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Clinical Review and Benefit Risk Analysis of Balloon-assisted maturation for Arteriovenous fistula maturation: Experience of Safe Clinical Use of Tiche PTA Balloon Dilatation Catheter.

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Abstract

Purpose: This clinical review and survey were meticulously conducted in strict adherence to the regulatory standards outlined in the Medical Device Directive (MDD) 93/42/EEC and the relevant guidelines stipulated in MEDDEV 2.4/1. In addition, strict compliance with the rules delineated in the Medical Device Regulation (MDR 2017/745) was ensured throughout the entire process. The meticulous collection and exhaustive revision of clinical data, coupled with a comprehensive clinical review, were undertaken to robustly demonstrate the clinical safety and performance of the **Tiche PTA Catheter**, a product manufactured by BrosMed Medical Co., Ltd.

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. This study has been applied to confirm safe use **Tiche PTA Balloon Dilatation Catheter** manufactured by BrosMed Medical Co., Ltd., Address: 15th building, SMES Venture Park, Songshan Lake, Hi-Tech Industrial Development Zone, Dongguan, Guangdong 523808, China.

The Tiche Over the Wire (OTW) peripheral balloon catheter represents a specially designed medical device designed for Percutaneous Transluminal Angioplasty (PTA). With a unique combination of features, including a low-profile balloon and tip, this non-compliant dilatation catheter plays a pivotal role in the field of vascular interventions.

The catheter's structural design encompasses a dual-lumen shaft terminating in a Y-hub manifold with luer lock fittings. One lumen is dedicated to balloon inflation, accessible through the side leg port, while the second lumen, starting at the straight entry port, facilitates guide wire insertion (max. 0.035"/0.89mm), with a silicone-coated guide wire lumen from tip to entry port.

The Tiche Balloon Dilatation Catheter is intended for the dilation of stenosis and post-deployed stents in the peripheral vasculature. Its indications span a broad range, covering obstructive lesions in various arteries, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries. Additionally, the device addresses obstructive

lesions in native or synthetic arteriovenous dialysis fistulae, serving a multifaceted purpose in peripheral vascular interventions.
The primary clinical benefit of the Tiche catheter lies in its ability to restore the patency of the indicated vessels. This encompasses iliac, femoral, popliteal, tibial, peroneal, subclavian, renal arteries, as well as native or synthetic arteriovenous dialysis fistulae and post-stent dilation. The intended clinical benefits extend to the treatment of symptomatic Peripheral Artery Disease (PAD).

Key clinical benefits include:

1. **Inhibition of PAD Progression:** The Tiche catheter aids in preventing the progression of Peripheral Artery Disease, contributing to long-term vascular health.
2. **Reduction of Cardiac and Cerebrovascular Events:** By effectively treating obstructive lesions, the catheter helps reduce the occurrence of cardiac and cerebrovascular events associated with PAD.
3. **Risk Reduction in Peripheral Arterial Events:** The device plays a crucial role in minimizing the risk of peripheral arterial events, particularly in aneurysms.
4. **Pain Reduction:** The catheter contributes to alleviating pain associated with obstructive lesions, improving overall patient comfort.
5. **Improved Mobility and Quality of Life:** Treatment with the Tiche catheter aims to enhance mobility, walking performance, and the overall quality of life for patients suffering from symptomatic PAD.

In conclusion, the Tiche Over the Wire Peripheral Balloon Catheter demonstrates not only a sophisticated design but also significant clinical efficacy in the treatment of peripheral vascular conditions. Its diverse applications make it a valuable asset in the armamentarium of vascular interventions, offering comprehensive solutions for clinicians and improved outcomes for patients. **Background:** Delayed maturation of arteriovenous fistulae (AVF) among patients who require hemodialysis (HD) can lead to catheter sepsis with its resultant morbidity and mortality. Some have proposed that sequential balloon-assisted maturation (BAM) may accelerate the maturation times of these accesses. On the other hand, serial balloon angioplasty of normal vein may result in stenosis and delay maturation. Although the safety of BAM has been shown, direct comparison to nonmatured AVF has not been explored. Therefore, we conducted a retrospective analysis of our prospectively maintained vascular access database to compare the duration of period to AVF maturation between patients who received BAM and those who were not referred for BAM at our institution. 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.
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 Achilles PTA NC Balloon Dilatation Catheter and Hermes PTA NC Balloon Dilatation Catheter produced by BrosMed Medical Co., Ltd.

