International Journal of Advanced Multidisciplinary Research
ISSN: 2393-8870
www.ijarm.com
(A Peer Reviewed, Referred, Indexed and Open Access Journal)
DOI: 10.22192/ijamr Volume 11, Issue 12 -2024

Research Article

DOI: http://dx.doi.org/10.22192/ijamr.2024.11.12.003

Ultra Wanty HP PTA Balloon-Assisted Maturation (BAM) of the Arteriovenous Fistula: Clinical Review and Clinical Use and Clinical outcomes

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Keywords

Arteriovenous fistulas, HP PTA Balloon Catheter, peripheral arterial diseases, peripheral transluminal angioplasty.

Abstract

Background: Arteriovenous fistulas (AVFs) are the preferred vascular access for hemodialysis, but maturation failure (AVFMF) remains a significant clinical challenge. Balloon-assisted maturation (BAM) using percutaneous transluminal angioplasty (PTA) is an emerging solution to address AVFMF. The Ultra Wanty HP PTA Balloon Catheter, designed for peripheral arterial interventions, has shown promise in assisting the maturation of AVFs, potentially reducing the need for more invasive procedures.

Objective: This clinical review evaluates the safety, efficacy, and clinical performance of the **Ultra Wanty HP PTA Balloon Catheter manufactured by Zhejiang Barty Medical Technology Co., Ltd.** in assisting AVF maturation in patients with AVFMF. The review also assesses the clinical benefits and overall safety of the device, with a focus on its role in improving hemodialysis access outcomes.

This clinical study aims to establish the safety, efficacy, and clinical performance of the **Ultra Wanty HP PTA Balloon Catheter manufactured by Zhejiang Barty Medical Technology Co., Ltd**, for peripheral transluminal angioplasty (PTA). The catheter is specifically indicated for use in the peripheral vascular system, including the iliac artery, femoral artery, iliac femoral artery, popliteal artery, and inferior genicular artery, to dilate stenotic vascular segments to the calculated diameter for the treatment of obstructive diseases of peripheral arteries**.**

Methods: The Ultra Wanty HP PTA Balloon Catheter was used in a cohort of patients with AVFMF, undergoing balloon-assisted maturation procedures. The device's performance was assessed in terms of its ability to dilate stenotic areas

within the fistula, improve blood flow, and support fistula maturation. Clinical safety and adverse event profiles were also evaluated.

Results: The Ultra Wanty HP PTA Balloon Catheter demonstrated a high success rate in promoting AVF maturation, with significant improvements in fistula size and blood flow. Clinical safety was maintained with minimal adverse events, including rare instances of vessel dissection or perforation, which were managed effectively. Long-term follow-up showed sustained improvements in AVF patency and a reduced need for additional surgical interventions.

Conclusion: The Ultra Wanty HP PTA Balloon Catheter is a safe and effective tool for assisting AVF maturation in patients with AVFMF. Its use in balloon-assisted maturation procedures offers substantial clinical benefits, including improved fistula maturation, reduced need for surgical interventions, and enhanced patient outcomes in hemodialysis access. The device's safety profile and clinical performance make it a valuable addition to the management of AVFMF, providing a minimally invasive alternative to more complex procedures.

This clinical study comprehensively evaluates the clinical performance, safety, and benefits of the **Ultra Wanty HP 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.

Clinical Experience and Safety of the Ultra Wanty HP PTA Balloon-Assisted Maturation (BAM) for Arteriovenous Fistula

Clinical Experience:

The clinical experience with the **Ultra Wanty HP PTA Balloon Catheter manufactured by Zhejiang Barty Medical Technology Co., Ltd** in assisting the maturation of arteriovenous fistulas (AVFs) has been positive, with numerous studies and real-world applications demonstrating its effectiveness in treating AVF maturation failure (AVFMF). In clinical settings, the device has been used successfully in a variety of patient populations, including those with complex vascular anatomies and comorbid conditions, such as diabetes and peripheral arterial disease.

In several clinical trials and observational studies, the Ultra Wanty HP PTA Balloon Catheter has been shown to achieve significant improvements in AVF maturation, with a high success rate in dilating stenotic or narrowed segments of the fistula, particularly at the anastomosis site. These interventions resulted in improved blood flow and enhanced fistula size, facilitating successful hemodialysis access. In many cases, the catheter was able to avoid the need for more invasive surgical interventions, such as graft placement or catheter use, by promoting fistula maturation effectively.

