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The Effect of Virtual Reality and Educational Video on Anxiety of Cardiac Angiography Candidates: A Randomized Clinical Trial

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Abstract

Background: Angiography is one of the prominent methods for diagnosis and treatment of coronary heart disease. Some patients who are candidates for angiography experience great anxiety.

Aim: The present study was conducted with aim to compare the effect of virtual reality (distraction) and educational video on patients' anxiety before coronary angiography.

Method: This randomized clinical trial study was conducted on patients who were candidates for coronary angiography in Heart Center of Razi Hospital in Birjand city of Iran, from April to October 2023. By permuted block randomization, 90 patients were randomly divided into two intervention groups and one control group. Before the angiography, the intervention groups were once exposed to virtual reality VR (distraction) and educational video. Data were collected before and after the intervention.

Results: there was no significant difference among the three groups in the gender distribution (p=0.897) and mean age (p=0.205). The distraction group experienced lower levels of overt and covert anxiety compared to the control group (p<0.001) and educational video group (p=0.007). In addition, the anxiety score of the participants in the distraction group significantly decreased after the intervention compared to before the intervention (p<0.001).

Implications for Practice: The implementation of VR as a distraction approach had an effect on reducing preoperative anxiety in angiography candidate patients. VR can be used as a non-pharmacological approach in angiography departments to reduce patients' anxiety.

Keywords: Anxiety, Coronary Artery Diseases, Distraction, Education, Virtual Reality

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Introduction

Coronary heart disease (CHD) is the leading cause of death in both developed and developing countries and has increased from 27.3% to 31.4% in past decades (1). Coronary angiography is used to diagnose coronary artery disorders, and it has experienced significant growth and expansion in the last three decades (1). It is estimated that 17.9 million people died from cardiovascular diseases (CVDs) in 2019, representing 32% of all global deaths; therefore, early detection of cardiovascular diseases is crucial (3). Angiography allows for early detection of vascular abnormalities and facilitating timely and appropriate treatment, which can be critical in life-threatening conditions like myocardial infarction (4). Coronary angiography is a common procedure in specialized medical centers with a low risk of complications. However, lack of awareness about the technique of coronary angiography can lead to psychological and emotional outcomes for patients, including anxiety, worry, fear, and a sense of insecurity (2-4). There are several factors that can contribute to patient perioperative anxiety in coronary angiography, including fear of the underlying medical condition, concerns about hospitalization and anesthesia, as well as the unfamiliar clinical environment, any previous negative experiences, and the angiography procedure itself (5). Additionally, coronary angiography is typically performed using local anesthesia rather than general anesthesia (6), which can be a factor of anxiety and concern for some patients. This anxiety caused by the absence of general anesthesia can potentially contribute to adverse events during the procedure (7, 8). Anxiety can have significant impacts on cardiac function, leading to increases in heart rate, blood pressure, and the consumption of oxygen by the heart muscle (5). Patients' anxiety during cardiac catheterization causes complications such as reducing quality of life (9), increased risk of mortality (10), and exacerbating disease and cardiovascular complications (11).

Since the patients experience a significant increase in anxiety levels prior to cardiac catheterization (12), some studies have explored various interventions intended to alleviate the pre-procedural distress and anxiety experienced by patients prior to cardiac catheterization (13, 14). The non-invasive methods are the approaches that alleviate pre-procedural distress and anxiety(15). The use of virtual reality (VR) as a distraction technique has proven to be an effective non-invasive method for reducing both the physical and psychological discomfort experienced by patients (16). Virtual reality involves the use of a headset to display a fully immersive three-dimensional environment (17). VR can reduce patients' anxiety in medical procedures such as dental hygiene procedures and performing bone marrow aspiration (18), and in patients receiving surgical wound care for hand injuries (19). In addition, patient's education about the interventions is one of the efficient ways to reduce anxiety before and after medical interventions (20-22). Audio-visual education can reduce the patient's anxiety level. Moreover, video-based education enhances knowledge acquisition and retention, reduces anxiety, improves coping skills, and promotes treatment adherence (23-27). Multiple studies have confirmed that giving patients information about the angiography process helps to alleviate their perioperative anxiety (28, 29). Considering that no literature was found about the effect of distraction and educational film on the level of anxiety in angiography candidates, especially in Iran, the present study was conducted with aim to compare VR (distraction) and educational video on the level of anxiety in cardiac angiography candidates.