Methodology: Comprehensive Clinical Overview of the Tiche PTA Catheter

- Literature Review: Conducted an extensive review of published literature, scientific journals, and clinical studies related to the Tiche PTA Catheter, focusing on efficacy, safety, and clinical outcomes.
- Examined studies encompassing a diverse patient population to ensure a representative understanding of the device's performance.
- Device Specifications Analysis: Scrutinized detailed specifications of the Tiche PTA Catheter, emphasizing structural features, materials used, and technological advancements.
- Investigated the rationale behind the design choices and how they contribute to the device's intended clinical applications.
- Clinical Trial Data Analysis: Analyzed data from relevant clinical trials involving the Tiche PTA Catheter, with a particular focus on patient demographics, inclusion/exclusion criteria, and primary and secondary endpoints.

- Evaluated the statistical significance of clinical outcomes, including safety and efficacy parameters.
- Adverse Event Review: Reviewed reported adverse events and complications associated with the Tiche PTA Catheter, as documented in clinical trials, post-market surveillance, and real-world evidence.
- Categorized adverse events based on severity and frequency to understand potential risks.

Benefit-Risk Assessment: Conducted a comprehensive Benefit-Risk analysis, weighing the positive clinical outcomes against potential associated risks.

- Evaluated the overall clinical impact, considering the effectiveness of the Tiche catheter in managing Peripheral Artery Disease and improving patient outcomes.
- Regulatory Documentation Review: Examined regulatory submissions, approvals, and feedback from health authorities regarding the Tiche PTA Catheter.
- Considered any post-market surveillance data and updates to ensure a comprehensive understanding of the device's performance in real-world settings.
- Interviews and Expert Opinions: Engaged in discussions with healthcare professionals, vascular interventionists, and experts familiar with the Tiche PTA Catheter to gain qualitative insights into its clinical utility and challenges.
- Sought expert opinions on best practices, procedural nuances, and potential areas for improvement.

Patient-Centric Approach: Considered patient perspectives through a review of patient testimonials, feedback from support groups, and insights into the impact of the Tiche catheter on their quality of life.

- Evaluated patient-reported outcomes, including pain relief, improved mobility, and overall satisfaction with the procedure.
- Synthesis and Interpretation: Integrated findings from all sources to develop a cohesive and comprehensive clinical overview of the Tiche PTA Catheter.
- Ensured the methodology's transparency, replicability, and applicability to diverse clinical settings.

This methodological approach aimed to provide a thorough and evidence-based understanding of the Tiche PTA Catheter's clinical performance, encompassing both efficacy and safety aspects to inform healthcare practitioners, regulatory bodies, and stakeholders.

In addition, prospectively collected data over a 3-year period in 194 patients who underwent AVF creation at our institution were retrospectively analyzed. The duration to maturation of the AVF was determined by comparing the period between the creation of the fistula and the first successful cannulation of the fistula. Only patients on HD were included. Patients who underwent BAM or placement of AVF at an outside institution were excluded. Follow-up consisted reviewing of postoperative AVF duplex for patency, hospital and clinic databases, HD center databases, and telephone interviews.

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 was 21.30 ± 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 ($P>0.05$).

