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Original Research Article

Incidence and predictors of groin complication after cerebral neurointervention procedure: single centre study

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ABSTRACT

Background: Cerebrovascular disease is characterized by an acute compromise of the cerebral perfusion or vascular which caused morbidity and mortality around the world. The most accurate imaging technique for the evaluation of cerebrovascular system is digital subtraction angiography (DSA), but it can cause many complications, one of the most is groin complication. Our objective was to determine incidence and predictors of groin complication after cerebral neurointervention procedure.
Methods: An observational prospective study was conducted in PELNI hospital, from January until June 2021, with a total sample of 246 patients. We observed hematoma that occurred within 24 h after procedure. Data was analysed using SPSS ver 24.
Results: There were 246 patients who underwent DSA procedures. The average age of patients was 54.3±11.9 years and the majority were male (59.5%). The incidence of groin complication was 37.4%. The predictors of groin complication evaluated with bivariate analysis were age (p=0.167), gender (p=0.827), frequency of puncture (p=0.178), catheter size (p=0.200), duration of compression (p=0.477), comorbidities (hypertension; p=0.839, diabetes; p=0.178, heart disease; p=0.373), and history of anticoagulant (p=0.022). Multivariate analysis showed that history of anticoagulant (p=0.023, OR=2.118 (95% CI 1.107-4.049) to be the most significant factors contributing to groin complication after the intervention.
Conclusions: Groin complications appeared to be the most complications after cerebral neurointervention procedure with incidence rate 37.4% and associated mostly with the history of anticoagulant.

Keywords: Neurointervention procedure, Groin complications, Hematoma

INTRODUCTION

Cerebrovascular disease is medical condition characterized by an acute compromise of the cerebral perfusion or vascular which was caused by hypertension, clotting disorder, and dissection of vascular. Incidence of stroke is around 800,000 people annually and it became the most leading cause of disability.[1] In Indonesia, based on the data from Riset Kesehatan Dasar (Riskesdas) in the year 2018, the prevalence of stroke is 10.9 for every 1.000 citizens. This number is increasing compared to the result of Riskesdas 2013, which is 7 for every 1.000 citizens. Stroke has become the leading cause of death in almost all hospitals in Indonesia, which is 15.4%.[2,3]

Stroke has significant mortality, morbidity, and social-economic consequence for the patients, their partner, and society.[4] Therefore, further examinations to diagnose stroke and provide an image of the brain's blood vessels are needed. Accurate results of imaging in stroke will be followed by better treatment and decreasing morbidity also mortality of stroke. Although many noninvasive neurovascular imaging techniques, including magnetic resonance angiography and computed tomography

angiography, however, DSA remains, most accurate imaging technique for evaluation of cerebrovascular system. DSA is gold standard and important diagnostic modality for cerebrovascular diseases, including occlusions, stenoses, dissections, and aneurysms, etc.[5]

Complications of DSA were varied, with overall risk of major complications only <2%, and 24-hour risk of stroke and death <1%, neurologic complications appeared to be 3.5% (2.5% reversible neurologic deficit and 1% permanent neurologic deficit), non-neurologic complications include renal failure 0.2%, pseudoaneurysm or arteriovenous fistula 0.2%, arterial occlusion requiring surgery 0.2%, hematoma requiring transfusion or surgical evacuation 0.5%. Groin complications appeared to be the most frequent complications that occurred after cerebral angiography.[6]

The socio-demographic and clinical characteristics were documented in literature to be risk factors for groin complications development post catheterization procedure in cardiac (CCP). Older age, female gender, BMI, and history of comorbidities such as hypertension, diabetes mellitus, peripheral vascular disease, and renal failure were concluded as associated factors with groin complications development post CCP.[7] However, there is still limited study in Indonesia about groin complications post neurointervention procedure, therefore, this study was aimed to determine the incidence rate and the predictors of groin complications post neurovascular intervention procedure, especially in PELNI hospital.

METHODS

This was an observational prospective study of patients undergoing DSA procedure, conducted from January until June 2021 in PELNI hospital after obtaining clearance from the institutional ethical committee. A total of 246 patients had met inclusion and exclusion criteria. Inclusion criteria were all patients age older than 18 years having cerebrovascular disease and had already signed informed consent, were stable, did not have contraindication criteria for neurovascular intervention. Exclusion criteria in this study were patients with kidney failure and had not given agreement towards procedure.

DSA procedure

All procedures were performed on a single-plane DSA machine. The angiographic technique remained relatively unchanged except for periodic updates in guide catheters and guide wires. All patients underwent common femoral artery access using a 5 to 7 Fr sheath set to a continuous heparinized saline infusion. We used vertebra, JR, and head hunter as the diagnostic and guiding catheters.

