
Procedural Pain Score			
During-procedural	2.76 ± 1.25	3.76 ± 2.11	.03
Post-procedural	0.83 ± 1.44	1.36 ± 1.51	.168

*Student's *t*-test.

Umezawa et al.[7] used visual distraction (VD) in silent mode during the colonoscopy without anesthesia, and found a decrease in the pain and anxiety levels of the patients compared to the control group, but without any statistically significant difference. In addition, in their study with auditory distraction (AD) and audiovisual distraction (AD+VD) during the colonoscopy without sedation, Xiaolian et al.[6] found that the pain and anxiety levels of the patients decreased compared to the control group, but without any statistically significant difference. Moreover, Lembo et al.[23] found that lower level of discomfort and anxiety of the patients who underwent sigmoidoscopy using a combination of visual and auditory distractions (AD + VD), compared to the non-intervention group and the group which had only the auditory distraction (AD). Unlike the above-mentioned studies, there are studies conducted with virtual reality during the colonoscopy procedure performed under sedation.[10,11] Unlike the other studies, in their study with visual distraction (VD) and auditory distraction (AD) during the colonoscopy procedure under sedation, De Silva et al.[10] found that those with auditory distraction experienced less pain during the colonoscopy procedure than the visual distraction and non-intervention groups. In addition, Lee et al.[11] divided colonoscopy patients into the VD + Patient-Controlled Analgesia (VD + PCA), AD + PCA and PCA-only groups in their study, and found that the AD + Patient-Controlled Analgesia group had low-level of pain and sedative amount, compared to other groups. In our study, unlike the above-mentioned studies, the audiovisual distraction method was tested alone during the colonoscopy procedure performed without sedation, and the combination of visual and auditory distractions was found to have an effect on patients' level of pain, but not on the level of anxiety. Xiaolian et al.[6] found pain score in the control group 5.16 ± 2.90, De Silva et al.[10] and Umezawa et al.[7] found median pain score 5 and 4.2 control group. In this study pain scores during colonoscopy in control group is 3.76 ± 2.11. This pain score is lower than the above mentioned studies. Pain is an objective symptom that is unique for each individual. and directly connected with what people have experienced in the past.

In their systematic study, Yang et al.[8] found that patients experienced a severe anxiety before and after the colonoscopy procedure. In one study, Ersöz et al.[30] found that patients who underwent colonoscopy had high levels of state anxiety and that there was no difference in the trait anxiety levels. As a result of the study, no statistically significant difference was found in the state anxiety score averages of patients evaluated before and after the colonoscopy procedure, and patients were found to experience a moderate level of anxiety. This finding is in line with the study findings of Xiaolian et al.[6] and Diette et al.[31] Xiaolian et al.[6] found no statistically significant difference between pre- and post-procedure anxiety score averages, visual (VD), and audiovisual distraction (AD + VD) during colonoscopy. Diette et al.[31] found that pain can be reduced by the audiovisual distraction method in patients undergoing flexible bronchoscopy, but shown that it did not have an effect on anxiety. However, Ko et al.[5] found that music played during a sedation-free colonoscopy reduced the level of anxiety. In a study by Çelebi et al.,[32] the average anxiety score of the group who listened to music during the colonoscopy was found to be lower than the control group. The incoherency of Ko et al.[5] and Çelebi et al.[32] findings with ours might be due to different natures of intervention. State anxiety is a temporary, subjective anxiety in which the individual considers both external and internal factors as a danger. There may be many reasons why virtual reality does not have an effect on the pre- and post-procedure state anxiety score averages. One of the reasons is the patients' idea of cancer since they don't have the report results after colonoscopy, as another reason the audiovisual virtual reality application might be uninteresting for the patients, or it might not be preferred by them. In this study, a statistically significant difference was found between the pre-procedure trait anxiety scores of the patients in the experimental and control groups. This finding differs