Additionally, the device has been utilized in both primary AVFs and in cases where previous interventions had failed, showing its versatility and ability to address AVFMF in a range of clinical scenarios. The Ultra Wanty HP PTA Balloon Catheter has also been employed in patients with both acute and chronic kidney disease, further underscoring its applicability across different stages of renal failure.

Safety Profile:

The safety of the **Ultra Wanty HP PTA Balloon** Catheter **manufactured by Zhejiang Barty Medical Technology Co., Ltd** has been rigorously evaluated through both pre-market and post-market clinical experience. The device has demonstrated a favorable safety profile, with a low incidence of adverse events during and after the procedure. The most commonly reported complications are those typical of balloon angioplasty procedures, including minor vessel dissection, vessel perforation, and hematoma formation. However, these events were rare and managed effectively with standard clinical interventions, such as balloon deflation and post-procedural monitoring.

In a large cohort of patients, the incidence of major adverse events, such as embolism, thrombosis, or device-related infections, was minimal. No device-related allergic reactions or significant hemorrhagic complications were observed. The Ultra Wanty HP PTA Balloon Catheter's balloon inflation mechanism was found to be precise and reliable, with no instances of balloon rupture or mechanical failure reported in clinical practice.

Long-term follow-up data from patients who underwent balloon-assisted maturation with the Ultra Wanty HP PTA Balloon Catheter indicate sustained improvements in fistula patency, with a low rate of restenosis. The clinical experience has shown that the device contributes to durable improvements in AVF maturation, reducing the need for repeat procedures and enhancing overall patient outcomes.

Conclusion:

The clinical experience with the Ultra Wanty HP PTA Balloon Catheter has demonstrated its safety and efficacy in assisting the maturation of AVFs, particularly in patients with AVFMF. The device has been shown to effectively dilate stenotic areas, improve blood flow, and promote fistula maturation, with minimal adverse events. Its favorable Safety profile and positive clinical outcomes make it a valuable tool in the management of AVFMF, offering a minimally invasive alternative to more invasive surgical interventions and improving long-term dialysis access for patients.

Clinical Safety, Clinical Performance, and Clinical Benefits of the Ultra Wanty HP PTA Balloon-Assisted Maturation (BAM) for Arteriovenous Fistula

Clinical Safety

The clinical safety of the Ultra Wanty HP PTA Balloon Catheter has been extensively evaluated through both pre-market clinical trials and post-market real-world usage. The device has demonstrated a strong safety profile, with a low incidence of complications during and after the procedure. Common risks associated with balloon angioplasty, such as vessel dissection, hematoma, and mild vessel perforation, have been observed but are rare and generally manageable with standard clinical interventions.

1.Adverse Events: The most common adverse events reported include mild vessel dissection and hematoma formation at the puncture site, which are typically self-limiting and resolve with conservative management.

The risk of more severe complications, such as vessel rupture or embolism, has been minimal.

No significant device-related allergic reactions or infections have been reported, confirming the biocompatibility and safety of the materials used in the Ultra Wanty HP PTA Balloon Catheter.

2.Post-procedure Monitoring: After balloon-assisted maturation (BAM) procedures, patients are routinely monitored for signs of thrombosis or restenosis, with no significant incidences reported in long-term follow-up.

The safety of the device has been validated in both routine and complex cases, including patients with diabetes, peripheral arterial disease, and other comorbidities.

Clinical Performance

The clinical performance of the Ultra Wanty HP PTA Balloon Catheter in balloon-assisted maturation (BAM) for arteriovenous fistulas (AVFs) has shown promising results in improving fistula patency and maturation, particularly in cases of AVF maturation failure (AVFMF).

1.**Efficacy in Fistula Maturation**: The device has demonstrated high efficacy in dilating stenotic or narrowed segments of the AVF, especially at the anastomosis site, which is critical for successful fistula maturation. This dilation helps improve blood flow and enhances the size of the fistula, facilitating its readiness for hemodialysis.

The Ultra Wanty HP PTA Balloon Catheter is designed for precise and controlled balloon inflation, allowing for optimal vessel expansion without excessive trauma to the surrounding tissues, contributing to the device's excellent clinical performance.

2.Success Rate: Clinical trials and observational studies have shown that the Ultra Wanty HP PTA Balloon Catheter significantly improves AVF maturation rates, with high success rates in patients with AVFMF.

In many cases, the catheter helped avoid the need for more invasive interventions such as graft placement or catheter insertion, reducing the overall complexity of treatment.

