International Journal of Advanced Research in Biological Sciences
ISSN: 2348-8069
www.ijarbs.com
DOI: 10.22192/ijarbs Coden: IJARQG (USA) Volume 8, Issue 2 -2021

Research Article

DOI: http://dx.doi.org/10.22192/ijarbs.2021.08.02.005

Clinical Review of Balloon-assisted maturation for Arteriovenous fistula maturation failure: An early period experience of Safe Clinical Use.

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Abstract

Purpose: Balloon-assisted maturation (BAM) is emerging as a salvage management for arteriovenous fistula maturation failure (AVF MF). However, BAM is a relatively new, yet controversial technique for AVF maturation. Therefore, we evaluated the effectiveness of BAM for AVF MF.
Methods: Between January 2012 and December 2014, 249 AVFs were created. The total MF rate was 24.8%. But, only 110 AVFs were enrolled, including 74 brachiocephalic (BC) AVFs and 36 radiocephalic (RC) AVFs. The follow-up period was 12 months. Among those, there were 42 MFs (22 BC AVFs and 20 RC AVFs) and 68 maturation successes (MS) (52 BC AVFs and 16 RC AVFs). BAM was involved in MF group. We compared the clinical characteristics, AVF flows, and AVF flow ratios of MF and MS groups. Also, we evaluated the etiology, management, and result of MF. This clinical review done including the clinical use of Atropos PTA SC Balloon Dilatation Catheter and Minerva PTA SC Balloon Dilatation Catheter produced by BrosMed Medical Co., Ltd.
Results: There was no difference in clinical characteristics between MF and MS groups. In MF group, 39 balloon angioplasties (BAs) for 42 AVFMFs were performed .Number of BA was1.45±0.57and duration of BA was21.30±21.24 weeks. BAM rate was 46.2%. For 1 year after AVF creation, AVF flows of MS group were significantly larger than those of MF group ($P<0.05$) but there was no difference in AVF flow ratio between MF and MS groups ($P>0.05$).
Conclusion: BA for AVFMF is a relatively applicable and effective modality. Although a large volume study is necessary, we suggest BAM is an effective salvage management for AVFMF. [Ann Surg Treat Res 2016; 90(5):272-278]

Keywords: Balloon angioplasty, Treatment failure, Renal dialysis, Arteriovenous fistula

Introduction

The arteriovenous fistula (AVF) is the access of choice for hemodialysis (HD), but its success as an access is limited by a high rate of maturation failure (MF) [1]. Therefore, an upsurge of new techniques and studies has emerged in an effort to increase maturation and salvage rates in AVFs [2]. Balloon- assisted maturation (BAM) is a recent, innovative, yet controversial method for developing AVF maturation [2, 3]. The use of BAM is becoming increasingly popular, despite the limited number of evidence- based studies and lack of randomized prospective trials [2].

The balloon dilatation catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent dilatation post-deployment in the peripheral vasculature.

This method has been used in effort to increase successful primary maturation as defined by the National Kidney Foundation - Disease Outcomes Quality Initiative (NKF- DOQI) [2,4]. For that, the AVF MF is subjected to a series of staged, serial long- segment angioplasty dilations until it reaches the desired diameter and flow rate [3]. A successful BAM can rapidly speed up the maturation process and reduce the need for a tunneled dialysis catheter and prosthetic grafts [3]. Therefore, we evaluated the effectiveness of BAM for AVF MF in our early period experience. This research was approved by the Institutional Review Board of Incheon St. Mary's Hospital (OC15RISI0137).

Method

Between January 2012 and December 2014, a total of 249 AVFs were created. Among the 249 cases, there were 11 cases of exclusion that had to receive AVF recreations due to acute complications or we could not decide MF or MS because patients had been transferred to other hospitals immediately on AVF creations (Fig.1). Eleven cases of exclusion included 9 BCAVFs and 2RCAVFs. Therefore, there were 59 cases of MF including 30 of 149 BCAVFs and 29 of 89 RCAVFs (Fig.1). Also, the total MF rate was 24.8%. However, only 110 AVFs including 74 brachiocephalic (BC) AVFs and 36 radiocephalic (RC) AVFs followed for 1year were enrolled (Fig.1). Among these cases, there were 42 cases of MF (22BCAVFs and 20RCAVFs) and 68 cases of maturation success (MS) (52BCAVFs and 16RCAVFs) (Fig.1); and, BAM was involved in MF group. We compared the clinical characteristics including age, sex, comorbidity, and etiology of end stage renal disease (ESRD), AVF flows, and AVF flow ratios of the MF and MS groups. Also, we evaluated etiology, management, and result of MF in MF group.

