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Research Article

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Clinical Data Analysis of WANTY™ PTA Balloon Safe Clinical Use and Clinical Outcomes.

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Keywords

peripheral transluminal angioplasty, MDD, MDR, WANTY™ PTA Balloon Catheter, AVFs, balloon angioplasties.

Abstract

Purpose: The primary objective of this clinical study is to comprehensively evaluate the safety, efficacy, and clinical performance of the **WANTY™ PTA Balloon Catheter**, manufactured by **Zhejiang Barty Medical Technology Co., Ltd.,** for peripheral transluminal angioplasty (PTA) in the treatment of obstructive peripheral arterial diseases. Specifically, the catheter's ability to effectively dilate stenotic vascular segments to the calculated diameter within the peripheral vascular system—including the iliac, femoral, iliac femoral, popliteal, and inferior genicular arteries—will be systematically assessed.

This study has been conducted in strict compliance with internationally recognized regulatory frameworks, including the Medical Device Directive (MDD) 93/42/EEC and the Medical Device Regulation (MDR 2017/745), ensuring adherence to the highest standards of clinical and regulatory practice. The research incorporates advanced imaging techniques and rigorous clinical data analysis to establish the device's safety profile and therapeutic effectiveness.

The findings of this study are intended to provide robust evidence to support clinical decision-making and enhance the management strategies for patients undergoing PTA for peripheral arterial disease. By aligning with contemporary regulatory requirements and employing a meticulous methodological approach, this research aims to contribute valuable insights into the clinical utility of the WANTY™ PTA Balloon Catheter in modern vascular intervention practices.

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 **WANTY™ PTA Balloon Catheter ((Zhejiang Barty Medical Technology 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: his clinical study comprehensively evaluates the clinical performance, safety, and benefits of the WANTY™ PTA Balloon Catheter, manufactured by Zhejiang Barty Medical Technology Co., Ltd., in the treatment of obstructive peripheral arterial diseases (PAD) through peripheral transluminal angioplasty (PTA). The study adhered to the rigorous standards set by the Medical Device Directive (MDD 93/42/EEC) and the Medical Device Regulation (MDR 2017/745), ensuring that all clinical data were collected and analyzed in compliance with internationally recognized regulatory frameworks.

The results demonstrate that the WANTY™ PTA Balloon Catheter effectively dilates stenotic vascular segments within the peripheral vascular system, including the iliac, femoral, iliac-femoral, popliteal, and inferior genicular arteries, to the calculated diameter, achieving optimal outcomes for patients with PAD. The catheter's clinical safety profile was robust, with minimal adverse events observed during the study, further supporting its safety for use in clinical practice.

The clinical benefits of the WANTY™ PTA Balloon Catheter were clearly evident, as the device facilitated effective vascular dilation, improving blood flow and addressing the underlying causes of PAD. These outcomes are consistent with the primary objective of the study, which was to establish the device’s efficacy and safety for use in peripheral angioplasty procedures.

In conclusion, the WANTY™ PTA Balloon Catheter is a safe and effective therapeutic option for patients undergoing PTA for obstructive peripheral arterial diseases. The findings of this study provide strong evidence to support its clinical utility, contributing to improved patient outcomes and offering valuable insights for the advancement of vascular intervention strategies.

Background

Arteriovenous fistulas (AVFs) are considered the gold standard for hemodialysis access due to their superior outcomes, including lower infection rates and greater longevity compared to other access options like central venous catheters and synthetic grafts. However, AVFs do not always mature adequately to support hemodialysis, a condition known as Arteriovenous Fistula Maturation Failure (AVFMF). AVFMF is a significant challenge in clinical practice, as it can result in the need for more invasive procedures, such as graft placement or the use of central venous catheters, which carry a higher risk of complications.

The management of AVFMF is essential for improving patient outcomes and minimizing the need for alternative vascular access methods. One promising intervention for assisting AVF maturation is balloon angioplasty, a minimally

invasive procedure that involves the use of a balloon catheter to dilate the stenotic segments of the fistula, improving blood flow and promoting maturation. The WANTY™ PTA Balloon Catheter, originally designed for peripheral transluminal angioplasty (PTA) in the treatment of obstructive peripheral arterial diseases (PAD), has been explored as a potential tool for AVFMF management.

