Original Article

The Efficacy of an Intervention Program for Pain Intensity Reduction in Patients Undergoing Arterial Sheath Removal after Coronary Artery Angioplasty

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Abstract

Background: Pain management after sheath removal is one of the most significant points in patient care. The use of a simple, practical, and combined method in this field is essential. The purpose of this study was to evaluate the efficacy of an intervention program for pain intensity reduction in patients undergoing arterial sheath removal after coronary artery angioplasty.

Methods: This semi-experimental study was conducted in 2020 on 90 eligible patients selected via the purpose-based method and randomly assigned to experimental and control groups. The intervention program for the experimental group included training to relax the abdominal muscles, deep and slow breathing, and precise pressure on the femoral pulse. Pain intensity was measured before, during, and several times after arterial sheath removal. The independent t, Fisher exact, and χ2 tests were used to analyze the data.

Results: Women comprised 66.6% of the study participants, who had a mean age of 58.20±8.70 years. No significant differences were observed concerning pain intensity, bleeding, pseudoaneurysm formation, and hematoma between the 2 groups before the intervention (P=0.531). However, during the intervention and in the fifth and tenth minutes after the intervention, pain intensity was lower in the experimental group (P<0.050), whereas no such differences were observed regarding bleeding, pseudoaneurysm formation, and hematoma.

Conclusion: Given the effectiveness of our intervention program in ameliorating pain intensity and vasovagal response after arterial sheath removal, we suggest that this program, along with prescription drugs, be used for the management of patients' pain.

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Introduction

Coronary artery disease (CAD) is the leading cause of death in most industrialized countries in that it accounted for about 20% of deaths by 2019.[1] Cardiovascular diseases and vascular disorders are chronic diseases that comprise more than 12% of the world's diseases, with the rate having shown a considerable rise in recent years to 78% of all deaths in developing countries.[2, 3] Evidence suggests that the CAD incidence will increase in the coming years and that this growing trend is not limited to low- and middle-income countries.[4, 5] Accurate diagnoses, cost-effective treatments, complications, and mortality rates should, therefore, be accorded great significance in decision-making about CAD.[2]

Cardiovascular diseases are frequent and constitute the most important cause of death and disability in Iran, where the age of patients with CAD is on the decrease.[6] Indeed, nearly 50% of deaths in Iran are due to CAD. One of the earliest manifestations of CAD is chronic persistent angina, which occurs in approximately 50% of patients, usually due to obstruction in at least 1 large coronary artery by atherosclerotic plaques.[7]

The inadequate control or relief of the pain caused by arterial sheath removal in patients following coronary artery angioplasty has consequences,[8] the most important of which are increased heart rate, blood pressure, and need for oxygen, possibly leading to left ventricular dysfunction, myocardial ischemia, and myocardial infarction.[9]

Today, valuable treatment strategies such as medication and coronary artery bypass graft surgery are employed to treat CAD. Nonetheless, coronary artery angioplasty is still the most common treatment.[10] The femoral pathway is more frequently utilized than the radial pathway to access the coronary arteries in most medical centers.[11] When the arterial sheath is removed, the patient may move due to severe pain, which in turn increases the risk of vascular accidents.[12] For the reduction of the complications of arterial sheath removal, 2 methods are drawn upon: the prescription of drugs such as atropine and topical drugs (eg, lidocaine gel and spray) and non-pharmacological means such as lavender inhalation and slow and deep breathing.[13]

Usually, arterial sheaths are removed and homeostasis is performed 4 hours after coronary artery angioplasty and the control of the blood clotting time. The most common and traditional method for controlling homeostasis is hand pressure is, which is performed for 15 to 20 minutes until the bleeding stops.[14] Pain in post-coronary artery angioplasty patients can be induced by the removal of arterial sheaths, the application of pressure to the catheter insertion area, or the patient's immobility in the supine position for several hours.[15, 16] The incidence rate of a documented vasovagal reaction after femoral sheath removal is variable. Huang[17] (2000) reported that 10% of patients had vasovagal reactions

and 7% had nausea or vomiting during surgery.

