RESEARCH ARTICLE

# Comparison between three and six hours' restriction of the lower limb after femoral artery sheath removal in patients who underwent percutaneous coronary intervention

Naowapanich S, Poolsawa U, Petchon U, Satsue S, Foosang W, Chotinaiwattarakul C

**Naowapanich S, Poolsawa U, Petchon U, et al. Comparison between three and six hours' restriction of the lower limb after femoral artery sheath removal in patients who underwent percutaneous coronary intervention. Clin Cardiol J. 2022; 6(4):37-40.**

**ABSTRACT**

**OBJECTIVES:** To test the non-inferiority in bleeding and/or hematoma after sheath removal with either three or six hours of restriction, and to compare back pain and satisfaction between these groups.

**METHODS:** The Randomized Controlled Trial (RCT) enrolled 378 patients who underwent PCI via femoral artery post procedure who were admitted at the cardiac care unit or at the intermediate cardiac care ward, between July 2012 and June 2014. After sheath removal, the experimental group (n=182) was restricted to complete bed rest for three hours, whereas six hours for the control group (n=196). Z-test for non-inferiority as a test for bleeding and/or hematoma of 90% CI and a p-value<0.05 was considered statistically significant. The primary outcome was bleeding and/or hematoma, the secondary outcomes were back pain and satisfaction.

**RESULT:** There were no significant differences in bleeding and/or hematoma (p-value=0.429, 90%CI:-0.92-2.38). Mean potential of bleeding and/or hematoma was 0.54. Restriction for 3 hours can reduce back pain by relative risk reduction 92.1%, back pain scores 4 to10 were significantly different (p=0.001), in control group than experimental group (0.5%, n=1, 6.8%, n=13), respectively. Patient's satisfaction levels 4 to 5 were significantly different (p=0.001), in experimental group than control group (58.1%, n=108, 35.9%, n=69), respectively.

**CONCLUSION:** Reduction of six hours to three of hours restriction after sheath removal in PCI patients does not increase risk of bleeding and/or hematoma and reduces back pain with more patient satisfaction. increase in heart and a chronic rise in splenic neutrophils and monocytes. Mechanistic studies show that eosinophil IL4 and the cationic protein mEar1 play a role in preventing $H_2O_2$ and hypoxia-induced cardiomyocyte death in mice and humans, as well as TGF-induced cardiac fibroblast Smad 2/3 activation and TNF-induced neutrophil adhesion on the heart endothelial cell monolayer. In vitro-cultured eosinophils from WT mice or recombinant mEar1 protein efficiently cure aggravated cardiac dysfunctions in eosinophil-deficient dblGATA mice, but not eosinophils from IL4-deficient animals. Eosinophils play a cardioprotective role in post-MI hearts, according to this study.

**Key Words:** *Percutaneous coronary intervention; Bleeding; Hematoma; Sheath removal; Back pain.*

## INTRODUCTION

Percutaneous Coronary Intervention (PCI) is performed at Siriraj hospital in over 1,200 cases per year, the most common route is a transfemoral artery. The most common complications after arterial sheath removal are bleeding and/or hematoma [1,2]. The traditional care to prevent complications, patients were restricted in the movement of the lower limb for six to eight hours, Totally, patients were restricted movement of the lower limb for 10 hours to 12 hours. The restriction caused 68% of patients to experience suffering from back pain or leg pain, arose anxiety in some patients, and led to a deficit in Activities of Daily Living (ADL)or increased length of stay (LOS) [3,4].

Several health institutions use:

- Angioseal to stop bleeding
- Change the suture site from femoral to radial or brachial artery
- Siriraj Leg Lock (SLL) to lower back pain by reducing the duration of restriction or early ambulation [3]. Previous studies in patients who underwent diagnostic cardiac catheterization (CAG) and PCI which were using angioseal or mechanical pressure to stop bleeding and studies in patients who were given GPIIb/IIIa inhibitor, low molecular weight heparin or Ticlopidine reported no statistical difference in vascular complications between short and long duration of restriction and most patients felt more uncomfortable with long duration of restriction [5-8].

However, PCI patients at Siriraj hospital were rarely given those drugs and mechanical pressure was not used. Thus, to this date, no studies to decrease the duration of restriction were conducted in Thailand. If there were no significant differences in bleeding and hematoma between 3 hours and 6 hours restriction after sheath removal this will change the protocol of PCI care. The objectives of the present study were to compare bleeding and/or hematoma and the level of back pain between three and six hours of restriction after femoral artery sheath removal in PCI patients [9].