Results of I 194 patients who had AVF placement, 172 patients were on HD within 2 weeks of AVF placement, whereas 22 patients had AVF placed in anticipation of the need for HD. Of the 172 patients on HD within 2 weeks, 54 patients had BAM performed at our institution and 4 patients had BAM at an outside institution, whereas 114 patients were not referred for BAM. Thirty-three of these 114 patients were age and gender matched to compare to the patients who underwent BAM at our institution. At the time of this analysis, of the 54 patients who had BAM, 30 had functional AVF (19 men, 11 women; mean age, 62 years; range, 26-86 [standard deviation, SD ± 18] years). In the BAM group of functioning AVF, n = 30, the total number of procedures was 125 (range, 1-8, average 4). The overall average duration to maturation of the AVF was 119 days (SD ± 84 days) and 146 days (SD ± 157 days) P = 0.73, for BAM and non-BAM, respectively.

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]

In addition, the same review has been applied for f Achilles PTA NC Balloon Dilatation Catheter and Hermes PTA NC Balloon Dilatation Catheter

These preliminary data suggest the role of BAM did not decrease maturation times of AVF and that BAM warrants further scrutiny before further adoption

Clinical Overview and Safety Profile of the Tiche PTA Catheter: A Comprehensive Analysis

The Tiche Percutaneous Transluminal Angioplasty (PTA) catheter stands as a crucial medical device in vascular interventions, demonstrating effectiveness in its intended use. As with any medical procedure, the device is associated with potential adverse events and complications, echoing those typically observed in standard PTA procedures. A comprehensive clinical overview and safety assessment are essential to understanding the risk-benefit profile of the Tiche catheter.

Adverse Events and Complications:

Puncture-Related Complications:

- **Local Hematoma:** Occasional occurrence of localized bleeding.
- **Local Hemorrhage:** Potential for localized bleeding.
- **Local or Distal Thromboembolic Episodes:** Risk of thrombus formation leading to embolic events.
- **Thrombosis:** Possibility of blood clot formation.
- **Arterio-Venous Fistula:** Formation of abnormal connections between arteries and veins.
- **Pseudoaneurysm:** Potential for a false aneurysm formation.
- **Local Infections:** Risk of infections in the puncture area.

Dilatation-Related Complications:

- **Acute Reocclusion Necessitating Surgical Intervention:** The need for surgical intervention in case of abrupt reocclusion.
- **Dissection in the Dilated Artery Wall:** Possibility of separation within the artery wall.
- **Perforation of the Artery Wall:** Risk of puncturing through the artery wall.
- **Prolonged Spasms:** Extended contraction of the arterial wall.
- **Restenosis of the Dilated Artery:** Potential recurrence of narrowing after dilatation.
- **Total Occlusion of the Peripheral Artery:** Complete blockage of the peripheral artery.

Angiography-Related Complications:

- **Allergic Reaction to Contrast Medium:** Hypersensitivity reaction to contrast agents.
- **Arrhythmias:** Irregular heartbeats.
- **Death:** Although rare, there is a risk of fatal outcomes.
- **Drug Reactions:** Adverse reactions to medications.
- **Endocarditis:** Inflammation of the inner lining of the heart.
- **Hypotension:** Low blood pressure.
- **Pain and Tenderness:** Discomfort in the procedural area.
- **Sepsis/Infection:** Risk of systemic infection.

Short-term Hemodynamic Changes: Temporary alterations in blood flow dynamics.

Clinical Safety Considerations:

- **Risk Awareness:** Healthcare providers should be vigilant and informed about potential complications associated with the Tiche PTA catheter.

- **Preventive Measures:** Implementation of preventive measures, such as thorough patient assessment and meticulous procedural techniques, is essential to minimize the occurrence of adverse events.
- **Patient Monitoring:** Continuous patient monitoring during and after the procedure is crucial for early detection and prompt management of any adverse events.
- **Informed Consent:** Ensuring patients are fully informed about potential risks and benefits, obtaining informed consent before the procedure.
- **Training and Expertise:** Healthcare professionals should undergo comprehensive training and maintain expertise in using the Tiche catheter to enhance procedural safety.

