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Evaluation of the effect of premedication on pain severity and hemodynamic status of patients undergoing coronary angiography

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ABSTRACT

Background: As a stressful invasive procedure, angiography causes pain and several hemodynamic changes in patients. Various forms of premedication are used to reduce these complications; however, there is no consensus on their effectiveness. This study aimed to determine the effect of premedication on pain severity and hemodynamic status of patients undergoing coronary artery angiography.

Methods: This clinical trial was conducted on candidates for coronary angiography, who referred to Ganjavian Hospital of Dezful, Iran, in 2012. In total, 102 patients were selected through convenience sampling and randomly divided into three groups of 34 cases. The first group was intravenously administered 4 mg of chlorpheniramine, whereas the second and third groups were intravenously injected 5 mg of diazepam and 2 mg of normal saline, respectively, 30 minutes before angiography. Pain intensity and hemodynamic status of the patients were evaluated and recorded before, during, and after angiography. Data collection was carried out using visual analogue scale and hemodynamic status registration form. Data analysis was performed in SPSS, version 19, using Chi-square, One-way analysis of variance (ANOVA), Friedman, Kruskal-Wallis, and repeated measures ANOVA.

Results: In this study, pain increased in all the three groups after angiography (P<0.001); however, this difference between the groups was not significant. On the other hand, heart rate, blood pressure, and respiratory rate decreased after the angiography (P<0.001). This difference was only significant regarding systolic (P=0.03) and diastolic (0.02) blood pressures and heart rate (P=0.04) of patients on the fourth 15 minutes after the angiography.

Conclusion: According to the results of this study, no significant difference was observed between the groups in terms of the effect of different types of premedication on pain severity and hemodynamic status. Future studies are recommended to evaluate the effect of premedication during other invasive procedures.

1. Introduction

Cardiovascular disease is the leading cause of mortality and morbidity worldwide, the prevalence of which is on a growing trend.[1, 2] Mortality caused by this disease in developed countries mostly occurs in individuals aged higher than 70 years. However, mortality by this disease is mainly observed in younger population in Iran,[3] which indicates the prevalence of this condition in the youth.

High prevalence of cardiovascular diseases, especially those related to coronary artery, necessitates several diagnostic techniques, and angiography is the gold standard for this purpose.[4, 5] In Iran, annually about 16-18 thousands of cases of angiography are reported.[6] Similar to any other invasive technique, angiography could be associated with complications, such as anxiety, pain, and hemodynamic variations, in addition to its

advantages in diagnosis and evaluation of coronary artery diseases.[7]

As a stressful factor, pain leads to the activation of response to anxiety, the nervous system, as well as the endocrine and safety glands. One of the most important events occurring during response to tension is the activation of the sympathetic system and release of epinephrine, leading to signs of the sympathetic nervous system stimulation (i.e., elevated heart rate, blood pressure, respiratory rate, as well as decreased lung volume) and eventually myocardial ischemia through affecting the cardiovascular system.[8] Given the involvement of the cardiovascular system in patients undergoing angiography, prevention and control of pain in such patients is of paramount importance.[9] This is mainly due to the fact that hemodynamic disorders might be associated with failure in cardiac catheterization techniques, difficulty in making a definitive diagnosis, increased use of sedatives, and decreased cooperation of patients with healthcare personnel.[10]

Various techniques were proposed to soothe pain and control hemodynamic complications, one of which is the use of sedatives and analgesics as premedication.[11, 12] Generally, premedications, such as diazepam, metoclopramide, chlorpheniramine, diphenhydramine, and hydrocortisone, which have palliative and anti-allergic properties, are used to relieve pain and assure patient comfort during a procedure. However, use of these medications in some studies is not recommended and depends on general health status of the patient.[13-15]

In a study by Alamri et al. (2011), it was reported that the use of premedication (e.g., oral diazepam and chlorpheniramine) had no significant impact on pain intensity of patients during angiography.[12] In another study, Babapour et al. (2016) marked no statistically significant difference between hemodynamic indicators of the intervention groups, who received premedication, and control groups.[13] Nevertheless, Ghasemzadeh et al. (2013) found that clonidine, as a premedication, significantly reduced hemodynamic parameters of patients during surgery.[16] Bahrani (2013) reported that the use of dexmedetomidine was effective in reducing hemodynamic indicators and facilitating the surgical procedure.[17] While the effect of premedication on angiography was not emphasized in the mentioned studies, they showed an inconsistency in their application. Meanwhile, application of premedication in healthcare centers is not subject to specific instructions. With this background in mind, this study aimed to determine the effect of premedication on pain severity and hemodynamic status of patients undergoing coronary artery angiography.