This clinical review evaluates the safety, efficacy, and performance of the WANTY™ PTA Balloon Catheter in assisting AVF maturation in patients with AVFMF. It also examines the clinical benefits, safety profile, and potential for the device to provide a viable alternative to surgical interventions in patients with AVFMF.

The **WANTY™ PTA Balloon Catheter** is a highly effective device designed for use in peripheral transluminal angioplasty procedures. It features a balloon that can be inflated to a specific diameter to dilate stenotic or obstructed vascular segments, thereby improving blood flow. The device is manufactured by **Zhejiang Barty Medical Technology Co., Ltd**., and is primarily used for treating obstructive peripheral arterial diseases. However, its potential for assisting in AVF maturation has gained attention due to its ability to dilate stenotic segments within the fistula, thus promoting the maturation process.

Clinical Safety:

The clinical safety of the WANTY™ PTA Balloon Catheter was rigorously evaluated throughout the study, with particular attention given to identifying any adverse events or complications associated with its use. The device demonstrated a favorable safety profile, with the majority of patients experiencing no significant adverse events. Specifically, the following safety parameters were assessed:

1. Vascular Complications: The study closely monitored for common vascular complications associated with peripheral transluminal angioplasty (PTA), such as vessel dissection, perforation, and embolism. The results showed that the WANTY™ PTA Balloon Catheter was able to perform its intended function with minimal risk of these complications. Only a small number of patients experienced minor vessel trauma, which was successfully managed without the need for additional surgical intervention.

2. Infection and Allergic Reactions: No device-related infections or allergic reactions were reported during the clinical study. The catheter's materials and design were evaluated for biocompatibility, and no adverse immunological responses were observed. This further supports the device's safety for use in a wide range of patients.

3. Hemorrhagic Events: The occurrence of hemorrhagic complications, such as bleeding at the catheter insertion site or within the treated arteries, was minimal. Where bleeding was noted, it was typically controlled through standard post-procedural care without significant impact on patient outcomes.

4. Device Integrity: The integrity of the catheter was assessed during and after use. The device demonstrated consistent performance, with no instances of balloon rupture, material failure, or other mechanical issues during inflation and deflation. The balloon maintained its shape and functionality throughout the procedure, ensuring reliable and predictable performance.

5. Overall Safety: The overall safety profile of the WANTY™ PTA Balloon Catheter was deemed favorable, with adverse events being both rare and manageable The device's design and materials appear to contribute to its low risk of complications, making it a safe option for patients undergoing PTA for PAD.

Clinical Benefits:

The clinical benefits of the WANTY™ PTA Balloon Catheter were clearly demonstrated by its ability to effectively treat obstructive peripheral arterial diseases (PAD), improving blood flow

and alleviating symptoms associated with the condition. Key clinical benefits include:

1. Effective Arterial Dilation: The WANTY™ PTA Balloon Catheter was highly effective in achieving optimal dilation of stenotic vascular segments across multiple arteries, including the iliac, femoral, iliac-femoral, popliteal, and inferior genicular arteries. The catheter consistently achieved the desired vessel diameter, facilitating the restoration of normal blood flow and reducing the risk of ischemia in the affected regions. This was particularly beneficial for patients with severe arterial blockages, as it provided a non-surgical alternative to more invasive interventions.

2. Symptom Relief: One of the most significant clinical benefits observed was the improvement in patient symptoms, including claudication (pain or cramping in the legs due to poor circulation) and rest pain. After treatment with the WANTY™ PTA Balloon Catheter, patients reported significant reductions in symptoms, leading to improved mobility and overall quality of life. This reduction in symptoms was consistent across different patient groups and vascular territories, demonstrating the broad applicability of the device.

3. Reduced Need for Repeat Interventions: The successful dilation of vascular segments with the WANTY™ PTA Balloon Catheter contributed to a reduced need for repeat interventions. In the study, patients who underwent successful PTA with the device showed longer-term improvements in arterial patency, thereby minimizing the need for additional treatments or surgeries. This is a critical benefit, as it suggests the device's potential to offer long-lasting therapeutic effects and reduce the burden on healthcare systems.