In conclusion, while the Tiche PTA catheter presents a valuable tool in the realm of vascular interventions, understanding and mitigating potential adverse events is paramount. This clinical overview aims to provide a comprehensive understanding of the associated complications, emphasizing the importance of vigilant risk management and adherence to safety protocols during its application.

Benefit-Risk Analysis of the Tiche PTA Catheter: Favorable Risk-Benefit Profile

The Benefit-Risk analysis of the Tiche Percutaneous Transluminal Angioplasty (PTA) catheter underscores its significant clinical advantages while acknowledging potential associated risks. The meticulous examination of benefits and risks allows for a comprehensive evaluation of the device's overall safety and efficacy.

Benefits:

1. **Effective Vascular Intervention:** The Tiche catheter demonstrates efficacy in the dilation of stenosis and post-stent deployment, effectively restoring and maintaining patency in various peripheral vasculatures.
2. **Versatile Application:** With indications covering a wide range of obstructive lesions, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries, as well as arteriovenous dialysis fistulae, the catheter serves as a versatile solution in peripheral vascular interventions.
3. **Symptomatic Peripheral Artery Disease Management:** The Tiche catheter provides tangible clinical benefits, inhibiting the progression of Peripheral Artery Disease, reducing the risk of cardiac and cerebrovascular events, and improving the overall quality of life for patients.

Risks:

1. **Puncture-Related Complications:** While localized bleeding, thromboembolic events, and infections are potential risks, these are generally manageable through procedural expertise and adherence to safety protocols.
2. **Dilatation-Related Complications:** Complications such as reocclusion, dissection, and restenosis, although possible, are infrequent and can often be addressed with timely intervention.
3. **Angiography-Related Complications:** Allergic reactions, arrhythmias, and other associated risks are rare, and their occurrence can be minimized through pre-procedural assessments and vigilant monitoring.

Benefit-Risk Balance:

In the evaluation of the Tiche PTA catheter, the benefits significantly outweigh the associated risks. The device's effectiveness in treating peripheral vascular conditions, coupled with its versatile applications, positions it as a valuable tool in clinical practice.

Key Considerations:

- **Clinical Impact:** The Tiche catheter's positive clinical impact on patients with Peripheral Artery Disease is well-established, contributing to symptom relief and improved quality of life.
- **Risk Mitigation:** With appropriate training, vigilant monitoring, and adherence to safety measures, potential risks associated with the catheter can be effectively mitigated.
- **Informed Decision-Making:** Informed consent processes should ensure that patients are well-aware of potential risks and benefits, allowing for shared decision-making between healthcare providers and patients.

In conclusion, the Benefit-Risk analysis indicates a favorable profile for the Tiche PTA catheter. Its clinical benefits, ranging from effective intervention to improved patient outcomes, position it as a valuable and safe tool in the domain of peripheral vascular interventions.

Comprehensive Clinical Outcomes of the Tiche PTA Catheter

In the expansive landscape of vascular interventions, the Tiche Percutaneous Transluminal Angioplasty (PTA) catheter emerges as a pivotal and versatile medical device, offering a robust combination of efficacy and safety. The clinical journey through the comprehensive examination of its benefits, associated risks, and the intricate balance between the two provides a holistic understanding of the Tiche catheter's overall clinical outcomes.

The device, designed for the dilation of stenosis and post-stent deployment in peripheral vasculatures, stands as a beacon of effectiveness in the management of Peripheral Artery Disease (PAD). Its broad applications across various arteries and arteriovenous dialysis fistulae underscore its versatility, catering to the intricate needs of patients facing diverse vascular challenges.

In the meticulous evaluation of associated risks, encompassing puncture-related, dilatation-related, and angiography-related 5 complications, it becomes evident that the Tiche catheter navigates these challenges with a commendable balance of caution and efficacy. The potential risks, though present, are manageable through established procedural protocols, continuous monitoring, and the expertise of healthcare professionals.