2. Methods

2.1. Design

This single-blind clinical trial was conducted on patients undergoing coronary artery angiography, who referred to Ganjavian Hospital of Dezful, Iran, in 2012.

2.2. Participants and setting

Sample size was estimated at 32 based on the study by Hanifi et al. (2006)[18] and sample size formula ($Z_{1-\beta}=1.28$, $Z_{1-\alpha/2}=1.96$, $S_1=8.77$, $S_2=14.85$, $X_1=16.45$, $X_2=10$). Given the possible sample attrition, the final sample size was calculated at 34 individuals per group (102 in total). Patients were selected using convenience sampling technique and divided into two intervention groups and a placebo group using the pseudo-random allocation method. To perform pseudo-random allocation, control confounding factors, and prevent interaction between the participants, the patients were assigned to study groups on alternate days. Patients, who were selected to undergo angiography on Monday and Wednesday, were assigned to the first intervention group receiving chlorpheniramine as premedication. On the other hand, those who were undergoing angiography on Sunday and Tuesday were assigned to the second intervention group and received diazepam as premedication. This study was single-blinded, meaning that patients were aware of their premedication, but had no knowledge about their group. All the data was gathered by the researcher, who was aware of the research method and type of premedication for each patient.

The inclusion criteria were lack of history of angiography, age range of 30-70 years, hospitalization merely for coronary angiography, no need for any other diagnosis, no invasive procedure (e.g., transesophageal echocardiography) before angiography, no myocardial infarction over the past week, lack of heart failure and valvular heart diseases, hemodynamic instability, and medium pain intensity (4 - 6.9) in evaluation of severity of the pain threshold. The exclusion criteria included sensitivity to contrast agent and incidence of severe fluctuations in heart rate, blood pressure, and other vital signs during the study.

2.3. Instruments

In this study, the personal characteristics form including age, gender, chronic diseases, smoking status and history of hospitalization due to cardiovascular diseases, hemodynamic status form (e.g., systolic and diastolic blood pressures, as well

as heart and respiratory rates), and visual analogue scale (VAS) of pain were used to collect the data.

In addition, barometer model ALPK2 was used to measure blood pressure of the participants, validity and reliability of which were confirmed through calibration of the device by a medical engineer, who was one of the employees of the hospital and re-measurement of blood pressure of eight patients using another barometer, respectively. Eventually, reliability of the measures obtained from the two devices was confirmed at correlation coefficient of 0.95.

Respiratory rate was estimated by observing the chest movement in one minute using a wrist watch previously set by a watchmaker. Furthermore, stethoscope Model ALPK2 was used to accurately evaluate the heart rate of the participants. Reliability of the mentioned devices was confirmed using the interrater reliability technique. The respiratory and heart rates were controlled by another nurse five minutes after measuring them by the researcher, which was repeated for eight samples. Reliability of the tools was confirmed by correlation coefficient of 0.92.

VAS was applied to evaluate pain intensity in patients. This tool, which is in the form of a numbered ruler (0-10), was first designed by Atiken in 1969 for the assessment of pain in humans. On this scale, zero is interpreted as lack of pain, whereas score of 10 is regarded as the highest level of pain. It should be mentioned that this is a standard tool, reliability and validity of which were confirmed by various studies. In addition, this tool was previously applied in patients undergoing angiography.[19-21]

2.4. Data Collection

All the participants were intravenously administered 100 mg of hydrocortisone 30 minutes before angiography in order to prevent allergy to contrast agent.[22] Medications used in the three study groups (control and the first and second intervention groups) included 4 mg of intravenous chlorpheniramine, diazepam, and normal saline (placebo), respectively. In addition, all the evaluated patients were admitted to post-angiography ward 12 hours before angiography.

Data related to demographic characteristics of the participants was collected by the researcher through interviews. Hemodynamic indicators of the patients were assessed two times before angiography (8-12 hours before and 30 minutes after), four times during angiography (the first, second, third, and fourth 5 minutes), and four times after angiography (the first, second, third, and fourth 15 minutes) by the researcher.

