



# Better Efficacy of Balloon Assisted Maturation in Radial-Cephalic Arteriovenous Fistula for Hemodialysis

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**Purpose:** Native arteriovenous fistula (AVF) is the first choice for hemodialysis access; however, the maturation failure rate remains high. Hence, balloon-assisted maturation (BAM) is increasingly being used to overcome maturation failure. This study evaluated the outcomes of BAM and compared the differences between radial-cephalic (RC) and brachial-cephalic (BC) AVF.

**Materials and Methods:** Between January 2013 and December 2017, 1,622 new AVFs were created. BAM was considered if the AVF did not satisfy the criteria for hemodynamic maturation (6-mm diameter and 500-mL/min flow rate within 8 weeks after the operation).

**Results:** Of the 1,622 AVFs, BAM was performed in 142 patients (8.75%). There were 92 RC and 50 BC AVFs. Multivariate analyses revealed that ipsilateral central vein catheter history was the sole risk factor for maturation failure after BAM. One-year functional primary patency (FPP) and functional secondary patency (FSP) in RC AVFs were higher than those in BC AVFs without statistical significance (FPP, RC vs. BC: 70.9% vs. 50.9%,  $P=0.099$ ; FSP, 95.5% vs. 81.1%,  $P=0.146$ ). Further, based on the multivariate analysis, the independent risk factors for FPP in the RC and BC AVFs were the number of BAMs (odds ratio [OR], 3.05; 95% confidence interval [CI], 1.11-8.37;  $P=0.03$ ) and age (OR, 1.04; 95% CI, 1.00-1.07;  $P=0.04$ ), respectively.

**Conclusion:** BAM is a relatively good salvage method with tolerable patency. However, the risk factors for patency and the outcomes of BAM differ between RC and BC AVFs.

**Key Words:** Arteriovenous fistula, Endovascular procedures, Balloon angioplasty, Renal dialysis

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## INTRODUCTION

A native arteriovenous fistula (AVF) is the first choice for hemodialysis access. Native AVFs are advantageous because they possess lower infection rates and better patency

than prosthetic arteriovenous grafts (AVGs) [1]. However, the main disadvantage of native AVFs is maturation failure, which remains high.

Assisted maturation procedures, including intervention or surgery, have produced acceptable outcomes. Several

studies have reported balloon-assisted maturation (BAM), which intervenes in immature AVFs with percutaneous transluminal angioplasty (PTA). They reported clinical success rates of 43%–97%, with 1-year primary and secondary patencies of 28%–72% and 68%–96%, respectively [2]. The outcomes of BAM have been extensively reported; however, there are a limited number of evidence-based studies and a lack of randomized prospective trials. In addition, there remains a concern that PTA causes endothelial and smooth muscle cell injury and may require more frequent intervention to maintain patency [3]. Based on the 2019 Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines [4], either surgical or endovascular techniques should be considered when intervention is required for AV access to enhance maturation postoperatively.

The 2019 KDOQI guidelines [4] recommend brachial-cephalic (BC) AVF as the first choice for anticipated limited duration on hemodialysis because it has a higher likelihood of unassisted maturation than radial-cephalic (RC) AVF. Therefore, we hypothesized that the outcomes of BAM would be different for RC and BC AVFs.

This study aimed to evaluate the outcomes of BAM, identify the risk factors for maturation failure, and compare the differences between RC and BC AVFs.

## MATERIALS AND METHODS

### 1) Study design and patients

This study was approved by the institutional review board of Seoul National University Hospital (H-2012-045-1180). Informed consent was waived due to the retrospective nature of the study. We retrospectively enrolled patients who underwent AVF creation at Seoul National University Hospital between January 2013 and December 2017. The inclusion criteria were all patients with RC or BC AVFs. The exclusion criteria were other autogenous vascular access usage, including transposed RC AVF, brachial-basilic AVF, and brachial-brachial AVF. In addition, patients with forearm and upper arm AVGs were excluded. We identified patients who underwent an intervention before maturation among these cohorts.