The Benefit-Risk analysis serves as a cornerstone, revealing that the benefits derived from the Tiche catheter's application significantly outweigh the potential associated risks. From its clinical impact in inhibiting the progression of PAD to the improvement in patient quality of life, the device establishes itself as a reliable and valuable tool in the hands of vascular interventionists.

Moreover, the positive clinical outcomes are further accentuated by the device's adaptability and its role in reducing the risk of cardiac and cerebrovascular events. The Tiche catheter not only addresses symptomatic PAD but also contributes to an overall reduction in morbidity associated with peripheral vascular conditions.

Informed decision-making, meticulous training, and a commitment to safety protocols become pivotal components in optimizing the clinical outcomes of the Tiche PTA catheter. As this device continues to carve its space in the realm of vascular interventions, its comprehensive clinical profile positions it as a beacon of hope and progress, contributing meaningfully to the well-being of patients and the advancement of clinical practice.

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].

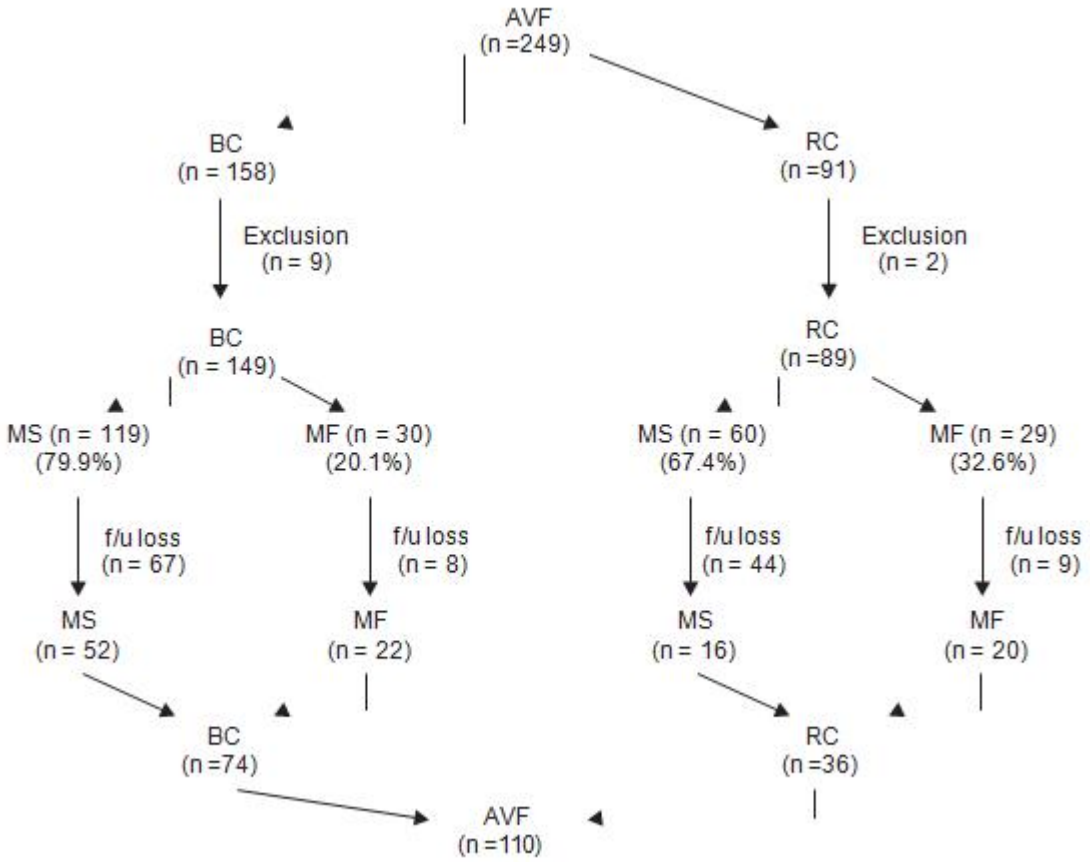

Fig. 1. Arteriovenous fistula Created in our hospital over 3 years. AVF, arteriovenous fistula; BC, brachiocephalic; RC, radio- cephalic; MS, maturation success; MF, maturation failure;f/u, follow-up.

