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# Comparison of the effect of manual compression and closure pad on postangiography complications: A randomized controlled trial

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*Background: Different methods are available for the closure of the femoral artery after catheterization. The present study aimed at comparing the effect of manual compression (MC) and closure pad (CP) on vascular complications (hematoma and bleeding) of coronary angiography.*

*Methods: In the current clinical trial, a total of 238 patients who were candidates for angiography were randomly assigned to the MC and CP groups. In the MC group, after removal of the arterial sheath, the arterial puncture site was manually compressed for 5–10 minutes and hemostasis was achieved. In the CP group, after removal of the arterial sheath, the arterial puncture site was first manually compressed for 5–10 minutes and initial coagulation was achieved. Then, to continue the coagulation process, a CP was attached to the artery puncture site. Postangiography complications including bleeding and hematoma were monitored in both groups immediately and up to 24 hours after hemostasis. Data were analyzed by SPSS-18 software.*

*Results: After angiography, 7 (9.5%) and 5 (2.4%) patients had hematoma in the MC and CP groups, respectively; however, no significant difference was found between the groups. Rebleeding after hemostasis was observed in 2 (7.1%) patients in the MC group, but none of the subjects in the CP group had rebleeding. There was no significant difference in bleeding volume between the groups.*

*Conclusion: The results indicated the same efficacy of MC and CP methods in the prevention of postangiography vascular complications. Given the advantages of CP such as the possibility of changing the position in bed and increased physical comfort in the patient, this method is recommended for angiography and catheterization.* (J Vasc Nurs 2020;38:2-8)

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## INTRODUCTION

Angiography is a standard method for the diagnosis of coronary artery disease.[1] The use of femoral artery is one of the most common ways to access the artery for angiography. For this purpose, a sheath is passed through the artery to the coronary or left ventricle and then the diagnostic or therapeutic intervention is performed.[2] After the angiography, the sheath should be removed and the vascular access site should also be closed. Because of the high blood flow to the artery and multiplicity of tissue layers, which should be passed through to get access to the femoral artery, the closure of the arterial access site might be extremely difficult.[3] On the other hand, angiography through the femoral artery is associated with numerous complications, such as hematoma, bleeding, and infection, which make the management of arterial puncture site crucial.[4] There are several ways to achieve hemostasis after angiography, that is, manual compression (MC) and vascular closure devices (VCDs).[2] In the MC method, to achieve hemostasis after removing the catheter sheath, the groin is compressed with a sand bag (SB) for 20–30 minutes.[5] MC is a standard and safe method to achieve hemostasis in the femoral artery; however, it has some limitations including prolonged hemostasis achievement and hospital stay.[6] Since the early 1990s, a variety of VCDs are designed.[5] Based on the mechanism of action, VCDs include clip-based, collagen plug–based, and suture-based devices.[7] Closure pad (CP) is a type of VCD

made of nonwoven proprietary polypropylene with a positive charge. The proprietary polyprolate used in CP reacts with erythrocytes with a negative charge, which accelerates the process of coagulation and homeostasis.[8] VCDs advantages include accelerated hospital discharge, rapid homeostasis, and greater patient comfort. Despite these advantages, VCDs also have some limitations; they are expensive, their utilization requires prior training, and should be used by qualified personnel.[2–4] However, there is no evidence on the superiority of VCDs over MC.[9,10] Several studies compared the efficacy of MC and VCDs in achieving homeostasis after angiography. In the study by Deuling et al, MC was more effective than VCDs (eg, Angio-Seal [AS] and StarClose).[11] But some other studies indicated the high efficacy of VCDs than MC.[4,12,13] Given the contradiction among the results of previous studies, the present study aimed at comparing the effect of MC and CP methods on vascular complications (ie, bleeding and hematoma) in patients undergoing coronary angiography via the femoral artery.

