



The effects of clinical simulation on stress, anxiety, and hemodynamic parameters among the candidates for coronary angiography

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Abstract

Background and aims: Stress and anxiety during coronary angiography (CA) can lead to serious complications such as cardiac dysrhythmias, coronary artery spasm, and coronary artery rupture. This study aimed to evaluating the effects of clinical simulation on stress, anxiety, and hemodynamic parameters among the candidates for CA.

Methods: This clinical trial was conducted on eighty candidates for CA. Participants were conveniently recruited from Tehran Heart Center, Tehran, Iran, and randomly allocated to a control and an intervention group through block randomization with a block size of 2. The Beck Anxiety Inventory, the Cohen Perceived Stress Scale, and a datasheet for hemodynamic parameters were used to assess participants' anxiety, stress, and hemodynamic parameters before and after the study intervention. Participants in the intervention group received routine care services and a clinical simulation intervention, while participants in the control group solely received routine care services. Data were analyzed using the chi-square, independent-sample *t*, and paired-sample *t* tests.

Results: The mean scores of stress and anxiety and the mean values of systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR) significantly decreased in the intervention group ($P < 0.05$), but did not significantly change in the control group ($P > 0.05$). The pretest posttest differences in the means of stress, anxiety, SBP, DBP, and HR in the intervention group were significantly greater than the control group ($P < 0.05$).

Conclusion: Clinical simulation is effective in significantly reducing stress, anxiety, and hemodynamic parameters among the candidates for CA. Therefore, clinical simulation is recommended before CA.

Keywords: Stress, Anxiety, Hemodynamic parameters, Clinical simulation

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Introduction

Coronary angiography (CA) is the gold standard for diagnosing coronary artery problems (1). It is also a low risk and effective procedure for managing some coronary artery problems (2). However, like other invasive procedures, CA is associated with high levels of stress and anxiety for patients (3). A study on 180 candidates for CA in Sari, Iran, reported that 55% of them had overt anxiety and 54% of them had covert anxiety (4).

Anxiety is an unpleasant state of strain caused by fear over disease, hospitalization, anesthesia, or surgery (5-7). Stress is also a psychological state in which individuals experience physical or psychological threat or instability. Stress severity largely depends on individuals' perceptions of potential or actual threats in a given situation so that an individual may experience little stress in a situation

while another person may experience high levels of stress in that situation (8). Stress and anxiety can negatively affect physiological and hemodynamic parameters such as respiratory rate, heart rate (HR), myocardial oxygen consumption, plasma levels of epinephrine and norepinephrine, cardiac output, and blood pressure, and may put patients at risk for different health problems during CA (5,6,9). Studies reported that anxiety is associated with increased risk of cardiac dysrhythmias, coronary artery spasm, and coronary artery rupture during CA (10,11). Therefore, effective measures should be used to diagnose and manage CA-associated stress and anxiety in order to prevent potential risks (12). Vital signs assessment is one of the best methods for assessing stress and anxiety. Vital signs reflect physiological conditions in different conditions (13) and are valuable criteria for

physiological assessment and clinical decision making (14). Studies showed that changes in vital signs had significant relationship with the levels of agitation (5,16).

There are pharmacological and non-pharmacological therapies for stress and anxiety. Medication therapy by benzodiazepines and sedatives is the most common pharmacological therapy for stress and anxiety management. However, medication therapy has short-term effects and is associated with different side effects. Therefore, non-pharmacological therapies have received great attention in recent years (17,18). Simulation is one of the non-pharmacological therapies with potentials for stress and anxiety management. Simulation is used to imitate realities in clinical conditions for exercising processes, decision making, and critical thinking using techniques such as role playing and equipment such as videos or interactive mannequins (19). In simulation, real conditions are simulated to improve the transferability of the learned materials and solutions to real world and improve learners' understanding of the intended tasks. Simulation is associated with no risk of injury to learners.