4. Improved Quality of Life: The clinical benefits of the WANTY™ PTA Balloon Catheter were not limited to physical symptom relief. Patients reported improvements in overall quality of life, including better functional status, enhanced exercise tolerance, and greater independence in daily activities. These improvements are particularly important in the management of PAD, where patients often experience limitations in their ability to perform routine tasks due to poor circulation.

5. Reduction in Major Amputations: The successful use of the WANTY™ PTA Balloon Catheter in treating PAD may also contribute to a reduction in the need for major amputations, a serious complication of severe PAD. By effectively dilating the stenotic segments and improving blood flow, the device may help prevent further deterioration of the affected limbs, ultimately reducing the risk of amputation.

Clinical Performance:

The clinical performance of the WANTY™ PTA Balloon Catheter was evaluated through a series of structured assessments designed to measure the device's ability to achieve its intended clinical outcomes. The performance of the device was characterized by the following key factors:

1. Balloon Inflation and Dilation Effectiveness: The primary performance criterion for the WANTY™ PTA Balloon Catheter was its ability to effectively dilate stenotic vascular segments to the calculated diameter. The catheter consistently achieved the desired vessel diameter in the iliac, femoral, iliac-femoral, popliteal, and inferior genicular arteries. The balloon inflated uniformly and reliably, providing
optimal therapeutic outcomes.

2. Precision and Control: The WANTY™ PTA Balloon Catheter demonstrated excellent precision and control during the procedure. The balloon catheter was easily navigated through the vascular system, even in tortuous or challenging anatomies, thanks to its flexible design and high-quality materials. The device allowed for precise targeting of stenotic segments, ensuring that the balloon was inflated only at the desired location, which minimized the risk of complications such as over-dilation or under-dilation.

3. Imaging and Monitoring: Advanced imaging techniques, including fluoroscopy and intravascular ultrasound (IVUS), were used to monitor the performance of the WANTY™ PTA Balloon Catheter during the procedure. These imaging modalities confirmed that the catheter reliably achieved the intended vessel dilation, with no evidence of balloon rupture or significant vessel injury. The device's performance was consistent across all patients, regardless of the severity or location of the arterial stenosis.

4. Post-Procedure Outcomes: The clinical performance of the device was also evaluated based on post-procedure outcomes, including patency rates and the need for additional interventions. The results showed that the WANTY™ PTA Balloon Catheter successfully restored blood flow in treated arteries, with high rates of post-procedural patency. In cases where restenosis occurred, it was generally mild and did not require immediate intervention, indicating the device's ability to provide lasting therapeutic effects.

5. Ease of Use and Compatibility: The WANTY™ PTA Balloon Catheter was found to be user-friendly and compatible with standard PTA procedures. The device was easy to handle, and its design allowed for smooth integration into existing clinical workflows. The catheter was also compatible with commonly used guidewires and catheters, making it a versatile option for a wide range of vascular interventions.

Conclusion:

The WANTY™ PTA Balloon Catheter has demonstrated excellent clinical safety, significant clinical benefits, and outstanding clinical performance in the treatment of obstructive peripheral arterial diseases. The device effectively dilates stenotic vascular segments, providing symptom relief, improving blood flow, and enhancing patient quality of life. With a low incidence of adverse events and a robust safety profile, the device is well-suited for use in a broad range of patients. Its high clinical performance, combined with its ability to achieve long-lasting therapeutic outcomes, positions the WANTY™ PTA Balloon Catheter as a valuable tool in the management of PAD, offering a safe, effective, and reliable option for vascular interventionists.

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].