## MATERIALS AND METHODS

### *Study hypothesis*

The effect of MC and CP was similar on the reduction of bleeding and hematoma volume caused by coronary angiography via the femoral artery.

### *Trial design*

This study is a randomized controlled clinical trial in which data were collected during 4 months from August to December 2015.

*Participants.* The study population consisted of all patients who were candidates for angiography in Imam Ali Hospital in Kermanshah; the largest cardiac surgery center in Western Iran. The study participants included eligible patients who were candidates for coronary angiography. Inclusion criteria were elective angiography, consciousness of the patient, use of right femoral artery for coronary angiography, age 18–80 years, utilization of 6-FR arterial sheath, lack of pregnancy or lactation (in female patients), lack of bleeding disorders such as hemophilia, lack of infection in groin, lack of peripheral artery diseases such as Raynaud's disease, normal blood pressure, normal coagulation tests (international normalized ratio, partial thromboplastin time, prothrombin time), lack of anticoagulants consumption, and glomerular filtration rate >50 mg/dL. Exclusion criteria were systolic blood pressure >190 mmHg and diastolic blood pressure >110 mmHg during hemostasis, initial hemostasis >30 minutes, administration of heparin and other anticoagulants during angiography, puncture of femoral artery more than once, not feeling the pulse in the right side of the body, impaired consciousness, and formation of hematoma before removal of the arterial sheath.

*Sample size.* Sample size was determined 230 based on the results of the study by Yeganekhah et al[14] considering a first-order error of 0.05 and a test power of 80%, assuming a 10% difference between the 2 study groups (N = 115); however, 8 patients were added to the sample size to increase the accuracy of the study and finally 238 patients were included.

*Outcomes.* Data collection tools included a demographic questionnaire, a grid ruler, and a digital notebook scale. The demographic questionnaire included items on age, gender, history of diabetes, history of hypertension, hemoglobin level, rate of ejection fraction, history of smoking, and history of myocardial infarction. In addition, several questions were asked to evaluate vascular complications after angiography, including hematoma, bleeding volume, and time to hemostasis. The hematoma was evaluated by the observation and measurement method using a grid ruler. For this purpose, the largest diameter of the hematoma was measured; the hematoma <3 cm was considered as mild and those ≥3 cm as severe. The grid ruler was designed by Rezaei-Adaryani et al[15] and its validity was confirmed by 12 nursing professors from Tehran Universities. In the present study, the validity of the grid ruler was evaluated by content validity method and 10 nursing and medical professors at Kermanshah University of Medical Sciences (KUMS) confirmed its validity. In studies that have been conducted in the field of vascular complications of angiography, plain observation or a standard ruler was used to measure the hematoma and no validity is mentioned.[16–18] In present study, the inter-rater reliability method was used to evaluate the reliability of the ruler. Two evaluators separately measured the hematoma of 12 patients with this ruler. Intraclass correlation coefficient was calculated between the measured values and a value of 0.83 was obtained indicating a high level of agreement between the 2 evaluators.

Measures taken to assess bleeding included observing the site of hemostasis and measuring hemoglobin level and weight of blood stained gauzes. The hemoglobin and hematocrit levels, along with other routine parameters, were measured the day before angiography. If the patient had rebleeding after achieving hemostasis by MC or CP method, hemoglobin and hematocrit levels were remeasured. Postangiography complications including bleeding and hematoma in both groups were monitored immediately and up to 24 hours after achieving hemostasis. In the present study, bleeding from the catheter insertion site was divided into 2 types: mild and severe. Criteria for severe bleeding included decreased hemoglobin level by 3 g/dL, bleeding that leads to blood transfusions, length of stay increase for more than 2 nights,[11,19,20] and weight of blood-stained gauzes more than 100 grams.[21] Reduced hemoglobin levels by >3 g/dL, length of stay less than 2 nights, weight of blood-stained gauzes <100 g, and no need for blood transfusions were mild bleeding criteria. The brand of the CP used in the present study was Angio-Closure Pad (SUNMED Ltd, China). A digital notebook scale measuring to the nearest 0.1 g (Pand Industries Co, Iran) with an electronic zeroing and a luminous display was used to measure weight of blood-stained gauzes. To evaluate the validity of the scale, it was calibrated before each use and re-evaluated after each 10 measurement by a 50-g weight. To determine the reliability of the scale, a standard weight was first selected and weighed with it; the standard weight was then weighed with 2 other scales, and because the difference among weights was less than 0.1 g, the scale reliability was confirmed.