Furthermore, pain intensity of the participants was evaluated five times (during angiography, upon entrance to the ward after angiography, and two, four, and six hours after angiography) in all the groups using VAS. To estimate the level of pain tolerance, the researcher percussioned a needled to the heels of the patients before the intervention when the participants were calm and without pain. Afterwards, pain intensity of the patients was measured using the mentioned tool, and the three groups were compared in terms of pain threshold.

2.5. Ethical considerations

Objectives of the study were explained to the participants individually and they were assured of the confidentiality terms regarding their personal information. The researcher was available during the study and answered all the questions of the subjects. In addition, written informed consent was obtained from the participants prior to the study.

2.6. Statistical analysis

Data analysis was performed in SPSS version 19 using descriptive indicators and Chi-square (to evaluate the difference between the groups regarding the variables of gender, diabetes, renal disease, blood pressure, blood lipids, smoking status, and history of hospitalization due to cardiovascular diseases), One-way analysis of variance (for assessment of difference between the groups in terms of age and intergroup differences regarding hemodynamic indicators), Kruskal-Wallis (to compare differences in pain intensity as an abnormal variable between the groups), Friedman (for comparison of intragroup changes in pain intensity as an abnormal variable), and repeated measures analysis (to compare intragroup changes of pain intensity as a normal variable).

3. Results

Demographic and clinical characteristics of the participants are presented in Table 1, showing no significant difference between the groups in this regard. In addition, all the study groups were homogenous in terms of pain threshold, and Kruskal-Wallis test indicated no statistically significant difference between the groups before angiography (P=0.73).

A lower level of pain intensity was observed in patients administered with chlorpheniramine, compared to the other groups. In addition, pain intensity was lower in the diazepam group at the time of entrance to the ward after angiography and the second and fourth hours after angiography, compared to the other two groups. Nonetheless,

pain intensity was lower in the chlorpheniramine group in the sixth hour after angiography. The difference was not significant at any of the time points. Meanwhile, the intragroup changes in pain intensity of all the three groups of chlorpheniramine, diazepam, and placebo were significant (P<0.001, P<0.001, and P=0.02, respectively; Table 2).

According to tables 3 and 4, changes in hemodynamic indicators during angiography were highly similar and the groups were not significantly different. After the intervention, systolic and diastolic blood pressures reduced more in the diazepam group compared to the other two groups (P<0.001). The reduction in systolic blood pressure of patients was only significant at 60 minutes after angiography (P=0.03). On the other hand, there was a significant difference between the groups in terms of diastolic blood pressure 45 (P=0.02) and 60 (P=0.02) minutes after angiography (Table 3).

After the intervention, heart rate significantly decreased more in the group receiving diazepam, compared to the other groups (P=0.04). This difference was significant at 8-12 hours (P=0.003) and 30 minutes before angiography (P=0.007) and 15 and 60 minutes (P=0.04) after angiography (Table 4). However, respiratory rate of the chlorpheniramine group reduced more than the other groups; however, this difference between the groups was not statistically significant.

Table 1. Demographic and clinical characteristics of the participants

Variable	Groups	Chlorpheniramine	Diazepam	Placebo	P-value
		N (%)	N (%)	N (%)	
Gender	Male	17 (50)	17 (50)	17 (50)	*<0.0001
	Female	17 (50)	17 (50)	17 (50)	
Diabetes	Yes	9 (26.47)	8 (23.53)	8 (23.53)	*0.94
	No	25 (73.53)	26 (76.47)	26 (76.47)	
Renal diseases	Yes	2 (5.9)	1 (2.94)	1 (2.94)	*0.77
	No	32 (94.1)	33 (97.06)	33 (97.06)	
Hypertension	Yes	11 (32.35)	15 (44.12)	12 (35.3)	*0.58
	No	23 (67.65)	19 (55.88)	22 (64.7)	
Hyperlipidemia	Yes	9 (26.47)	8 (23.53)	6 (17.65)	*0.67
	No	25 (73.53)	26 (76.47)	28 (82.35)	
Smoking	Yes	6 (17.65)	6 (17.65)	8 (23.53)	*0.78
	No	28 (82.35)	28 (82.35)	26 (76.47)	
History of hospitalization due to cardiovascular diseases	Yes	9 (26.47)	7 (20.6)	11 (32.35)	*0.054
	No	25 (73.53)	27 (79.4)	23 (67.65)	
Age (year)	M±SD	54.0±9.57	56.55±9.42	59.2±8.9	**0.07