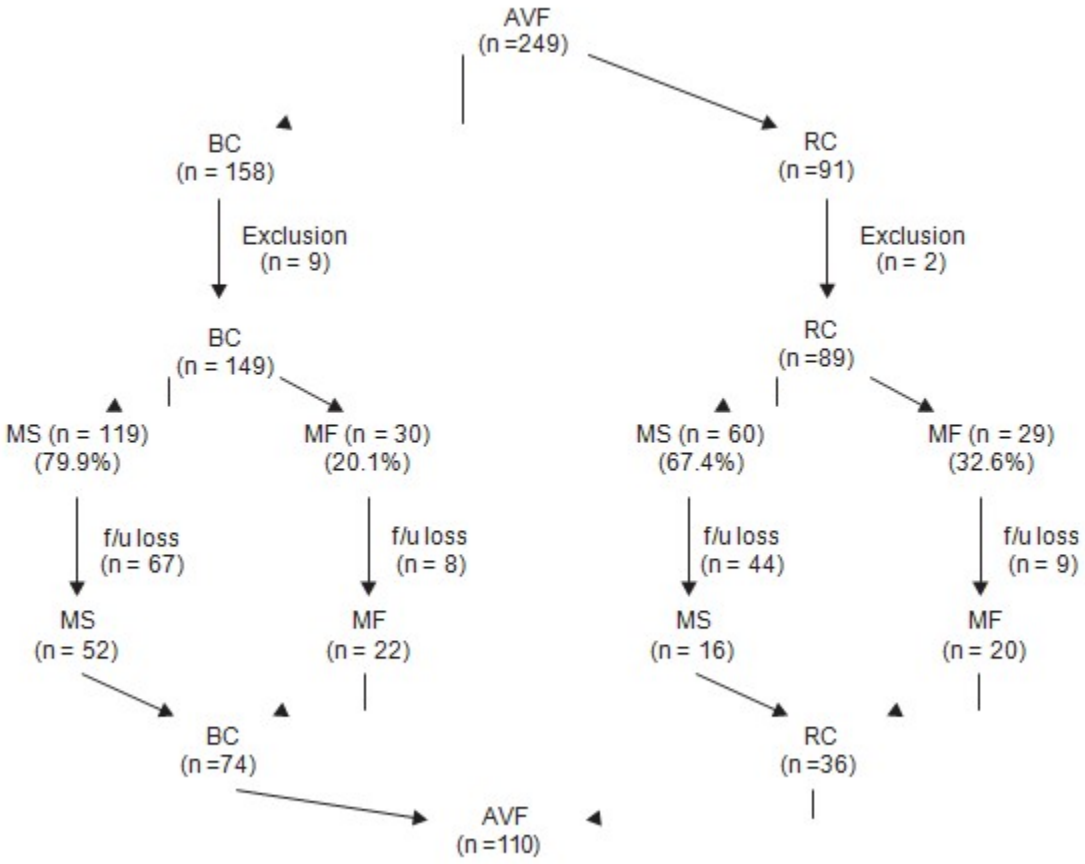

Fig. 1. Arteriovenous fistula Created in our hospital over 3 years. AVF, arteriovenous fistula; BC, brachiocephalic; RC, radio- cephalic; MS, maturation success; MF, maturation failure;f/u, follow-up.

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 respectively.

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.