*Randomization.* The samples were enrolled in the study by the first author using convenience sampling method. The subjects were enrolled in the study based on randomized block design to prevent a specified order and a predetermined pattern that may cause bias in the author and the participant. Initially, 10 binary blocks were considered for both groups in which the groups order was randomly selected. Likewise, a 20th term sequence was determined that was followed until the completion of sample size. Finally, 238 subjects were included in the MC (n = 119) and CP (n = 119) groups. The following 20th-term sequence was used to enroll the subjects:

Subject: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20.
Treatment: A B A B B A A B A A B B B A A B A B A B.

*Interventions.* After obtaining the study approval from the Ethics Committee of the KUMS, the first author referred to the angiography unit for sampling. First, the study objectives were explained to the patients and after answering their questions, the interested ones were enrolled in the study. Patients were divided into 2 groups of MC and CP based on randomized blocking design. Hemostasis in all patients was performed by the first author. He was also responsible for evaluating postangiographic complications, including hematoma size, bleeding volume, and homeostasis time. The interval between patients entering and leaving the angiography room was recorded as the duration of angiography. The interval between the removal of the arterial sheath and complete bleeding control was recorded as the time to homeostasis. In the MC group, after removing the femoral arterial sheath, the initial coagulation was achieved by MC of outlet area for 5–10 minutes. To continue the coagulation process, the SB was placed on the catheter insertion site for 4 hours. After SB removal, the patient could change his/her position in bed for up to 12 hours, but was prohibited from leaving the bed. All SBs weighed the same. In the CP group, after removal of the sheath from the femoral artery, the outlet area was manually compressed for 5–10 minutes, and initial coagulation was achieved. Then, to continue the coagulation process, a CP was attached to the outlet area, and the cavity was filled with 15–20 mL saline. To assess blood flow, dorsalis pedis pulse was assessed by palpating and comparing to the contra lateral lower extremity. All patients were instructed to notify the nurse immediately if they felt any pain, tingling, or numbness in the right leg. Figure 1 illustrates the process of study.

*Data analysis.* Data were analyzed by SPSS-18 software using descriptive and inferential statistics. The Kolmogorov–Smirnov test was used to test the normality of the data. The chi-squared test was used to compare the frequency of hematoma in the 2 groups and the Fisher exact test was used to compare the frequency of bleeding in the 2 groups. The Mann–Whitney *U* test was used to compare the mean of quantitative variables including time to homeostasis, serum level of cholesterol, triglyceride, prothrombin time and partial thromboplastin time, and creatinine, number of cigarettes smoked per day, duration of angiography, fasting blood sugar, and heart rate between the 2 groups. The significant level was set at less than 0.05.

## *Ethical considerations*

This trial was conducted in accordance with the Declaration of Helsinki. The Ethics Committee of KUMS approved the study with code kums.rec.1394.30. The study was also registered with IRCT201404134736N5 at the Clinical Trials Registration Center of Iran. The purpose of the study was explained to the participants and their written and informed consent was obtained. Patients were also assured of their confidentiality.

## RESULTS

A total of 119 individuals in each group were enrolled in the study. The mean age in the MC and CP groups was 57.2 ± 9.1 and 55.5 ± 9.8 years, respectively. Most of the samples (64.3%, n = 153) belonged to the age group of 50–69 years. Most participants were male (53.8%, n = 128) and urbanized (81.1%, n = 193). The MC and CP groups were homogeneous in terms of all variables, except the history of myocardial infarction (Tables 1 and 2).