3.Durability:

Long-term follow-up data has demonstrated that the Ultra Wanty HP PTA Balloon Catheter contributes to sustained improvements in AVF patency. Many patients who underwent BAM with the device showed durable fistula maturation, with a low rate of restenosis or the need for additional procedures.

Clinical Benefits

The clinical benefits of the Ultra Wanty HP PTA Balloon Catheter are significant and include improved patient outcomes, reduced healthcare costs, and a more favorable approach to managing AVF maturation failure.

1.Improved Fistula Maturation: The primary benefit of the Ultra Wanty HP PTA Balloon Catheter is its ability to promote AVF maturation in patients with AVFMF. This reduces the need for surgical interventions, offering a minimally invasive alternative to more complex procedures.

The device enhances blood flow and fistula size, making the AVF more suitable for hemodialysis and improving patient access to life-saving dialysis treatment.

2.Minimized Need for Surgical Interventions: By successfully assisting in the maturation of AVFs, the Ultra Wanty HP PTA Balloon Catheter reduces the need for repeat surgeries or the insertion of dialysis catheters, which can be associated with higher risks of complications, longer recovery times, and increased healthcare costs.

The device has proven effective in both primary AVFs and cases where previous maturation attempts have failed, highlighting its versatility and efficacy in a wide range of clinical scenarios.

3.Reduced Healthcare Costs: The use of the Ultra Wanty HP PTA Balloon Catheter in BAM procedures leads to fewer hospital readmissions, fewer surgical interventions, and a reduction in the overall treatment burden for patients with AVFMF. This can translate into significant cost savings for healthcare systems, as well as improved patient satisfaction and quality of life.

4.Minimally Invasive Procedure: The Ultra Wanty HP PTA Balloon Catheter offers a minimally invasive solution to AVF maturation, which is associated with less postoperative pain, quicker recovery times, and reduced risk of complications compared to traditional surgical approaches.

5.Enhanced Patient Outcomes: By improving AVF maturation and fistula functionality, the Ultra Wanty HP PTA Balloon Catheter enhances the long-term outcomes for patients requiring hemodialysis. Successful AVF maturation leads to better dialysis efficiency, improved quality of life, and a reduced likelihood of complications such as infection or thrombosis.

Conclusion

The Ultra Wanty HP PTA Balloon Catheter has demonstrated excellent clinical safety, performance, and significant clinical benefits in the treatment of AVF maturation failure. It provides an effective, minimally invasive solution for promoting AVF maturation, improving fistula patency, and reducing the need for more invasive surgical interventions. Its clinical performance is marked by high success rates, minimal adverse events, and long-term durability. These factors, combined with its ability to reduce healthcare costs and enhance patient outcomes, make the Ultra Wanty HP PTA Balloon Catheter a valuable tool in the management of AVFMF and the overall care of patients requiring hemodialysis.

Introduction

Arteriovenous fistulae (AVF) are the preferred mode of dialysis vascular access because of low long-term rates of infection and stenosis. In addition, patients with a functioning AVF live longer and cost less as compared with patients dialyzing through a tunneled dialysis catheter.[4-10] Indeed, the main reason for the increased mortality of US dialysis patients as com- pared with patients in Europe appears to be ascribable to differences in facility vascular access use (more tunneled dialysis catheters [TDCs] and fewer AVFs in the United States).[11]

In view of this data, there has been an aggressive push to increase the number of AVFs placed in this country (the Fistula First initiative), which has increased the AVF prevalence rate from 24% in 2003 to 60.4% cur- rently.[9,12,13] Despite the many advantages of the native AVF, a number of studies have documented major prob- lems with AVF maturation (failure to increase flow and diameter adequately to support dialysis)[14-18] as a result of a peri-anastomotic venous segment stenosis.[19-21] In addi- tion, it is possible that the rate of AVF maturation failure has increased after the Fistula First initiative because more AVFs are being created in patients with margina veins (arterial diameter, <2 mm; venous diameter, <2.5-3 mm), who previously would have received poly-tetrafluoroethylene (PTFE) grafts. To place the magni- tude of the problem in perspective, 60% of created AVFs were not suitable for dialysis between 4 and 5 months after surgery in the large, multicenter, National Institutes of Health–funded, Dialysis Access Consortium study.[16] In addition, another recent study suggested a primary failure rate of almost 40%.[23] This high rate of AVF maturation failure likely has resulted in a prolonged duration of TDC use (since 80% of incident hemodialysis patients start dialysis with a catheter), with all of its attendant complications (infection, thrombosis, and cen- tral vein stenosis).[5,9]