## MATERIALS AND METHODS

### Patient population

This prospective, Randomized Controlled Trial (RCT) included ACS patients who underwent PCI via femoral artery sheath and received standard care at the Cardiac Care Unit or the Intermediate Cardiac Care Unit of the Division of Cardiology, Department of Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand between July 2012 and June 2014. Patients aged older than 18 years with good consciousness and hemodynamic stability were eligible for inclusion [10].

Patients with one or more of the following were excluded. The patient was diagnosed with cardiogenic shock.

- Developing any complications during the procedure or before femoral arterial sheath removals such as vascular rupture, bleeding or hematoma, or cardiac tamponade.
- Body mass index>30
- Post PCI patient with systolic blood pressure>190 mmHg. or diastolic blood pressure>110 mmHg.
- The patient experiencing back pain.

*Division of Medical and Psychiatric Nursing, Department of Nursing, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand*

*Correspondence: Chunhakasem Chotinaiwattarakul, Division of Medical and Psychiatric Nursing, Department of Nursing, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand, E-mail: sicchot@yahoo.com*

*Received: 16-June-2022, Manuscript No. PULCJ-22-5047; Editor assigned: 19-June-2022, PreQC No. PULCJ-22-5047(PQ); Reviewed: 27-June-2022, QC No. PULCJ-22-5047(Q); Revised: 30-June-2022, Manuscript No. PULCJ-22-5047(R); Published: 5-July-2022, DOI: 10.37532/pulcj.22.6(4).37-40*

- Patient with creatinine clearance (CCr.)<30 ml/min prior to PCI.
- Patient with INR>1.5 or Platelet count<100,000/ul. before PCI. The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB) (COA no 283/2012), and all patients provided written informed consent to participate.

**Study protocol**

Patients were randomly assigned to receive restricted complete bed rest for three hours in the experimental group and six hours in a control group, using the double-dummy technique. Randomization codes were generated by the nurses at our centre using a computer-generated random number scheme based on an individual assignment. The primary endpoint was the first occurrence of bleeding and/or hematoma which occurred after the patients are permitted to early ambulate after 24 hours of admission or at discharge time [11, 12]. The secondary endpoint was back pain which was assessed after sheath removal at 3 hours and 6 hours of restriction and satisfaction will be immediately assessed at 3 hours of restriction in the experimental group, and 6 hours of restriction in the control group.

**Statistical analysis**

Descriptive statistics were used to summarize demographic and clinical data. Qualitative data were compared using the chi-squared test or Fisher's exact test, and are expressed as numbers and percentages. Quantitative data were compared using the Mann-Whitney U test, and are presented as mean ± standard deviation. Z-test for non-inferiority was employed to test for non-inferiority between 3 and 6 hours of restriction. Comparison of primary endpoint data between groups is shown as the percentage difference between groups and a 95% confidence interval [13]. SPSS Statistics (version xx; SPSS, Inc., Chicago, IL, USA) was used for all statistical analyses, and a p-value of less than 0.05 was regarded as being statistically significant for all tests (Figure 1).

## RESULTS

The study consisted of 378 patients, with 186 cases in the experimental group, consisting of 152 males and 34 females, with an average age of 60.8 years and 192 cases in the control group, comprised of 146 males and 46 females, had an average age of 62.5 years. The demographic data are shown in (Table 1). All patients completed the study protocol. There were