Some previous studies reported the positive effects of simulation on learning outcomes among students. For instance, a study reported that using simulation-based teaching in clinical skills centers reduced learning-related strain and promoted experiential and self-directed learning (20). A systematic review also showed the positive effects of using patient simulation mannequins on critical thinking skills and the ability to identify patient problems among nursing students (21). Simulation also helps effectively manage phobias (22,23). A study into the effects of different teaching methods also showed that simulation produced better outcomes compared with conventional teaching methods (23). Moreover, a study reviewed different studies into the effects of clinical simulation and concluded that clinical simulation was associated with richer experiences compared with conventional teaching methods and helped learners face and correct their misconceptions (24).

Most previous studies into simulation evaluated its effects on students (20,21). To the best of our knowledge, no study had yet evaluated the effects of simulation on stress and anxiety among candidates for CA. Therefore, the present study was conducted to narrow this gap. The aim of the study was to evaluate the effects of clinical simulation on stress, anxiety, and hemodynamic parameters among the candidates for CA.

Methods

Design

Using a single-blind two-group design, this clinical trial was conducted in 2016 in Tehran Heart Center, Tehran, Iran. Participants were eighty eligible candidates for CA. Eligibility criteria were an age of 20–70 years, affliction by class II or III cardiac problem according to the New York Heart Association classification, ability to read and write in Persian, no cognitive or anxiety disorder, no

previous history of CA, no need for simultaneous CA and right heart catheterization (due to the likelihood of blood pressure fluctuations), no previous history of stressful diagnostic measures such as transesophageal echocardiography, no known valvular heart disease (due to its potential effects on hemodynamic status and anxiety), no in-depth knowledge about cardiac problems, no auditory verbal disorders, no family history of mental disorders, and consent for participation. Exclusion criteria were voluntary withdrawal from the study, need for emergency CA or hospitalization, and hospital discharge with personal consent before CA. Eligible CA candidates were conveniently recruited to the study and randomly allocated to a control ($n=40$) and an intervention ($n=40$) group through block randomization with a block size of 2 (12). Participants were blind to the study groups.

Sample size was calculated based on the results of three former studies (13,14,25). Accordingly, with a confidence level of 0.95 and a d of 2, sample size was determined to be 33 per group (Equation 1). Considering a potential attrition rate of 20%, sample size was increased to forty per group.

$$n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 (S_1^2 + S_2^2)}{d^2} = \frac{(1.96 + 1.28)^2 (2.5^2 + 2.5^2)}{2^2} = 32.8 \text{ Eq. (1)}$$

Instruments

Data collection instruments were a demographic questionnaire, the Beck Anxiety Inventory, the Cohen Perceived Stress Scale, and a datasheet for hemodynamic parameters. The demographic questionnaire had items on age, gender, educational level, employment status, and insurance. The Beck Anxiety Inventory has 21 items scored on a 0–3 scale with a possible total score of 0–63. The score of this inventory is interpreted as follows: scores 0–21: low anxiety; scores 22–35: moderate anxiety; scores 36–63: severe anxiety with the need for assessment and treatment (26–28). A former study reported the acceptable validity and reliability of this inventory with a Cronbach's alpha of 0.92 (28). Other studies also reported this inventory as an appropriate anxiety measurement instrument in Iran (15,27,29–32).

The Cohen Perceived Stress Scale has ten items in three main subscales, namely unpredictability of life, uncontrollability of life, and overloadedness of life. Items are scored on a 0–4 scale, resulting in a possible total score of 0–40. Scores 0–10, 11–20, and 21–40 are interpreted as low, moderate, and severe perceived stress, respectively (33). Previous studies reported that the Cronbach's alpha of the scale was 0.78 (34), 0.85 (35), and 0.81 (36).