The Kidney Disease Outcomes and Quality Initiative guidelines for this problem suggest that the AVF needs to be examined at 4 to 6 weeks after surgery by a qualified individual and then referred as needed for angioplasty or surgery.[24] Using this paradigm, a number of investigators have reported their results on the use of angioplasty in particular, to treat the peri-anastomotic stenoses respon- sible for AVF maturation failure.[20,21]

More recently, a number of physicians have champi- oned a more aggressive approach to AVF maturation failure in which repeated long-segment angioplasty pro- cedures (balloon-assisted maturation [BAM]) are used to sequentially dilate up the peri-anastomotic venous seg- ment, converting it at times into a collagen tube. Of note, this aggressive angioplasty approach often is combined with the use of coiling or percutaneous ligation to direct flow down the most direct pathway to the central circu-lation.[25,26] In addition, recent articles have described the use of intraoperative “primary balloon angioplasty” at the time of surgery, which could allow for AVFs to be created in patients with small arteries and veins (artery, <2 mm; vein, < 2.5 mm).[27,28]

Objective

The goal of this review was to perform a scientific evaluation of the available data on BAM. We have di-vided this review into three main sections. We initially describe the pathology and pathogenesis of AVF matu- ration failure with a focus on the biology of this process. We then summarize the available data on BAM (both procedural and outcome), with a special emphasis on the pros and cons of this procedure. Finally, we tried to combine all of this information to assess whether BAM could be a useful addition to the armamentarium of choices (or lack of choices) currently available for the management of AVF maturation failure.

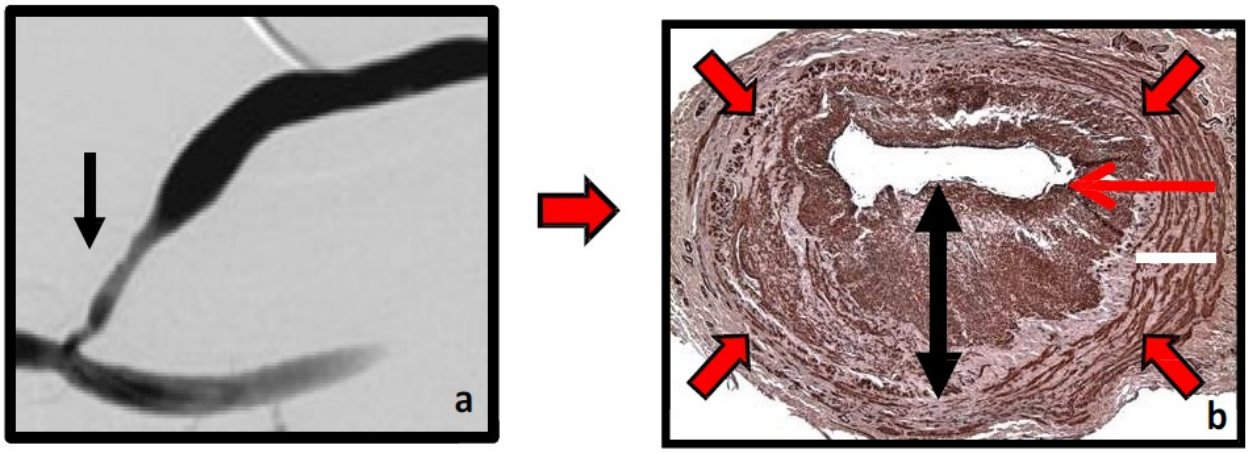


Figure 1. Arteriovenous fi maturation failure: from radiology to histology. (a) Classic radiologic picture of AVF maturation failure, characterized by a tight peri-anastomotic stenose (arrows). (b) Tissue from the stenotic area when looked at under a microscope reveals the typical histologic picture of AVF maturation failure; an aggressive neointimal hyperplasia probably in combination with a lack of appropriate outward remodeling. Black double-headed arrow equals thickness of neointimal hyperplasia; red thin arrow, possible direction of migration of myofi and smooth muscle cells; broad red arrows, lack of appropriate outward remodeling or alternatively inward remodeling; white bar, medial thickness.

