



## The Effect of a Multi-Modal Preparation Package on Anxiety in Patients Undergoing Coronary Angiography

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### ABSTRACT

**Background:** There are differences in studies on the effect of non-pharmacological methods of anxiety reduction in patients undergoing coronary angiography.

**Objectives:** The present study aimed to evaluate the effect of implementing a multi-modal preparation package on anxiety in patients undergoing coronary angiography.

**Patients and Methods:** This single blind randomized clinical trial was conducted on 100 patients undergoing coronary angiography. The patients were equally assigned to an intervention and a control group. The preparation package was implemented about two hours prior to angiography. Spielberger's anxiety inventory was used for measuring anxiety. The patients' anxiety level was measured the day before, immediately before, and after implementing the preparation package and 30 minutes before angiography. Then, the data were entered into the SPSS statistical software, version 11.5 (SPSS Inc., Chicago, IL, The USA) and analyzed using T-test and repeated measures ANOVA. Chi-square test was also used to compare the two groups' demographic characteristics. P values < 0.05 were considered as statistically significant.

**Results:** The results revealed no significant difference between the control group ( $34.36 \pm 5.56$ ) and the intervention group ( $34.64 \pm 4.71$ ) regarding baseline anxiety mean scores ( $P = 0.787$ ). This score increased in the control group ( $38.14 \pm 7.36$ ) as well as in the intervention group ( $38.94 \pm 5.36$ ) 2 hours before angiography ( $P = 0.536$ ). However, the mean anxiety score decreased to  $34.16 \pm 2.75$  in the intervention group and to  $40.38 \pm 8.16$  in the control group immediately after applying the preparation package ( $P = 0.001$ ).

**Conclusions:** The preparation package reduced anxiety before angiography. Considering the beneficial effects of this preparation package on reducing anxiety, this method is recommended for preparation of patients for coronary angiography.

#### ► Implication for health policy/practice/research/medical education:

The preparation package reduced anxiety before angiography. Considering the beneficial effects of this preparation package on reducing anxiety, this method is recommended for preparation of patients for coronary angiography.

### 1. Background

Cardiovascular diseases are known as the leading cause of death in the world (1). According to World Health Organization, about 18 million deaths occurred due to cardiovascular diseases in 2008 and this value has been estimated to reach 23 million by 2030 (2).

Coronary Angiography (CA) is one of the most common and the best method for diagnosis of coronary artery

diseases (3). Annually, more than one million cardiac catheterizations and angiographies are performed in the United States (4). However, no comprehensive statistics on the number of cardiac catheterizations are available in Iran. One study estimated that a total of 260514 CAs (347 per 100000 people) were performed in Iran in 2011 and this procedure was cited as the fourth most common invasive treatment in Iran (5). Also, local information shows that 1700 CAs were performed in 2012 at angiography unit in Kashan University of Medical Sciences where the present study was conducted, representing a rate of 235 per 100000

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people in the city.

Studies have demonstrated that most patients waiting for CA lacked adequate information about the procedure and this made them anxious and worried (1, 6). Fear, anxiety, and other unpleasant emotional experiences are common before CA and other cardiovascular interventions (7). Surprisingly, the anxiety level before CA was reported to be higher than that before open heart surgery. The reason might be that the patients were less prepared for this procedure compared to open heart surgery (8). Another study revealed that over 82% of patients had experienced fear and anxiety before CA (9).

Anxiety causes irritability and agitation and increases some physiological parameters, such as respiratory rate, heart rate, blood pressure, and catecholamine release, consequently increasing the myocardial oxygen demand. The adverse physiological and psychological responses to anxiety may also reduce the patients' collaboration with the healthcare team and increase the need for sedative drugs (6).