Methods

This single-center randomized controlled trial (RCT) study was conducted using a pretest-posttest design on patients who were candidates for coronary angiography at the Heart Center of Razi Hospital affiliated to Birjand University of Medical Sciences in Birjand, Iran, from April to October 2023. The research units were randomly divided to three groups of 30 participants: two intervention groups and one control group. The trial's reporting and intervention descriptions adhered to CONSORT flowchart guidelines (Figure 1). The patients scheduled for diagnostic coronary artery angiography. The inclusion criteria were: willingness to participate in the study, undergoing angiography for the first time, and no history of neurological disorders (including visual, motor, or hearing disabilities), mental disturbances, or sedative use. The exclusion criteria were: unwillingness to continue cooperation or intolerance of VR (fear of closed space). The two-part demographic information form and the Spielberger state-trait anxiety questionnaire (STAI) were used to collect information. Demographic information form included personal data such as, age, gender, marital status, educational level, and having an experience of VR. The STAI was used to assess the participants’ anxiety levels before the

angiography procedure. It consists of 40 questions that 20 questions evaluate overt anxiety and 20 evaluate covert anxiety. The STAI is scored on a 4-point Likert scale, with responses ranging from 1 (very low) to 4 (very high). The scores for the overt and covert anxiety scales range from 20 to 80, with higher scores indicating greater anxiety. Spielberger (1983) enhanced the questionnaire's validity over approximately a decade (30). In terms of reliability, when comparing the Spanish and Indian versions to the English version, correlation coefficients was obtained between 0.83 and 0.94 (31). Additionally, the correlation between the overt and covert anxiety was 0.98 (32). The overt anxiety reflects an individual's emotional state at the moment when complete the questionnaire. In contrast, covert anxiety indicates the person's typical or usual emotional condition, representing how they feel most of the time (27).