### 2) Definition and outcome assessment

The primary outcomes were maturation failure, functional primary patency (FPP), and functional secondary patency (FSP). Secondary outcomes were the risk factors for patency and maturation failure. The risk factors included old age, sex, comorbidity, number of BAMs, flow and size of the artery and vein, and lesion of the BAM. We classified

the location of the lesion into five groups: anastomosis, juxta-anastomosis, venous outflow, arterial inflow, and central vein. Juxta-anastomosis was defined as the venous side within 3 cm of the anastomosis, and venous outflow was defined as the venous side, which was more than 3 cm from the anastomosis site. Arterial inflow was defined as the arterial side within 3 cm of the anastomosis [5].

The 2019 KDOQI guidelines define maturation failure as an AV access that cannot be successfully used for dialysis for 6 months after its creation, despite radiological or surgical intervention. FPP was defined as the duration from functional matured AVF to any intervention or thrombosis. Conversely, FSP was defined as the duration from functional matured AVF to AV access abandonment. Functional matured AVF was defined as consistently providing dialysis with two needles for two or more dialysis sessions within four consecutive weeks [4].

### 3) Arteriovenous access protocol

Preoperative duplex mapping was performed in all patients to evaluate vein and artery status. Using the criteria of 2 mm and 1.5 mm diameter for the vein and artery, respectively, the RC or BC AVF was created. Following the KDOQI guideline recommendation, RC AVF was first considered in patients undergoing hemodialysis for more than a year. If the RC AVF was inadequate, BC AVF was subsequently considered. If hemodialysis was not expected for more than a year or the RC and BC AVF were not appropriate, an AVG was created [4]. Although the conditions of the blood vessels were of utmost importance, in the event of a borderline diameter, the surgeon determined the AVF type by considering other risk factors including old age, diabetes mellitus, and other comorbidities.

AVF was monitored at the outpatient clinic within 2 and 6 to 8 weeks post-creation. AVF was first performed in our hospital, and the data were recorded. The criteria for hemodynamic maturation assessed by Doppler ultrasound (DUS) are a diameter  $\geq 6$  mm and flow volume  $\geq 500$  mL/min within 8 weeks post-operation [6]. If the AVF did not fulfill the ultrasound criteria for maturation and showed focal stenotic lesions within 8 weeks post-operation, BAM was considered. The final decision regarding whether to wait for another 4 weeks for maturation or to perform BAM was made by vascular surgeons. Additional BAM was considered if the AVF had a focal stenotic lesion or responded to BAM.

The fistula was cannulated with a micropuncture needle and sheath using ultrasonography. A 0.035-inch guidewire and a 5 to 6-Fr sheath were inserted. Following angiography, a 4 to 6-mm balloon dilatation catheter was used for dilatation of the stenotic segment. Each balloon dilatation

was insufflated between 8 and 12 atm, with insufflation times of less than 1 min.

The size and number of dilatations were determined by the diameter of the vessel and the preference of the surgeon. Usually, stenotic lesions in juxta-anastomosis or arterial inflow are dilated using a 4-mm balloon. Stenotic lesions in the venous outflow and central vein were dilated using a 6-mm balloon. A total of 1,000 or 2,000 units of systematic heparinization were used during the procedure.

#### 4) Statistical analysis

Differences between the RC and BC AVFs were analyzed using the chi-square test for categorical variables and Student t-test for continuous variables. Kaplan–Meier curves were used for FPPs and FSPs to determine the association between AVF type and patency. Univariate and multivariate analyses were performed using Cox proportional hazards regression analysis with a backward stepwise process. In the univariate analysis, variants with  $P < 0.1$  were selected for the multivariate analysis. The data were examined using the IBM SPSS ver. 21.0 (IBM Corp., Armonk, NY, USA) and  $P < 0.05$  was considered statistically significant.