Evidence has indicated that properly preparing the patients and giving them some information about the procedure before surgery and invasive procedures might not only decrease their anxiety, but could also increase their tolerance to deal with post-operative pain. Besides, it was associated with feeling a higher level of well-being and quality of life (1, 7, 10-12). However, some studies have suggested that the patients waiting for CA were not adequately prepared, had not received the necessary information (7, 13), and a large number of them were still anxious and worried (9). Up to now, several studies have focused on patients' anxiety before CA. Nevertheless, some of them were descriptive and only reported that these patients were anxious and their anxiety level significantly increased with approximating the time scheduled for CA (3, 9, 14, 15). Different pharmacological and non-pharmacological methods have been used to reduce anxiety before surgery and invasive procedures (16). A review study reported that non-pharmacological interventions could even reduce the need for sedation and general anesthesia in invasive procedures (17). A number of studies have also examined the effects of some interventions on reducing anxiety before CA. In two studies, Benson's relaxation techniques (18, 19) and hearing the Quran recitation (20) were effective in improving hemodynamic status and reducing anxiety in the patients waiting for CA. In a recent randomized placebo-controlled study, Vardanjani et al. investigated the effect of reflexology on anxiety among patients undergoing CA. The patients in the intervention group received 30 minutes of general foot massage and stimulation of three reflex points on their feet, while the placebo group only received the general foot massage. According to the results, anxiety reduction was significantly higher in the intervention group compared to the placebo group. However, this study was not double-blinded, was conducted only on male patients, and the study groups did not have the same anxiety levels at the beginning of the study (21). On the other hand, one study demonstrated that a 10-minute massage before CA was not sufficient to decrease stress level (22). In two reports, Buffum et al. randomized the patients waiting for CA into music and non-music groups and reported that

music therapy was effective in reducing the anxiety levels before CA. However, the patients and staff were not blinded to the assignment (6). Another study also revealed that patient-controlled music therapy had no significant effects on anxiety levels before and after CA (23). Also, applying sensory information and music therapy in Chinese patients undergoing CA had no significant effects on anxiety (24). Moreover, in a study by Astley et al., no significant reduction of anxiety was found in the patients undergoing CA after using audiovisual educational methods (25). Most of the above-mentioned studies used one intervention. Furthermore, most of these studies were conducted in western countries. Thus, evidence generated from these studies cannot be directly transferred to an eastern context without a context-specific investigation. Also, there are evidences suggesting that cultural factors may affect patients' responses to such interventions (25). Moreover, although medical technologies have rapidly advanced in Iran, the culture of healthcare delivery does not prioritize the provision of preoperative education for patients. In fact, lack of communication between healthcare providers and patients and inadequate provision of preoperative information are the key concerns in Iran's hospitals (26-28).

Due to the differences among the studies and the limited number of studies performed on the impact of multidimensional preparation in patients undergoing CA, it is still questionable whether a comprehensive preparation package, including individualized face-to-face patient education, provision of an educational pamphlet, presenting a video, and performing a round in the angiography department, can be effective in reducing patient anxiety before the procedure.

## 2. Objectives

The present study aims to evaluate the effect of implementing a multi-modal preparation package on anxiety in the patients undergoing CA.

## 3. Patients and Methods

### 3.1. Design

This single-blind randomized clinical trial was conducted on 100 patients assigned to intervention and control groups.

### 3.2. Human Subjects' Approval

The study was started after the approval of the Research Ethics Committee and the Research Council of Kashan University of Medical Sciences and registration at Iranian Registry of Clinical Trials (IRCT2013042313102N1). All the study participants were informed about the study objectives and signed written informed consents. They were also assured about the confidentiality of their personal information and the voluntary nature of participation. Permissions were sought from the hospital and the angiography unit authorities, as well.

### 3.3. Participants

The present study was conducted on the patients referred to the CA unit of Shaid Beheshti medical center, Kashan, Iran. The patients who were candidate for CA for the first time, were between 30 and 70 years old, and were alert,

literate, physically and mentally capable to complete the questionnaire, and had no recognized mental disorders were enrolled into this study. The exclusion criteria were occurrence of an active bleeding from the catheter during and after angiography and need for cardiopulmonary resuscitation during the procedure.