A datasheet was also used to document hemodynamic parameters, namely systolic blood pressure (SBP), diastolic blood pressure (DBP), and HR. Participants' blood pressure was measured using a sphygmomanometer. The sphygmomanometer was calibrated using another sphygmomanometer. The reliability of the sphygmomanometer was assessed through inter-rater reliability assessment, in which two assessors measured

blood pressure with a five-minute interval without changing the place of the sphygmomanometer cuff. HR was also measured in a whole minute using an analogue watch.

Stress, anxiety, SBP, DBP, and HR in both groups were measured and documented at the time of hospital admission (i.e., one day before CA) and two hours before CA.

Intervention

Participants in the control group solely received care services routinely provided to all candidates for CA in the study setting, while their counterparts in the intervention group received both routine care services and clinical simulation. The clinical simulation intervention included five main components. The first component was a twenty-minute nursing visit program, in which the researcher provided participants with educations about coronary artery disease, its etiology, its diagnostic procedures, and the benefits of CA and then, participants' probable misconceptions were assessed and corrected and their questions were answered. The second component was a twenty-minute video-based education about CA. The video was created in the CA and the recovery units of the study setting and included educations about patient entrance into the CA unit, patient preparation for CA, patient transfer from CA bed to stretcher, patient transfer from stretcher to bed in the recovery unit, and patient collaboration before, during, and after CA. The video was played for participants using a computer in the study setting. The third component was a CA unit tour. During the tour, participants were taken to the CA unit, where they were provided with educations about CA equipment, procedure, and process. The fourth component was mannequin-based education about patient preparation for CA, puncture site preparation, and puncture site dressing after CA. In the fifth component, a trained hypothetical patient showed participants how to collaborate with CA team during the procedure and how to move from CA bed to stretcher. The simulation intervention was provided to participants in the intervention group in four- to six-person small groups.

Data analysis

The SPSS software was used for data analysis. The independent-sample *t* and the chi-square tests were used for between-group comparisons while the paired-sample *t* test was used for within-group comparisons. The level of confidence was set at more than 0.95.

Results

Eighty candidates for angiography in two forty-person groups participated in and completed this study. The mean of participants' age was 57 ± 41 years in total, 56.95 in the intervention group, and 57.87 in the control group. Most participants in the control and the intervention groups were male (73% vs. 77%) and married (95% vs.

95%), had insurance (97% vs. 97%), and had below-diploma education (73% vs. 65%). At the beginning of the study, most participants reported high levels of stress (87%) and anxiety (53%). The results of the chi-square test revealed no statistically significant between-group differences respecting participants' gender, marital status, educational level, employment status, and insurance coverage ($P > 0.05$; Table 1).

The pretest mean score of stress was 22 ± 1 in the control group and 23 ± 1 in the intervention group and the posttest mean score of stress was 21 ± 2 in the control group and 13 ± 4 in the intervention group. Within-group comparisons revealed no significant change in the mean score of stress in the control group ($P = 0.680$) and significant decrease in the mean score of stress in the intervention group ($P \leq 0.001$). Between-group comparisons also indicated that although there was no significant difference between the groups respecting the pretest mean score of stress ($P = 0.875$), the posttest mean score of stress in the intervention group was significantly less than the control group ($P \leq 0.001$; Table 2).

The pretest and the posttest mean scores of anxiety were respectively 33 ± 3 and 28 ± 6.06 in the control group and 32 ± 5.02 and 15 ± 8.09 in the intervention group. Within-group comparisons showed that the mean score of anxiety did not significantly change in the control group ($P = 0.725$), while it significantly decreased in the intervention group ($P < 0.001$). Moreover, although there was no significant difference between the groups respecting the pretest mean score of anxiety ($P = 0.521$), the posttest mean score of anxiety in the intervention group was significantly less than the control group ($P < 0.001$; Table 2).