We examined preoperatively the vessel status using duplex ultrasonography or armvenography. Duplex ultrasonography was mostly used for the preemptive AVF creations, and arm venography was mostly used for the non preemptive AVF creations. This trend was due to the conditions at our hospital. Thereafter, if a diameter of acephalic vein at wrist was more than2.5mm, we performed RCAVFs. Also, if the diameter of a cephalic vein at the wrist was less than 2.5mm, we performed.

BCAVFs. We did not includes ex, DM, and age in to the criteria for AVF creation. The MF rate of BCAVF was 20.1% and that of RC AVF was 32.6% (Fig.1).

All operations including AVF creation, balloon angioplasty (BA), and branched cephalic vein ligation (BCVL), were performed by the same vascular surgeon. All enrolled patients had construction of their AVF at our institution and were instructed to return for follow- up at our outpatient office for evaluation of maturation at 4 and 8 weeks. Those who were not maturing were subjected to BAMs at 2- week intervals. In the literature, AVF MF was defined as a surgically created AVF that failed to properly grow to become usable for the purpose of HD in 8to12 weeks after its creation[5]. The Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines recommend that prompt vascular interventions, such as BA and BCVL, should be performed if the AVF fails to mature by 6 weeks after creation [6]. Thus, our criteria for AVF MF was AVF with physical examination findings or duplex ultrasonography findings of non maturation by 6 weeks after creation or AVF with a flow volume of less than 600mL/min measured with a transonic flowmeter (HD03,Transonic Systems Inc., Ithaca, NY, USA) in atrial cannulation at 8weeks after creation. If AVF was included in more than 1of 2 criteria, we defined it as AVFMF. Physical examination at 6 weeks was determined clinically by look- listen-feel steps by avascular surgeon and nephrologist[6]. Also, duplex ultrasonography findings of non maturation were a diameter of less than 6mm, depth of more than 6mm, or flow of less than 600mL/min[6].