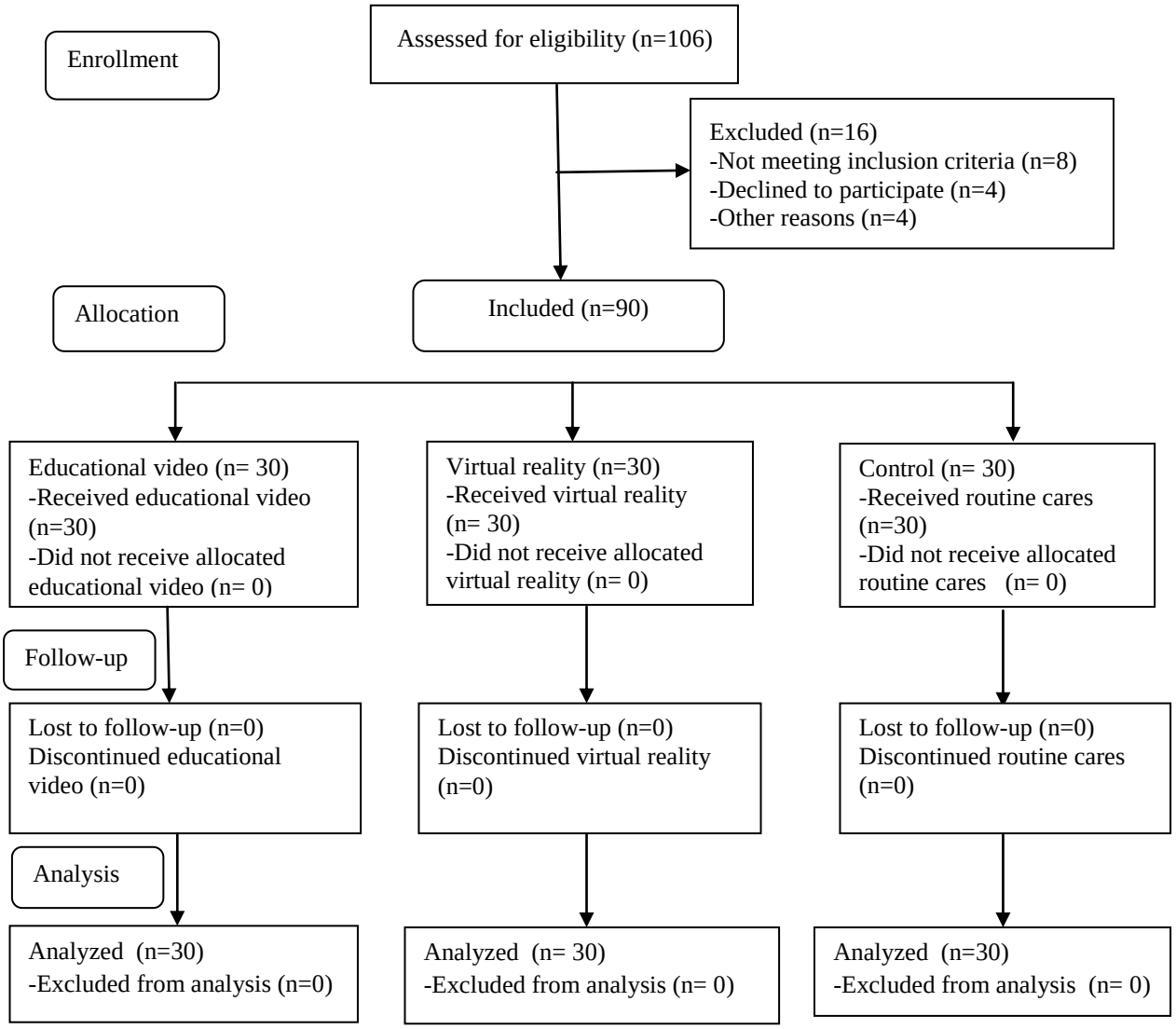

Figure 1. Flow diagram of the study process

The number of Participants was determined according to the level of anxiety reported in a similar study (5), and according to the parameters of that study, the formula (sample size for comparison of means for more than two independent groups) (33), And considering that the Type I Error (α) and the Type II Error (β) are usually considered to be 0.05 and 0.20 respectively. The value for α and β error ($Z_{1-\alpha/2} + Z_{1-\beta}$) were estimated (1.96+ 0.84). The sum standard deviation of two groups (σ1+ σ2) was (5.27+7.75) and the difference between the means of two groups (μ1- μ1) were (49.22-44.09). After putting these parameters in the formula, the sample size of 30 people was calculated for each group. As a result, 90 participants were distributed among three groups. Eligible patients were randomly divided into three groups after completing the demographic questionnaire. Placement of participants

in each group was blocked. They were placed in one of the three intervention groups A (educational video), intervention B (VR distraction) or control group C (no intervention). First, different triple blocks were created on different cards (ABC, CAB, CBA, BCA, BAC and ACB). One of these blocks was randomly selected and participants were divided into one of three groups A, B or C, and then randomization was performed for other participants.. The person who assigned the participants to different groups was unaware of the types of the groups. This process ensured the random assignment of participants to the different study groups, while also maintaining allocation concealment.

It should be noted that the entire intervention and data collection process was performed before angiography, therefore 11 hours before interventions (pretest), therefore 11 hours before interventions (pretest), the participants in the first intervention group watched a 5-minute 3D educational video about the angiography procedure, using the content from medical books, articles, and experts. The second intervention group was shown a 5-minute VR distraction of natural scenes like beaches, mountains, and waterfalls, accompanied by soothing sounds like music, birdsong, and waterfall noises. The VR distraction was played using a headset that allowed 360-degree viewing and head movement. control group received no intervention. Immediately after the 5-minute interventions, all participants completed the STAI anxiety questionnaire again. The interventions were conducted in a private, quiet room. The control group filled in the study questionnaires at the same time points as the intervention groups, but without receiving any treatment. The parameters were evaluated at two time points, 11 hours before and immediately after the intervention. Then, one hour after the intervention, the participants entered the cat lab room for angiography.

Data were analyzed using SPSS software (version 19) and frequency tables and statistical indices. The Kolmogorov-Smirnov test was used to check the normality of the data. If the data were not normal, non-parametric tests such as Wilcoxon and Kruskal Wallis were used, and if they were normal, one-way analysis of variance (ANOVA) was used. $p<0.05$ was considered statistically significant.