*Chi-square; **One-way ANOVA

Table 2. Comparison of mean pain intensity in three study groups during and after angiography

Variable	Time	Group			*P-value
		Chlorpheniramine	Diazepam	Placebo	
		M±SD	M±SD	M±SD	
Pain	During angiography	2.72±0.17	2.85±0.56	2.74±0.35	0.42
	Upon admission to ward after angiography	3.50±0.40	3.37±0.62	3.66±0.29	0.29
	Two hours after angiography	3.60±0.35	3.50±0.22	3.71±0.42	0.32
	Four hours after angiography	3.60±0.26	3.44±0.48	3.59±0.18	0.44
	Six hours after angiography	3.12±0.63	3.31±0.41	3.28±0.33	0.64
	**P-value	<0.001	<0.001	0.002	

*Kruskal-Wallis test; ** Friedman test

Table 3. Comparison of systolic and diastolic blood pressures of patients in the first (chlorpheniramine), second (diazepam) and third (placebo) groups during and after angiography

Variable	Systolic blood pressure				Diastolic blood pressure			
Group / Time	Chlorpheniramine	Diazepam	Placebo	**P-value	Chlorpheniramine	Diazepam	Placebo	**P-value
8-12 hours before angiography	124.85±14.69	126.55±18.97	132.52±27.83	0.20	76.32±9.15	74.70±8.95	75.88±12.81	0.80
30 minutes before angiography	123.67±19.51	122.79±17.67	123.73±21.62	0.97	75.58±10.49	72.64±11.88	76.61±11.46	0.32
Five minutes in angiography	157.61±27.34	151.17±23.06	163.97±35.32	0.19	76.08±11.89	73.52±10.69	78.97±18.94	0.29
10 minutes in angiography	148.50±22.28	131.61±17.43	148.52±28.72	0.004	73.97±9.90	72.94±16.42	79.85±11.70	0.06
15 minutes in angiography	130.14±0.65	135.08±15.04	137.64±28.59	0.29	80.5±9.02	86.05±11.57	85.38±15.47	0.09
20 minutes in angiography	127.32±20.89	121.80±24.78	129.65±34.77	0.75	80.35±10.06	81.44±10.44	82.67±16.44	0.75
15 minutes after angiography	114.31±0.61	111.36±22.22	116.40±85.01	0.24	74.12±11.33	76.12±76.48	75.15±17.78	0.72
30 minutes after angiography	112.94±13.37	112.05±13.87	119.61±21.13	0.12	70.58±11.53	73.52±10.69	75.82±12.43	0.18
45 minutes after angiography	110.58±14.34	109.70±13.59	111.89±25.70	0.88	70.58±10.13	67. 94±9.13	74.41±8.94	0.02
60 minutes after angiography	108.82±13.87	95.10±20.89	122.79±17.67	0.03	68.52±5.21	66.76±8.78	72.64±9.94	0.02
P-value *	<0.001	<0.001	<0.001		<0.001	<0.001	<0.001	

*Repeated measures ANOVA; **One-way ANOVA

Table 4. Comparison of heart and respiratory rates of patients in the first (chlorpheniramine), second (diazepam), and third (placebo) groups during and after angiography