The pretest and the posttest mean values of SBP were respectively 133 ± 6.02 and 132 ± 5.02 in the control group and 135 ± 7.02 and 124 ± 7.02 in the intervention group. Within-group comparisons indicated no significant change in the mean value of SBP in the control group

Table 1. Between-group comparisons respecting participants' demographic characteristics

Characteristics	Groups		P value ^a	
	Intervention	Control		
	No. (%)	No. (%)		
Gender	Male	31 (77)	29 (73)	0.183
	Female	9 (22)	11 (27)	
Marital status	Married	38 (95)	38 (95)	1
	Single	2 (5)	2 (5)	
Educational level	Below-diploma	26 (65)	29 (73)	0.171
	Diploma and higher	14 (35)	11 (27)	
Employment status	Unemployed	14 (35)	12 (30)	0.113
	Employed	12 (30)	16 (40)	
	Retired	14 (35)	12 (30)	
Insurance coverage	Yes	(97)39	39 (97)	1
	No	(2)1	1(2)	

^a Chi-square test.

Table 2. Within- and between-group comparisons respecting the means scores of stress and anxiety and the mean values of SBP, DBP, and HR

Variables	Groups	Time		P value ^a	Pretest posttest mean difference Mean ± SD
		Before	After		
		Mean ± SD	Mean ± SD		
Stress	Intervention	23 ± 1	13 ± 4	<0.001	9 ± 1
	Control	22 ± 1	21 ± 2	0.680	2 ± 1
	P value ^b	0.875	0.001	—	-
Anxiety	Intervention	32 ± 5.02	15 ± 8.09	0.001	17 ± 8
	Control	33 ± 3.02	28 ± 6.06	0.725	5 ± 4
	P value ^b	0.521	0.001	—	-
SBP	Intervention	135 ± 7.02	124 ± 7.02	<0.002	6 ± 4
	Control	133 ± 6.02	132 ± 5.02	<0.865	1 ± 3
	P value ^b	0.575	<0.003	—	-
DBP	Intervention	82 ± 4.01	76 ± 3.02	<0.003	6 ± 4
	Control	81 ± 5.02	80 ± 4.01	<0.665	4 ± 1
	P value ^b	<0.875	<0.005	—	-
HR	Intervention	80 ± 4.02	71 ± 3.02	<0.002	8 ± 4
	Control	79 ± 3.02	78 ± 3.02	<0.865	1 ± 4
	P value ^b	<0.865	<0.001	—	-

^a The paired-sample *t* test; ^bThe the independent-sample *t* test.

($P=0.865$) and a significant decrease in the mean value of SBP in the intervention group ($P\leq 0.002$). Between-group comparisons also showed that while there was no significant difference between the groups respecting the pretest mean value of SBP ($P=0.003$), the posttest mean value of SBP in the intervention group was significantly less than the control group ($P<0.001$; Table 2).

The pretest and the posttest mean values of DBP were respectively 81 ± 5.02 and 80 ± 4.01 in the control group and 82 ± 4.01 and 76 ± 3.02 in the intervention group. Although no significant change was observed in the mean value of DBP in the control group ($P=0.665$), the mean value of DBP significantly decreased in the intervention group ($P<0.003$). Moreover, there was no between-group difference respecting the pretest mean value of DBP ($P=0.875$), while the posttest mean value of DBP in the intervention group was significantly less than the control group ($P<0.005$).

The pretest and the posttest mean values of HR were 79 ± 3.02 and 78 ± 3.02 in the control group and 80 ± 4.02 and 71 ± 3.02 in the intervention group. Although the within-group change in the mean value of HR was not statistically significant in the control group ($P=0.865$), the mean value of HR significantly decreased in the intervention group ($P<0.001$). Moreover, between-group difference respecting the pretest mean value of HR was not significant ($P=0.865$), while the posttest mean value of HR in the intervention group was significantly less than the control group ($P<0.001$; Table 2).

Between-group comparisons respecting the pretest posttest mean differences also showed that pretest posttest changes in the mean scores of stress and anxiety and the mean values of SBP, DBP, and HR in the intervention

group were significantly greater than the control group ($P<0.05$; Table 2).

