

Patency rate difference of the arteriovenous fistula with and without pre-anastomosis balloon dilatation in chronic kidney disease patients

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ABSTRACT

Background: Arteriovenous fistula (AVF) failure rate in chronic kidney disease patients is relatively high due to inadequate feeding arteries and draining veins. The primary balloon angioplasty (PBA) dilatation technique is a way to mitigate AVF failure. There have not been many studies to determine the patency rate with and without PBA. This study analyzed the patency rate and the number of patency failures in Indonesia AVF patients with and without PBA.

Methods: A retrospective cohort study was conducted in AVF surgery patients from 2019 to 2021 with or without PBA with a total sample technique. The patient was chosen without AVF surgery in the same arm with had follow-up every three months for three years. We excluded incomplete medical record data and unfollowed patients six weeks after surgery. The Kaplan–Meier method used the log-rank test to estimate each group's patency rate. The p-value < 0.05 was considered significant.

Results: There were 60 subjects, of which 29 were with PBA and 31 were without PBA. There was a significant difference between the two groups regarding venous diameter and postoperative venous flow volume (p < 0.01). The log-rank test showed a significant difference in patency failure in the group without PBA (35.5%, mean patency rate 56.3 weeks) compared to the group with PBA (10.3%, mean patency rate 104.4 weeks) with p = 0.028. The median duration showed that 50% of the group without PBA experienced patency failure at week 59.3. In contrast, until the observation's end, the PBA group experienced patency failure of less than 50%.

Conclusion: Using the PBA technique can reduce the incidence of patency failure and maintain longer patency in patients with AVF.

Keywords: Arteriovenous fistula, AVF, Balloon angioplasty, Patency rate, Indonesia.

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INTRODUCTION

In 2015, approximately 10% of the world's population suffered from Chronic Kidney Disease (CKD) and End-Stage Renal Disease (ESRD), both of which are the main causes of morbidity and mortality in both developed and developing countries.¹ There are 77,892 ESRD patients who are actively undergoing hemodialysis, according to the Indonesian Renal Registry (IRR). Arteriovenous fistula (AVF) is still the preferred vascular access for hemodialysis in Indonesia.^{2,3} Arteriovenous fistula maturation failure can be mitigated by dilatation techniques such as balloon angioplasty: primary balloon angioplasty (PBA)—performed before the AVF procedure, and balloon angioplasty maturation (BAM)—performed serially after the AVF procedure. However, serial BAM procedures

have a disadvantage, namely the risk of intimal injury that can lead to restenosis and thrombosis compared to PBA, which is performed before surgery.^{4,5}

PBA is known to have an increased percentage and rate of maturation in AVF.⁶ It also has the advantage of a lower initial thrombosis rate and lower venous outflow resistance; consequently, it is associated with a higher rate of patency and a significantly reduced need for reinvention.^{7,8} In addition, studies showed that in the PBA group, there was an increase in primary patency and accelerated FAV maturation compared to the non-PBA group.^{7,8}

This study aimed to analyze the difference between the patency rates of PGTA patients undergoing FAV with a PBA measuring 1.5 times the initial venous diameter compared to those

without the balloon.

METHODS

This study is a retrospective cohort in which patients recorded in the operating register who underwent AVF surgery from 2019 to 2021, with and without PBA, were traced for their medical records and or contacted to undergo follow-up examination to determine the last date the AVF location was still used for hemodialysis access or records of patent failure. The inclusion criteria of study subjects were: CKD patients had undergone surgery to create an arteriovenous fistula with or without a balloon, had never had AVF surgery on the same arm before, the patient’s medical record could be found, and the patient had follow-up every three months for three years. The exclusion criteria were that the patient’s medical record could not be found or the patient was no longer in control six weeks after surgery.

Data from medical records were gender, age of the patient at the time of AVF surgery, the comorbid status of hypertension and diabetes mellitus, and the date of AVF surgery. The data obtained from the patient’s information is the last date the AVF location was used for hemodialysis access or the date it was stated that the AVF location could no longer be used because of a patent failure. The study’s primary outcome was patency duration in weeks, which could be patency or patency failure.

Statistical analysis was performed with SPSS software ver. 23.0 (IBM Corp., NY, USA). The Kaplan–Meier method used the log-rank test to estimate each group’s patency rate. Results were considered significant if the p-value was <0.05 with a confidence interval of 95%.

RESULTS

The number of patients whose medical record data were available was 109, of which 48 subjects received balloon dilatation while 61 did not. A total of 49 subjects did not come for control for follow-up, so they were excluded from the study. The number of subjects whose data were analyzed was 60, of which 29 received balloon dilatation, while the rest did not. Table 1 shows the characteristics of the

Table 1. Subject Characteristics.

	With PBA n = 31	Without PBA n = 29	p-value*
Sex			
Male	17 (54.8%)	15 (51.7%)	1.00
Female	14 (45.2%)	14 (48.3%)	
Age			
<65 years old	26 (83.9%)	22 (75.9%)	0.53
≥65 years old	5 (16.1%)	7 (24.1%)	
Comorbidity			
Hypertension	16 (51.6%)	20 (69%)	0.20
Diabetes Mellitus	11 (35.5%)	8 (27.6%)	0.59

*Fisher-exact test; PBA: primary balloon angioplasty

Table 2. Number of Event Patency Failure and Patency Rate.

