Primary Balloon Angioplasty or Hydrostatic Dilatation for Arteriovenous Access: Which Technique has Better Outcomes in Poor Caliber Cephalic Veins?

Kamran Ali Khan, Varinder Singh Bedi, Ajay Yadav, Sandeep Agarwal, Ambarish Satwik, Manikanda Prabhu

Abstract

**Background:** The success of hemodialysis depends on a functioning vascular access. The most important factor limiting the arteriovenous fistula (AVF) growth and patency is the availability of a good caliber venous segment: Cephalic veins smaller than 2.5 mm have been reported to have increased failure rates. Unfortunately, in the Indian population, we frequently come across patients with a poor cephalic vein diameter ≤2 mm. The present study was done to evaluate if primary balloon angioplasty (PBA) of these small cephalic veins could improve the primary patency rates and maturation time of autogenous AVFs, and also to compare this technique with the standard hydrostatic dilatation technique.

**Materials and Methods:** Sixty patients requiring arteriovenous access surgery (but having small cephalic veins (≤2 mm) were randomized into two groups of thirty patients each. All patients underwent a thorough preoperative evaluation, after which they were subjected to AVF surgery. Thirty of these patients underwent standard hydrostatic dilatation (HD) whereas the remaining thirty were offered PBA of the vein before creating the fistula. These patients were followed up for 6 months and primary patency, reintervention rates, and maturation times were recorded.

**Results:** Immediate technical success was 100% in the PBA group, with 6-month primary patency of 93.3%, whereas HD group had 73.3% immediate success and a 6-month primary patency of 63.3%. In HD group, 36.7% patients underwent re-intervention over a follow-up of 6 months, as compared to only 6.7% in PBA group. The average maturation time for PBA group was 32.83 days, whereas in HD group, it was 52.53 days.

**Conclusions:** PBA of very small cephalic veins (≤2 mm) is a safe and feasible procedure. The technique is associated with excellent primary patency rates and decreased maturation time, significantly decreases the need for re-intervention, and is superior to the standard hydrostatic dilatation technique. It has the potential to maximize the number of patients with autogenous AVF by including those patients who have been rejected due to small cephalic veins.

**Key Words:** Arteriovenous fistula, hydrostatic dilatation, maturation time, primary balloon angioplasty, primary patency

Introduction

Chronic kidney disease (CKD) is increasingly being recognized as a global public health problem. The pattern of disease burden in the 21st century has significantly shifted toward chronic disease. India, with the highest incidence of diabetes mellitus and systemic hypertension in the world, is likely to face a catastrophic number of patients with CKD/end-stage renal disease (ESRD), with 25%-40% of its population at risk.

Hemodialysis and renal transplant are the treatment options for ESRD patients. Graham developed dialysis across semi-permeable membrane for the treatment of renal failure in 1854. More than 300,000 individuals in the United States rely on a vascular access to receive hemodialysis treatment. Vascular access continues to be a leading cause for hospitalization and morbidity in patients with CKD.

Of the different types of access available, the surgically created arteriovenous fistula (AVF) comes closest to fulfilling the criteria of an ideal access. Studies over several decades consistently demonstrated that native fistula access has the best 4–5-year patency rates and requires the fewest interventions compared with other access types. To achieve this, duplex study plays a key role in the assessment of the arterial and venous anatomy of the upper limb. Duplex ultrasound (DUS) is the preferred method for preoperative vascular mapping.

Vein diameter is an important concern while creating an arteriovenous (AV) access, and it has been proven beyond...
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The concept of multiple balloononing during the maturation of AVF can be appealing, patients are exposed to the risk of multiple angiograms, renal function deterioration, and embolism. Repeated balloononing may also cause intimal injury, which increases the risk of restenosis and thrombosis. Moreover, this technique is highly expensive and not comfortable for the patients.

The present study was an effort to evaluate if primary balloon angioplasty (PBA) of small cephalic veins (diameter of ≤2 mm) at the time of fistula creation, could improve the primary patency rates and maturation time of autogenous AVFs.

**Materials and Methods**

This was a prospective study conducted in the Department of Vascular and Endovascular Surgery, Sir Ganga Ram Hospital, New Delhi, India, on patients admitted with a diagnosis of ESRD requiring hemodialysis. The study was carried out from July 2013 to December 2014 with a sample size of thirty patients in each group.

Patients that were included in the study had ESRD requiring hemodialysis with normal radial artery or brachial artery DUS parameters (normal triphasic flow with the absence of turbulent flow) and had poor caliber cephalic veins at wrist or elbow (≤2 mm in diameter). Those patients with segmental cephalic vein occlusions, extensive brachial and radial artery disease, and ipsilateral venous outflow obstruction on the side of the planned AVF were excluded from the study.