Discussion

This study evaluated the effects of clinical simulation on stress, anxiety, and hemodynamic parameters among the candidates for CA. Findings indicated the significant positive effects of clinical simulation on stress, anxiety, and hemodynamic parameters.

Our findings showed that clinical simulation significantly reduced stress among the candidates for CA. In agreement with this finding, two former studies showed the effectiveness of orientation programs in significantly reducing stress among patients undergoing CA (26,37-43). Another study showed that mind simulation significantly reduced stress and increased cognitive flexibility among adults with stuttering disorder (41). Simulation has significant roles in ensuring patient safety and manipulating or predicting behaviors (37). It helps create an artificial environment for safely exercising activities without causing serious injuries (39). Before attending real clinical environment, most patients experience some levels of anxiety and stress mostly due to having limited knowledge. Accordingly, they prefer to receive education about the environment and even have a brief visit of it. Simulation provides patients with the opportunity to safely visit clinical settings and receive education about accurate behaviors in different situations and thereby, reduces their stress and anxiety, improves their ability to perform tasks, increases their self-confidence, strengthens their relationships with healthcare providers, and gives them a sense of worthiness (40).

Study findings also showed no significant between-

group difference respecting the pretest mean score of anxiety, denoting the homogeneity of the groups in terms of baseline anxiety level. Several earlier studies also reported the same finding (42-44). Moreover, findings showed that clinical simulation significantly reduced anxiety among the candidates for CA. A former study also showed the effectiveness of a CA orientation tour in significantly reducing anxiety among patients (45). Another study reported that simulation-based learning can significantly reduce anxiety and stress among patients and learners (46). Two other studies also reported the positive effects of simulation on anxiety among patients (26,44). Almost all patients experience some levels of stress and anxiety when they attend healthcare settings to receive healthcare services due to unfamiliarity with healthcare environment, separation from family members, and imaginations about diagnostic and therapeutic procedures and their results (47). They attribute their stress and anxiety to factors such as fear over the unknown, potential procedural threats, necessity for surgery, CA complications, and uncertainties over the future. Fear over the unknown is mainly due to the lack of knowledge (26). Stress, anxiety, and their contributing factors can endanger patient life during CA and cause them serious complications such as cardiac dysrhythmias, coronary artery spasm, or even coronary artery rupture (11,26). Therefore, careful stress and anxiety assessment is needed before CA in order to identify patients with high levels of stress and anxiety, take appropriate measures for managing their stress and anxiety, and improve the accuracy and the outcomes of CA (12). Unlike our findings, two previous studies reported that orientation programs had no significant effects on procedural anxiety among patients (48,49). This contradiction is attributable to the differences among studies respecting their interventions, anxiety measurement protocols, and baseline anxiety levels.

We also found that clinical simulation significantly reduced SBP, DBP, and HR among the candidates for CA. A previous study also reported the significant positive effects of an orientation program on hemodynamic parameters (26). Another study revealed that anxiety reduction training had significant positive effects on vital signs among candidates for elective surgeries (50).

Like other studies, this study had some limitations. For instance, participants might have acquired information about CA from media or from patients with previous CA experience. Such information might have affected their stress and anxiety.

Conclusion

This study concludes that clinical simulation is effective in significantly reducing stress, anxiety, SBP, DBP, and HR among the candidates for CA. Therefore, simulation-based interventions are recommended for CA candidates.

Conflict of Interests

None declared.

What does this paper contribute to the wider global clinical community?

- Clinical simulation is effective in significantly reducing stress, anxiety, and hemodynamic parameters among the candidates for coronary angiography.
- Clinical simulation can be used to improve patient satisfaction.

Ethical Approval

The Ethics Committee of Shahrekord University of Medical Sciences, Shahrekord, Iran, approved this study (code: IR.SKUMS.REC.1395.294). Moreover, the study was registered in the Iranian Registry of Clinical Trials (code: IRCT2017061734584N1).

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