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THE INFLUENCE OF USE ARTERY-FEMORAL BAND (ARFEBAND) TO HAEMATOM INCIDENT IN PATIENTS AFTER PERCUTANEUS CORONARY INTERVENTION (PCI)

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Abstract

Background: Haematoma is the main vascular complication in the patients after percutaneous coronary intervention (PCI). This incidents is important to be prevented and be overcome because the internal bleeding is not easy to be control and it can be make extend the mass of patients to inpatient in the hospital. Artery-femoral Band (arfeband) is a device designed that worthy and safe to keep the stability of haemostasis after PCI.

Aim: it is to know the influence of use arfeband to haematoma incidents in patients after PCI.

Methods: this research used the quasy - experiment pre-post control trial design, it involves 121 patients after the elective of PCI that receives the intervention group (IG) and control group (CG) that is done for 6 hours after the removal of the sheath femoral artery, 60 IG used arfeband and 61 CG with the sand bag. The measurement of diameter haematoma is done when before and after intervention.

Results: this research shows that before the intervention, there are no differences that significant between IG and CG $p=0,909$. There are the significant differences to haem atom incidents after the use of IG with $P<0,05$, OR 0,398 with CI 95% 0,172 – 0,919. It means that arfeband is reducing the haematoma incidents for 60,2 %. The size of the diameter of pre and post procedure, it is decrease in average of 30,4($\pm 13,6$)mm to be 10,9 ($\pm 15,9$) $p<0,05$.

Conclusion: The intervention of use arfeband influences to decrease the haematoma incidents significantly after percutaneous coronary intervention (PCI).

Keywords: arfeband, percutaneous coronary intervention (PCI), haematom.

Background

Percutaneous coronary intervention (PCI) is one kind of procedure of revascularisation of coronary heart disease (CHD) (Kern, 2016; Rilantono, 2012; Schwartz, Burstein, Economides, Robert et al., 2011; Nuray, Umman, Arbal, Altok,

Enuzun, Uysal, Ncekara, Ulusoy, & Baran, 2007; Woods, et al., 2005; Heintzen & Strauer, 2009; and Gray, Dawkins, Morgan, & Simpson, 2005).

The important thing in the medical act of PCI chooses of access of catheter coronary artery, the main operators that choose such as femoral

artery, brachial artery, and radial artery. When the artery accesses are chosen, it is influenced by the experience, the skill of cardiology, indication and technique procedure, also vascular condition to minimalist the complication (Hassan, Hasan-Ali, Demetry, Refaat, & Ali, 2015).

Although transradial PCI have been proven that it is more safety and decrease the vascular complication in the catheter access, but it has not been welcomed and popular therefore it still used transfemoral (Hassan, Hasan-Ali, Demetry, Refaat, & Ali, 2015).

Haematoma is one kind of incident that often happens between vascular complication accesses the heart catheter in patient after PCI (Kern, 2016; Vlastic, Almond, & Massel, 2001; Armendaris, et al., 2008; and Sinaga, 2016).

Haematoma is the internal bleeding that is not easy to be control therefore because of the haematoma impact, the patient can be lose more their blood from 500 ml without detected first, especially for the patient obesity who have the big thighs (Vaitkus, 2004; Augustin & Sarmiento-Leite, 2010; Gregory, Midodzi, & Pearce, 2013; and Jones, et al., 2002).

There are many devices that is offered as the alternative of standard procedure with pillow health, *vascular closure device such as, haemostasis pads, FemoStop, Clamp Ease, Mynx,*