A total of sixty patients were selected for the study. The patients were randomized according to a closed envelope system where an envelope was opened by the patient at the time of selection and he/she was allocated into either of two study groups according to the technique used to increase the vein caliber (hydrostatic vein dilatation or PBA).

**Preoperative workup**

Patient demographic data were recorded. Data regarding associated comorbid illnesses and previous history of fistula creation were elicited. The preoperative workup included a complete physical examination (including upper arm inspection with and without the tourniquet and Allen’s test to evaluate the quality of the collateral flow to the hand) and DUS. Parameters evaluated by DUS were patency, diameter, and blood flow pattern of the brachial and radial arteries and diameter, patency, and depth of the cephalic veins [Figures 1 and 2]. In particular, vein diameter was measured by DUS with a tourniquet, inner wall to inner wall, using B-mode technique. The nondominant upper limb was usually preferred.

All patients were made to sign a written informed consent before their surgical procedure. Medical therapy included acetylsalicylic acid given for 4 weeks after the procedure.

**Surgical technique**

The cephalic vein and the radial/brachial artery were dissected through a standard incision made above the wrist or elbow crease, depending on the vein chosen after duplex evaluation. All patients received systemic anticoagulation using 2500 IU of heparin 3 min before clamping the radial/brachial artery. No intravenous or local vasodilators were used. Patients were randomized into two groups.

**Hydrostatic dilatation**

After isolation of about 5 cm of cephalic vein at the wrist or elbow, with ligation of collateral veins, the vein was dilated by injection of high-pressure sterile saline solution through a syringe of 20 ml and 18- or 20-gauge plastic cannula [Figure 3]. The anastomosis was performed...
Follow-up visits with the surgeon were scheduled at 1 week, 4 weeks, 3 months, and 6 months after the creation of the AVF. At each follow-up, the patency of the AV access was evaluated clinically and by Doppler ultrasound. A tourniquet was not used during this examination. A high-resolution (7 MHz or higher) linear ultrasound probe was used. All complications were recorded. All patients with suboptimal fistula function or nonfunctional fistulae were evaluated, and intervention for salvage of the fistula was offered if considered feasible. Patients and the treating nephrologists were advised to report any complications as and when detected.

The diameter of the draining vein was measured in the caudal, mid, and cranial portions of the forearm, and similarly in the upper arm when a forearm AVF was evaluated. The entire draining vein was scanned, and the minimum diameter was measured even if it occurred at a location not routinely measured. This diameter was recorded to confirm patency of the fistula. Blood flow end-to-side with the radial/brachial artery, with 7-0 polypropylene running sutures [Figure 4].

**Postoperative follow-up**

All patients were followed up for a duration of 6 months after the formation of AVF. The follow-up was done during visits of the patient to the hospital for dialysis and by means of telephonic conversation. As a standard protocol, all patients received 75 mg of oral aspirin (acetylsalicylic acid) daily for 1 month following the operative procedure.
was also measured using the volume flow measurement function of the duplex instrument. A minimum venous diameter of 4 mm or greater and flow volume equaling or exceeding 500 ml/min was taken to confirm patency of the fistula at 4 weeks. Primary end points were primary patency at 6 months and re-intervention rates in both the groups. Secondary end points were maturation time and the rate of working AVFs at the end of 6 months.

Diminished or absent thrill and decreased flow rate (<250 ml/min) were considered an indication for early evaluation beyond the established protocol for surveillance. Fistula failure was defined as any event that required an intervention to maintain or reestablish patency of the fistula including stenosis, thrombosis, hemorrhage, or ischemia of the hand, leading to a new access. Maturation time (in days) was defined as the interval from AVF creation to first successful hemodialysis use. Working AVF was defined as an AVF functional as a hemodialysis access at a period of 6 months.

Statistical analysis
Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0 (IBM Corporation). Continuous variables were presented as mean and standard deviation or median if the data were unevenly distributed. Categorical variables were expressed as frequencies and percentages. The comparison of normally distributed continuous variables between the groups has been performed using Student’s t-test. Nominal categorical data between the groups have been compared using Chi-squared test or Fisher’s exact test as appropriate. Nonnormal distribution continuous variables have been compared using Mann–Whitney U-test. For all statistical tests, a $P < 0.05$ was taken to indicate a significant difference.

Results
A total number of patients enrolled in this study were sixty (who met the inclusion criteria), of which thirty underwent hydrostatic dilatation and the remaining thirty patients were offered PBA of their cephalic veins at the time of fistula creation. Out of the sixty patients, 38 underwent radiocephalic fistula surgery at the wrist, whereas 22 underwent brachiocephalic fistula surgery at the elbow. Nine patients belonged to CKD Stage IV. In CKD Stage V, there were 51 patients. Most of the patients underwent surgery in the nondominant limb, 43 on the left side and 17 on the right side.