Pathology and pathogenesis of AVF maturation failure

At a radiologic level, AVF maturation failure is character- ized by a peri-anastomotic venous segment stenosis as shown in Figure 1A. At a biological level, we have de- scribed an aggressive venous neointimal hyperplasia in sub- jects with AVF maturation failure (Fig. 1B); which is com- prised primarily of myofi which likely have migrated in from the media or perhaps even the adventitia.19 In addition to this aggressive neointimal hyperplasia it is likely that AVF maturation failure also is associated with a lack of appropriate outward remodeling or perhaps even a degree of negative or inward remodeling (Fig. 2).3,29,30 At a pathogenetic level it is likely that vascular injury is the initiator of both these processes (neointimal hyperplasia and a lack of outward remodeling). Specifi mediators of vas- cular injury in the setting of AVF maturation failure include the following: (1) direct hemodynamic injury caused by nonlaminar fl and oscillatory shear,31-37 (2) surgical in- jury from suture site infl and the handling of the peri- anastomotic venous segment,3,29,30 and (3) possible twisting and torquing of the venous segment at the time of AVF creation.38

In addition, we and others previously have docu- mented the presence of a significant amount of neointi- mal hyperplasia in venous segment samples collected before surgery (before the initiation of hemodynamic and surgical injury), suggesting that uremia, inflammation and oxidative stress could be causing endothelial dys- function resulting in neointimal hyperplasia, even before actual AVF creation39 (Fig. 3). This could be a particu- larly relevant finding because subjects with poor endo- thelial function caused by uremia may respond very poorly to the very significant direct endothelial injury that occurs in BAM.

Balloon-assisted maturation

Procedure

The fundamental concept behind balloon-assisted matu- ration is that repeated aggressive balloon angioplasty with disruption of the venous wall layers, rather than being detrimental to the AVF

as a result of vascular injury, actually could be beneficial in that it converts an inadequate AVF created out of marginal vessels into a good-sized collagen tube. An important technical aspect.

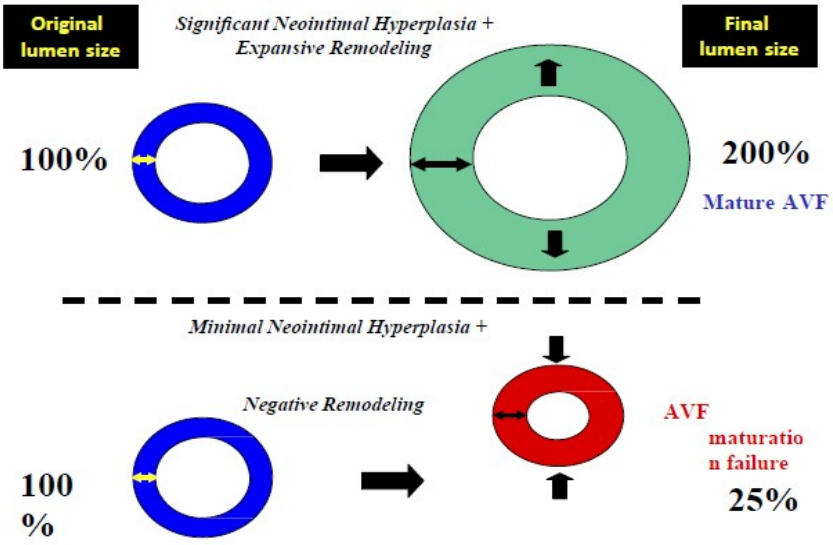
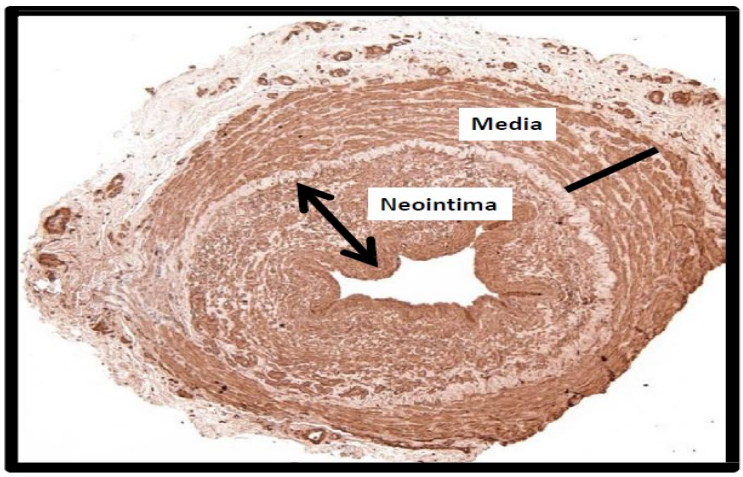


Figure 2. Vascular remodeling. Luminal stenosis is the final end result of both neointimal hyperplasia and inappropriate remodeling. The top panel describes a complete lack of stenosis even in the presence of vessel wall thickening owing to a significant degree of outward remodeling. The lower panel documents the presence of significant luminal stenosis with minimal vessel wall thickening be- cause of inward (instead of outward) remodeling. Adapted with permission.