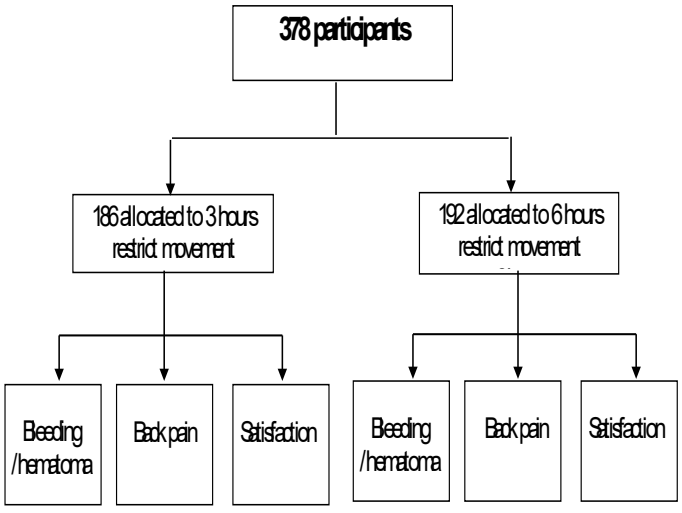


**Figure 1)** *Statistical analysis*

**TABLE 1**

**Demographic, clinical, and treatment data of the study population (n=378)**

| Patient characteristics | Experimental (n=186) | Control (n=192) | p-value |
|---|---|---|---|
| Sex, n (%) | | | 0.21 |
| Male | 152 (81.7) | 146 (76) | |
| Female | 34 (18.3) | 46 (24) | |
| Age (years) | 60.8 ± 10.9 | 62.5 ± 9.6 | 0.33 |
| Weight (kilogram) | 67.6 ± 10.4 | 60.3 ± 10.4 | 0.87 |
| Height (centimeter) | 164.3 ± 8.2 | 163 ± 8.6 | 0.65 |
| Body mass index | 25 ± 3 | 25.3 ± 3.4 | 0.44 |
| Length of stay (day) | 1.3 ± 1 | 1.3 ± 0.9 | 0.92 |
| Systolic blood pressure | 138 ± 18 | 141 ± 19 | 0.93 |
| Diastolic blood pressure | 78 ± 11.9 | 80 ± 11.9 | 0.65 |
| Heart rate | 70 ± 12 | 70 ± 11 | 0.3 |
| Underlying diseases, n (%) | | | |
| Diabetes mellitus | 69 (37.1) | 70 (36.5) | 0.91 |
| Hypertension | 134 (72) | 144 (75) | 0.56 |
| Dyslipidemia | 65 (34.9) | 79 (41.1) | 0.24 |
| Smoking | 24 (12.9) | 11 (5.7) | 0.02 |
| Chronic renal failure | 4 (2.2) | 5 (2.6) | 0.52 |
| Clinical diagnosis, n (%) | | | 0.36 |
| UA | 11 (5.9) | 9 (4.7) | |
| NSTEMI | 13 (7.0) | 14(7.3) | |
| STEMI | 28 (15.1) | 18 (9.4) | |
| CAD | 134 (72) | 150 (78) | |
| History of PCI, n (%) | | | 0.76 |
| Yes | 88 (47.3) | 87 (45.3) | |
| No | 98 (52.7) | 105 (54.7) | |
| PCI result, n (%) | | | |
| LM stenosis | 4 (2.2) | 2 (1.0) | 0.44 |
| LAD stenosis | 107 (57.5) | 106 (55.2) | 0.68 |
| CX stenosis | 48 (25.8) | 57 (29.7) | 0.42 |
| RCA stenosis | 78 (41.9) | 72 (37.5) | 0.4 |
| Other lesions | 22 (11.8) | 23 (12.0) | 0.54 |
| Antiplatlets drug, n (%) | | | 0.84 |
| Aspirin | 7 (3.8) | 9 (4.7) | |
| Plavix | 11 (5.9) | 6 (3.1) | |
| Aspirin and Plavix | 168 (90.3) | 177 (92.2) | |
| Laboratory result | | | |
| CrCl | 68.6 ± 23.7 | 67.3 ± 23.7 | 0.39 |
| Total Heparin (unit) | 7640.5 ± 1287.1 | 7405 ± 1337.1 | 0.93 |
| ACT post procedure | 263.4 ± 57.1 | 250.5 ± 50.2 | 0.56 |
| ACT pre-sheath removal | 141.8 ± 20.9 | 143.1 ± 21.9 | 0.23 |
| Total manual pressure time | 13.9 ± 5.5 | 13.6 ± 5.8 | 0.68 |

*UA: Unstable Angina, NSTEMI: Non ST Segment Elevated Myocardial Infarction, STEMI: ST Segment Elevated Myocardial Infarction, CAD: Coronary Artery Disease, LM: Left Main Coronary Artery, LAD: Left Anterior Descending Artery, CX: Circumflex Artery, RCA: Right Coronary Artery, CrCl: Creatinine Clearance, ACT: Activated Clotting Time*

no statistically significant differences between the two groups, and no PCI results were found in either group [14].

The occurrence of bleeding and/or hematoma in both groups was not significantly different (Table 2). The level of back pain in both groups after a restriction at 3 hours was not significantly different, but after a restriction at 6 hours was significantly different. In 6 hours, the event rate occurred of back pain at a lower rate in the experimental group than in the control group (Table 3). There were significant differences in satisfaction levels among those living with others (Table 4)

## DISCUSSION

According to the study, the population in both groups had no significant differences. The underlying disease UA, NSTEMI, STEMI, CAD (p=0.36). Most patients were male (experimental group=81.7%, control group=76%, mean age of 50 years-70 years, with co-morbid diseases including hypertension (experimental group=72%, control group=75%), dyslipidemia (experimental group=34.9%, control group=41.1%) and diabetes (experimental group=37.1%, control group=36.5%). Most patients were male, ST-segment elevation of the European Society of Cardiology (ESC) reports a higher incidence of myocardial infarction in men than women, which may be due to male behaviour thus are at risk of developing cardiovascular disease [1].