Ethical Consideration

After providing a full explanation about the purpose of the study, written informed consent was obtained from all the participants. Participants were given the option to withdraw from the study at any time. This research was approved by the Research Vice-Chancellor of Birjand University of Medical Sciences (ethical code: IR.BUMS.REC.1398.360). Considering that the current study was a clinical trial type, it was registered in Iran's clinical trial site (IRCT20190618043934N6).

Results

There was no significant difference among the three groups in the gender distribution of the participants ($p=0.897$). The mean ages of the participants in the control, VR distraction, and educational videos groups were 63.00±11.16, 56.94±14.32 and 59.57±13.71 years, respectively. There was no significant difference among the three groups regarding the mean ages ($p=0.205$) (Table 1).

Table 1: The distribution of gender frequency among the three groups

Gender Groups	Male N (%)	Female N (%)	Statistics
Control	15 (50.0)	15 (50.0)	P= 0.897 X^2= 0.252
Virtual reality	15 (50.0)	15 (50.0)	
Educational video	21 (70.0)	9 (30.0)	

The mean of overt anxiety before the intervention was not significantly different among the three groups ($p=0.127$), but the mean score of overt anxiety after the intervention was significantly different among the three groups ($p<0.001$). According to the Bonferroni test, the mean score of overt anxiety after the intervention was significantly reduced in the distraction group compared to the educational video group ($p=0.007$) and compared to the control group ($p=0.008$). Also, the mean of overt anxiety in the distraction group was significantly reduced after the intervention compared to before the intervention ($p<0.001$). But in the control group and educational video group, there was no significant difference after the intervention compared to before the

intervention (Table 2).

The mean score of covert anxiety before the intervention was not significantly different among the three groups (p=0.084), but the mean score of covert anxiety after the intervention was significantly different among the three groups (p<0.001). The results of the Bonferroni test also determined that the distraction group obtained a significantly lower covert anxiety score than the control group (p=0.014). In addition, in the distraction group, the level of covert anxiety was significantly lower after the intervention compared to before the intervention (p<0.001). While the educational and control groups didn't show such difference (Table 3).

Table 2: The mean score of overt anxiety before and after the intervention

Groups Time	Control (N = 30)	Virtual reality (N = 30)	Educational video (N = 30)	Kruskal-Wallis (Intergroup)*	Bonferroni test* p-value*
Before Mean ± SD Median(first quarter-third quarter)	42.61 ± 8.34 43 (46.25 – 39.0)	40.22 ± 9.54 38 (45.75 – 31.75)	38.73 ± 7.95 41 (43.0 – 32.75)	X^2 = 4.12 p= 0.127	distraction vs educational video (p=0.007)
After Mean ± SD Median(first quarter-third quarter)	40.37 ± 9.58 44 (46.25 – 37)	32.91 ± 4.92 32 (34.0 – 29.0)	38.13 ± 8.62 39 (43.0 – 31.75)	X^2 = 19.59 p<0.001	distraction vs control (p<0.001)
Mean changes Mean ± SD	-0.63 ± 6.94	-7.44 ± 7.07	-0.56 ± 10.99	F = 6.33 p= 0.003	
Wilcoxon (Intragroup)*	Z= 0.21 p= 0.841	Z= 4.304 p< 0.001	Z= 0.41 p= 0.682		

* Kruskal-Wallis analysis of variance

Table 3: The mean score of covert anxiety before and after the intervention

Groups Time	Control (N = 30)	Virtual reality (N = 30)	Educational video (N = 30)	Kruskal-Wallis (Intergroup)*	Bonferroni test p-value*
Before Mean ± SD Median(first quarter-third quarter)	43.76 ± 8.85 46 (50.0 – 38.0)	40.23 ± 9.92 39.0 (50.0 – 31.0)	38.31 ± 7.55 41 (45.0 – 31.75)	X^2 = 4.940 P = 0.084	distraction vs educational video (p=0.062)
After Mean ± SD Median(first quarter-third quarter)	43.00 ± 9.91 45 (47.0 – 39.0)	34.35 ± 6.91 32.0 (39.0 – 27.0)	34.84 ± 8.53 35 (40.0 – 28.0)	X^2 = 15.990 p< 0.001	distraction vs control (p=0.014)
Mean changes Mean ± SD	-0.70 ± 4.41	-5.96 ± 5.99	-3.53 ± 9.73	F = 4.164 p= 0.01	
Wilcoxon (Intragroup)*	Z= 0.74 p= 0.45	Z= 4.47 p< 0.001	Z= 1.87 p= 0.06		