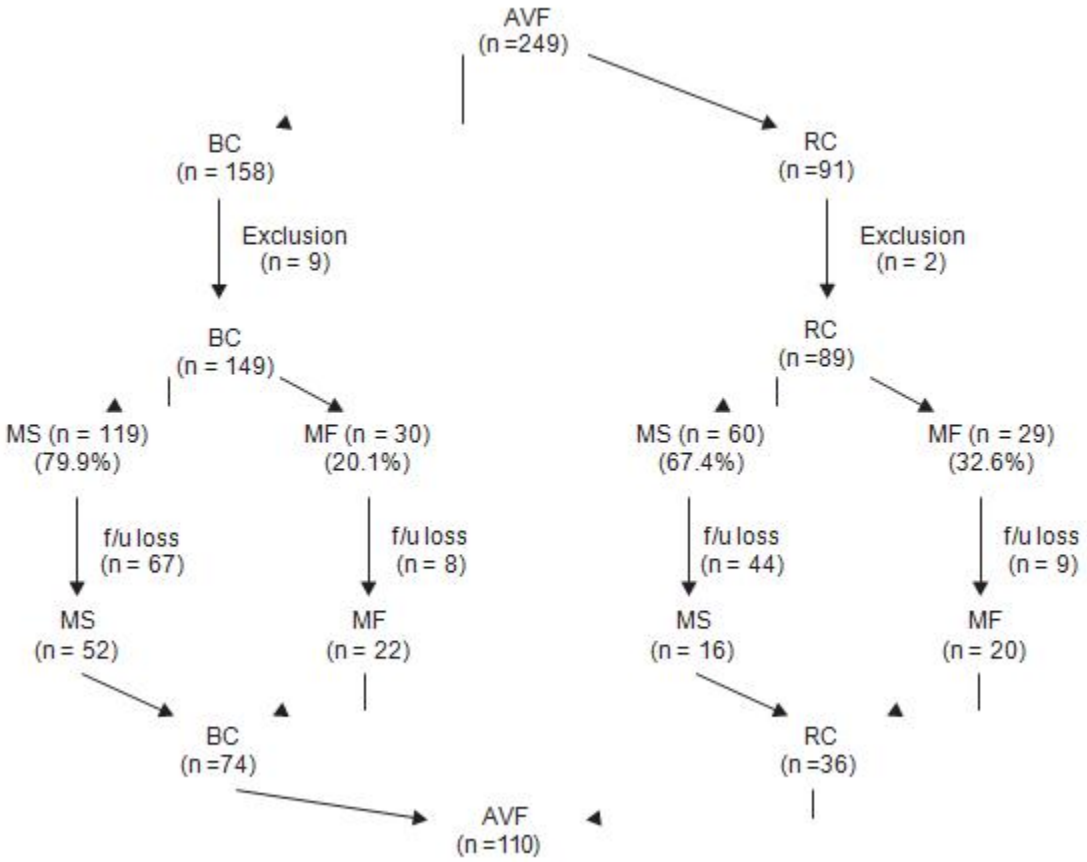

Fig. 1. Arteriovenous fistula Created in our hospital over 3 years. AVF, arteriovenous fistula; BC, brachiocephalic; RC, radio- cephalic; MS, maturation success; MF, maturation failure;f/u, follow-up.

We performed vascular interventions, such as BA and BCVL starting at 8 weeks after their creation in 2- week intervals until successful cannulation and desired flow rate (600 mL/min) were reached. We checked results by physical examination or duplex ultrasonography at outpatient clinicat 2 weeks after vascular interventions. If their results metour criteria, we attempted cannulation. But, if their results were inferior to our criteria, we attempted rein terventions.

The BA for BAM procedure was performed under a standard protocol using local anesthesia and fluoroscopy guidance (Fig.2). The C- arm (ARCADIS Avantic, Siemens AG, Erlangen, Germany) was used in all cases to provide excellent visualization of the entire fistula. All procedures were performed in the operation room, with the same vascular team.

The fistula was then cannulated using an 18 gauge angiocath- needle directly or a micropuncture needle and sheath. A 0.035- inch Glide wire (Terumo Medical Corp., Somerset, NJ, USA) and 5- Frsheathwere then inserted and positioned into the proximal artery or distal vein during retrograde and ante grade cannulation, respectively [7]. Serial dilatations were then performed using a 4- to6- mm Atropos PTA SC Balloon catheter (BrosMed Medical Co., Ltd) depending on vein caliber and surgeon preference (Fig.2). Mostly, we used a balloon 1to 2 mm larger than the estimated vein caliber [8]. Each balloon dilatation was performed multiple times with full insufflation, between2.5and3.0MPa (or2533125 and 3039750 Pa), for 50 seconds [5].

Patients were instructed to return for follow- up for physical examination and AVF flow measurement with atransonic flow meter (HD03) at 4 to 6 weeks postoperatively. Subsequent Bas were performed as necessary, at 2- week intervals following each procedure. Interval BA procedures were performed until successful HD using the AVF or clinical evidence of maturation on follow- up [8]. We checked AVF flows with a transonic flow meter by1- to3- month intervals post operatively, and followed up on enrolled patients for 1 year retro spectively.

Statistical analysis was done by Student t- test, chi- square test, Mann- Whitney test, and Fisher exact test using the IBM SPSSver.18.0 (IBMCo., Armonk, NY,USA). AP- value<0.05 Was considered statistically significant. Data were presented as mean ± standard deviation.