Seven and 5 patients in the MC and CP groups had hematoma, respectively; however, there was no significant difference between the 2 groups in this regard. In the CP group, one subject had >3 cm hematoma, but none of the patients in the MC group

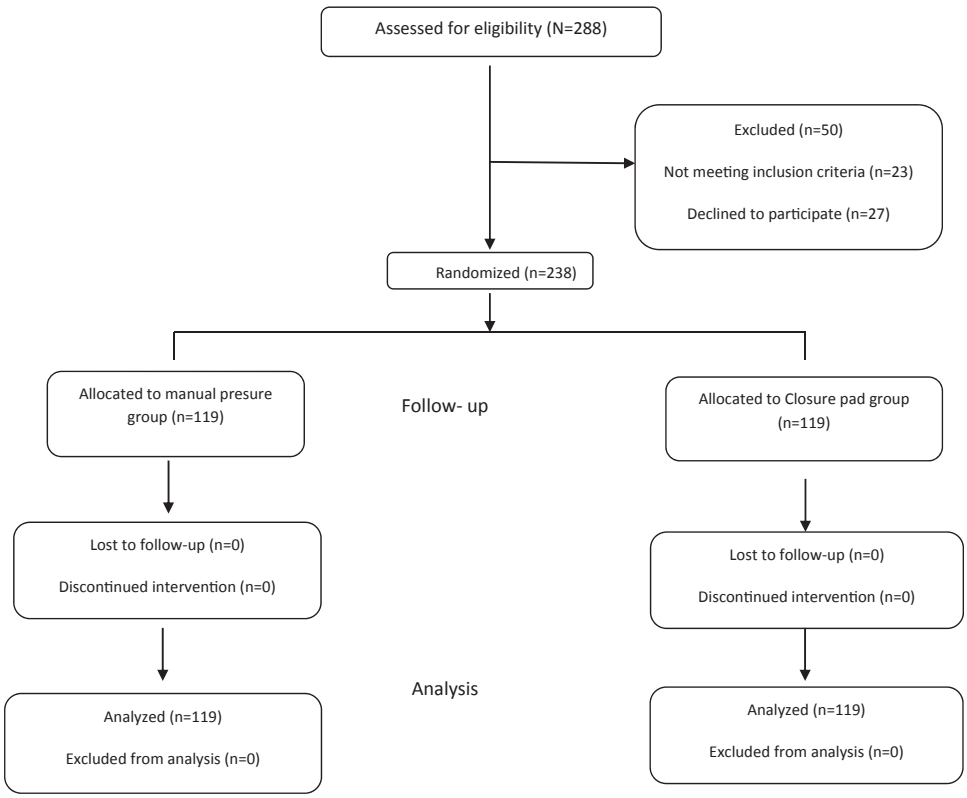


***Figure 1.*** *CONSORT diagram of the study.*

**TABLE 1**

**SOCIODEMOGRAPHIC CHARACTERISTICS OF PATIENTS IN 2 GROUPS OF MANUAL COMPRESSION AND CLOSURE PAD**

| | *Groups* | | |
|---|---|---|---|
| ***Variables*** | ***Closure pad number (%)*** | ***Manual compression number (%)*** | **P-*value*** |
| Age (y) | | | |
| 30–49 | 33 (27.7) | 28 (23.5) | .164 |
| 50–69 | 74 (62.2) | 79 (66.4) | |
| ≥70 | 12 (10.1) | 12 (10.1) | |
| Gender | | | |
| Male | 65 (54.6) | 63 (52.9) | .795 |
| Female | 54 (45.4) | 56 (47.1) | |
| Habitant | | | |
| Urban | 95 (79.8) | 98 (82.4) | .619 |
| Rural | 24 (20.2) | 21 (17.6) | |
| History of diabetes | | | |
| Yes | 19 (16) | 21 (17.6) | .729 |
| No | 100 (84) | 98 (82.4) | |
| History of hypertension | | | |
| Yes | 36 (30.3) | 45 (37.8) | .218 |
| No | 83 (69.7) | 74 (62.2) | |
| History of hyperlipidemia | | | |
| Yes | 36 (30.3) | 49 (41.2) | .079 |
| No | 83 (69.7) | 70 (58.8) | |
| History of smoking | | | |
| Yes | 23 (19.3) | 23 (19.3) | .631 |
| No | 96 (80.7) | 96 (80.7) | |