Increased heart rate and blood pressure and, consequently, increased heart rate and oxygen demand lead to left ventricular dysfunction, myocardial ischemia, and, eventually, myocardial infarction, all of which are the most significant side effects of the failure to control or treat the pain caused by arterial sheath removal.[18] The risk of bleeding is due to high blood pressure and impaired homeostasis, and the chances of vasovagal attacks are increased by pain. Vasovagal reactions induced by vagal stimulation and stimulus-response manifest themselves as bradycardia and hypotension, and they constitute one of the most common complications of coronary artery angioplasty, with a prevalence rate of about 10%.[19] Vasovagal reactions resolve naturally but sometimes lead to shock, heart attack, and asystole, especially in patients with coronary artery stenosis.[20] Pain during and after arterial sheath removal can cause the patient to move and, thus, increase the risk of vascular complications due to improper homeostasis such as bleeding and hematoma.[21]

As was mentioned above, for the control of the pain caused by arterial sheath removal, different pharmacological and non-pharmacological methods, including topical or systemic analgesics,[22] cold compresses,[23] and music therapy, are used.[24] Nevertheless, some studies have reported the inefficacy of these measures in pain control or relief. Aktas and Karabulut[25] (2019) compared the efficacy of cold therapy, music therapy, and lidocaine spray in reducing pain due to chest tube removal and reported no significant difference in pain intensity at the time of chest tube exit and 20 minutes afterward between the cold therapy group and the control group. Alikhani et al[8] considered the use of cold compresses as a suitable way to alleviate pain intensity due to arterial sheath removal in patients undergoing coronary angiography. Sarabi et al[26] examined the effects of changing the position of patients and stated that position alteration to a semi-seated one was effective and safe for the reduction of pain without increasing vascular complications. Therefore, the hypothesis of the effect of the simultaneous use of various methods was proposed.

A standard and comprehensive intervention program for relaxation and pain reduction after arterial sheath removal has yet to be devised.[27] Some studies have focused solely on the effect of deep and slow breathing on pain after the removal of arterial sheaths and failed to propose a comprehensive training program.[28] In many centers, arterial sheath removal is followed by the manual homeostasis method, which is associated with severe pain.[29] Additionally, the formulation of a comprehensive educational program may be effective in assuaging pain intensity among patients. We, therefore, sought to investigate the efficacy of an intervention program in alleviating pain intensity in patients undergoing arterial sheath removal after coronary artery angioplasty.

Methods

This semi-experimental study with 2 parallel groups was performed in 2020 at the angiography and post-angiography wards of selected hospitals affiliated with Tehran University of Medical Sciences and Mahallati Hospital, Iran. Ninety eligible patients with CAD undergoing coronary artery angioplasty were randomly assigned to either the experimental group or the control group. Based on a previous study,[30] the sample size was estimated with a power of 80% and an α of 0.05. Thirty patients were allocated to each group considering a 10% dropout rate during the investigation. The sample size of 90 patients was selected via the purposive sampling method, and the study population was randomly assigned to the experimental and control groups by coin tossing (Figure 1).

The inclusion criteria were composed of first-time coronary artery angioplasty, fluency in Persian, ability to communicate, having shortness of breath and respiratory problems, ability to learn, having no history of mental disorders, having no history of hemophilia and coagulation disorders, having no vascular supplies before the arterial sheath, and having a systolic blood pressure of less than 130 mmHg. The exclusion criteria consisted of consuming analgesics for any reason, exhibiting cardiac dysrhythmia, suffering from congestive heart failure, having a history of myocardial infarction or cardiac arrest, and exhibiting decreased levels of consciousness. Ultimately, 90 patients were selected for the purposes of the present study.

The study protocol was approved by the Ethics Committee of Baqiyatallah University of Medical Sciences (code: IR.BMSU.REC.1398.251), and the conduct of the study complied with the Helsinki Declaration. To obtain informed consent, the researcher introduced himself and described his research goals to patients and their companions and noted that participation in the study was entirely voluntary and had no impact on the treatment process and that all participants' information would remain confidential. After receiving complete information about the research goals and the process thereof, the patients signed a written consent form.