## RESULTS

### 1) Study population and baseline characteristics

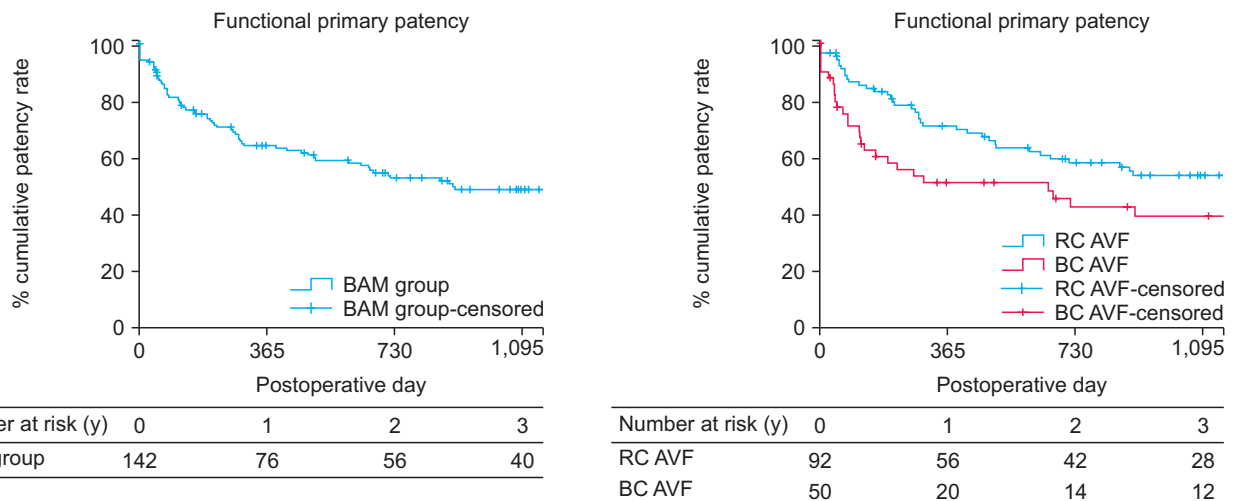
A total of 1,622 BC and RC AVFs were created between January 2013 and December 2017. A total of 142 patients (8.75%) were included in the final analysis of BAM (Fig. 1). The BAM group included 92 (64.8%) RC and 50 (35.2%) BC AVFs.

The mean age was  $64.1 \pm 14.0$  years, and 45.8% were men. Twenty-three (16.2%) patients had an ipsilateral central vein catheter history, and 34 (23.9%) patients were in a preemptive state. In the preoperative DUS, the mean artery diameter and flow were  $2.7 \pm 1.1$  mm and  $19.9 \pm 16.7$  mL/min, respectively. The mean vein diameter was  $2.8 \pm 0.9$  mm. The first BAM was performed  $53.4 \pm 22.2$  days following the AVF operation. BAM was performed once in 129 patients (90.8%), twice in 14 patients (7.7%), and three times in two patients (1.4%). The first BAM lesions were classified into five groups. The most frequent lesion was the juxta-anastomosis site (60.6%), followed by venous outflow (44.4%), anastomosis (9.9%), central vein (2.8%), and arterial inflow (2.1%). There were 98 (69.0%) single lesions in the first BAM.

The preoperative artery and vein diameters in the DUS were larger in the BC group than in the RC group (artery,  $2.2 \pm 0.6$  mm vs.  $3.9 \pm 0.8$  mm,  $P < 0.001$ ; vein,  $2.5 \pm 0.6$  mm vs.  $3.3 \pm 1.1$  mm,  $P < 0.001$ ; Table 1). In addition, the BC group had a higher preoperative artery flow than the RC group ( $11.1 \pm 9.5$  vs.  $35.7 \pm 14.9$ ,  $P < 0.001$ ). There was no difference between the two groups, with the exception of the preoperative vessel size and flow.

### 2) Outcomes for balloon-assisted maturation

There were nine cases (6.3%) of maturation failure in the total BAM group. The BC group exhibited a higher maturation failure rate, with no statistical difference (3.3% vs. 12.0%,  $P = 0.067$ ; Table 2). In the multivariate analysis of the risk factors of maturation failure, the history of the ipsilateral central vein catheter was the sole risk factor for maturation failure (odds ratio [OR], 4.381; 95% confidence



**Fig. 1.** Kaplan–Meier analysis for functional primary patency in total and subgroup. BAM, balloon-assisted maturation; RC, radial-cephalic; AVF, arteriovenous fistula; BC, brachial-cephalic.