had >3 cm hematoma; the difference between the groups was not significant in this regard. Bleeding volume in 2 patients in the MC group was >100 mL, but no bleeding was seen in the CP group. There was no significant difference in bleeding volume between the MC and CP groups (Table 3).

## DISCUSSION

The present study aimed at determining the effect of MC and CP on postangiography vascular complications. Several studies also compared the effect of MC and vascular closure devices (VSDs) on postangiography vascular complications. In a study by Scheinert et al,[22] a total of 190 patients who were candidates for angiography and angioplasty were evaluated for complications of hemostasis performed by Mynx (a kind of VCD). Their results showed that 6 (0.03%) patients had hematoma and none of them had bleeding. Jack et al investigated the complications of homeostasis using MC and AS methods. The results showed that none of the subjects in the AS group had hematoma and only one (1.42%) patient had hemorrhage.[19] The results of the present study also showed a relatively low prevalence of vascular complications due to hemostasis in patients undergoing angiography, which is in line with the results of the aforementioned studies. Coronary interventions through the skin are associated with vascular complications such as hematoma and bleeding and can lead to dissatisfaction and discomfort in patient, prolonged hospital stay, exacerbation of patients' clinical condition, and even death.[12,23] MC is a standard method with 50 years history to achieve hemostasis at the arterial access site. In this procedure, the sheath insertion site is manually compressed for 10–20 minutes, and the patient should then take rest for 4–6 hours in bed. This procedure has disadvantages such as prolonged immobility and discomfort in patients.[24] Different types of VSD are available that can reduce the time to hemostasis and accelerate getting out of bed in patients.[25,26] The results of a meta-analysis of 16 clinical trials comparing complications of arterial access site (except hematoma) between MC and VSD methods on more than 5,000 patients showed that VSDs can reduce the risk of such complications.[27] The results of the study by Wong et al[28] showed that the time to homeostasis in VSD method

**TABLE 2**

**CLINICAL CHARACTERISTICS OF PATIENTS IN 2 GROUPS OF MANUAL COMPRESSION AND CLOSURE PAD**

| | *Groups* | | |
|---|---|---|---|
| ***Variables*** | ***Closure pad M ± SD**** | ***Manual pressure M ± SD*** | **P-*value*** |
| Systolic blood pressure (mm Hg) | 141.92 ± 19.32 | 139.42 ± 18.34 | .308 |
| Diastolic blood pressure (mm Hg) | 76.60 ± 10.28 | 75.48 ± 9.75 | .391 |
| Heart rate (beats per minute) | 77.39 ± 12.15 | 77.04 ± 13.90 | .550 |
| Cholesterol (mg/dL) | 203.02 ± 47.86 | 212.84 ± 47.58 | .052 |
| Triglyceride (mg/dL) | 167.06 ± 43.96 | 179.34 ± 66.50 | .075 |
| Ejection fraction (%) | 49.63 ± 8.90 | 49.37 ± 9.22 | .960 |
| Hemoglobin (g/dL) | 14.17 ± 1.56 | 14.23 ± 1.58 | .758 |
| Partial thromboplastin time (s) | 31.35 ± 4.22 | 31.2 ± 4.63 | .612 |
| Prothrombin time (s) | 12.71 ± 12.5 | 12.64 ± 0.31 | .236 |
| Platelet (X $10^3$/mL) | 241.88 ± 56.94 | 249.65 ± 53.80 | .280 |
| Average daily smoking, in 1 y | 4.71 ± 9.52 | 4.19 ± 9.76 | .561 |
| Glomerular filtration rate (mg/dL) | 79.31 ± 22.37 | 76 ± 17.35 | .204 |
| Creatinine (mg/dL) | 1.09 ± 1.00 | 1.06 ± 0.11 | .323 |
| Blood urea nitrogen (mg/dL) | 37.81 ± 10.24 | 36.38 ± 7.49 | .221 |
| Fasting Blood Sugar (mg/dL) | 108.98 ± 38.97 | 108.57 ± 42.74 | .486 |
| Duration of angiography (min) | 24.55 ± 5.36 | 25.31 ± 6.01 | .406 |
| Duration of homeostasis (min) | 5.43 ± 1.01 | 5.46 ± 0.71 | .231 |