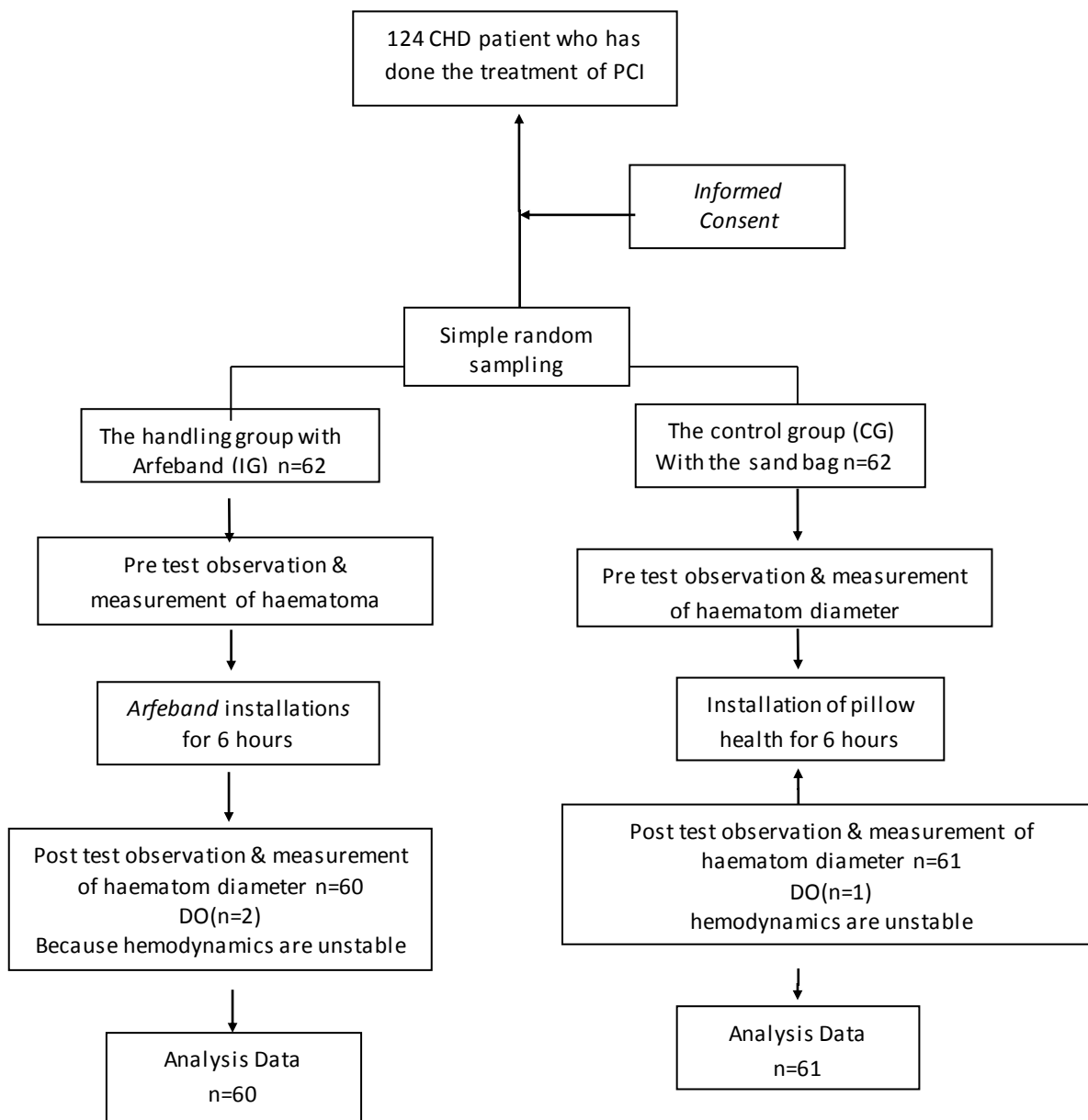
Method

Method of the research that used in this research is *quasy- experiment with pre-post control trial design* method with the sample of 124 patients after the elective PCI that has inclusion criteria, the age of the respondent is 40 – 65 years old, the right of femoral artery access, the size of *sheath femoral 7 French*, and one times of puncture. The exclusion criteria, they are suffered procedural complication (acute myocardial infarction or severe chest pain, severe bleeding, ventricular fibrillation), hemodynamic instability, coagulation disorders, the loss of consciousness. Three of 124 patients are

Duett, Boomerang, ExoSeal, Starclose, VasoSeal, Angio-Seal and Perclose devices (Schwartz, Burstein, Economides, Robert et al., 2011; Jones, et al., 2002; Kimmel & Jesse, 2007; Travis, Dey, Albrecht-Gallauresi, Brindis, Shaw, Weintaub, & Mitchel, 2005; Yilmaz, Gurgun, & Dramali, 2007; Hyyh, 2012; Behan, 2006; Trabattoni, et al., 2011; and Mohammed, Said, & Salah, 2013), but those device is less popular to use in Indonesia with the some consideration likes the efficiency of that device.