**Table 1.** Baseline characteristics of patients treated with BAM

Variant	Total	RC	BC	P-value
Patient number	142	92	50	
Age (y)	64.1±14.0	67.0±11.4	58.9±16.6	0.003
Sex, male	65 (45.8)	41 (44.6)	24 (48.0)	0.695
Comorbid condition				
Hypertension	93 (65.5)	63 (68.5)	30 (60.0)	0.310
Diabetes mellitus	66 (46.5)	43 (46.7)	23 (46.0)	0.933
Cerebrovascular disease	38 (26.8)	24 (26.1)	14 (28.0)	0.806
Coronary arterial disease	14 (9.9)	11 (12.0)	3 (6.0)	0.255
Peripheral arterial disease	7 (4.9)	4 (4.3)	3 (6.0)	0.664
Preemptive to hemodialysis	34 (23.9)	22 (23.9)	12 (24.0)	0.991
Ipsilateral CVC history	23 (16.2)	14 (15.2)	9 (18.0)	0.667
Preoperative artery diameter (mm)	2.7±1.1	2.2±0.6	3.9±0.8	<0.001
Preoperative artery flow (mL/min)	19.9±16.7	11.1±9.5	35.7±14.9	<0.001
Preoperative vein diameter (mm)	2.8±0.9	2.5±0.6	3.3±1.1	<0.001
Interval of BAM from operation (d)	53.4±22.2	54.4±22.8	53.0±21.4	0.735
Number of BAM				0.576
1	129 (90.8)	83 (90.2)	46 (92.0)	
2	11 (7.7)	7 (7.6)	4 (8.0)	
3	2 (1.4)	2 (2.2)	0 (0.0)	
First PTA location				
Arterial inflow	3 (2.1)	3 (3.3)	0 (0.0)	0.552
Anastomosis	14 (9.9)	9 (9.8)	5 (10.0)	>0.999
Juxta-anastomosis	86 (60.6)	57 (62.0)	29 (58.0)	0.645
Venous outflow	63 (44.4)	37 (40.2)	26 (52.0)	0.177
Central vein	4 (2.8)	1 (1.1)	3 (6.0)	0.125
Number of first PTA lesion				
Single lesion	98 (69.0)	67 (72.8)	31 (62.0)	0.183
Multiple lesion	44 (31.0)	25 (27.2)	19 (38.0)	0.183

Values are presented as mean±standard deviation or number (%).

BAM, balloon-assisted maturation; RC, radial-cephalic; BC, brachial-cephalic; CVC, central venous catheter; PTA, percutaneous transluminal angioplasty.

**Table 2.** Outcomes of BAM

Result	Total (n=142)	RC (n=92)	BC (n=50)	P-value
Maturation failure	9 (6.3)	3 (3.3)	6 (12.0)	0.067
First cannulation day after BAM	123.86±109.29	129.94±123.19	112.74±77.71	0.327
Functional primary patency (%)				0.099
1-year	63.9	70.9	50.9	
3-year	48.4	53.3	39.0	
Functional secondary patency (%)				0.146
1-year	90.5	95.5	81.1	
3-year	85.7	88.7	81.1	

