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Comparison of the Effect of Organized Evidence-based Education by Group Discussion and Film Screening on Anxiety of Coronary Catheterization Patients: A Randomized Clinical Trial

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Abstract

Background: Anxiety is one of the most prevalent psychological complications in patients undergoing cardiac catheterization.

Aim: This study was performed with aim to compare the effect of organized evidence-based education by group discussion and film screening on anxiety of Coronary Catheterization Patients.

Method: This randomized clinical trial study was performed at Javad-Al-Aemeh Hospital, in Mashhad, Iran, 2018. The coronary catheterization patients were randomly allocated to the three groups. An evidence-based educational program was presented to 75 patients waiting for cardiac catheterization by 25 min film, also it was discussed with 70 patients in small groups, and 70 patients were considered as the control group. The pre-procedural anxiety was assessed using Spiel Berger Inventory before and 1 hour after the education. Data were analyzed by SPSS (version 15) and Kolmogorov–Smirnov, ANOVA, t student and Paired t, Kruskal-Wallis and Wilcoxon tests. $P<0.05$ was considered statistically significant.

Results: The three groups were not significantly different in mean scores of age (p=0.922) and left ventricle ejection fraction (P=0.112) at the beginning of the research. Three groups didn't have significant difference in anxiety score before the intervention (P= 0.58), but after the intervention, the anxiety significantly decreased in the film screening (33.72±4.92) and discussion groups (36.54±6.4) (p<0.001) compared to the control group (46.7±9.78). However, the results showed no significant difference between the film and discussion groups (P=0.09).

Implications for Practice: An evidence- based education by film screening and group discussion in the cardiac wards can reduce the anxiety in catheterization candidates.

Keywords: Anxiety, Coronary catheterization, Evidence based education

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Introduction

Coronary angiography (CAG) is a procedure which uses a special dye (contrast material) and x-rays to see how blood flows through the arteries in heart (1). Coronary angiography is often done along with cardiac catheterization. Percutaneous transluminal coronary angioplasty (PTCA) also called percutaneous coronary intervention (PCI) is a minimally invasive procedure to open blocked or stenosis coronary arteries allowing unobstructed blood flow to the myocardium (2, 3). Despite the success, experience, and reliability of cardiology health care professionals in practice, this interventional technique can cause a temporary increase in preoperative psychological parameters such as anxiety and stress in most patients (4).

Pre-procedural anxiety is one of the most prevalent psychological complications in patients undergoing cardiac catheterization. More than 82% of patients, especially women, experience high levels of anxiety (5) before CAG because of the fear and lack of knowledge about the procedure and the results of the diagnosis (6). The study performed in Turkey reported that the patients undergoing CAG had high anxiety level according to state anxiety scale mean score, and moderate anxiety level according to trait anxiety scale mean score (4).

Anxiety increases cardiovascular reactivity, heart rate and blood pressure, resulting in increased endothelial injury and platelet aggregation through increased sympathetic nervous system activity (7) which cause the risk of ischemia during cardiac catheterization (7). The high risk of ischemia may affect the patient's recovery that increase the duration of process and amount of sedative medication (8). Then, planning to do strategies to minimize anxiety in these patients is not only important for patients' comfort but also could potentially improve the outcomes of cardiac catheterization (9).

Patients' education, which is considered a learning-teaching process between health care professionals and patients, imposes responsibilities for nurses to focus on both improving and maintaining the health of individuals, families, and societies since Florence Nightingale. In this respect, nurses who consider all dimensions and environment should assume the role of an effective educator.(10) So nurses should remove lack of knowledge which causes psychological burden on individuals.

According to the literature search, most studies aimed to reduce the anxiety by using the methods which need the continued presence of the nurse, such as: reflexology (11), relaxation (12), music therapy (13), listening to Quran (14), acupressure (15),and intentional presence (16),. Also, the studies evaluated the effect of one method of education like face to face (17, 18), video or multimedia (19, 20) or group discussion (21) on the patients' anxiety. Additionally, some studies recommended the guidelines for nurses to care the patients (22, 23). A deep assessment in the content of the patients' education showed that the content of most educational researches were based on informing the patients about the subjects which can reduce the anxiety like knowing about how the procedure would be done? The anatomy and physiology of heart and coronary arteries, and what the physicians do during the procedures? (24, 25). Although the self-care strategies during and after the cardiac catheterization are very important subjects, few studies mentioned these topics in their patient educational contents (22). There are some patient education self-care applications in cirrhotic patients (26), heart valve replacement surgery patients (27), but there is no exact self-care application in coronary angiography patients.