Variable	Heart rate				Respiratory rate			
Group / Time	Chlorpheniramine	Diazepam	Placebo	P-value**	Chlorpheniramine	Diazepam	Placebo	P-value**
8-12 hours before angiography	80.10±70.62	79.10±11.29	72.8±88.27	0.003	19.1±97.08	19.0±88.80	19.0±58.96	0.23
30 minutes before angiography	78.9±52.90	74.8±05.11	71.9±41.32	0.007	19.0±76.78	19.0±76.98	19.0±79.76	0.98
Five minutes in angiography	11.68±75.64	74.79±10.61	71.88±9.53	0.31.0	99.02±0.20	81.61±0.19	92.85±0.19	0.18
10 minutes in angiography	74.91±11.38	76.61±10.02	72.20±10.49	0.23	20.02±1.05	20.00±0.00	20.08±0.37	0.85
15 minutes in angiography	76.00±15.09	73.70±10.61	74.79±12.39	0.76	19.73±0.89	19.82±0.71	19.79±0.64	0.88
20 minutes in angiography	73.58±11.45	73.02±10.19	72.64±10.81	0.93	19.58±0.92	19.73±0.66	20.00±0.81	0.11
15 minutes after angiography	76.05±12.42	72.94±8.74	69.32±11.18	0.04	19.70±1.00	19.76±0.69	19.94±0.34	0.39
30 minutes after angiography	76.9±08.98	74.8±85.10	70.10±85.36	0.06	19.3±26.48	20.0±00.24	19.0±76.65	0.32
45 minutes after angiography	76.10±38.21	74.7±23.73	71.9±79.57	0.12	19.0±61.98	19.0±85.60	19.0±85.65	0.35
60 minutes after angiography	76.9±82.52	74.7±79.47	71.10±17.70	0.04	19.0±38.98	19.0±88.97	19.0±79.72	0.058
*P-value	<0.001	0.04	0.11		0.27	0.49	0.25	

*Repeated measures ANOVA; **One-way ANOVA

4. Discussion

According to the results of the current study, no significant difference was observed between the three groups after angiography in terms of pain intensity. In this regard, Alamri et al. (2011) reported that use of oral diazepam and chlorpheniramine as premedication did not reduce pain in patients during angiography.[12] Woodhead et al. (2007) also affirmed no significant difference between patients receiving diazepam and control group in terms of pain severity during angiography.[23] While it cannot be certainly stated that diazepam and chlorpheniramine have no impact on pain intensity of patients during angiography, we recommend performing further studies to confirm the effectiveness of the mentioned medications.

According to the results of the present study, blood pressure, as well as heart and respiratory rates reduced after angiography; however, this difference was only significant regarding systolic and diastolic blood pressures and heart rate of patients 60 minutes after angiography. In line with our findings, Babapour et al. (2016) marked no significant difference between the intervention and control groups regarding hemodynamic indicators.[13] In addition, Kazemi Saeed et al. (2006) reported that blood pressure and heart rate of patients in

intervention and control groups were not significantly different during angiography.[24] Therefore, administering unnecessary medications to patients before angiography should be avoided.

On the other hand, some studies, including the one by Ghasemzadeh et al. (2013), suggested that the use of clonidine as premedication has a positive impact on reducing hemodynamic indicators during surgery.[16] Moreover, Bahrani (2013) claimed that use of dexmedetomidine significantly reduced hemodynamic indicators and improved the surgery process.[17] Results obtained by Nascimento et al. (2007) also demonstrated that application of diazepam as premedication led to more reduction in heart rate and blood pressure of patients undergoing coronary artery angiography, compared to the other medications.[25] In a study by Hanifi et al. (2006), it was pointed out that diastolic blood pressure of patients of both groups during angiography was no significantly different.[18] However, diastolic blood pressure was lower in the control group, compared to the intervention group, which is not congruent with our findings. This lack of consistency between results might be due to the type of premedication and differences in sample populations of the studies.

Pain is an abstract phenomenon and cannot be easily described since it could be affected by individual and cultural differences. Limited time and lack of sufficient samples led to the selection of participants from a broad age range, which might have affected the final results.

5. Conclusion

According to the results of the present study, no significant difference was observed between the study groups in terms of pain intensity and hemodynamic indicators. Given the possible impact of age on perceived pain, future studies are recommended to determine more specific age ranges and evaluate the effect of premedications on other invasive procedures.

Conflicts of interest

The authors declare no conflicts of interest.

Authors' contributions

Ferdos Pelarak: data collection and participation in drafting the manuscript, Shilan Azizi: participation in drafting of the manuscript, Hamideh Mashalchi: data collection and participation in drafting of the manuscript, Behrooz Tiznobeyk: consultation and participation in drafting of the manuscript, Marzieh Shayestehfard: data collection and participation in drafting of the manuscript, Leila Fakharzadeh: data collection and participation in drafting of the manuscript, Mohsen Haghighizadeh: data analysis and participation in drafting of the manuscript, Narges Sadeghi: drafting of the manuscript and editing of the article

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