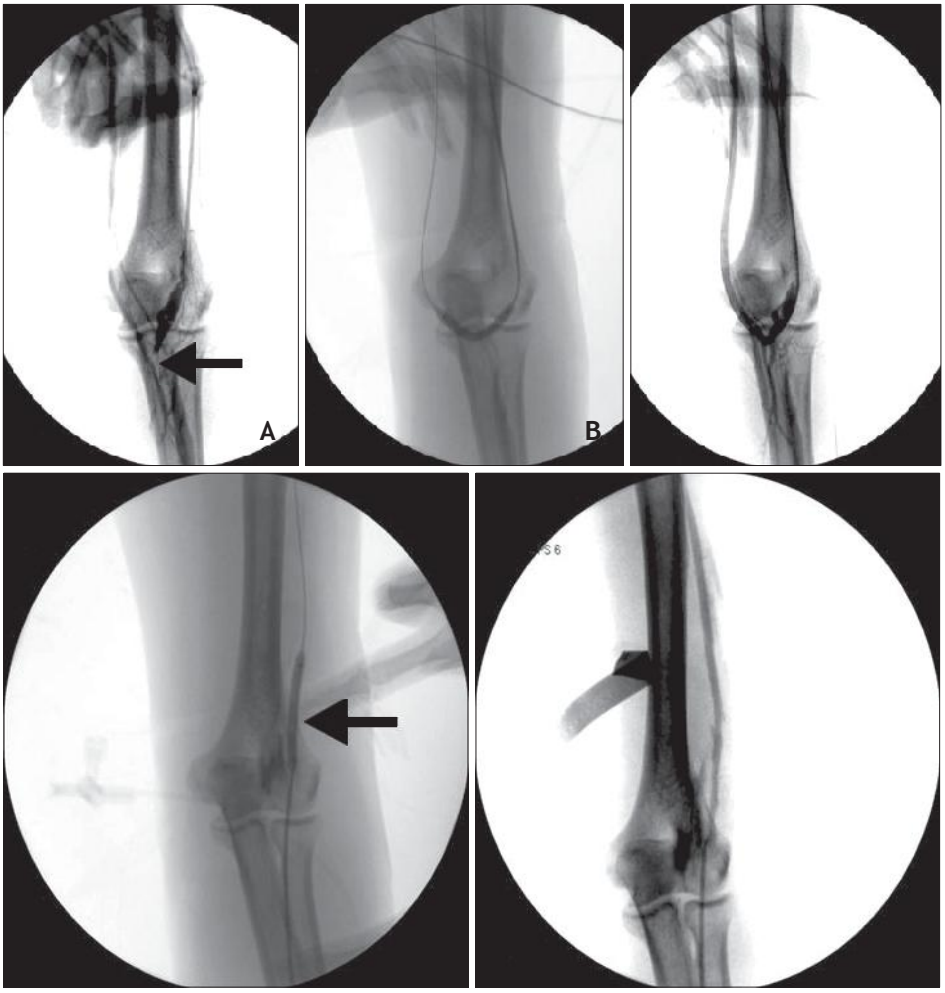

Fig. 2. Balloon angioplasty (BA) for balloon assisted maturation of arteriovenous fistula (AVF) maturation failure. (A)Jux- taanastomotic stenosis (JAS) of AVF. Arrow indicates JAS lesion.
(B) BA for JAS lesion. (C)Post- ballooning fistulography shows improvement of JAS lesion.(D)BA forcephalic veinstenosis (CVS) lesion. Arrow indicates inflated balloon. (E)Post ballooning fistulography shows improvement of CVS lesion.

Results

Between MF and MS groups, sexual distribution, age, comorbidities, and etiologies of ESRD were statistically insignificant in BCAVF, RCAVF, and total AVF groups, separately (P>0.05) (Table1).

Table 1. Baseline clinicalcharacteristics

	BCAVF (n=74)			RCAVF (n=36)			Total (n=110)	
Characteristics	MF(n=22)	MS(n=52)	P-value	MF(n=20)	MS(n=20)	P-value	MF(n=42)	MS(n=68)	P-value
Sex									
Male: Female	12:10	30:22	0.803	14:6	11:5	0.936	26:16	41:27	0.866
Age(yr)	63.33±15.32	58.40±13.97	0.212	52.67±16.71	57.19±13.13	0.391	58.23±16.89	58.12±13.69	0.971
Comorbidity									
DM	16	30	0.223	13	11	0.813	29	41	0.354
HTN	19	43	0.697	17	14	0.832	36	57	0.790
CAD	4	2	0.040	4	0	0.061	8	2	0.004
Hepatitis	2	1	0.156	1	1	0.873	3	2	0.306
Dyslipidemia	13	37	0.311	15	13	0.659	28	50	0.441
ESRD etiology									
DM	16	27	0.097	13	11	0.813	29	38	0.169
HTN	4	12	0.642	7	5	0.813	11	17	0.889
GN	0	6	0.099	0	0	-	0	6	0.049
IgA Nephropathy	0	1	0.515	0	0	-	0	1	0.432
Idiopathic	2	6	0.758	0	0	-	2	6	0.428

BC, brachiocephalic; AVF, arteriovenous fistula; RC, radiocephalic; MF, maturationfailure; MS,maturationsuccess; DM, diabetesmellitus; HTN, hypertension; CAD, coronaryartery disease; ESRD, end stage renal disease; GN, glomerulonephritis.