The sample size was calculated based on Majidi's study on the effect of Quran recitation on patients' anxiety before CA. In that study, the level of anxiety was  $50.03 \pm 8.64$  in the control group and  $45.61 \pm 6.42$  in the intervention group on the day of CA (11). Based on Majidi's study and considering  $\beta = 0.20$ ,  $\alpha = 0.05$ ,  $S1 = 6.42$ ,  $S2 = 8.64$ ,  $\mu1 = 45.61$ , and  $\mu2 = 50.03$ , a 100 - subject sample size (50 subjects in each group) was determined for the study.

The study data were collected using a two-part instrument. The first part consisted of 6 questions about the patients' demographic characteristics, including age, gender, marital status, place of living, education level, and occupation. Besides, the second part included the state section of Spielberger's anxiety inventory. This inventory consists of 20 questions related to anxiety on a four-point Likert scale with options ranging from "not at all" = 1 to "very much" = 4. Summing up the responses yielded an anxiety score ranging from 20 to 80, with higher scores representing greater anxiety. Accordingly, scores of 0 - 20, 21 - 40, 41 - 60, and 61 - 80 were considered as no, low, moderate, and

severe anxiety, respectively.

The Persian version of the Spielberger's inventory has been used in several studies. The validity of the Persian version was approved by Dehghan-Nayeria and Adib- Hajbaghery (29) and Bassampour (30). Besides, its reliability was confirmed by Cronbach's alpha of 0.94 for the total score (30).

### 3.4. Procedure

Sampling was carried out consecutively. The patients who met the inclusion criteria were identified and invited to the study by daily file review of the patients admitted to the angiography unit. Then, the patients were randomly assigned to the intervention or the control group. To prevent contact between the two groups, the patients were allocated to each group in a weekly approach. In doing so, the first week of the study was randomly assigned to the intervention by flipping a coin. Afterward, all the eligible patients were assigned to the intervention or the control group every other week.

The first measurement of each patient's anxiety level was performed a day before angiography in a quiet room. The second anxiety test was given 2 hours before angiography. Immediately, the preparation package was offered only to the intervention group, and another anxiety test was given to both control and intervention groups 1.5 hours before angiography. The fourth anxiety test was given to the two groups 30 minutes before angiography (Figure 1). For this