Therefore, the present study was performed aimed to design an evidence based patient education based on group discussion and film screening to reduce the anxiety of patients undergoing coronary catheterization.

Methods

This randomized controlled clinical trial study was performed on patients who were candidates for CAG or PCI in three groups without blinding during September 2017 to March 2018 at Javad-Al-Aemeh Hospital, Mashhad, Iran.

The sample size was calculated as 49 subjects in each group according to a guide study (28) by considering anxiety as a main variable, using the formula of mean scores comparison and 95% confidence interval and 80% test power. Considering the probability of 20% loss and the difference between two angiography and angioplasty procedures, the study population increased to 70 patients per group.

Since sampling in the present study was done based on time blocks, therefore all the patients hospitalized in the shift who met the inclusion criteria were included in the study. As a result, the

sample size obtained was more than the estimated sample size in each group. Finally, 225 eligible patients were selected and then randomly assigned to three groups of film screening (n= 76), group discussion (n= 74) and control (n= 75).

To prevent the dissemination of information between patients in the three study groups, the researchers used the time block method to randomize the samples. Thus only one form of intervention was necessarily implemented in each day. Therefore, the numbers of days of month (1 to 30) were first given to www.Randomization.com. The first 10 random permutations (7,20,27,16,21,5,17,15,26,24) were assigned as the days of the month to perform videotape intervention, the second 10 random days (10,6,13,8,18,28,25,11,19,3) of the month were considered to do the routine care of the ward for patients in the control group, and the third 10 random days (22,1,12,23,14,29,9,2,4,30) of the month were considered to perform discussion groups for patients who were candidate electively to do PCG or PCI . The process continued until sampling was completed. During the study, 5 individuals in the control group, 4 in the discussion group, and 3 in the film screening group were excluded from the study. The final analysis was performed on 213 patients (Figure 1).
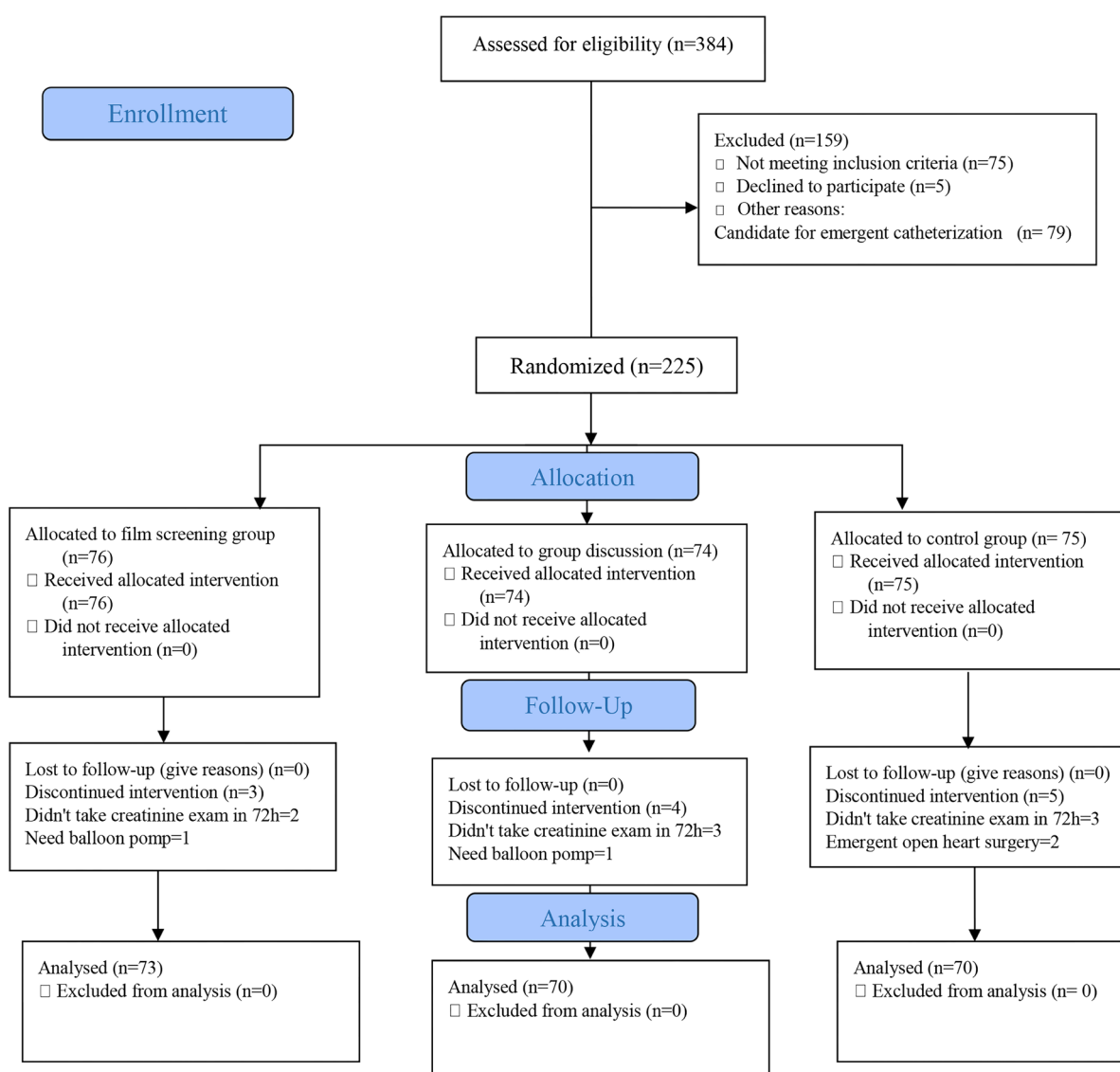