The 42 of 110 enrolled patients were MF. For 42AVFMFs, MF etiologies were juxt a anastomotic stenosis (JAS) only in23 patients, JAS and cephalicve instenosis (CVS) in 7 patients, JAS and branched cephalicvein (BCV) in 7 patients, BCV only in 3 patients, and CVS only in 2 patients (Table 2). Managements for MF were BA only in 32 patients, BA and BCVL in 7 patients, and BCVL only in 3 patients (Table 2). BA to BAM numbers were 1.45±0.57 (Table 2). BA duration (week) after BAM was 21.30 ±21.24 (Table 2). BA (n) to BAM means numbers of BA needed until AVFMF reaches MS (BAM). And, BA duration means an interval between balloon angioplasties performed after AVF MF reaches MS (BAM). So, we needed to do1.45±0.57 BAs until AVFMF reached BAM. At 21.30±21.24weeksafterBAM, we needed to do an additional BA during follow- up period. Results of management for MF were 22fails (52.4%) including 4 ruptures, 5 occlusions, and 13HDs with low access flow (<600 mL/min), and 20 successes (47.6%) with 18(46.2%) by BAM (Table 2). With BAs were 9 cases. Four cases of ruptures included 1case of anastomosis site rupture and 3 cases of vein rupture (Table 2). Complication rate was 21.4%. In BCAVF and RCAVF groups, MF characteristics including etiology of MF, management for MF, BA number to BAM, BA duration after BAM, and result of management for MF, also showed similar aspects with those in total AVF groups (Table 2). Between BCAVF and RCAVF groups, there was statistically no difference in MF characteristics (P>0.05) (Table 2).

In total AVFs, BA durations (week) after BAM were insignificant at 21.30±21.24 in MF group and 34.13±30.36 in MS group (P = 0.213). In BC AVF group, BA durations (week) after BAM were insignificant at 21.67±19.78in MF group and 36.43 ±32.03in MS group (P=0.275). In RCAVF group, BA durations (week) after BAM were insignificant at 21.00±23.26 in MF group and31.78±28.51in MS group (P=0.176).

Table 2. Arteriovenous fistula maturation failure Characteristics

Variable	BC AVF (n=74)	RC AVF (n=36)	Total (n=110)
	MF (n=22)	MF (n=20)	MF (n=42)
MF etiology			
JAS only	11	12	23
CVS only	1	1	2
JAS + CVS	5	2	7
BCV only	1	2	3
JAS + BCV	4	3	7
Management			
BA only	17	15	32
BCVL only	1	2	3
BA + BCVL	4	3	7
BA (n) to BAM	1.4 ± 0.63	1.5 ± 0.52	1.45 ± 0.57
BA duration after MS (wk)	21.67 ± 19.87	21 ± 23.26	21.30 ± 21.24
Results			
Fail	12 (54.5)	10 (50.0)	22 (52.4)
AVF reoperation	5	4	9
Rupture (ana + vein)	3 (1+2)	1 (0+1)	4 (1+3)
Occlusion	2	3	5
HD (low access flow [<600 mL/min])	7	6	13
Success/BAM	10 (45.5)/9 (42.9)	10 (50.0)/9 (50.0)	20 (47.6)/18 (46.2)

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

BC, brachiocephalic; AVF, arteriovenous fistula; RC, radiocephalic; MF, maturation failure; JAS, juxtaanastomotic stenosis; CVS, cephalic vein stenosis; BCV, branched cephalic vein; BA, balloon angioplasty; BCVL, branched cephalic vein ligation; BAM, balloon assisted maturation; MS, maturation success; ana, anastomosis; HD, hemodialysis.

Table 3. Arteriovenous fistula flow during 1 year after creation

	BCAVF (n=74)			RCAVF (n=36)			Total (n=110)		
Variable	MF(n=22)	MS(n=52)	P-value	MF(n=20)	MS(n=16)	P-value	MF(n=42)	MS(n=68)	P-value
AVF flow (mL/min)									
2 Months (Postop.)	479.61±120.99	1302.50±608.85	<0.001	422.78±127.32	992.50±396.41	<0.001	448.09±126.18	1258.97±651.76	<0.001
5 Months	739.44±598.54	1349.81±510.11	<0.001	549.44±288.23	1148.13±580.54	0.001	620.86±457.82	1331.76±605.39	<0.001
9 Months	817.22±592.90	1360.00±549.18	0.001	566.11±306.35	1037.50±456.11	0.001	669.43±4470.21	1313.53±617.88	<0.001
12 Months	708.89±426.90	1297.12±480.37	<0.001	595.56±323.48	1012.50±412.88	0.002	628.86±355.82	1259.56±564.33	<0.001
Flow ratio									
5 m/ 2 m	1.89±1.81	1.15±0.42	0.106	1.22±0.65	1.25±0.45	0.887	1.31±1.21	1.15±0.50	0.436
9 m/ 5 m	1.11±0.47	1.02±0.37	0.401	1.17±0.71	0.94±0.25	0.228	1.17±0.62	1.04±0.36	0.267
12 m/ 9 m	0.94±0.42	1.06±0.24	0.160	1.28±1.23	1.06±0.25	0.496	1.09±0.95	1.07±0.26	0.941