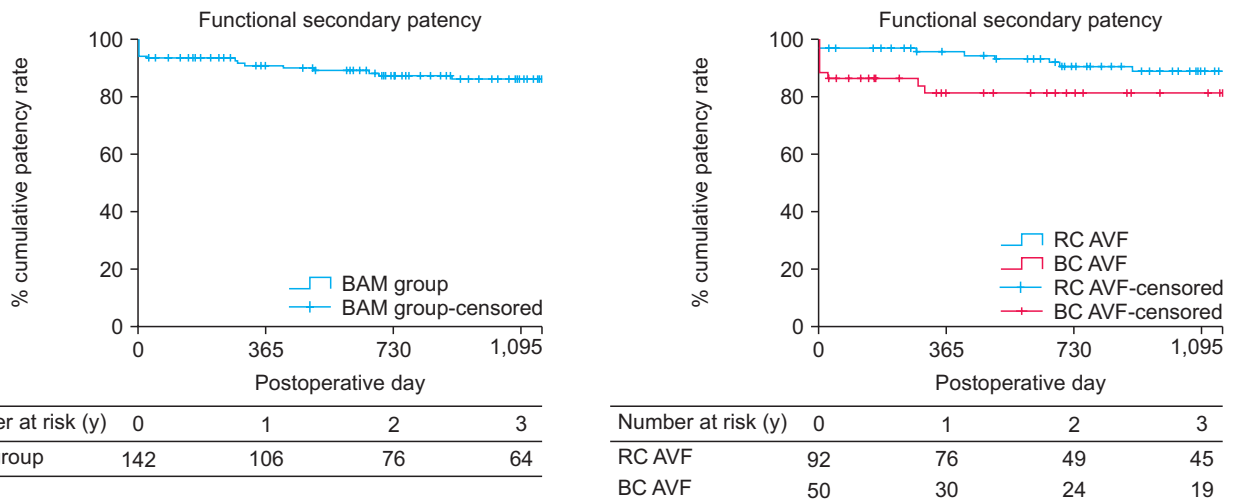
Values are presented as number (%) or mean±standard deviation.

BAM, balloon-assisted maturation; RC, radial-cephalic; BC, brachial-cephalic.

**Table 3.** Logistic regression for risk factors of maturation failure in total groups

Variable	Univariate analysis			Multivariate analysis		
	P-value	OR	95% CI	P-value	OR	95% CI
Age	0.097	1.055	0.990-1.124			
Sex, male	0.934	1.059	0.272-4.119			
Diabetes mellitus	0.420	1.800	0.432-7.5			
Hypertension	0.939	0.946	0.226-3.956			
Operation before hemodialysis	0.901	1.109	0.219-5.609			
RC vs. BC AVF	0.056	4.045	0.966-16.942	0.352	2.311	0.395-13.51
Ipsilateral CVC history	0.028	0.208	0.051-0.846	0.047	4.381	1.018-18.857
Interval to first PTA	0.239	0.981	0.95-1.013			
PTA lesion						
Venous outflow	0.495	1.644	0.394-6.851			
Juxta-anastomosis	0.288	0.418	0.084-2.089			
Anastomosis	0.897	0.867	0.100-7.486			
Artery inflow	0.999	NA	NA			
Central vein	0.999	NA	NA			
Early branching	0.999	NA	NA			
Single vs. multiple lesion	0.373	1.860	0.475-7.291			
Preoperative artery flow	0.022	1.040	1.006-1.076	0.27	1.025	0.981-1.072
Preoperative artery diameter	0.456	NA	NA			
Preoperative vein diameter	0.155	NA	NA			
Number of intervention, 1 vs. 2	0.999	NA	NA			
Number of intervention, 1 vs. 3	0.999	NA	NA			

OR, odds ratio; CI, confidence interval; RC, radial-cephalic; BC, brachial-cephalic; AVF, arteriovenous fistula; CVC, central venous catheter; PTA, percutaneous transluminal angioplasty; NA, not available due to separation.



**Fig. 2.** Kaplan–Meier analysis for functional secondary patency in total and subgroup. BAM, balloon-assisted maturation; RC, radial-cephalic; AVF, arteriovenous fistula; BC, brachial-cephalic.

interval [CI], 1.018-18.857;  $P=0.047$ ; Table 3).

In the total group, the FPPs at 1 and 3 years were 63.9% and 48.4%, respectively, whereas the FSPs were 90.5% and 85.7%, respectively. The patencies of the RC AVF were

higher than those of BC AVF, with no statistical significance (FPP at 1 year, 70.9% vs. 50.9%,  $P=0.099$ ; FSP at 1 year, 95.5% vs. 81.1%,  $P=0.146$ ; Fig. 1, 2).