Arfeband (*artery-femoral band*) is local device compression of femoral artery that is designed with more the consideration of safety, the patient safety and also the efficiency of device from the other devices. This research used arfeband that compared with the pillow health in the 92 patients after angiography coronary with *randomized controlled trial* method that more effective to prevent hematoma incident (Junait & Sodiqur, 2013). This research is continued to the patient after PCI who have the vascular complication risk because of they get antithrombotic therapy aggressively before, during, and after the medical act, also the size of femoral sheath is the largest (Nuray, Umman, Arbal, Altok, Enuzun, Uysal, Ncekara, Ulusoy, & Baran, 2007; Han & Cho, 1999; and Matic, et al., 2015; Chair, et al., 2005). The purpose of the research is to know the influence of use arfeband to haematoma incidents in patients after PCI.

executed. 121 patients are divided at random with *simple random sampling* into two groups, the handling group with arfeband 60 (IG) and the control group with the sand bag 61 (CG). The observation and the measurement of haematoma diameter are done before and after intervention, the measuring instruments that used, they are observation paper, tensiometer, and the meter that used to measure the cloth. The experimental instrument has been checked and approved by the *ethical clearance* committee; all patients are given informed consent for inclusion in the study.



Picture 1. The Flow of Research

Result

From this research, the researcher found 121 respondents that consist of 60 IG and 61 CG. The characteristic of demography and the basic clinic

that influenced the hematoma incidents from both of group test is summarized in Table 1.

The characteristics of the subject

Table 1. The demography data and clinical characteristic in patient that influenced to haematom incidents (n=121)

Characteristics	Handling (IG) (n = 60)	Control (CG) (n=61)	Total (n=121)	<i>p-value</i>
Gender				0,098
Male	49 (81,7%)	52(85,2%)	101 (83,5%)	
Female	11(18,3%)	9 (14,8%)	20 (16,5%)	
Ages				0,059
Means	57,32	56,77	57,04	
Deviation Std	±6,28	±8,211	±7,29	
MAP (mmHg)				0,142
Means	14 (87,5%)	68,2	69,5	
Deviation Std	2 (12,5%)	±6,34	±7,20	
Heparin Dose (international unit)				0,70
Median	7000	7000	7000	
Minimum	5500	5000	5000	
Maximum	8000	9000	9000	
BMI				0,400
Means	25,32	25,26	25,19	
Deviation Std	±2,85	±3,99	±2,93	

About of 83,5% the respondents are male who has aged average 57,04 ($\pm 7,29$) years old. The main arterial pressure (MAP) is 69,5 ($\pm 7,20$) mmHg and (the body mass index (BMI) of the

patient averaged in 25,19($\pm 2,93$) kg/m². The dose of heparin that is given when the medical action of PCI is at most 7000 international units (iu) the lowest dose of 5000 iu, and the highest 9000iu

Table 2. The analysis result pre effectively procedure of IG vs CG to haematom incidents (n=121)

		Haematom PRE				<i>p</i>
		Yes		No		
		n	%	n	%	
Groups	(IG)	23	38.3	37	61.7	0,909
	(CG)	24	39.3	37	60.7	
Total		47	27.3	88	72.7	

After removal of sheath femoral and before the intervention has been observed, there are the hematoma incidents in the puncture site. From this observation, there are IG 23 (38,3%) vs CG 24 (41%) that is showed in the table 2. Before the intervention procedure is done, the researcher also measures the hematoma diameter average

in IG 30,4 ($\pm 13,6$)mm vs CG 30,8 ($\pm 21,8$) mm. Then the measurement of hematoma is done after 6 hours of intervention and there is of decrease of diameter between IG 10,9 ($\pm 15,9$)mm vs CG 27,5 ($\pm 21,7$) mm that is showed in table 3.