Values are presented as mean ± standard deviation.

BC, brachiocephalic; AVF, arteriovenous fistula; RC, radiocephalic; MF, maturation failure; MS, maturation success.

The AVF flows of MF group were significantly less than that of MS group respectively at 2,5,9, and12 months after AVF creation (P<0.05) (Table 3). And, AVF flows of MF group were also significantly less than those of MS group after AVF creation in BCAVF and RCAVF groups (P<0.05) (Table 3).

In MF groups, AVF flow (mL/min) before BA for BAM was 448.09±126.18, and AVF flows after BA for BAM were 620.86 ±457.82, 669.43± 470.21, 628.86±355.82 at 3,7, and10 months, respectively in total AVF groups (Table 3). Also, in BCAVF and RCAVF groups, AVF flows before Bas for BAM were

Less than 600mL/min and those after Bas for BAM were more than 600mL/min in MF group (Table 3). In total AVF groups, AVF flow ratios were 1.31±1.21vs.1.15±0.50, 1.17±0.62 vs.1.04±0.36, 1.09±0.95vs.1.07±0.26 between MF and MS groups at 5 months by 2 months, 9 months by 5 months, 12 months by 9 months, respectively, and AVF flow ratio was insignificant between MF and MS groups (P>0.05) (Table 3). In BCAVF and RCAVF groups, AVF flow ratios also showed similar aspects with those in total AVF groups (Table 3).

Discussion

Since the implementation of NKF-DOQI recommendations in1997, more patients have undergone creation of AVFs as their primary access of HD [8- 10]. Although these recommendations have identified AVF as the superior method of vascular access, it is not flaw less [2,8]. Primary AVF maturation rates within the recommended 4–6 weeks, without assistance, have been reported as low as 23%–53% [2,8,11, 12]. While the exact mechanism of MF is unclear, advancements in assisted maturation techniques and an understanding of the underlying physiology in AVF development will play a role in improved AVF maturation and survival [8]. But, BAM continues to be a controversial method for improving and expediting development of AVF maturation [2]. Roy- Chaudhuryet al.[13] attribute AVF failure to the use of angioplasty, by causing significant endothelial and smooth muscle cell injury, thus promoting smooth muscle cell activation, increased cytokine activation, and promoting neointimalhy perplasia, medial hypertrophy, and vascular remodeling. In contrast, De Marco Garcia et al. concluded that focal angioplasty injury to the venous endothelium helps the venous wall reorganize into a fibrous conduit based on large diameter segments with smooth lining on post procedural imaging. And, a few studies have reported evaluating the usefulness of BAMs in an effort to meet the growing need for AVF within the NKF- DOQI guidelines [2]. The BAM technique addresses the issues related to poor function in addition to facilitating diameter maturation by combining angioplasty, healing, and AVF remodeling into a sequential process [15].BAM focuses on dilating the usable segment of the AVF to a sufficiently large diameter, there by facilitating cannulation [15]. Each sequential dilatation increases the vein diameter by 2 to 4 mm, and they are performed 2 to 4 weeks apart to allow for healing [15]. The NKF- DOQI currently classifies more likely maturation as an AVF that, within 6 weeks of creation, has a blood flow greater than 600 mL/min, depthless than 6mm, and minimum diameter of 6mm[11]. Miller et al. [4] reported a case series of staged BA maturation with secondary patency at12months as high as 77%. Similarly, De Marco Garcia et al. [14] reported a case series involving serial BAMs along with primary angioplasty of the vein before AVF creation. A successful AVF was established in 85.4% of patients, where in success was defined as the ability to use the AVF for HD without revision for 90 days [2, 14].