In the multivariate analysis (Table 4), the independent

risk factor for FPP in RC AVF was the number of BAMs (OR, 3.05; 95% CI, 1.11-8.37; P=0.03). The 1-year patency rates for BAM once, twice, and three times were 72.8%, 57.1%, and 0%, respectively. However, the risk factor for BC AVF was old age (OR, 1.04; 95% CI, 1.00-1.07; P=0.04; Table 5). Other factors, including preoperative diameter and flow of the artery and vein, history of ipsilateral central venous catheter (CVC), and location of the index lesion of the BAM were not associated with patency.

## DISCUSSION

Due to lower infection and reintervention rates, autologous AVF is considered the first choice for hemodialysis

access [7]. However, the maturation failure rate was the main limitation. According to Asif et al. [8], 28%-53% of autologous AVFs cannot mature to support dialysis. An assisted maturation procedure with angioplasty has recently emerged to overcome the high rate of maturation failure. In the narrow sense, BAM helps maturation by ballooning all the non-dilated long segments of the vein. However, we used the term BAM in a broad sense to aid maturation by performing PTA on stenotic lesions.

In this study, BAM was performed in 142 cases (8.75%) among 1,622 AVFs, which is quite low compared to that reported in the literature [9]. We believe this is due to the thorough duplex mapping prior to AVF creation in all patients. DUS can reveal hidden inflow and outflow problems

**Table 4.** Cox regression for risk factors of functional primary patency in RC AVF

Variable	Univariate analysis	Multivariate analysis	
	P-value	OR (95% CI)	P-value
Age	0.893	-	-
Sex, male	0.683	-	-
Diabetes mellitus	0.924	-	-
Hypertension	0.436	-	-
Cerebrovascular disease	0.910	-	-
Coronary artery disease	0.644	-	-
Peripheral artery disease	0.788	-	-
Operation before hemodialysis	0.345	-	-
Ipsilateral CVC history	0.909	-	-
First PTA day	0.580	-	-
First cannulation day	0.664	-	-
PTA for venous limb lesion	0.640	-	-
PTA for juxata-anastomosis lesion	0.150	-	-
PTA for anastomosis lesion	0.435	-	-
PTA for arterial lesion	0.126	-	-
PTA for central arch lesion	0.376	-	-
Single/multiple lesion	0.638	-	-
Preoperative artery flow	0.223	-	-
Preoperative vein diameter	0.580	-	-
Preoperative artery diameter	0.456	-	-
Number of BAM, 1 vs. 2	0.033	3.05 (1.11-8.37)	0.03
Number of BAM, 1 vs. 3	0.204	13.50 (1.578-115.443)	0.017

RC, radial-cephalic; AVF, arteriovenous fistula; OR, odds ratio; CI, confidence interval; CVC, central venous catheter; PTA, percutaneous transluminal angioplasty; BAM, balloon-assisted maturation; -, not available.

**Table 5.** Cox regression for risk factors of functional primary patency in BC AVF

Variable	Univariate analysis	Multivariate analysis	
	P-value	OR (95% CI)	P-value
Age	0.036	1.04 (1.00-1.07)	0.04
Sex, male	0.722	-	-
Diabetes mellitus	0.437	-	-
Hypertension	0.918	-	-
Cerebrovascular disease	0.115	-	-
Coronary artery disease	0.951	-	-
Peripheral artery disease	0.528	-	-
Operation before hemodialysis	0.848	-	-
Ipsilateral CVC history	0.363	-	-
First PTA day	0.716	-	-
First cannulation day	0.513	-	-
PTA for venous limb lesion	0.157	-	-
PTA for juxta-anastomosis lesion	0.239	-	-
PTA for anastomosis lesion	0.227	-	-
PTA for arterial lesion	-	-	-
PTA for central arch lesion	0.389	-	-
Early branching	0.310	-	-
Single/multiple lesion	0.875	-	-
Preoperative artery flow	0.169	-	-
Preoperative vein diameter	0.108	-	-
Preoperative artery diameter	0.871	-	-
Number of BAM, 1 vs. 2	0.961	-	-
Number of BAM, 1 vs. 3	-	-	-

BC, brachial-cephalic; AVF, arteriovenous fistula; OR, odds ratio; CI, confidence interval; CVC, central venous catheter; PTA, percutaneous transluminal angioplasty; BAM, balloon-assisted maturation; -, not available.

and assist in the selection of AVF locations. In addition, the rationale behind why the BAM procedure was not established as a routine procedure is due to the surgeon preference.