Table 3. The analysis result of post procedure of the affectivity IG vs CG to haematom incidents (n=121)

Groups	Haematom POST				P	OR (CI 95%)
	Yes		No			
	n	%	n	%		
(IG)	11	18.3	49	81.7	0,029	0,398 (0,172-0,919)
(CG)	22	36.1	39	63.9		
Total	33	27.3	88	72.7		

Analysis

The result of the research showed that both of those groups are comparable. There is no differences that significant in the basic characteristics and characteristics clinic in the patients ($p>0,05$). Before the intervention of hematoma incident is done, there is no differences that significant between both of those groups ($p>0,05$) that is showed in table 2. After the intervention has been done for 6 hours and re-observed to hematoma incidents that is showed in table 3, the test result of *chi-square* procedure, it shows that there are the

significance differences between both of groups. They are $p<0,05$, OR 0,398CI 95% (0,172 – 0,919). It means that IG is able to prevent the hematoma incidents to 60,4%.

Based on the result of statistic test especially in the change of the size of diameter pre and post procedure, it concluded that IG $p=0,001$ vs CG $p>0,05$, it means that there are the change of the size of the hematoma diameter if it used IG that compared with CG, seen the table 4.

Table 4. The analysis result of the effect IG to the change of the size of diameter in all patient with hematoma incidents n=121

Groups		n	Median (min-max) (mm)	Means \pm SD (mm)	P
IG	Preprocedure	60	30,0 (10-60)	30,4(\pm 13,6)	0,001
	Postprocedure	60	0 (0-5)	10,9 (\pm 15,9)	
CG	Preprocedure	61	20,0 (1-10)	30,8 (\pm 21,8)	0,544
	Postprocedure	61	25 (0-10)	27,5 (\pm 21,7)	

Discussion

According to the table 1, the demography factor and the basic clinic condition of patients, it shows that the refraction selection does not happen because of the adequate randomization. The tests are randomly controlled, IG that used the simple of the local device of femoral artery, it shows that the procedure that used in this

research has the high success with significant to prevent hematoma incident in patient PCI after the removal of the *sheath femoral* therefore it is more working than uses the sand bag in standard procedure.

There are differences that significant between the advantages of the use of arfeband in the patient after PCI and the control group in the

prevent of hematoma incident, that is IG 11(18,3%) vs CG 22 (36,1%), $p < 0,05$. Meanwhile, for the change of the size of hematoma diameter before and after of the device use, there are differences that significant. That is 30,4 mm to be 10,9 mm ($p=0,002$) vs 30,8 mm to be 27,5 mm ($p>0,05$).

The main factor that becomes the factor of hematoma incident to be less is the advantage of IG position since it is more stable in the area of pressure. It is not easy influenced by the movement of the patient and the pressure that gives more relative constant and measurable if it is compared with the sand bag. Several of the great researches have been compared the hemostasis strategy vascular access in patient who is going to the elective percutaneous coronary procedure.

Several devices have been developed to help in the closure of femoral arteriotomy lesions, including extravascular covering devices such as Vaso Seal, Angio Seal, and Exo Seal. There are some device that used such as Percutaneous closure suture device, and mechanical suppressor devices (Hassan, Hasan-Ali, Demetry, Refaat, & Ali, 2015). The mechanical compression devices that often to use are C-clamp or compresor and pneumatic Femostop device. All of these devices are not to be choosing because the efficiency reason therefore people choose the manual pressure that is continued by the pressure of the sand bag. Arfeband is cheaper than all devices that often are used and it is easy to be made. When people made one arfeband, it needs 20 \$ and it is used repeatedly. All of devices included the arfeband, are given with the constant pressure in the injuries area and still keep peripheral distal perfusion in the right leg in the dorsalis pedis pulse.

Arfeband has advantages to be the local alternative device and replacement the sand bag like to the early mobilization therefore the comfort of the patient is kept with right and left tilt without changing the quality of pressure. It also is designed to keep everything possible.

Conclusion

The result of this study shows that arfeband is simple device and effective as the alternative device to reach homeostasis and prevent the hematomas incident after PCI. The effects of the arfeband use are reasonable and safe to keep the stabilization of homeostasis after PCI. The use of arfeband is done as an independent nurse in the treatment of injuries access a catheter heart.

Conflict of interest: There is no conflict of interest.

Ethical approval: Approved by the Institutional Com-mittee on Human Research at the institution

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