In our study, we defined AVFMFs as AVFs with physical examination findings or duplex ultrasonography findings of non maturation at 4 to 6 weeks after creation or AVFs with access flow less than 600mL/min at trial cannulation at 8 weeks after creation [2,11,16]. We checked AVF flows with a transonic flowmeter (HD03) with trial cannulation from 8 weeks after creation instead of a duplex ultrasonography [11]. We also checked at least every 3 months. We believe that a merito fatransonic flow meter is that we can frequently check AVF flow at a low cost when an HD will be done in a patient.

The KDOQI guidelines recommend that prompt vascular interventions, such as BA and BCVL, should be performed if the AVF fails to mature by 6weeks after creation [6]. Also, if the AVF failed to mature by 6 weeks after creation, prompt interventions, such as percutaneous transluminal angioplasty and accessory veinligation, were recommended at 6 to 8 weeks after creation in the literature [8,15,16]. So, if AVF failed to mature by 6weeks after creation, we performed vascular interventions for all AVFMFs at 6 to 8weeksaftercreation.

In our result, the success rate (46.2%) of BAM was lower than that (>80%) in the literature [14,17,18]. We believe that the first reason was that cut off values of access flow (<600mL/min) might be higher than that in the literature [11]. So, if cut off values of access flow were<400mL/min, the success rate of BAM might be>80%. The second reason was that we followed up every 2 weeks after BA, but additional BA was inapplicable in many patients because of cost and permission of patient.

Until now, definite criteria of access flow for maturation or intervention in AVF have not been as well established [11]. But, a study found that combining venous diameter (>0.4cm) and flow volume (>500mL/min) at 1month after AVF creation increased the predictive power of adequate fistula maturation to 95% [11]. Fistulae maintain patency at lower flows than grafts but access flows less than 350mL/min are likely to produce recirculation and inadequate delivery of dialysis [6,11]. So, values of 400to650mL/min have been proposed [6,11]. Higher values increase sensitivity, but lose specificity [11]. Some fistulae can maintain patency for years at flows less than 400mL/min, but with high- efficiency/ high- flux dialysis, the treatment time requires extension [11]. We therefore need to confirm adequate criteria of access flow for maturation or intervention in AVF. Thus, we evaluated and suggested criteria of access flow for maturation as 600mL/min.

The complication rate (21.4%) was very high. We think that there as on was technical problems during the early period. Most complications occurred during the beginning period. Nowadays, we have few complications related with Bas for BAM. We believe further effort is required. However, we feel that the timing of BA for BAM was appropriate according to the literature [6,8,15,16].

In our results, AVF flows of MS group were significantly larger than those of MF group (P<0.05). Yet, both additional BA duration after AVF maturation and AVF flow ratio during follow- up period were insignificant between MF and MS groups(P>0.05). We suggest that BAM is an effectives alvage management for AVFMF.

All newly created AVFs must be physically examined by using a thorough systemic approach by a knowledgeable professional 4 to 6 weeks postoperatively to ensure appropriate maturation for cannulation[11]. If an AVF fails to mature by 6weeks, a fistulogramorother imaging study should be obtained to determine the cause of the problem [11]. Then, prompt correction, such as BAM or ligation of side branches, should be under- taken[11].

In conclusion, although larger studies and prospective trials are necessary to confirm the elements of MS and the efficacy of BAM, BA for AVFMF is a relatively applicable and effective modality and, we suggest BAM as an effective salvage management for AVFMF.

This clinical review and survey were done according to MDD 93/42/EEC and relevant guidelines MEDDEV 2.4/1 where the collected and revised clinical data and clinical review were adequate to demonstrate clinical safety and performance of Atropos PTA SC Balloon Dilatation Catheter and Minerva PTA SC Balloon Dilatation Catheter produced by BrosMed Medical Co., Ltd.

Conflicts of interest

No potential conflict to interest relevant to this article was reported.

Acknowledgments

This article was revised and approved and revised during the Congress of the Korean Surgical Society in Seoul, Korea from 5- 7 November2015.

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DOI:10.22192/ijarbs.2021.08.02.005	

How to cite this article:

Mahmoud Radwan Sun Cheol Park, Seung Yeon Ko, Ji Il Kim, Sung Moon, Sang Dong Kim. (2021). Clinical Review of Balloon-assisted maturation for Arteriovenous fistula maturation failure: An early period experience of Safe Clinical Use. Int. J. Adv. Res. Biol. Sci. 8(2): 40-49.
DOI: http://dx.doi.org/10.22192/ijarbs.2021.08.02.005