Post procedure

Hemostasis was obtained through manual compression was about 15 minutes. Patients were monitored by a nurse in the recovery area during strict bed rest for at least 6 h. All patients underwent a neurological and peripheral vascular examination at the time of discharge performed by the interventional neurology team.

In this study, we collected data including age, gender, diagnoses, fluoroscopy time, the amount of puncture needed to attain femoral artery access, catheter French size, duration of manual compression, coagulation marker (PT and APTT), comorbidities, and history of using anticoagulant. We followed the patients after cerebral DSA or procedure within 24 hours. The groin complications were diagnosed if there was hematoma near of or at the puncture site. We analyzed data using SPSS version 24 for windows. The analytical method in this study was using Chi-square and Fischer exact test.

RESULTS

In this study, there were 246 patients who underwent neurovascular intervention procedure and had met inclusion criteria. The mean age was 54.3±11.9 years old and there were more patients same or older than 55 years (56.1%). The majority of the patients were male with a percentage of 59.3%, and diagnosed with CVD SI (92.7%). The average time for fluoroscopy procedure was 22.8±8.2 minutes. The most frequency of puncture needed to access femoral site for neurointervention procedure was once (80.5%), with the Catheter Fr 5 had been the most used catheter size (97.6%). The average time for manual compression was 12.4±2.8 minutes for bleeding to stop, with less than 15 minutes compression becoming the most duration of time needed (77.2%). We measured coagulation marker in this study including PT and APTT values. Mean PT value 13.6±2.1 meanwhile APTT was 30±3.9 seconds. There were many patients with a history of hypertension (73.2%), otherwise, there were few who had diabetes (19.5%) and heart disease (4.9%). The history of taking anticoagulants was 18.7%. In this study we found groin complications in the form of hematoma presented only in less than half (37.4%), There were more patients underwent the procedure without having the groin complications (62.6%) (Figure 1).

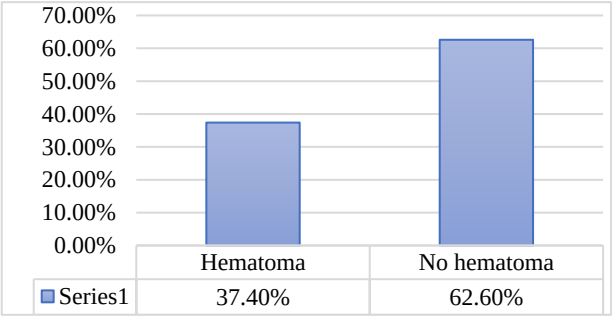

Figure 1: Incidence rate of groin complication after neuro-intervention procedure within 246 patients from January-June 2021 in PELNI hospital. Data was collected within 24 h after procedure, and measured when there was complication in form of hematoma.

Table 1: Characteristics of patients underwent DSA procedure.

Characteristics	N (%)	Mean ± SD
Age (Years)		
≥55	138 (56.1)	54.3±11.9
<55	108 (43.9)	
Gender		
Female	100 (40.7)	
Male	146 (59.3)	
Diagnosis		
CVD SI	228 (92.7)	
Malformations	8 (3.3)	
Aneurysm	4 (1.6)	
Vascular headache	4 (1.6)	
Moya disease	2 (0.8)	
Fluoroscopy time		22.8±8.2
The frequency of puncture		
1	198 (80.5)	
> 1	48 (19.5)	
Catheter Fr size		
5 Fr	240 (97.6)	
6 Fr	4 (1.6)	
7 Fr	2 (0.8)	
Duration of manual compression (minutes)		
≥15	56 (22.8)	12.4±2.8
<15	190 (77.2)	
Coagulation marker (seconds)		
PT value		13.6±2.1
APTT value		30.0±3.9
Comorbidities		
Hypertension		
Yes	180 (73.2)	
No	66 (26.8)	
Diabetes mellitus		
Yes	48 (19.5)	
No	198 (80.5)	
Heart disease		
Yes	12 (4.9)	
No	234 (95.1)	
History of anticoagulant used		
Yes	46 (18.7)	
No	200 (81.3)	
Groin complication		
Hematoma	92 (37.4)	
No hematoma	154 (62.6)	

We also analyzed risk factors (Table 2) that contributed to groin complications after procedure. Characteristics included age, gender, the frequency of puncture, catheter Fr size, durations of manual compression, comorbidities, and history of using anticoagulant were analyzed using comparative study Pearson chi-square and Fischer exact test. We found that history of using anticoagulant statistically significant factor for groin complication (p=0.022 and OR 2.1 (1.1-4.0), which interpreted as if patient had a history of using anticoagulant, then they would have more risk of developing hematoma after procedure. Duration of manual compression is also statistically significant factor for groin complication with (p=0.027 and OR 1.9 (95% CI 1.1-3.6).