Data were gathered using the participants' demographic characteristics, visual analog scale (VAS) score for pain, Christensen scale score for hematoma, and blood-stained gauze count. Demographic characteristics included age, sex, marital status, level of education, and occupation. VAS is a validated, subjective measure for acute and chronic pains, the scores of which are recorded by making a handwritten mark on a 10 cm line that represents a continuum between "no pain" and "worst pain.[31] On the Christensen scale, a small hematoma is considered to be between 2 and less than 5 cm2 and a large hematoma equal to or greater than 5 cm2. In an irregularly shaped hematoma, the largest and smallest diameters of the hematoma are measured, and the area of the hematoma is calculated by multiplying the diameters by each other.[32] The amount of blood loss was calculated based on counting the number of gauze pieces impregnated by blood. The amount of bleeding in each gauze piece (4×4 cm) impregnated by blood was considered to be about 10 mL. The number of blood-stained gauze pieces was multiplied by 10 mL, and the amount of the blood lost was calculated in mL.[31]

The training program for the patients in the experimental group included how to breathe slowly and deeply, how to keep the abdominal muscles relaxed, and how to completely empty the bladder before arterial sheath removal. Additionally, patients who suffered from tachycardia were
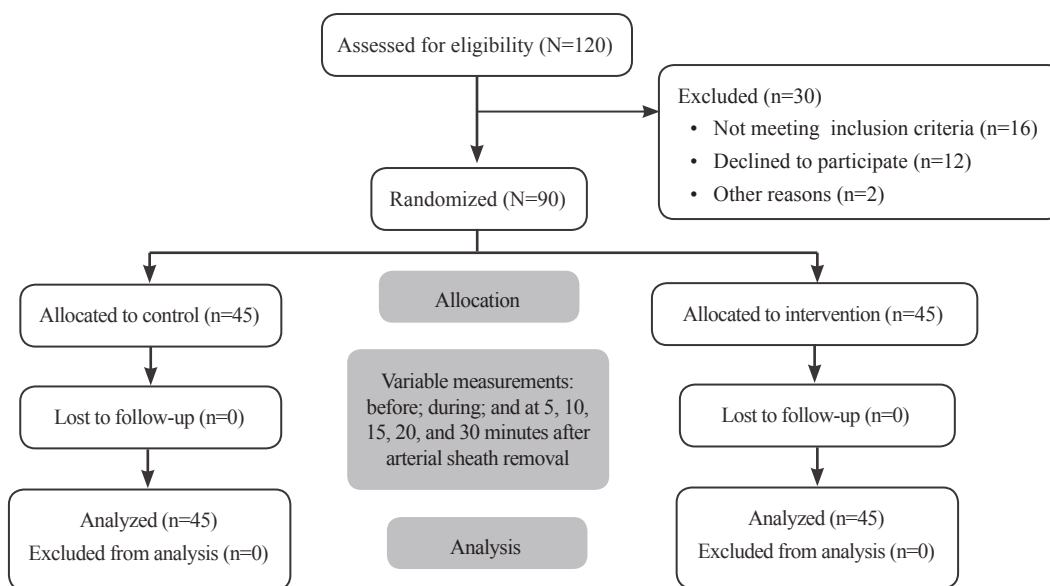

Figure 1. The image depicts the CONSORT flowchart of study enrollment and randomization.

trained in relaxation and medication adherence to normalize heart rate and blood pressure. The training program for physicians and nurses responsible for removing the arterial sheath included direct pressure training exactly on the femoral pulse, attention to patients' bladder emptiness, and the management of patients' tachycardia and the possible preprocedural rise in their blood pressure.[33] The patients in the experimental group performed deep and slow breathing and abdominal muscle relaxation 5 minutes before until 10 minutes after arterial sheath removal.[34] All arterial sheaths were removed 5 minutes after the onset of abdominal muscle relaxation and slow and deep breathing. The physicians and nurses responsible for performing the procedure were given the necessary training regarding finger pressure on the upper area of the arterial sheath entry site, as well as the correction of tachycardia and possible hypertension in the experimental group patients. For the patients in the control group, arterial sheath removal was performed routinely.