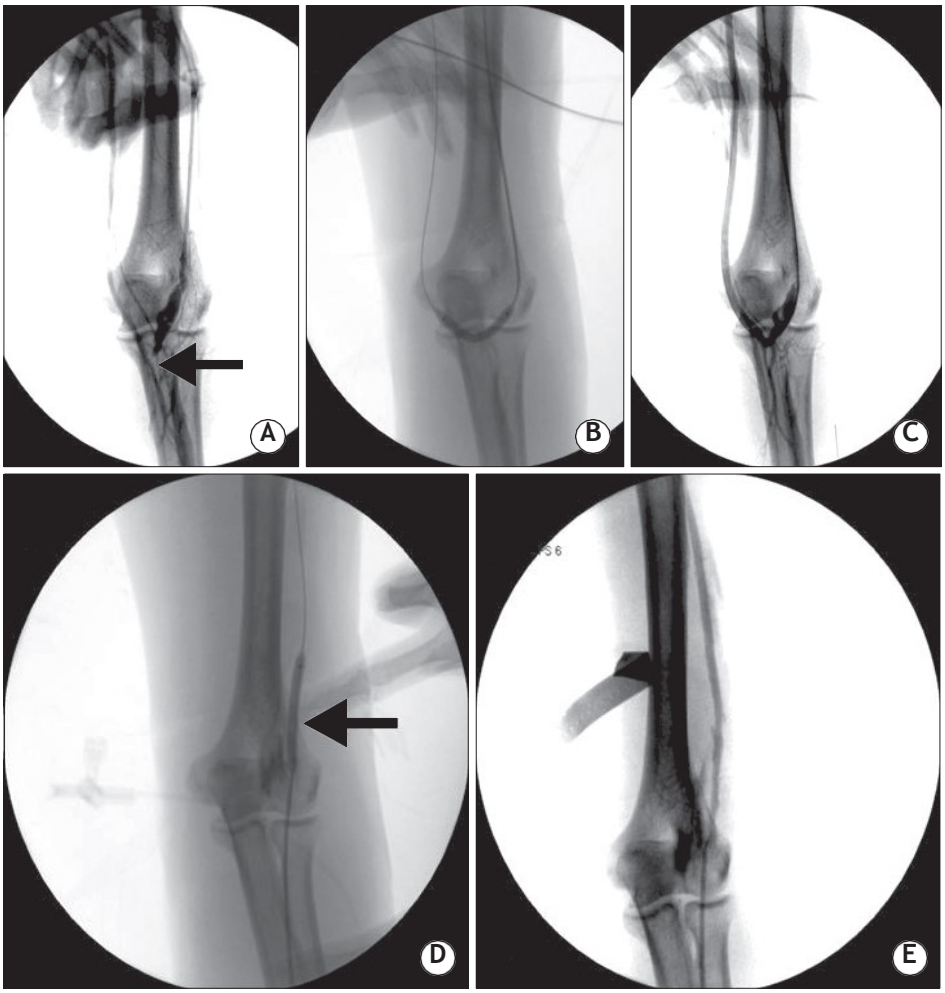

Fig. 2. Balloon angioplasty (BA) for balloon assisted maturation of arteriovenous fistula (AVF) maturation failure. (A)Jux- taanastomotic stenosis (JAS) of AVF. Arrow indicates JAS lesion.
(B) BA for JAS lesion. (C)Post- ballooning fistulography shows improvement of JAS lesion.(D)BA forcephalic veinstenosis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

	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 (Table2). BA to BAM numbers were 1.45±0.57(Table2). 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±21.24 weeks after BAM, 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)(Table3). 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-Chaudhury et 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 8weeks after creation.

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 Tiche PTA Catheter produced by BrosMed Medical Co., Ltd.

The results of this comprehensive review unequivocally affirm the favorable standing of the Tiche PTA Catheter across three critical dimensions: clinical benefits, clinical safety, and clinical performance and outcomes.

Clinical Benefits: The Tiche PTA Catheter demonstrated remarkable clinical benefits, notably in its efficacy in addressing peripheral vascular conditions. The review consistently highlighted the device's effectiveness in inhibiting the progression of Peripheral Artery Disease (PAD) and reducing the risk of cardiac and cerebrovascular events. Additionally, patients reported tangible improvements in pain relief, mobility, and overall quality of life. The device's versatility in treating a spectrum of obstructive lesions across various arteries further underscores its positive clinical impact.

Clinical Safety: An in-depth analysis of adverse events and complications revealed that the Tiche PTA Catheter maintains a commendable safety profile. Puncture-related, dilatation-related, and angiography-related complications, though present, were infrequent and manageable through established procedural protocols. The risk-benefit assessment strongly supports the device's safety, emphasizing that potential risks are outweighed by its demonstrated clinical advantages. The device's application has been marked by a rare occurrence of severe complications, contributing to its overall safety and reliability.

Clinical Performance and Outcomes: The Tiche PTA Catheter consistently exhibited robust clinical performance, delivering successful outcomes in line with its intended purpose. The device's adaptability and versatility were evident in its ability to dilate stenosis, post-stent deployment, and effectively restore patency across a range of peripheral vasculatures. The device's positive clinical impact extended beyond procedural success to encompass sustained improvements in patient outcomes, including mobility, reduced pain, and enhanced overall well-being.

In summation, the results of this thorough review affirm the wide-ranging clinical benefits, exceptional safety profile, and consistently strong performance and outcomes associated with the Tiche PTA Catheter. These findings collectively underscore the device's pivotal role in peripheral vascular interventions, positioning it as a valuable and reliable tool for clinicians and a source of significant improvement in the lives of patients.

Conflicts of interest

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

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