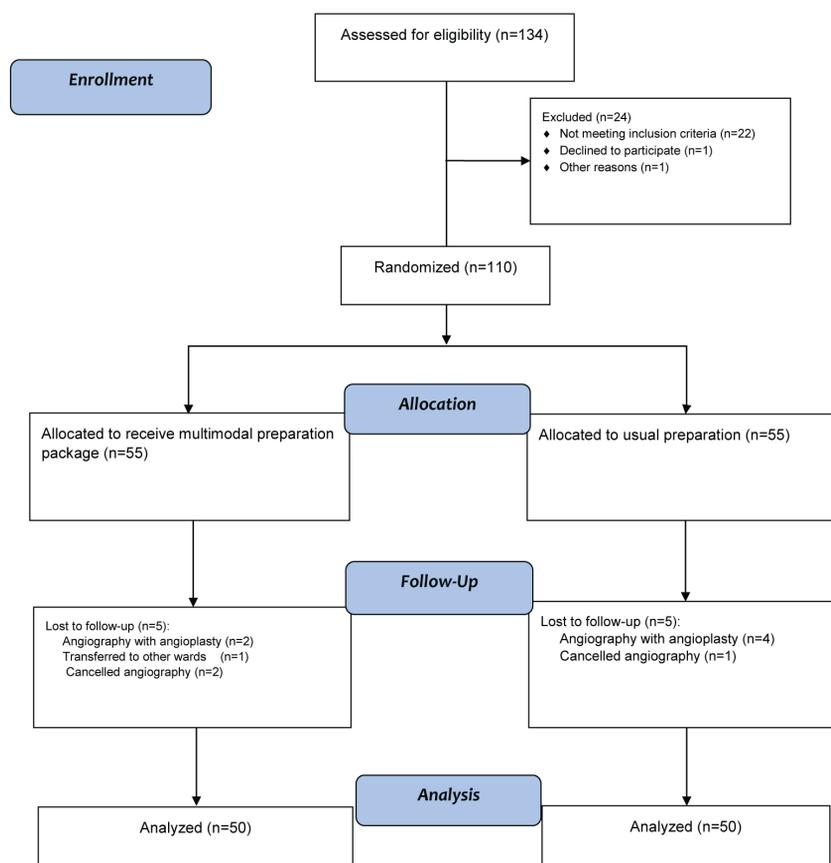


Figure 1. Consort Flow Diagram

purpose, the first author of this paper was present during the study. This researcher referred to each patient in the morning, discussed the research objectives, and measured the patient's anxiety using Spielberger's inventory. Then, a session (that usually lasted for about 30 minutes) was held with each patient in a calm and comfortable room. During this session, angiography was explained to them. Also, the patients were provided by an educational pamphlet about the process of angiography and pre- and post-angiography care along with some explanations. Then, pictures of different parts of the angiography unit and a 10-minute video describing the environment of the unit, the process of angiography, pre- and post-angiography care, and experiences of a patient who had undergone angiography were shown to the patients. Finally, the researcher answered their questions (Box 1). The content validity of the video and the educational pamphlet was confirmed by 4 faculty members of School of Nursing and Midwifery, 2 cardiologists, and one specialist nurse in Kashan University of Medical Sciences. The first author of this manuscript conducted all the sessions and collected the

study data. She was trained for conducting the preparation sessions and the consistency and appropriateness of her work was checked by the study supervisor before the study and also at some points during the study.

### 3.5. Data Analysis

Data analysis was performed using the SPSS statistical software, version 11.5 (SPSS Inc., Chicago, IL, USA). T-test was used to compare the differences between the two groups regarding the mean scores of anxiety. Besides, repeated measures ANOVA was used to compare the differences among the mean scores of anxiety in each group. Also, chi-square test was used to compare the two groups' demographic characteristics. P values < 0.05 were considered as statistically significant.

## 4. Results

This study was conducted on 100 patients undergoing CA. In total, 60% of the patients were male, 40% were female, and all were married. The mean (SD) age of the intervention and the control group participants was  $55.92 \pm 10.03$  and

### Box 1: The Content of the Preparation Package for Coronary Angiography

#### - Greetings

#### - Giving face to face explanation about angiography, including:

- What coronary angiography is and why it is done
- Which preparations are needed before the procedure
- What nurses will do for you before the procedure
- When and how you will be transferred to the coronary angiography unit and what measures may be done at this stage
- What actions or events will be done during coronary angiography, how long the procedure will be taking
- What feelings you will experience during the procedure
- Where you will be transferred immediately after the procedure, and what steps will be taken there, where you will be transferred next
- How long you will be hospitalized after coronary angiography
- When you will be discharged and what is needed to be done after discharge
- What your doctor will advise you after normal or abnormal results of coronary angiography and what the follow up steps for patients are

#### - Providing the patients with an educational pamphlet about:

- What is coronary angiography and why is it done?
- It is a procedure in which a special X-ray is taken of the heart vessels.
- Coronary angiography is performed if you are suspected to have coronary heart disease. This test may be done if your doctor wants to assess the degree of narrowing in your heart vessels in order to choose the best treatment.
- Which preparations are needed before the procedure?
- Medications before the procedure, fasting for six hours, shaving the hair of the catheter insertion area (i.e. the groin), notifying your physician of any iodine allergies, time of admission to hospital.
- What actions or events will be done during coronary angiography?
- You will be taken to the angiography room by a wheelchair. You should lie on a narrow table which can be moved from side to side during the test. You will be connected to a machine that will monitor your heartbeat. A special catheter will be inserted into your groin or arm vessels under local anesthesia and will be moved to the beginning of the heart vessels. All the steps of the procedure will be shown on a monitor. A small amount of special dye will be injected and X-rays will be taken from your heart vessels. Then, the catheter will be removed and bleeding is stopped by application of firm pressure.