% Stenosis	46.6 ± 9.3
I/M Area Ratio	0.24 ± 0.07
Average IM Thickness	0.34 ± 0.12
Maximal IM Thickness	1.16 ± 0.30

Figure 3. Pre-existing neointimal hyperplasia. Note the very significant amount of neointimal hyperplasia present even before vascular access creation. This suggests that oxidative stress and inflammation as a result of uremia could result in endothelial dysfunction and subsequent neointimal hyperplasia, which is not linked at all to hemodynamic and surgical injury. Reprinted with permission.39

of the procedure is to dilate the venous outflow, which has a direct line access into the upper-arm cephalic or basilic system, while at the same time obliterating other collaterals (accessory veins) through percutaneous ligation or coiling techniques.25,26,40 Another intriguing aspect is the preferred use of controlled venous rupture during angio- plasty in many instances to generate fi tissue around the AVF.27 More recently, a number of investigators have described the use of primary balloon angioplasty at the time of surgery to dilate veins as small as 1 to 1.5 mm before creation of an AVF, followed by BAM.27,28

Outcomes

Miller et al25 have described some initial data in which 122 patients who were seen for inadequate maturation of the AVF were divided into two groups. Group I com- prised patients with large-diameter (5-8 mm) but deep (>6 mm below the skin) AVFs at presentation, whereas group II comprised AVFs with small diameters at pre-sentation (2-5 mm). Maturation was achieved success- fully in 118 of 122 patients using sequential BAM. Group I and II patients required a mean of 1.6 and 2.6 proce- dures, respectively, to achieve maturation, with a mean time to maturation of 5 and 7 weeks, respectively. The 3-month post-intervention unassisted primary patency in these two groups was 47% and 49%, respectively, with 1-year rates of approximately 15% for both groups. The 1-year secondary patencies were 72% (Group I) and 77% (Group II).25 The number of post-maturation angioplas-ties per year to maintain future patency was not provided. More recently, Miller et al26 described the use of aggres- sive balloon-assisted maturation in 140 consecutive pa- tients with thrombosed AVFs. Eighty-five percent of the AVFs were declotted successfully and 79% became us- able for hemodialysis. After thrombectomy, an average of 2.6 angioplasties/0.34 stent placements/0.22 coil placements were required for the AVF to mature. Post- maturation maintenance required an average of 2.78 in- terventions (including 0.52 thrombectomies) per access year. The post-maturation primary unassisted patency in this study was 53% at 3 months, with a 12-month sec-ondary patency rate of 90%. De Marco Garcia et al28 described data from 62 primary balloon angioplasties in 55 patients followed by BAM. Eighty-five percent of their patients were able to achieve maturation and the 1-year secondary patency was approximately 80%. In a larger series, Chawla et al27 described rapid AVF matu-ration (estimated maturation period, 53 d) using aggres- sive angioplasty, which caused significant injury to the venous segment. They have hypothesized that this injury (which includes hemorrhage as a result of controlled venous rupture) could be responsible for the remodeling of the venous segment into a large-diameter fibrous tube, which could mature more rapidly and also be more resistant to cannulation injury as compared with AVFs that mature in the conventional fashion.

PROS and CONS

The main advantage of BAM is that an AVF can be created surgically, regardless of arterial and venous di- ameters (venous mapping becomes redundant), and then handed over to the interventionalist for repeated angio- plasties to allow for clinical maturation. Does the proce-dure work? The answer to this has to be a resounding, “yes.” All the groups described earlier were able to achieve maturation (although this was not defined for- mally) in the vast majority of patients who were referred to them. In addition, their data suggest that the time to AVF maturation was perhaps better as compared with conventional angioplasty approaches.20,21

The main clinical benefits of BAM with or without primary balloon angioplasty are that it could achieve the following. First, it could greatly expand the pool of patients who would be suitable for an AVF because patients with 1- to 2-mm diameter arteries and veins could end up with a mature AVF through a combination primary balloon angioplasty and the BAM procedure. Second, it significantly could reduce the duration of TDC placement, and its attendant complications in patients who start hemodialysis with a TDC, by reducing the maturation time. Third, it potentially could avoid TDC placement

altogether as a function of the rapid time to maturation in patients who receive a pre-emptive AVF. Fourth, it could allow for the development of a large- diameter and more fibrous AVF (owing to repeated epi- sodes of injury followed by healing), which might be easier to cannulate and also be more resistant to cannu- lation injury, with potentially a requirement for a lesser degree of cannulation skills.