The non-inferiority study demonstrated that 3 hours of restriction after femoral artery sheath is not inferior to 6 hours of restriction, with no significant difference (p=0.429) and the mean potential of bleeding and/or

**TABLE 2**

**Complications (bleeding and hematoma) between the experimental group and control group**

| Complication | Experimental group | Control | Risk Difference% | p-value |
|---|---|---|---|---|
| | (n=186) | group (n=192) | (90%CI) | |
| Bleeding and/or hematoma | 1 (0.5%) | 0 (0%) | | |
| | | | 0.0054 (- 0.92 - 2.38%) | 0.492 |
| No bleeding and/or hematoma | 185 (99.5%) | 192 (100%) | | |

**TABLE 3**

**Level of back pain between the experimental group and control group**

| Duration of restriction/back pain | Experimental group | Control Group | p-value |
|---|---|---|---|
| | (n=186) | (n=192) | |
| Back pain at 3 hours | | | 0.333 |
| ≤ 3 | 180 (96.8%) | 182 (94.8%) | |
| 4-10 | 6 (3.2%) | 10 (5.2%) | |
| Back pain at 6 hours | | | 0.001* |
| ≤ 3 | 185 (99.5%) | 179 (93.2%) | |
| 4-10 | 1 (0.5%) | 13 (6.8%) | |

**p-value<0.05 indicates a statistically significant difference between groups*

**TABLE 4**

**Patient satisfaction between the experimental group and control group**

| Level of satisfaction | Experimental group | Control | p-value |
|---|---|---|---|
| | (n=186) | Group (n=192) | |
| Score 4-5 | 108(58.1%) | 69(35.9%) | 0.001* |

**p-value<0.05 indicates a statistically significant difference between groups*

hematoma in the experimental group is 0.54% and the maximum potential of bleeding and/or hematoma in the experimental group compared to the control group is 2.38%, less than the acceptable rate of 6%. The study was consistent with Pollard SD, et al. who reported that restricted movement whilst in bed for either 4.5 hours or 2.5 hours and Meta-Analysis of Early Ambulation Trials by Timothy Logemann et al, reported that restriction whilst in bed between 2 hours and 6 hours were not significantly different [15].

By the way in the study, one patient was bleeding 100 ml in the experimental group, which occurred 15 minutes after early ambulation, first aid care and manual pressure were applied for 15 minutes, without blood transfusion or medications, and he was restricted movement until the morning as the protocol of care, and he was discharged as planned.

Comparing the level of back pain in both groups after a restriction at 3 hours was not significantly different (p=0.333). The level of back pain was 4-10 in the experimental group less than in the control group at 6 hours' restriction, with statistical significance (p=0.001). These results demonstrated that back pain levels 4-10 in the experimental group decreased from 6 to 1 patient (3.2% to 0.5%), whereas an increase in the control group from 10 to 13 patients (5.2% to 6.8%). Decrease restriction from 6 hours to 3 hours reduces the level of back pain 4 -10 by a relative risk of 92.1%. Our findings are consistent with Bark man and Keeling who reported that patients who were a restricted movement for 3 hours and 4 hours compared to 6 hours experienced less back pain [16,17].

Furthermore, this study revealed that the satisfaction level was 4-5 (satisfied to very satisfied) in the experimental group, which is higher than the control group, with statistical significance (p=0.001). This shows that a shorter duration of restriction can reduce back pain and lead to increased satisfaction in the patient undergoing PCI via the femoral artery.

However, the study found the incidence of bleeding and hematoma was very low (2.98%), lower than the acceptable rate 6%). This may be because the base rate (8%) of bleeding and hematoma was from all PCI patients, including patients who were unstable in hemodynamics (severe disease progression, cardiogenic shock, post-cardiac arrest or GPIIb/IIIa inhibitor was given) and cigarette smoking in the experimental group than the control group (p-value=0.02). This may have affected the clotting factor such that plasma fibrinogen concentration was significantly higher and platelet aggregation was increased in smokers rather than nonsmokers [18,19]. The duration of smoking inversely affected Bleeding Time (BT), Whole Blood Clotting Time (WBCT) and Prothrombin Time (PT) [20].

## CONCLUSION

The results revealed no significant difference between 3 hours and 6 hours of restriction. However, the restricted movement for 3 hours may reduce back pain and increase satisfaction. It could also encourage the patient to early ambulation which may minimize back pain and discomfort from limited mobility for a long period resulting in increased patient satisfaction. In conclusion, the results of the study may be utilized to guide and develop the standard of care implemented for patients who are undergoing PCI.

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