EFFECTIVENESS OF COLD PACK WITH EARLY AMBULATION IN PREVENTING COMPLICATIONS OF HAEMORRHAGE AND HAEMATOMA IN PATIENTS POST CARDIAC CATHETERIZATION

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Abstract
Objective: To examine the effect of early ambulation with cold pack on the prevention of bleeding and haematoma complications in patients post-cardiac catheterization.
Methods: This research used an experimental method with randomized posttest-only control group design. Thirty respondents were randomly selected using simple random sampling, with 15 assigned in the experiment and control group. The experiment group was given cold pack and early mobilization, while the control group was given sand pillow with immobilization for 6 hours. Independent t-test and Fisher’s exact test were used for data analysis.
Results: Findings showed that there was no significant difference in haemorrhage between experiment and control group after given intervention (p= 1.000), and found a significant difference in haematoma between the two groups (p=0.001).
Conclusion: Cold packs with early ambulation and sand pillow with immobilization for 6 hours were equally effective in preventing haemorrhage. However, cold packs with early ambulation was more effective in preventing haematoma.

Keywords: sand pillow; cold pack; haemorrhage; haematoma; cardiac catheterization

INTRODUCTION

Coronary Heart Disease (CHD) is a heart disease caused by a narrowing of the coronary arteries due to a blockage of atheroma plaque. CHD is also called as atherosclerosis, which disturbs the blood flow to the myocardium. One of the medical management in patients with CHD is by cardiac catheterization (Kern, Sorajja, & Lim, 2015).

Cardiac catheterization is divided into coronary angiography and Percutaneous Coronary Intervention (PCI). Coronary angiography is performed by inserting a small plastic tube (catheter) into the artery and vein to the heart to obtain an X-ray image of the coronary artery and heart, as well as to measure hemodynamic in the heart (Kern et al., 2015). When a coronary block is identified, small wire with a floppy tip can penetrate the blockage and then widen with a balloon and if necessary stents are installed to revascularize the myocardium (Rifki, 2013).

At the Hospital of Jantung Harapan Kita, there were 5372 cardiac catheterization actions in 2015 consisting of 4728 angiography, 508 stents and 136 other actions. While in the Hospital of Dr. Kariadi Semarang there were 718 cardiac catheterizations in 2011 (Junait & Rifqi, 2018).
The success rate of coronary revascularization by cardiac catheterization is very high. According to previous study, the success of PCI to open up clogged coronary arteries reaches above 90% and continues to increase from year to year, compared with fibrinolytic drug therapy which is only about 50-60% (Rifki, 2013).

Cardiac Cath has a risk of complications that need to be wary of. Vascular complications that can occur include haemorrhage and haematoma (Rifki, 2013). Previous study used a sand cushion pressure of 2.3 kg at femoral access, and 10% had haematomas from a total sample of 30 patients (Sinaga, Nurachmah, & Gayatri, 2012).

The principle of wound care after cardiac catheterization after the removal of the femoral sheath is by closing the access of catheter stabbing, immobilization and pressure (Kern et al., 2015). The purpose of mechanical suppression with a sand cushion is to stop bleeding and haematoma from the femoral artery by suppressing the arteries and allowing the formation of clot (Manik, 2015).

A study conducted by King to compare the compression of sand cushions with cold pack applications after cardiac catheterization showed a significant difference (95% confidence interval, p<0.05) that vasoconstriction produced by cold pack applications was more effective in reducing haematoma complications than sand cushions (King, Philpott, & Leary, 2008). Use of a cold pack should not exceed 20 minutes as it may damage the skin surface, the occurrence of hypersensitivity and cold allergic reactions (Wnorowski, 2016).

Research conducted by Doyle with the result that early ambulation 1 hour after angiography with femoral access using 5Fr. catheter was safe, associated with low incidence of vascular complications (Doyle et al., 2006). Kern also argues that immobilization with small catheter diameter (e.g. ≤ 5Fr) can be immobilized in a short time of less than 2 hours (Kern et al., 2015).

Additionally, early ambulation 2 hours after cardiac catheterization with 6Fr. catheter is also declared safe, no large haematoma, no bleeding, or indication of the need for blood transfusion (Boztosun et al., 2008). Previous study also undertook a 3-hour early ambulation evaluation post catheterization of the heart with a 7Fr. catheter and the results suggest that it is safe as well as reducing the potential length of hospitalization and improving patient comfort (Mah, Smith, & Jensen, 1999).

Referral hospitals require a one-day surgery program for mild surgery, one of which is the diagnostic action of cardiac catheterization. Nevertheless, there is no evidence based post-cardiac catheterization care to change the program into one day surgery while the standard of operational procedure that is still implemented is immobilization program and sand pillow for 6 hours then observed in 2-3 days. The purpose of this study was to examine the effect of early ambulation with cold pack on the prevention of bleeding and haematoma complications in patients post-cardiac catheterization.

**METHODS**

**Study design**

This study was randomized control trial (RCT), with randomized posttest-only control group design.