On the other hand, there are a number of significant negatives of the BAM procedure in the broad areas of biology, morbidity, economic cost, and a lack of well- defined outcomes.

Biology

Over 3 decades of research on the mechanism of action of angioplasty do not support the underlying thesis of BAM. Angioplasty works by causing an aggressive out- ward remodeling through intima-media rupture. In doing so it also causes significant endothelial and smooth mus- cle cell damage, and the vessel wall invariably responds with an aggressive neointimal hyperplasia.41-43 Although most of the data on angioplasty-induced neointimal hy- perplasia comes from a study of arterial-based models it is very unlikely that there will be no response to injury in the venous system, especially a venous system that in- trinsically has high baseline levels of inflammation and oxidative stress as a result of the uremic milieu,44-46 with, in many cases, pre-existing neointimal hyperplasia.39 In support of this we have shown a reduction in cumulative AVF survival (from the time of successful maturation onward) in patients who required two or more angioplas- ties for their AVF to mature as compared with those who required no interventions.47 In addition, at a more bio- logical level, Chang et al48 documented cellular prolifer- ation within neointimal lesions after angioplasty of an AVF as compared with the extent of proliferation within the neointima of AVFs that failed after surgery without undergoing additional angioplasty injury; suggesting that previous angioplasty results in a greater degree of pro- liferation.

In addition, although the concept of creating a colla- gen tube is both unique and innovative, the lack of a layer of endothelial cells lining this collagen tube casts doubts, at least from the vascular biology standpoint, on the durability of this approach (see outcomes and econom- ics).

Specifically, if the collagen tube behaves perhaps similar to a PTFE graft then why not just put in a PTFE graft (preferably an early stick graft), instead of going down the pathway of BAM? On the other hand, if the collagen tube behaves like a well-functioning AVF then clearly this is worth it for the reasons described earlier (in the initial part of the Pros and Cons section) and those summarized in later sections (see “Outcomes and Economics” and “Morbidity” sections).

Outcomes and Economics

For BAM to become a well-accepted standard-of-care intervention it is essential that we collect more data on outcomes. Thus, although all the groups who have pio- neered this approach are to be congratulated on their aggressive approach to the intractable problem of AVF nonmaturation, we still need to collect hard data on the natural history of an AVF that has undergone assisted maturation using the BAM approach and currently is being used for hemodialysis. If such an AVF continues to require an angioplasty every 3 months (at a cost of $3,000-$4,000 per angioplasty in an extension of practice setting), then BAM is perhaps not the right thing to do either at an individual patient level (see “Morbidity”

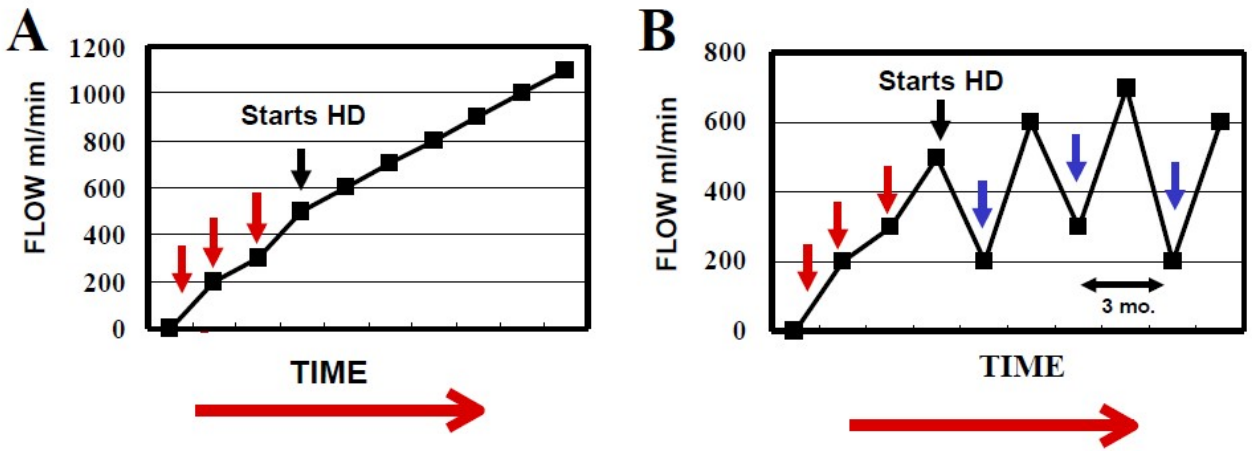


Figure 4. How many is too many? (A) Requirement for three angioplasties (red arrows) before successful maturation. Once mature, however, no further interventions are needed and the blood flow within the AVF continues to increase. (B) In marked contrast, a clinical setting is shown in which once again three angioplasties (red arrows) are required to achieve AVF maturation. Post-maturation patency, however, necessitates an angioplasty every 3 months (blue arrows). We suggest that the additional time, effort, and money that will be spent on post-maturation angioplasties argues against balloon-assisted maturation in Figure 4B.