	With PBA	Without PBA
Number of subjects	31	29
Number of events	11 (35.5%)	3 (10.3%)
Number of censored	20 (64.5%)	26 (89.7%)
Mean duration in weeks (95%CI)	56.3 (36.8-75.8)	104.4 (91.5-117.3)
Median duration in weeks (95% CI)	59.3 (0.0-159.6)	-
Patency Rate p-value (Log Rank Mantel-Cox)	0.028	

PBA: primary balloon angioplasty

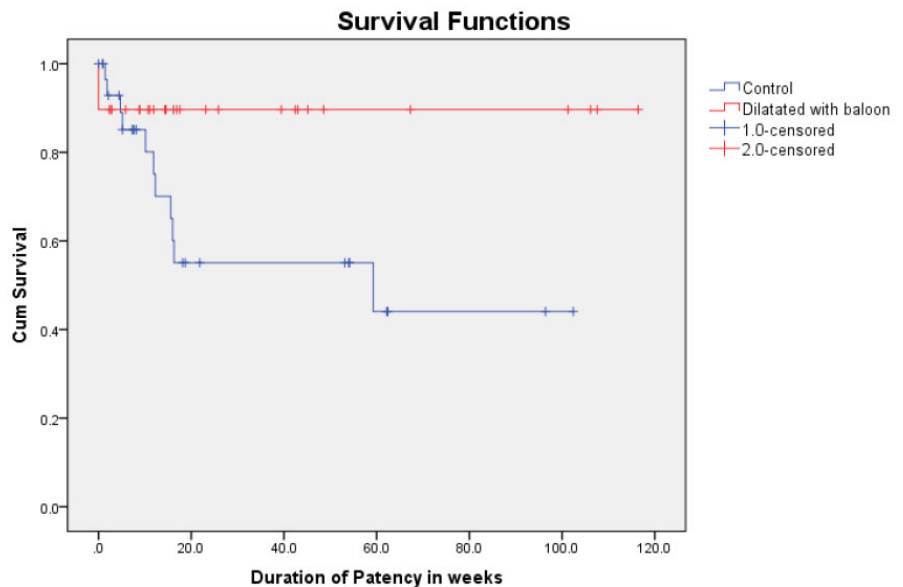


Figure 1. Kaplan-Meier Curve Showing Patency Rates of FAV with PBA (red) and Without PBA (blue).

subjects, and no significant differences were found between groups based on gender, age, or comorbidities such as hypertension or diabetes mellitus.

Survival analysis (Table 2) showed that patent failure occurred in the group without balloon dilatation in 11 of 31 subjects (35.5%). In comparison, 20 subjects were still patent until the end of

their lives or until the end of follow-up. As for the group that underwent balloon dilatation, from 29 people, patent failure occurred in 3 subjects (10.3%), while the remaining 26 were still patent at the end of their life or until the end of the survey. The mean duration of the mean patency rate in the control group was 56.3 weeks, while the intervention group was 104.4 weeks. The

median duration showed that 50% of the control group experienced patency failure at week 59.3. In comparison, until the end of the observation, the intervention group experienced less than 50% of the control group, which is also seen in the Kaplan-Meier curve in [Figure 1](#). The log-rank test indicated a significant difference in the patency rate between the two groups.

DISCUSSION

The subjects of the two groups in this study were homogeneous because there were no significant differences between groups based on the proportion of gender, age, and comorbidities such as diabetes mellitus and hypertension (see [Table 1](#)). Therefore, the difference in patency failure and patency rate in this study can be assumed not to be affected by confounding factors such as gender, age, or the presence of comorbid hypertension or diabetes mellitus.⁹

[Table 2](#) shows that patent failure occurred in the group without balloon dilatation in 11 of 31 subjects (35.5%), while 20 subjects were still patent until the end of their lives or until the end of the survey. As for the group that underwent balloon dilatation, from 29 people, there was patency in 3 subjects (10.3%), while the remaining 26 were still patent at the end of their life or until the end of the follow-up. It means that more subjects in the control group experienced patency failure compared to the intervention group. Our study supports the statement by Gabr et al. that AVF in combination with PBA can prolong the functional life of AVF.¹⁰

The log-rank test showed a significant difference in the patency rate between the two groups. The mean duration showed the mean patency rate in the control group was 56.3 weeks, while the intervention group was 104.4 weeks, with a p-value = 0.028. It shows that the duration of patency in the control group is shorter than that of the intervention group, or it can be concluded that in the intervention group, AVF patency lasts longer. The median duration of our study showed that 50% of the control group experienced patency failure at week 59.3. In contrast, until the end of the observation, the intervention

group experienced less than 50% of the control group, which is also seen in the Kaplan-Meier curve in [Figure 1](#). Based on these data, it is clear that patency failure is more common in the control group. These results are similar to the results of Gabr et al., which also showed that up to 24 months, the group with PBA who experienced patency failure did not reach 50%.¹⁰ In addition, the study by Veroux et al. also showed a higher patency rate in the PBA group.¹¹ Therefore, PBA in AVF surgery for hemodialysis access prolongs patency life and reduces the incidence of patency failure.

The limitation of our study is the high rate of censored subjects in both groups (64.5% in the PBA group and 89.7% in non-PBA). It may influence the precision of the statistical analysis of the survivors' patency rate since more subjects passed away before patency failure. We plan to conduct another study to investigate biochemical factors influencing vascular patency in AVF, so suitable therapeutic drug modalities might be utilized to improve the patency rate.

CONCLUSION

Using PBA in AVF is recommended because it prolongs patency life and reduces the incidence of patency failure in AVF surgery for hemodialysis access.

FUNDING

None.

ETHICAL STATEMENT

This study has been approved by the Institutional Review Board of Dr. Cipto Mangunkusumo Hospital (KET-516/UN2.F1/ETIK/PPM.00.02/2022).

CONFLICT OF INTEREST

The authors declared no conflict of interest regarding this research and publication.

AUTHORS' CONTRIBUTIONS

All authors contributed to the study concept and design, analysis and interpretation, data collection, writing the article, and conducting critical revision.

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