**Sample**

Thirty respondents were randomly selected using simple random sampling, with 15 assigned in the experiment and control group. The inclusion criteria of the sample were all patients diagnosed with coronary heart disease, already undergone angiography, not more than 65 years old, and using 6Fr. cath. The exclusion criteria were unconscious patient, having angiography with more than 1 puncture in the femoral artery, overweight (BMI >30), having complications such as CABG, conduction and heart rhythm disturbance, severe haemorrhage on the groin immediately after the removal of the sheath in
the femoral artery, and patients with comorbidities such as blood clotting disorders and chronic renal failure.

**Intervention**

This study distinguished the incidence of bleeding and haematoma complications in the group of early ambulation with cold pack compared with the use of a 2.5 kg sand pillow and immobilization for 6 hours. Data collection was done by qualified research assistants (Diploma III Nursing, Clinical nurse II and having BTCLS certificate). After removal of the post-angiographic sheath catheter, the stitch mark was given a cold pack for 20 minutes, then 1 hour after the release of the post-angiographic sheath catheter, the respondents were asked to walk for 10 meters away, with the note that the respondents cannot fold the thighs. After that 6 hours observation was implemented to determine the complications of haemorrhage and haematoma. For the control group, after removal of the post-angiographic sheath catheter, the stitch mark was given a 2.5 kg sand pillow and immobilized for 6 hours.

**Instrument**

An observation sheet developed by the researchers was used to measure the occurrence of bleeding, and a measuring tape was used to measure haematoma and its diameter in centimetres.

**Data analysis**

Univariate analysis was used to describe gender, age, BMI, systolic and diastolic. One-sample Kolmogorov Smirnov was used to test the normality, which showed that the experiment group (p= 0.696) and control group (p= 0.275) have normal data distribution. Independent t-test was used to examine the effect of cold pack with early ambulation on haematoma, and chi-square test was used to examine the effect of cold pack with early ambulation on haemorrhage, but there were unfulfilled conditions that there were 2 columns had value under 5 and sample below 50, so Fisher's Exact Test was used.

Analysis of confounding variable of age, BMI, systolic and diastolic on haemorrhage using linear regression with Durbin Watson test obtained p = 1.856 indicating no relationship. While the result of normality data test based on residual standard with one sample Kolmogorov Smirnov test showed normal distribution data with p= 0.15. And analysis of confounding variables of age, BMI, systolic and diastolic on haematoma using linear regression with Durbin Watson test obtained p = 1.006, which indicated no relationship. While the result of normality data test based on residual standard with one sample Kolmogorov Smirnov test showed normal distribution data with p = 410.

**Ethical consideration**

This research was conducted in the Hospital of dr. Kariadi Semarang. Ethical approval was obtained from the Health Research Ethics Committee of the Health Polytechnic of Kemenkes Semarang (Approval Number: 018/KEPK/ Poltekkes-Smg/ EC/2017). All respondents were given an explanation of the data collection process and signed informed consent.

**RESULTS**

Table 1 shows that the there was no respondents experienced haemorrhage in the experiment group and 1 respondent (6.7%) in the control group. For haematoma variable, the majority of respondent had haematoma with diameter of 0.1-1 cm (53.3%) in the experiment group and 33.3 % of respondents had no haematoma; while in the control group 53.3% of respondents had haematoma with diameter of 1.1-5 cm and 46.7% had haematoma with diameter of 0.1-1 cm.

Fisher’s extract test result in the table 2 obtained p-value 1.000 (>0.05), which indicated that there was no significant difference in haemorrhage between experiment and control groups.
Table 1 Frequency distribution of haemorrhage and haematoma in the experiment and control group

| Variable          | Group       | Experiment | Control |
|-------------------|-------------|------------|---------|
|                   | f | % | f | % |
| Haemorrhage       |   |   |   |   |
| No                | 15 | 100 | 14 | 93.3 |
| Yes               | 0 | 0 | 1 | 6.7 |
| Haematoma (cm)    |   |   |   |   |
| 0.1-1             | 8 | 53.3 | 7 | 46.7 |
| 1.1-5             | 2 | 13.3 | 8 | 53.3 |

Table 2 Difference in haemorrhage in the experiment and control group using Fisher’s Extract test (n=30)

| Haemorrhage | Group       | X² | p-value |
|-------------|-------------|----|---------|
|             | Experiment |    |         |
|             | Control    |    |         |
| No          | 15 | 100 | 14 | 93.3 | - | 1.000 |
| Yes         | 0 | 0 | 1 | 6.7 |

Table 3 Difference in haematoma in the experiment and control group using Independent t-test (n=30)

| Haematoma | Mean ± SD | t    | p-value |
|-----------|-----------|------|---------|
| Experiment | 0.420±0.4057 | 3.604 | 0.001 |
| Control   | 1.307±0.8623  |      |        |

Independent t-test as shown in the table 3 obtained p-value 0.001 (<0.05), which indicated that there was a significant difference in haematoma between experiment and control groups. And Linear regression as shown in the table 4 shows that there was no significant effect of confounding variables on haemorrhage (p=1.856) and haematoma (p=1.006).