Hemodynamic parameters such as systolic and diastolic blood pressure, heart rate, and respiration rate were measured at intervals before, during, and immediately at 5, 10, 15, 20, and 30 minutes after arterial sheath removal. The patients were asked to indicate the intensity of pain at intervals before, immediately after the exit of the arterial sheath, and at 10, 20, and 30 minutes after homeostasis control and pressure removal from the site by showing the desired number.[35]

Variables were compared between the groups by using the independent t, Fisher exact, and χ^2 tests. A P-value of less than 0.05 was considered statistically significant. The statistical analyses were performed using the SPSS statistical software package, version 19, (IBM SPSS Statistics for Windows, Version 19.0, Armonk, and NY: IBM Corp).

Results

The present study was conducted on 90 patients, at a mean age of 58.20±8.70 years. All the participants completed the study period.

The results of the independent t test showed that the experimental and control groups were not statistically significantly different in terms of age (P=0.392). Most of the patients in both groups were male (P=1.000), were married (P=0.612), and had university qualifications (P=0.361) (Table 1).

The mean pain score was compared between the 2 groups during and after arterial sheath removal (between 0 and 30 min). The results showed statistically significant differences at 5 and 10 minutes after the removal of the sheath, whereas at the other time points, there were no statistically significant differences between the experimental and control groups concerning the mean pain score (Table 2).

The incidence of vascular complications, comprising bleeding, hematoma, and pseudoaneurysm formation, was

Table 1. Demographic characteristics of the patients in the experimental and control groups*

Characteristics	Groups		P
	Experimental (n=45)	Control (n=45)	
Age (y)	57.23±9.41	59.32±8.12	0. 392
Sex			1.000
Male	15 (33.4)	15 (33.4)	
Female	30 (66.7)	30 (66.6)	
Marital Status			0.612
Single	4 (9.0)	6 (13.0)	
Married	41 (91.0)	39 (87.0)	
Level of Education			0.361
Under high school diploma	14 (31.1)	10 (22.2)	
High school diploma	10 (22.2)	12 (26.7)	
University education	21 (46.7)	23 (51.1)	

*Data are presented as mean±SD or n (%).

Table 2. Comparison of the mean pain score during and after arterial sheath removal (0 to 30 min) between the experimental and control groups*

Time	Groups		P
	Experimental (n=45)	Control (n=45)	
Before sheath removal	2.19±0.78	2.44±0.62	0.531
Zero minute	6.42±1.71	8.14±1.77	0.001
Fifth minute	4.14±2.16	5.50±2.24	0.025
Tenth minute	2.31±1.66	5.63±2.31	0.013
Twentieth minute	0.95±0.43	1.30±1.18	0.862
Thirtieth minute	0.81±0.43	0.94±0.91	0.432

*Data are presented as mean±SD

Table 3. Comparison of the frequency distribution of bleeding, hematoma, and pseudoaneurysm formation between the experimental and control groups[*]

Time	Groups		P
	Experimental (n=45)	Control (n=45)	
Bleeding			
Immediately before sheath removal	2 (4.4)	4 (8.8)	0.215
4 hours after homeostasis	0	1 (1.2)	0.331
24 hours after homeostasis	0	1 (1.2)	0.232
Hematoma			
Immediately before sheath removal	1 (2.2)	3 (6.6)	0.863
4 hours after homeostasis	0	0	0.513
24 hours after homeostasis	0	1 (2.2)	0.314
Pseudoaneurysm Formation			
Immediately before sheath removal	0	1 (2.2)	0.261
4 hours after homeostasis	1 (2.2)	1 (2.2)	0.234
24 hours after homeostasis	0	1 (2.2)	0.762

[*]Data are presented as n (%).

analyzed at 3 time points: immediately after homeostasis control and then 4 hours and 24 hours afterward. No statistically significant differences were noted between the 2 groups in this regard (Table 3).

Discussion

In coronary artery angioplasty, the prevailing view is that the pain caused by arterial sheath removal can cause vasovagal reactions in some patients.[36]

We evaluated the efficacy of an intervention program aimed at alleviating pain intensity in patients undergoing arterial sheath removal after coronary artery angioplasty. Our training program in the experimental group featured training on how to breathe slowly and deeply, how to keep the abdominal muscles relaxed, and how to completely empty the bladder before arterial sheath removal. In addition, patients who suffered from tachycardia were trained to relax and adhere to their medications for the normalization of heart rate and blood pressure. Based on our results, the program was effective in controlling pain and reducing the incidence of vasovagal attacks but failed to prevent vascular complications. Pain intensity was significantly lower in the experimental group than in the control group at 0 minutes (immediately after arterial sheath removal) and then 5 and 10 minutes subsequently, with the patients reporting less pain. In the control group, the mean frequency of vasovagal attacks was significantly higher than that in the experimental group.