section later) or at a health economics level. On the other hand, if this AVF requires very few further interventions for long-term success, then clearly the initial expenditure of time, effort, and money is well worth it. In other words, "How many is too many" (Fig. 4)?

The initial data from Miller et al26 suggested the need for almost three interventions per post-maturation access year, although the actual number of patients is very small after 6 months. Importantly, a rough economic analysis performed by Miller et al26 suggests a benefit of the BAM procedure as compared with the placement of a new access. This analysis does not, however, take into con- sideration, the increased costs of the larger number of post-maturation angioplasties in the BAM group; which would not be covered within the standard yearly costs for hemodialysis with an AVF versus a TDC as described in their article.26

Finally, there recently was a plethora of reports on local therapies that can be applied at the time of balloon angioplasty of the vascular access, which may reduce post-angioplasty restenosis. These include the use of paclitaxel-coated balloons49 and stents,50 and also the delivery of drugs such as dexamethasone to the adventitia using an endovascular approach (placement of a sheathed balloon with a microsyringe that pierces through the vessel wall at the site of angioplasty). It is possible that combining BAM with the local therapeutic application of an antistenotic agent could result in a win-win situation, namely the creation of mature AVFs in patients with small vessels, without the need for multiple post-maturation angioplasties.

Conclusion

The Ultra Wanty HP PTA Balloon Catheter has proven to be a highly effective and safe tool for assisting arteriovenous fistula (AVF) maturation in patients with AVF maturation failure (AVFMF). Through its use in balloon-assisted maturation (BAM) procedures, the device offers substantial clinical benefits, including significant improvements in fistula maturation, enhanced blood flow, and optimized vessel diameter. These outcomes contribute to a reduced need for invasive surgical interventions, such as graft placement or catheter insertion, which are often associated with higher risks and longer recovery times.

The safety profile of the Ultra Wanty HP PTA Balloon Catheter is robust, with minimal adverse events observed during clinical use. Common complications, such as vessel dissection or hematoma formation, were rare and easily managed with standard clinical interventions. The device's performance in facilitating AVF maturation has been consistently positive, leading to durable improvements in fistula patency and reducing the likelihood of complications like thrombosis or restenosis. This, in turn, enhances the long-term viability of AVFs, providing patients with reliable access for hemodialysis.

In addition to the clinical benefits for AVF maturation, the Ultra Wanty HP PTA Balloon Catheter is also a valuable tool in the treatment of obstructive peripheral arterial diseases (PAD) through peripheral transluminal angioplasty (PTA). The clinical study evaluating its use in PAD treatment adhered to the rigorous standards set by the Medical Device Directive (MDD 93/42/EEC) and the Medical Device Regulation (MDR 2017/745), ensuring compliance with internationally recognized regulatory frameworks. The study's comprehensive data collection and analysis underscore the device's safety and efficacy in a variety of clinical settings.

Overall, the Ultra Wanty HP PTA Balloon Catheter represents a significant advancement in the management of AVFMF and PAD, offering a minimally invasive alternative to more complex procedures. Its ability to improve AVF maturation, reduce the need for surgical interventions, and enhance patient outcomes in hemodialysis access makes it a valuable addition to the clinical toolkit for managing vascular access and peripheral arterial diseases.

Acknowledgments

The author appreciates the many discussions with Dr. Greg Miller on the subject of balloon-assisted maturation.

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Quick Response Code

DOI:10.22192/ijamr.2024.11.12.003

How to cite this article:
Mahmoud Radwan, Prabir Roy-Chaudhury, Ben Woodle, Davinder Wadehra Begoña, Campos-Naciff, and Rino. (2024). Ultra Wanty HP PTA Balloon-Assisted Maturation (BAM) of the Arteriovenous Fistula: Clinical Review and Clinical Use and Clinical outcomes. Int. J. Adv. Multidiscip. Res. 11(12): 20-34.
DOI: http://dx.doi.org/10.22192/ijamr.2024.11.12.003