#### - Other issues:

- Length of the procedure
- Possible risks and complications
- Transferring to the ward and nursing care after the procedure
- What feelings will you experience during the procedure?
- How long will you be hospitalized after coronary angiography, when will you be discharged and what is needed to be done after discharge?
- What will your doctor advise you after normal or abnormal results of coronary angiography?

#### - Orientation of the patients with different parts and the staff of the angiography unit

- Presenting to the patient a few pictures of the staff and various parts of the angiography unit, including the admission unit, entrance, inpatient section, passage ways, angiography room with its special bed and equipment, and recovery room.

#### - Showing a video of the process of coronary angiography.

- In this video, the researcher describes the meaning of angiography and explains its process, including preparations, procedure, and after care, to a real patient. The video also shows admission of a real patient, explanation and checking of pre-procedure preparations, transporting the patient to the angiography unit, and lying of the patient on the special angiography table. The video also presents prepping and draping, insertion of the catheter, dye injection while the patient is awake and the doctor asks him to cough, removing the catheter and applying pressure to the area where it was inserted, and moving the patient to the recovery area and then to the ward. At the end of the video, a patient briefly reviews his experiences during the procedure and a cardiologist explains the result of the angiography and the necessary follow-ups to the real patient.

#### - The sessions were terminated with summarizing and answering the patients' questions.

56.46 ± 7.76 years, respectively (P = 0.870). All the patients were literate among whom, 78% had elementary education and 22% had high school or above degrees. In addition, 32% of the patients were employed and the rest were retired and unemployed. No significant differences were observed between the two groups in terms of age, gender, education level, and occupation (Table 1).

According to the results presented in Table 2, no significant difference was found between the control group (34.36 ± 5.56) and the intervention group (34.64 ± 4.71) regarding the mean scores of baseline anxiety (P = 0.787). Although the anxiety mean scores increased in the control group (38.14 ± 7.36) and the intervention group (38.94 ± 5.36) 2 hours before CA, the difference was not statistically significant (P = 0.536). However, the intervention group's mean score of anxiety decreased to 34.16 ± 2.75 immediately after receiving the preparation package and to 34.02 ± 2.32 thirty minutes before CA (P = 0.001). In contrast, the mean score of anxiety increased in the control group while approaching the time of CA. In this group, the mean score of anxiety increased to 40.38 ± 8.16 and 41.44 ± 8.45 after the usual preparations and 30 minutes before CA, respectively. These differences between the two groups were statistically significant (Table 2).

## 5. Discussion

The present study showed that the two groups' mean anxiety levels were the same and low the day before angiography, but gradually increased by approaching the time of angiography. The highest level of anxiety was observed in the control group 30 minutes before angiography. However, the mean level of anxiety decreased in the intervention group after the intervention, such a way that this group's mean anxiety level was close to the baseline value the day before angiography. Several studies have also reported that patients are anxious and stressful before and during invasive procedures, such as CA, and percutaneous coronary interventions (14, 15, 23, 31). Patients' lack of knowledge about and unfamiliarity with the environment and the intended procedure are the main reasons for this anxiety (14, 15, 23, 31, 32).

In the current study, a significant difference was observed between the mean scores of anxiety before and after implementing the preparation package, such a way that the patients' anxiety significantly reduced after the intervention and before CA. However, the anxiety mean score increased in the control group by approaching the time of CA. Other studies have also examined the effect of various training methods on reduction of anxiety in patients undergoing cardiovascular interventions (10,

**Table 1.** Demographic Characteristics of the Participants

Variable	Groups		Statistic	P value	
	Control; Number (%)	Intervention; Number (%)			
Gender	Male	28 (56)	32 (64)	X <sup>2</sup> = 0.667	P = 0.410
	Female	22 (44)	18 (36)		
Education level	Elementary school	41 (82)	37 (74)	X <sup>2</sup> = 0.932	P = 0.330
	High school or above	9 (18)	13 (26)		
Place of residency	City	30 (60)	26 (52)	X <sup>2</sup> =0.649	P = 0.420
	Village	20 (40)	24 (48)		
Occupation	Employed	14 (28)	18 (36)	X <sup>2</sup> = 0.735	P = 0.390
	Retired	36 (72)	32 (64)		