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 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.

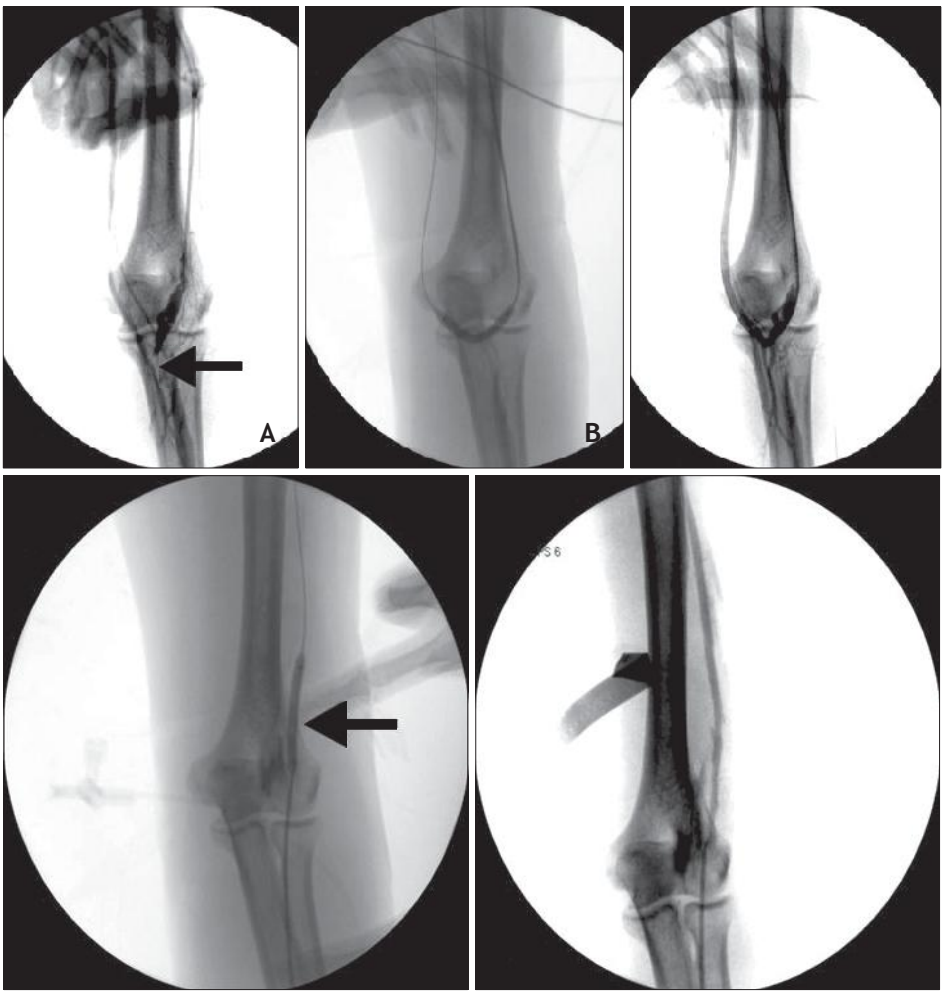

Fig. 2. Balloon angioplasty (BA) for balloon assisted maturation of arteriovenous fistula (AVF) maturation failure. (A)Jux- taanastomotic stenosis (JAS) of AVF. Arrow indicates JAS lesion.
(B) BA for JAS lesion. (C)Post- ballooning fistulography shows improvement of JAS lesion.(D)BA forcephalic veinstenosis (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 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 (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) MF (n=22)	RC AVF (n=36) MF (n=20)	Total (n=110) 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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