*Mean and standard deviation.

was shorter than that of MC method. However, in the present study, arterial complications and time to homeostasis were similar in both the MC and CP methods. The sample size difference (401 patients in the study by Wong et al, vs 238 patients in the present study) may be one of the possible causes of this discrepancy. In addition, in the study by Wong et al, patients with complications of arterial access site were followed up for 30 days, but in the present study, postangiography complications,

**TABLE 3**

**COMPARISON OF 2 GROUPS OF MANUAL COMPRESSION AND CLOSURE PAD IN TERMS OF HEMATOMA AND BLEEDING IN 24 H AFTER ANGIOGRAPHY**

| | *Groups* | | |
|---|---|---|---|
| ***Variables*** | ***Closure pad number (%)*** | ***Manual compression number (%)*** | **P-*value*** |
| Hematoma | 5 (4.2) | 7 (5.9) | .554* |
| Bleeding | 0 (0) | 2 (1.7) | .498† |

*Based on chi-squared test.
†Based on Fisher's exact test.

including bleeding and hematoma, were monitored up to 24 hours after achieving hemostasis. In a cross-sectional study by Deuling et al,[10] femoral artery hemostasis was compared among 3 methods of AS, StarClose, and MC, and the results showed that all the 3 methods had significant differences in terms of safety and the AS method was introduced as the superior method. However, in the present study, the incidence of vascular complications and successful homeostasis were similar in both MC and CP methods. The sample size difference (450 patients in the study by Deuling et al vs 238 patients in the present study) could be one of the possible causes of inconsistency of results. On the other hand, in the study by Deuling et al, data were collected during hospital stay and one month after discharge (telephone follow-up), but in the present study, patients were followed up only 24 hours after achieving homeostasis.

## LIMITATIONS

We faced some limitations in this study. In this study, the hematoma was evaluated by the observation and measurement method using a grid ruler which is less accurate than ultrasound. Another limitation was that the subjects were selected from only one center, which can affect the generalizability of the results. The last limitation was that a baseline arterial duplex ultrasound was not performed to evaluate the dorsalis pedis pulse.

## CONCLUSION

The CP, like MC, can be effective in achieving hemostasis and preventing bleeding from femoral artery puncture site. As the patients using CP can change their position in bed, its application improves the patients' physical comfort and therefore increases their satisfaction with nursing services. Although the use of these devices can be more costly than MC but various studies have established important benefits of the use of VCDs such as facilitating hemostasis and consequently reducing duration of hospital stay that may outweigh the cost. In other words, decreased duration of hospital stay will lead to less use of hospital resources. Therefore, considering these benefits, using CP by nurses seems to be a better choice. The present study was performed in patients undergoing coronary angiography. It is recommended to perform similar studies on angiography through other arteries such as the carotid artery. Further studies to compare the effect of different VCD methods, such as AS, on the risk of post-angiography vascular complications are recommended.

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