**Table 2.** Comparison of Anxiety Levels in the Two Groups before and after the Intervention

Time of Assessment	Group		95% CI	Statistical Indicators
	Control (Mean ± SD)	Intervention (Mean ± SD)		
On the day before CA	34.36 ± 5.56	34.64 ± 4.71	2.32, 1.76	t = 0.272 P = 0.787
2 hours before CA	38.14 ± 7.36	38.94 ± 5.36	-3.35, 1.75	t = 0.621 P = 0.536
Immediately after preparation	40.38 ± 8.16 <sup>a</sup>	34.16 ± 2.75 <sup>b</sup>	3.80, 8.64	t = 5.101 P = 0.001
30 minutes before CA	41.44 ± 8.45	34.02 ± 2.32	-4.96, 9.88	t = 5.985 P = 0.001
Repeated measures ANOVA	P = 0.001 <sup>c</sup>	P = 0.001 <sup>d</sup>		

Abbreviations: CI, Confidence interval of the difference

<sup>a</sup> After usual preparation; <sup>b</sup> After receiving the preparation package; <sup>c</sup> Bonferroni Post Hoc test was applied to do pair wise comparisons among the control group's mean anxiety levels in the four consecutive times and the results showed significant differences in all pair wise comparisons (P = 0.001); <sup>d</sup>, Bonferroni Post Hoc test was applied to do pair wise comparisons among the intervention group's mean anxiety levels in the four consecutive times and the results only showed significant differences between 2 hours before CA and other three times (P = 0.001).

30, 33). Philippe et al. investigated the effects of video information in patients undergoing CA and reported a significant decrease in the patients' anxiety levels after presenting the training video (34). Another study indicated that both individual and group training significantly reduced anxiety in patients undergoing CA (35). Yeganeh Khah et al. also reported that patient education through face to face training and using pamphlets or CDs could reduce the anxiety level in patients with myocardial infarction (36). The results of the present study were also consistent with several previous studies, reporting that answering patients' questions, giving detailed information about the intended procedure, and environmental orientation of patients could reduce patients' anxiety and uncertainties before different surgeries and invasive procedures (37-43). Therefore, it could be concluded that where single interventions could decrease anxiety, more comprehensive patient preparations, such as the preparation package used in the current study, might be more effective in reducing patients' anxiety and concerns before CA.

This study examined the impact of a patient preparation package on anxiety level of the patients undergoing CA and showed the effectiveness of the preparation package in reduction of anxiety. Considering the beneficial effects of this method, application of this preparation package is highly recommended to reduce anxiety of the patients before CA. Since Spielberger's inventory used in this study is a self-report instrument, the results might be biased. Moreover, this study was conducted on the patients who were waiting for angiography; thus, a similar study is recommended to be performed on patients undergoing other invasive procedures. Furthermore, this study was started 24 hours prior to angiography, while patients are usually selected for CA from several days earlier and they may suffer from concern and anxiety during this time. Hence, starting the preparation program immediately after selecting the patients for CA may even reduce their anxiety more significantly. Additionally, this study was conducted in a single center with a limited number of samples and patients' anxiety was the only parameter under investigation. Therefore, another study with a larger sample size and assessing more outcomes, such as vital signs, hemodynamic parameters, and stress hormones, is highly recommended to be performed in future.

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#### Authors' Contribution

Mohsen Adib-Hajbaghery and Tayebeh Moradi were responsible for the study conception and design. Tayebeh Moradi performed the sampling and data collection and prepared the draft of the manuscript. Mohsen Adib-

Hajbaghery made critical revisions to the paper for important intellectual content, performed data analysis, and supervised the study.

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