However, we were not able to determine the maturation failure rate of the entire group and how many BAMs were performed in the maturation failure group because only 142 patients who underwent BAM were analyzed. In another study conducted in our center, the maturation failure rate was 13.6% for RC and BC AVF [6].

The overall FPP and FSP rates were 63.9% and 90.5% at 1 year and 48.4% and 85.7% at 3 years, respectively, which were quite good and comparable with those of other recent studies [10-12]. Therefore, BAM should be actively performed in immature autogenous RC or BC AVFs. RC AVF had higher FPP and FSP rates than BC AVF, but the difference was not statistically significant. This is an unexpected result because BC AVF usually has better patency than RC AVF.

In our study, there were 9 (6.3%) cases of maturation failure after BAM. In the multivariate analysis, the ipsilateral CVC was the only risk factor for maturation failure. History of CVC is a known risk factor for maturation failure, along with vein diameter, diabetes, smoking, and other factors [13]. Therefore, the CVC location should be carefully decided to avoid an ipsilateral location to the future AVF.

Although data on endovascular assisted maturation have been published with various results, there are limited studies on the risk factors that influence the outcome of BAM [12,14-16]. In our study, the number of interventions was a risk factor for primary patency in RC AVF, consistent with a previous study by Lee et al. [16]. They reported a retrospective national hemodialysis cohort study of 7,301 patients. The number of interventions before maturation was positively associated with primary patency loss and the frequency of post-maturation intervention. However, in our study, BC AVF had different risk factors, such as old age and primary patency. This may reflect more venous cannulation and injuries in older patients. However, it was also suggested that the risk factors for primary patency could differ between BC and RC AVFs. Therefore, more researches are required on the effects of BAM according to the AVF type.

Most lesions of the first BAM were located at the juxta-anastomosis, followed by venous outflow. There were no differences between the RC and BC AVFs. Park et al. [11] reported that juxta-anastomosis was the most frequent lesion in the maturation failure group. Lee et al. [16] reported that the proximal draining vein was the most frequent lesion in the BAM group, followed by the juxta-anastomosis vein. However, this was not associated with primary patency or

maturation failure in our study. Therefore, BAM should be considered regardless of the location of the stenotic lesions.

This study has several limitations. First, as mentioned above, we did not analyze the entire AVF cohort and could not present the maturation failure rate in the entire cohort. Therefore, we could not determine the number of BAM procedures performed in the BAM group, which could be considered as a selection bias. Second, we could not compare the non-BAM and BAM groups in the entire group or the maturation failure group. Further studies are required for an accurate comparison and group selection. In addition, although the DUS criteria for BAM were used, the surgeons' decisions regarding BAM could affect the outcomes. Third, this study was limited by its small sample size. Although some important findings were revealed, we could not prove any relationship between BAM outcomes and preoperative duplex findings. Large population studies and confirmative protocols are required for further studies.

## CONCLUSION

BAM is a relatively good salvage method for immature AVFs with acceptable patency and high success rates. However, the risk factors for patency and the outcomes of BAM differ between RC and BC AVFs. Further studies are required to define the mechanism of BAM failure in each AVF.

## CONFLICTS OF INTEREST

The authors have nothing to disclose.

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## AUTHOR CONTRIBUTIONS

Concept and design: AH. Analysis and interpretation:

HKK, SM, SKM. Data collection: HKK. Writing the article: HKK, AH, SKM. Critical revision of the article: AH, SA, SM, JH, CTYC, HK, KWC. Final approval of the article: all authors. Statistical analysis: HKK, AH. Obtained funding: none. Overall responsibility: SKM.

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