Table 2: The predictors of groin complication in patients underwent DSA procedure.

Variables	Groin complications		P value	Risk
	Yes (%)	No (%)		
Classifications of age (Years)				
≥55	54 (39.1)	84 (60.9)	0.526[a]	1.2 (0.7-1.9)
<55	38 (35.2)	70 (64.8)		
Gender				
Female	38 (38.0)	62 (62.0)	0.872[a]	1.0 (0.6-1.8)
Male	54 (37.0)	92 (63.0)		
The frequency of puncture				
>1	22 (45.8)	26 (54.2)	0.178[a]	1.5 (0.8-2.9)
1	70 (35.4)	128 (64.6)		
Catheter Fr size				
> 5 Fr	4 (66.7)	2 (33.3)	0.200[b]	3.4 (0.6-19.2)
5 Fr	88 (36.7)	152 (63.3)		
Duration of manual compression (min)				
≥15	28 (50)	28 (50)	0.027[a]	1.9 (1.1-3.6)
<15	64 (33.7)	126 (66.3)		
Comorbidities				
Hypertension				
Yes	68 (37.8)	112 (62.2)	0.839[a]	1.1 (0.6-1.9)
No	24 (36.4)	42 (63.6)		
Diabetes mellitus				
Yes	22 (45.8)	26 (54.2)	0.178[a]	1.5 (0.8-2.9)
No	70 (35.4)	128 (64.6)		
Heart disease				
Yes	6 (50.0)	6 (50.0)	0.373[b]	1.7 (0.5-5.5)
No	86 (36.8)	148 (63.2)		
History of anticoagulant				
Yes	24 (52.2)	22 (47.8)	0.022[a]	2.1 (1.1-4.0)
No	68 (34.0)	132 (66)		

[a] Pearson chi square, [b] Fischer exact test

Table 3: Multivariate analysis of predictors of groin complication in patients underwent DSA (enter method).

Variables	P value	Risk	95% CI	
			Lower	Upper
The frequency of puncture (> 1)	0.361	1.361	0.702	2.693
Duration of manual compression ≥15 min	0.053	1.838	0.992	3.406
History of DM	0.175	1.570	0.818	3.013
History of anticoagulant	0.043	1.985	1.021	3.858

We analyzed the data using multivariate analysis (Table 3) with logistic regression. We calculate variables with p<0.2 into multivariate analysis and we found that history of using anticoagulant became the most significant factor

that influenced the groin complication with p=0.043, and risk 1.985 (CI 1.021-3.858).

DISCUSSION

In this study we found the average age was 54.3±11.9 years. We found more patients with the age same or more than 55 years. Cross-sectional research by Tini et al in Indonesia reported that most of the patients with stroke was in the range age between 55-59 years with mean age was 55±14 years.[8] Another study by Setyopranoto et al showed younger age than our result with mean age of 49.91±14.16 years, but the highest prevalence was also between 50-59 years. Age was one of the risk factors for chronic diseases, including neurodegeneration and cardiovascular disease.[9] Increase age was associated with reduction of the elastin component and to an increase of collagen component, which led to an increase of media arterial wall stiffness and contributed to cerebrovascular incidence.[10] In the elderly, skin retains less moisture and loses its elasticity,[11] and so it could increase the risk for developing hematoma or groin complication at the site of catheter insertion after neurointervention procedure. We analyzed age with hematoma after neurointervention and showed no significant corelation. This could happen because of our patients' age were varied and the mortality rate of stroke patients was high, and so the elderly (more than 65 years) were only 38 patients (15.4%).

In this study, we found more male participants (59.3%) than female (40.7%). The study by Tini et al showed more male (61%) patients among all patients who suffered from stroke in Stroke Unit at Sanglah hospital in Bali.[8] Another study by Collo et al stated that incidence in global stroke for men (IS 132.77/100.000; HS 64.89/100.000) exceeded those of women (IS 98.85/100.000; HS 45.48/100.000).[12] The women had circulating estradiol which was linked to the relative protection from ischemic injury, the mechanism of neuroprotection appeared to be multifactorial.[13] Our study also analyzed the relationship between gender and groin complication after neurointervention procedure, and we found no significant relationship. A study by Al-Momani and AbuRuz (2019) about incidence and predictors of groin complications early after coronary intervention reported that females were nearly two times more likely to develop groin complications (OR=2.13, p=0.024, 95% CI: 1.11-4.01) compared to other groups.[7] These differences might happen because our study only evaluated hematoma and not all groin complications. An interesting fact by Rahvohran et al showed that even though men had dermal thickness more than women, but this would decrease at early at the age of 20 compared to women at 50 years, and women had more skin elasticity than men.[14]