Figure 1. The CONSORT flow diagram of the process of the study

Inclusion criteria were: age of 30-70 years, ability to speak and communicate, literacy, electively candidate of PCG or PCI, no previous history of cardiac catheterization, no kidney (eGFR (Estimated glomerular filtration rate) <30 ml/ min), heart (LVEF(Left Ventricular Ejection

Fraction <40%) and liver failure, no history of mental diseases (using psychiatric drugs) or severe stressors (divorce or death of closed relatives) in the past six months. Exclusion criteria were: life-threatening heart rhythm (ventricular fibrillation, pulse-free ventricular tachycardia), need for CPR, systolic blood pressure less than 90mmHg, embedded balloon pump, and more than once attempt at arterial access (multi-puncture).

Recruitment of the participants

This study was designed as three phases: 1- designing an evidence-based education package for CAG and PCI patients, 2- Preparing a professional film for patients' education, and 3- doing clinical trial study.

Phase 1: Designing an evidence-based education package for CAG and PCI patients

In this phase, an integrative review was done to prepare an organized educational package. To find the related articles, databases of Pubmed, Google Scholar, clinical key, Eric and SID were searched from October 2010 to October 2018. The key words were Anxiety, contrast- induced Nephropathy, Coronary Catheterization, Patient education, and Nursing care which were searched using the operators of AND, OR. After revising the literature, 17 articles were included in the integrative review. Then the recommendations were prepared to prevent anxiety and also contrast- induced nephropathy (an important issue after CAG and PCI). The recommendations for anxiety prevention included informing and educating the patients about the hospitalization (18, 25), the procedure of coronary catheterization (29), the complications and limitations, and the hospital environment (17). Also the recommendation to prevent contrast induced nephropathy were categorized in to: fluid therapy (30, 31) (intravenous and oral intake) (32, 33), caution to order and use drugs (34) and monitoring the serum creatinine and GFR(35).

Phase2: Preparing the patient education film

The second phase was film making. After preparing the organized educational content, a scenario was provided in a simple language. The researcher contracted with a professional film maker team. The 30-minute film was made in the actual hospital environment. The benefits of this film were the use of real-time contexts, spoken and written explanation, special effects, music, standard animation as well as the use of professional, experienced team of directing, filming, sound recording and editing.

Phase 3: The three group clinical trail

The third step was the clinical trial which was conducted in three groups. So that the patients' demographic and disease data were first recorded. Then, the patients' blood pressure and pulse rates were measured. Thereafter, the pre-procedure blood samples were taken from patients. The Spiel Berger state-trait anxiety inventory was given to the patients prior to the intervention.

In the discussion group, 4 to 6 patients with a circular-shaped arrangement with researcher created a group in the education class of the angiography ward. The researcher stated the purpose of group formation and the patients introduced themselves to the group. The 15 minutes educational content (based on the organized educational guideline) was then provided, followed by discussion between the team members by asking purposive questions led by the researcher. Finally, the researcher made sure that all members understood the content correctly. The group discussion lasted for approximately 30 minutes.

In the film screening group, the film (based on the instructional guideline) was displayed in the patient's room television for 30 minutes.

The instructional pamphlets and routine hospital care were provided for the control group. After the intervention and one hour before transferring the patients to the Cath Lab, the Spiel Berger state anxiety inventory was again completed by the patients.