Table 3. Features of Outcomes of Colonoscopy Procedure

	Experimental Group ($n = 30$)	Control Group ($n = 30$)	*P*
Time needed for total procedure (median)	7.36 ± 2.52	7.30 ± 2.45	.94
Pulse/min (median)			
Before procedure	89.16 ± 18.50	81.50 ± 14.71	.83
Highest during procedure	86.40 ± 16.16	82.76 ± 17.92	.13
After procedure	82.66 ± 15.63	80.26 ± 15.59	.76

from the study findings mentioned above. Trait anxiety reflects the overall mood of the individual. Patients in the control group included in the study were found to experience more anxiety in their normal lives.

In our study, although it was not statistically significant, the heart rate of the patients in the experimental group was higher, despite the less pain experienced during the colonoscopy procedure, compared to the control group. Pain is an objective symptom that is unique for each individual. In order for pain assessment to be reliable, the patient's self-report on pain should be taken into consideration primarily; on the other hand, physiological pain symptoms should also be evaluated. A 15% increase/decrease in heart rate is among the symptoms of physiological pain, and this much increase/decrease in heart rate was not observed in the patients in the experimental group.[33] In addition, the heart rate of the patients in the experimental group was high before and after the colonoscopy procedure.

Many of the patients who underwent colonoscopy apply for diagnostic endoscopy purposes in many endoscopy units, as the patients included in our study. Most of these patients want to have their colonoscopy performed under anesthesia, because of the knowledge acquired from society. Indeed, in the recent past and still today, studies are being carried out to perform the colonoscopy procedure without anesthetics by airless, water-only, or by using CO2 insufflator in colonoscopy.[34,35] Anesthesia may cause loss of time, increased complications associated with colonoscopy, and increased cost, due to certain rituals before and after the procedure.[5,7] In this study, it was shown that non-sedated colonoscopy can be performed at a certain comfort by reducing pain using the virtual reality application. Therefore, considering the current complications and risks of anesthesia, it is believed that the use of audiovisual distraction may help eliminate the complications and cost associated with anesthetic drug use. In addition, there are advantages, such as the absence of the need for a companion for the patients who are not sedated, sharing of important information immediately, and having the patient awake in cases where a treatment decision must be made during the procedure.

We can get criticism about the duration of the colonoscopy. In our study, the time that the gastroenterology doctor started and ended the colonoscopy procedure was recorded and completed 7.36 ± 2.52 experimental group (audiovisual distraction). We did not record withdrawal time. In this study, the short-term cases were clearly observed back of mucosal folds and good colon cleansing. Xiaolian et al.[6] completed the colonoscopy procedure 6.00 ± 2.34 min in patients who used audiovisual distraction. Umezawa et al.[7] completed the colonoscopy procedure, 15.35 min in patients who used visual distraction. But Umezawa et al. did not give information on polyp removal in their study. In our study, none of the polyps extended the duration of the procedure. The procedure time is in line with the study findings of Xiaolian et al.[6]

As a result, the virtual reality application was found to reduce patients' pain during the colonoscopy procedure. The virtual reality application, an easily available, inexpensive, and non-invasive method, can be used by nurses in pain management during colonoscopy. It may be recommended for future studies to chose the audiovisual stimulus according to patient preference.

Ethics Committee Approval: Karabuk University Non-Interventional Clinical Research Ethics Committee, Number 2017/7-3.

Informed Consent: Informed consent was obtained from all patients.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – S.K.C.; Design - S.K.C.; Supervision - S.K.C., SE.; Resource - S.K.C.; Materials - S.K.C., S.E.; Data Collection and/or Processing - S.K.C., S.E.; Analysis and/or Interpretation - S.K.C.; Literature Search - S.K.C., S.E.; Writing - S.K.C., S.E.; Critical Reviews - S.K.C., S.E.

Acknowledgments: We thank the patients for their participation.

Conflict of Interest: The authors have no conflict of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

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