We assessed the groin complication within 24 hours after the neurointervention procedure, and from all of the patients, there were 92 patients (37.4%) developing hematoma as the clinical sign of groin complication. A study by Al-Momani et al CCP stated that 38% patients had groin complications. This result was along with our study.[7] The femoral artery was the most common access route for cerebral neurointerventional procedures. Complications of the transfemoral approach included groin hemorrhages and hematomas, and others. Risk factors included obesity, use of anticoagulation, insufficient manual compression, large sheath, early ambulation, and peripheral vascular disease. Puncturing below the femoral bifurcation as well as poor hemostatic techniques increased the risk of developing a groin hematoma. The incidence of groin hematoma was higher than other groin complications.[15]

The frequency of puncture that was needed to attain femoral access was once to five times. One punctured appeared to be the most frequent of puncture needed with percentage of 80.5%. The bivariate analysis between the frequency of puncture and the incidence of groin complication showed that there was no significant relationship (p=0.178). The size of the catheter used in this study was varied from 5 until 7 Fr. We also evaluated the relation between the catheter size and the incidence of groin complication and found no correlation with p=0.200. A study by Kurisu et al about ultrasound guided femoral artery access for minimally invasive neurointervention and risk factors for access site hematoma reported that the number of attempts puncture in first pass success was 63.6%, and it did not contribute significantly to groin hematoma after the procedure with p=0.788, but, when they evaluated the relationship between catheter size and hematoma, they found that catheter size 6 Fr (21.2%) was a risk factor for hematoma formation with p=0.099.[16] This could happen because they also classified hematoma into very tiny with size less than 20 mm, meanwhile we did not use any classification for our hematoma and we only used manual evaluation that was based on qualitative measurement.

We recorded the time for manual compression after removal of the catheter until the bleeding stopped. The time was 12.4±2.8 minutes on average, and mostly below 15 minutes. Interestingly, we found a correlation between the time for manual compression and the incidence of hematoma or groin complication after the procedure with p=0.027. Manual compression was the most commonly used technique to achieve hemostasis after removal of a femoral artery sheath. Manual compression was then applied with the fingertips with the 3-finger approach from the skin nick proximally along the length of the artery while the distal pulse was preserved.[17] In a study by Doyle et al low risk patients (diagnostic catheterization through a 5-Fr sheath, no anticoagulant) had excellent outcomes with 10-15 minutes of manual compression.[18] A study by Koreny et al compared VCD (vascular closure device) and manual compression stated that the risk of bleeding or hematoma formation was less with manual compression.[19] To our knowledge, this was the first study that analyzed the relationship between

manual compression duration and hematoma formation in neurointervention procedures.

In this study, there were 73.2% of patients had hypertension, 19.5% had diabetes mellitus, and 4.9% had heart disease. We found there was no relationship between comorbidities and incidence of groin complication. A study by Kurisu et al found that hypertension to be the risk factor for access site hematoma formation with p=0.099, and diabetes mellitus and cardiac disease were not correlated with p=0.904 and 0.764. The systolic blood pressure more than 180 before the procedure was about the time more likely to develop groin complications compared to other categories.[16] Meanwhile, patients with chronic hypertension were more adapted than acute hypertension, Dumont reported that chronic hypertensive patients were 60% less likely to have vascular complications.[20] In this study we did not record pre-procedural blood pressure, that might be why we did not have similar results with previous study.

There were only 46 patients (18.7%) who had history of using anticoagulants, but when we analyzed between this variable with the incidence of groin complication, we found a significant relationship between these two variables through bivariate and multivariate analysis, which meant people who had anticoagulant obediently before as their daily treatment following their original disease had more chance to developed hematoma after neurointervention procedure, and this likely to be 2.1 more times than people with no history of using anticoagulant. A study by Kuriso et al showed that the used of anticoagulant therapy had a significant relationship with hematoma formation (p=0.007), and it became the most significant factor besides BMI that were independently at risk for access site hematoma formation with multivariate analysis.[16] The used of anticoagulants caused interference in thrombin-mediated activities and might interfere with wound healing, stall wound progression, and complications after wound healing, including bleeding, excessive wound exudate, and also hematoma.[21]

To our knowledge, we were the first to find the incidence rate of hematoma or groin complication after neurointervention procedure and the significant factor associated with it in Indonesia. Even though, our study also had several limitations. We did not classify groin complications into subgroups like ecchymosis, small hematoma, medium or large hematoma, and others so that we could not specify our groin complications. We also did not use a quantitative measurement for evaluating the hematoma, we only used a qualitative method based on clinician decision. We hope this study could be a reference for future research.

CONCLUSION

Neurointervention procedures are safe and groin hematoma complications had occurred in only less than half of patients with incidence rate of 37.4%. The history of using anticoagulants was the most predicting factor in groin hematoma.

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