The results of our study are similar to those reported by Mall et al[37] (2019), Su et al[38] (2019), Rolantova et al[39] (2019), and Hassan et al[13] (2015) insofar as they demonstrated improvements in patients' hemodynamics during and after the removal of arterial sheaths. These results can be used as a preventive method to reduce pain in patients with CAD undergoing coronary artery angioplasty. Gunjal et al[9] (2015),

in a study on 120 patients after open-heart surgery, reported that the use of slow and deep breathing exercises, along with the consumption of palliative drugs (eg, narcotics), could have a greater impact on pain control following the removal of arterial sheaths than drug use alone.

Parach et al[30] (2018) conducted a study at Baqiyatallah Hospital and found significant differences between their intervention and control groups in terms of bleeding, hematoma, vasovagal reactions (n=11 vs n=24), urinary retention (n=8 vs n=31), and back pain after arterial sheath removal (P<0.050 for all).

Stegemann et al[40] (2015) studied 140 patients with CAD following coronary artery angioplasty. They divided the patients into a group that received only the relaxation technique before and during arterial sheath removal and a group that received only opioids. According to their findings, the control group reported less pain. Still, some studies assessing the implementation of the relaxation method to reduce pain in patients during chest tube removal have reported its ineffectiveness in assuaging pain.[36]

Zencir et al[17] (2016) evaluated the effects of cold therapy and breathing exercises on pain among 90 patients following median sternotomies with burn wounds and reported that the mean pain score was significantly different between the control and experimental groups (4.2 in the experimental group vs 4.9 in the control group). The mean score in the experimental group in subsequent interventions was 3.9. One of the most important strengths of this study compared with previous studies such as that by Parach et al[30] (2018) is the relative control of confounding factors like the degree of burn separation in the participants and the type of dressing.

Valikhani et al[41] (2020) examined the effects of sandbags and ice packs on the rate of hemorrhage and hematoma after percutaneous coronary intervention and found no significant differences between the 2 groups with respect to demographic characteristics and the rates of bleeding and hematoma before the intervention (P=0.001). The conclusion

was that the use of sandbags and ice packs reduced bleeding and hematoma postprocedurally.

Sasongko et al[42] (2019) investigated the effects of a combination of range motion and deep breathing exercises on pain following orthopedic surgery. The results showed that increased parasympathetic activity was associated with decreased pain perception.

In the present study, the mean pain score at time 0 (immediately after arterial sheath removal) and at 5 and 10 minutes afterward in the experimental group was significantly reduced compared with that in the control group. In line with some previous studies, we did not use local or systemic analgesia.

Concordant with previous studies,[8, 43] in the current investigation, we expected that our intervention program could lessen vascular complications due to disturbed homeostasis after arterial sheath removal. Nonetheless, we found that despite the reduction in bleeding in the experimental group and the decrease in the rates of hematoma and pseudoaneurysm formation in the control group, these differences did not constitute statistical significance. The novelty of the current study is the use of a combination of different interventions with an emphasis on educating patients to take actions themselves.

One of the limitations of this study is the effect of external factors and psychological conditions during the intervention, which may have affected the experience of pain. Furthermore, the removal of arterial sheaths by physicians and nurses was not performed in exactly the same manner, which may have affected the severity of the pain reported by the study participants. Such limitations can be eliminated in future studies by holding briefings.

Conclusion

Our intervention program of how to breathe slowly and deeply, how to keep the abdominal muscles relaxed, how to completely empty the bladder, and how to manage possible tachycardia through relaxation and medication adherence succeeded in ameliorating pain intensity in patients undergoing arterial sheath removal after coronary artery angioplasty. Further research on more samples aimed at finding more such safe and easy methods to control pain in this group of patients seems prudent.

Acknowledgments

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