The tools included the demographic and disease information questionnaire and the Spiel Berger Anxiety Inventory, including the state and trait anxiety. The inventory consisted of 40 questions, 20 of which were about state anxiety and the other 20 were related to trait anxiety. Scores of 1, 2, 3 and 4 were assigned to four options (very low, low, high and very high, respectively). The State-Trait Anxiety Inventory (STAI) is a common anxiety measurement tool, and its Persian translation validity has been confirmed in a master thesis in Allameh Tabatabaee university of Tehran By Mahram in1994

(36). Its reliability was confirmed by Cronbach's alpha of 0.86 in the present study.

Data were analyzed by SPSS (version 15). The normality of data was assessed by Kolmogorov–Smirnov test. If the data were normal, ANOVA, student t test and Paired t test were used. If they were not normal, Kruskal-Wallis and Wilcoxon were used to analyze the data. Moreover, Chi-square and multiple regression analysis were used. $P < 0.05$ was considered statistically significant.

The present study was conducted according to the ethical criteria of the Helsinki statement and was approved by the Ethics Committee of Mashhad University of Medical Sciences with Ethics Code of (IR.MUMS.REC.1396.66). Participants were informed of study nature and written consent to participate in the study was obtained. If the patient didn't want to continue the educational sessions he/she could leave the research any time.

Results

The findings showed that the participants in three groups were not significantly different in mean scores of age (p=0.922), BMI (P=0.822) and left ventricle ejection fraction (P=0.112) at the beginning of the research. But the patients were significantly different in sex distribution (p=0.0061) (Table 1).

Table 1. Patients' demographic and disease information in three groups

Variable		Mean±SD/ frequency (percentage)			Test result
		Control N=70	Group discussion N= 70	Film screening N=73	
Age		55.22±8.98	54.64±9.06	55.26±7.72	P=0.992* =0.955
Sex	Female	29 (41.4)	42 (60.00)	25 (34.2)	P=0.009** X^2=9.40
	Male	41 (58.6)	28 (40.00)	48 (65.8)	
Hypertension		36 (51.4)	41 (58.6)	38 (52.1)	P= 0.739** X^2=0.605
Diabetes		12 (21.4)	19 (27.1)	22 (30.1)	P= 0.521** X^2=1.303
Hyperlipidemia		37 (52.9)	41 (58.6)	42 (57.7)	P= 0.761** X^2=0.685
Type of procedure	Angiography	44(62.9)	51(72.9)	44(60.3)	P-value= 0.25 X^2= 2.76**
	Angioplasty	26(37.1)	19(37.1)	29(39.7)	
Arterial access way	Femoral	52(74.3)	60(85.7)	60(82.2)	P-value=0.21 X^2= 3.08**
	Radial	18(25.7)	10(14.3)	13(17.8)	

* Kruskal-Wallis test   **Chi-square test

Also the results showed that the patients in the three groups weren't significantly different in the history of chronic diseases such as hypertension (P=0.641), diabetes (P=0.481), and hyperlipidemia (P=0.761) (Table 1).

Kruskal-Wallis test was used to compare the trait anxiety of the patients in the three groups before the intervention and the results indicated no significant difference between the three groups (P =0.56); in other words, the groups were homogeneous in terms of mean trait anxiety scores.

The results of the one-way ANOVA test indicated that the mean state anxiety scores in the pre-intervention phase were not statistically different in the three groups (P=0.05).

After the intervention, the score of state anxiety decreased by 9.74 in the film group and a reduction of 8.76 in the group discussion, while in the control group it increased by 2.49.

In the post-intervention phase and according to ANOVA test, there were statistically significant differences in mean scores of anxiety in the three groups of control, group discussion and film screening (p<0.001). According to the results of Bonferroni test, there were statistical significant differences between the control and group discussion (p<0.001) and the control and film groups (p<0.001) after the intervention.

The intragroup comparison indicated statistical significant differences between the mean score of anxiety in the pre and post intervention in the control group (p=0.02) (increase level of anxiety);

and between mean scores of anxiety in the group discussion (p<0.001) and film screening (p<0.001) (reduce level of anxiety) (Table 2).