Table 4 Analysis of confounding variables (BMI, age, systolic, diastolic) on haemorrhage and haematoma

| Variable         | R      | R²    | Adjusted R²  | Std. Error of the Estimate | Durbin-Watson |
|------------------|--------|-------|--------------|----------------------------|---------------|
| Confounding on haemorrhage | 0.363 | 0.131 | -0.008       | 0.183                      | 1.856         |
| Confounding on haematoma    | 0.319 | 0.102 | -0.042       | 0.8178                     | 1.006         |

DISCUSSION

Findings of this study showed that there was no significant difference effect of both interventions in the experiment and control group on haemorrhage. According to literature, angiography can only be done through an artery. The arteries distribute oxygenated and nutrient-rich blood to the distal tissues. Arteries injured by stab wounds during angiography will lead to the risk of bleeding (Kern et al., 2015). However, in this study, haemorrhage only occurred one time in the control group. The risk of haemorrhage is strongly related to platelet value, normal haemorrhage time and time of blood clotting that support the haemostasis process.

According to Corwin, the factors that affect haemostasis are the role of platelets, platelet accumulation, and coagulation reactions. Platelets in normal circumstances circulate throughout the body through the bloodstream. After blood vessel damage, platelets are
attracted to the area in response to exposed collagen in the subendothelial vessel layer. Platelets adhere to a damaged surface and then clot together to form a platelet plug that effectively blocks the injured area (Corwin, 2008). Platelets secrete various compounds such as prostaglandins and thromboxane derived from essential fatty acids, both of which are chemical attractants capable of summoning more platelets and leukocytes to the site (Sadikin, 2001). Platelets also secrete serotonin that causes vasoconstriction of blood vessels as the first step to reduce blood flow to the area. Blood clots in blood vessels from 15 seconds to 2 minutes. After 20 minutes to 1 hour, the clot will close the wound (Hall, 2015).

Cold packs help vasoconstriction of blood vessels and accelerate blood clotting time and formation of blood clots (Wnorowski, 2016). However, the purpose of this study was not to know the effect of cold pack on blood coagulation time that occurred in this angiography wound. Respondents in the experiment group who used cold packs did not bleed (n = 15). The other study using cold packs also did not bleed (n = 20) (Manik, 2015). Previous study showed that the use of sand pillow of 2.3 kg for 2, 4 and 6 hours resulted in no haemorrhage in all groups (n = 90) (Sinaga et al., 2012). While another study using sand pillow for 6 hours had 2 (2.2%) respondents bleeding (Junait & Rifqi, 2014).

In addition to cold packs, respondents also did 1-hour early ambulation, which was expected that there was no prolonged accumulation of platelet clumps that can lead to thrombosis (Sadikin, 2001). Excessive platelet accumulation can cause a decrease in blood flow to the tissue or lead to the form of an embolus (Smeltzer et al., 2008).

Results of this study were not in line with previous study, which showed that 19 respondents (1.9%) post-angiography using 5Fr. Cath were bleeding after early ambulation for 1 hour (Doyle et al., 2006). The other study that conducted early ambulation for 2 hours after angiography resulted in mild haemorrhage in 25 respondents (2%) (Boztosun et al., 2008). Similar study comparing early ambulation for 3 hours (n = 472) with 5 hours (n = 408) after angiography found that there were mild haemorrhage in 53 respondents (13%) in the group of 3 hours ambulation and 115 respondents (24.4%) in the group of 5 hours ambulation (Mah et al., 1999).

This study used 6Fr catheter with no bleeding in 15 respondents (100%). The difference in sheath size catheter affects the size of the femoral artery wound. However, with no incidence of bleeding in the experiment group showed that for the use of 5 or 6Fr catheter is safe post-angiography treatment with cold pack followed by early ambulation after 1 hour.

The haemostasis condition in angiography lesions should be monitored periodically. In certain condition, blood clots may decompose and blood out of the blood vessels and spread in the surrounding muscles, or called haematoma. The occurrence of haematoma can be seen clearly on the surface of the skin but can also be seen vague, depending on the amount of blood in the muscles. The shape and extent of haematoma are irregular.

In this study, the measurement of haematoma was only measured visibly using haematoma diameter. Finding of this study showed a significant difference of haematoma after given cold pack. This result is in line with previous study revealed that the use of cold pack for 20 minutes can prevent and reduce the amount of haematoma (P <0.05; CI = 95%) (King et al., 2008).

It can be concluded that cold pack with early ambulation is as effective as sand pillow and immobilization in reducing the incidence of haemorrhage although there was an incidence in the control group. In addition, cold pack with early ambulation is more effective than sand pillow and immobilization in reducing the incidence of haematoma.
Limitation
The use of diameter in measuring haematoma might not be well enough. In addition, the variable of anxiety and environment were not measured as confounding variable that may affect the effect of the study.

CONCLUSION
Based on data processing and analysis, it can be concluded that cold pack with early ambulation was significant in preventing the complications of haemorrhage and haematoma. The research results can be used as an alternative in the prevention of haemorrhage and haematoma in patients post cardiac catheterization.

Declaration of Conflicting Interest
None declared.

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Author Contribution
All authors contributed equally in this study.

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