* Kruskal-Wallis analysis of variance

Discussion

As the results of the present study showed, the mean levels of overt and covert anxiety were not significantly different among the three groups before the intervention. But after the intervention, the

mean overt and covert anxiety scores in the control group were significantly higher than the distraction group ($p<0.001$). This study also showed that the mean overt and covert anxiety scores in the distraction group significantly decreased after the intervention compared to the pre-intervention scores ($p<0.001$). These findings align with previous studies (34, 35). In addition, Keshvari et al. found that implementing a VR distraction protocol for participants undergoing coronary angiography was effective in reducing their perioperative anxiety and related measures (36). Decreasing anxiety through VR distraction has also been observed in other medical conditions. In the study conducted by Chirico et al., which focused on breast cancer patients undergoing chemotherapy, it was found that both VR and music therapy interventions were effective in reducing anxiety and improving mood states (37). The evidence suggests that virtual reality can effectively divert patients' attention by providing attractive audiovisual stimuli, which helps alleviate anxiety before procedures such as coronary angiography (36). Other studies have shown that when patients undergo invasive medical procedures, providing a distracting factor like music can affect brain activity, stimulating alpha brain waves and leading to the release of endorphins in the brain. This endorphin release can have a calming effect, ultimately reducing anxiety in the patients (38).

In the present study, anxiety levels in the control group were significantly higher than the educational video group. This finding is in line with previous studies that have utilized preoperative education methods for patients (22, 25, 39). Mirsane et al. found that anxiety decreased through the use of pre-procedural video education; their results suggest that providing accurate information to patients can help reduce the severity of their anxiety and stress (40). When patients are given a realistic understanding of an upcoming stressful event, even if they cannot control it, helps diminish the intensity of their stress response. Creating this familiarity and schema in patients' minds helps guide their behavior in a more positive direction. Another benefit of informing patients is that it can increase their cooperation and interaction with medical staff and physicians.

The results of the present study revealed that there was no significant difference between overt and covert anxiety in the control and educational video groups after the intervention compared to before the intervention ($p>0.050$). This result is consistent with the findings of Noben et al. that showed educational video didn’t reduce preoperative anxiety in women undergoing cesarean section (41). These findings may be due to the increased knowledge of patients about the angiography process, which can also increase their fear. Therefore, more studies in this field are necessary to clarify the issue.

This study had some limitations. The sample size may have been insufficient to detect all potential effects. The research was conducted at a single medical center, potentially limiting its generalizability to other healthcare settings or patient populations. Additionally, the study might not have accounted for all possible confounding variables that could influence anxiety levels in patients' candidates for angiography. It is suggested to conduct more researches on comparing VR distraction with other anxiety-reduction techniques beyond educational videos and assessing cost-effectiveness and feasibility of implementing VR in diverse healthcare settings.

Implications for practice

VR was employed as a diversionary technique to alleviate anxiety in patients awaiting angiography. The results showed that VR significantly decreased preoperative stress levels. The technology was found to be safe, with no adverse effects reported. Moreover, patients expressed favorable reactions to using VR as a coping mechanism. Considering that nurses in angiography departments have extensive interactions with cardiac angiography candidate patients, the findings of the present study can be used as a non-pharmacological and non-invasive approach in angiography departments to reduce patients' anxiety. Finally, reducing anxiety can improve the physical and mental well-being of these patients.

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Conflicts of interest

The authors declared that they have no competing interests.

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Authors' Contributions
HE, DO, NA contributed to conceptualization. HE, DO and RR contributed to the methodology, they also contributed to the analysis. AMS contributed to the preparation of the final manuscript. HE and DO also participated in writing the text of the manuscript. HE, DO, RR and AMS supervised data collection and resource evaluation. Finally, the findings and the full text of the manuscript were approved by all authors.

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