Table 2. Comparison of mean and standard deviation of state anxiety in three groups

State anxiety	Control (n= 70)		Group discussion (n= 70)		Film screening (n= 73)		intragroup test
	Mean±SD	Median (IR[a])	Mean±SD	Median (IR)	Mean± SD	Median (IR)	
Before	44.21±10.67	45(16.25)	45.3±10.96	55(14.5)	43.46±10.22	43 (14)	F=0.53[b] P-value= 0.58
After	46.7±9.78	46(15.25)	36.54±6.4	36(7)	33.72±4.92	34(5.5)	F = 68.3[c] P-value<0.001
before and after differences	2.48±9	-5(11)	8.75±8.17	-8(10)	9.73±8.25	-10(12.5)	F=64.02[c] P-value<0.001
intergroup test	t= 10.08[d] P-value= 0.02		t= 2.3 [d] P-value<0.001		Z= 6.25[e] P-value<0.001		

[a] Interquartile range, [b] One-way ANOVA, [c] Kruskal Wallis test, [d] Paired t-test, [e] Wilcoxon test

Also, the result of the Quantile regression method showed that the regression coefficient (RC) of film screening education on the anxiety was -12.69 while the RC of the group discussion education was-11.14 (Table 3).

Table 3. The results of quantile regression analysis according to the regression coefficient of each method of education on anxiety

Anxiety	Regression coefficient	Standard error	R^2	Test result
Group discussion(n= 70)	-11.14	0.98	0.33	t=11.3 P-value<0.001
Film screening (n= 73)	-12.69	0.96	0.36	T=13.15 P-value<0.001

In this case, the control group considered zero and the baseline score was controlled as covariate

Discussion

The purpose of the present study was to compare the effect of education by film screening and group discussion on anxiety of patients undergoing cardiac catheterization. The findings of the present study indicated that applying evidence- based educational package in both group discussion and film screening could reduce the patients' anxiety. The results showed a significant increase in the anxiety of control group before catheterization, while the anxiety scores of patients in both two intervention groups significantly decreased. There was no significant difference between the mean anxiety score of film screening and group discussion after the intervention.

The results of this study were comparable to the results of some other studies which used the method of showing film to educate patients before PCG or heart surgery (19, 24, 37). Additionally Moradi et al. (2015) (25) in their research applied an educational package of pamphlets, face-to-face education and videos to reduce the mean anxiety score of patients who were candidates for angiography half an hour before the procedure. While the anxiety mean scores of patients of both intervention and control groups were not significantly different two hours and the day before angiography, they also didn't find any significant reduction in the anxiety of patients after the intervention.

According to the results of the present study, applying an evidence-based educational package by film screening based on nursing guidelines can be more effective on anxiety reduction than using face to face education with pamphlets and videos which were not exactly based on a systematic review.

Also, the regression model showed that the regression coefficient (RC) of the anxiety score of the film screening group compared to the control group was RC= -12.69, while the RC of group discussion compared to the control group was RC=-11.4. Therefore based on this result, the film screening method can be considered as more successful method than group discussion to reduce the anxiety of patients who are candidate for PCG or PCI.

The study of Mohammadi et al. (2012) which compared the effects of two methods, group and

individual education on the knowledge and anxiety of patients admitted for coronary angiography indicated that both educational methods reduced the anxiety mean scores of these patients. The reduction of patients' anxiety in group training was significantly more than individual training. But Mohammadi and colleagues didn't report the RC of group education method comparing with the control group. They used face-to-face education with questions and answers and didn't use any educational technology (21). Most studies on patients' education used existing educational pamphlets and traditional methods for training patients, and none of them were based on instructional guidelines or systematic reviews. In the present study, the researcher used an organized educational guideline emerged from an integrative review of the literature which was unique between many articles mentioned above.

Accordingly, in the present study, film screening and group discussion by providing sufficient evidence-based information significantly reduced the anxiety of patients undergoing PCG or PCI. Therefore, it is suggested to use these techniques to reduce anxiety in patients waiting for PCG. Since one of the most important barriers to patient education is large numbers of patients in contrast with less number of nurses that leads to no enough of time to do patient education (38), it is suggested to use face to face or group discussion methods. Although the effectiveness of the educational methods based on the nurse's presence, it is suggested to use the film screening as a suitable alternative to do patient education.

One of the limitations of this study was although the patients were randomly allocated to the groups by the admit day, but sometimes the patients in three groups might meet each other. Thus the researcher couldn't limit the distribution of information between the patients.

Implications for practice
As reported in the results, applying organized educational guidance in both group discussion and film screening groups decreased the anxiety of candidate patients for coronary catheterization. According to the limitation of time of nurses, this study suggests to use film screening for patient education in coronary catheterization wards. It is recommended that further studies be performed on the use of the educational guidance to evaluate its effect on patient's life style and quality of life after cardiac catheterization.

Acknowledgments

Conflicts of interest
The authors declared no conflict of interest.

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