The common etiologies of CKD in this study were systemic hypertension (62%), diabetes mellitus (32%), amyloidosis (1%), chronic glomerulonephritis (2%), obstructive nephropathy (2%), and allograft nephropathy (1%). The age range of patients in both the groups was comparable. Most of the patients operated were within the range of 51–60 years. The sex distribution of patients in both the groups was also comparable with no statistically significant difference. There were 23.3% females in the HD group with 76.7% males, whereas there were 30% females and 70% males in PBA group. Different comorbidities such as hypertension, diabetes, hyperlipidemia, tobacco use, heart disease, peripheral vascular disease, and chronic pulmonary disease were equally distributed in the two groups. Around 80% of these patients were already on dialysis at the time of fistula creation.

The mean arterial diameter of patients in HD group was 1.90 ± 0.22 mm, whereas in PBA group, it was 1.80 ± 0.25 mm. The average vein diameter in HD group was 1.77 ± 0.15 mm, whereas in PBA group, the average vein diameter was 1.80 ± 0.14 mm.

It was seen that following creation of fistula, immediate success with good palpable thrill was achieved in 100% patients in the PBA group, whereas in the HD group, only 73.3% cases achieved immediate success and there was a failure in 26.7% of cases [Table 1]. This result was statistically significant with $P = 0.005$. Causes of failure included early AVF thrombosis in eight patients (26.7%) belonging to the HD group. All these cases were taken up for immediate surgical revision, and thrombectomy of the AVF combined with balloon angioplasty of the cephalic vein was performed. Finally, a new anastomosis was made.

During the follow-up of 6 months, five patients underwent re-intervention for stenosis (three in the HD group and two in the PBA group). Anastomotic stenosis was found in three cases and in the remaining two cases, stenosis was located a little distance away from the anastomosis. All patients underwent diagnostic angiography of the AVF, followed by percutaneous transluminal angioplasty (PTA) of the stenotic lesion. The PTA was performed by proximal catheterization of the AVF with introduction of 4 Fr sheaths. The vessel was dilated using a 0.018-inch guidewire and a drug-coated balloon (DCB). The DCB insufflations were maintained for 180 s. PTA was successful in two patients. In the remaining three patients (HD group), success could not be achieved through PTA; therefore, a surgical approach was utilized. A new anastomosis at a more proximal level of the cephalic vein was performed. Overall, In HD group, 36.7% patients underwent re-intervention over a follow-up period of

| Table 1: Comparison of proportion of immediate success between hydrostatic dilatation and primary balloon angioplasty groups |
|---------------------------------------------------------------|
| Immediate success | Frequency (%) | $P$ |
|-------------------|---------------|-----|
| **Group HD** | | |
| Failure (F) | 8 (26.7) | 0 | 0.005 |
| Success (S) | 22 (73.3) | 30 (100) |
| **Total** | 30 (100) | 30 (100) |
| **Group PBA** | | |
| Failure (F) | 0 | | |
| Success (S) | 30 (100) | | |
| **Total** | 30 (100) | | |

HD: Hydrostatic dilatation, PBA: Primary balloon angioplasty
In HD group, primary patency of the fistula at 6 months was 63.3%, whereas in PBA group, primary patency at 6 months was 93.3% [Table 3]. This difference in value was statistically significant ($P = 0.010$).

In HD group, 90% patients had working fistulae with good palpable thrill at 6 months, whereas in PBA group, 100% patients had working fistulae with good palpable thrill at 6 months [Figure 7]. This value was not statistically significant ($P = 0.237$).

**Discussion**

An AVF is the procedure of choice for hemodialysis access. AVFs have a reduced infection rate and cost compared with grafts and indwelling catheters and also have increased overall patency and improved patient survival. Small diameter cephalic veins are often a limiting factor for the successful creation of AVF. This study evaluated the use of intraoperative PBA as a technique to upgrade small diameter cephalic veins during AVF creation. Our primary aim of this study was to compare hydrostatic dilatation of a small segment of cephalic vein versus PBA of a long segment of vein during fistula creation and its impact on primary patency, reintervention rates, and maturation time of the fistula over a period of 6 months.

In our study, the mean age of the patients in HD group was $55.10 \pm 6.49$ years (range 39–66 years), whereas in PBA group, the mean age was $53.77 \pm 6.72$ years (range 39–68 years) with maximum number ($n = 34$) of patients in the age group of 51–60 years. CKD has been reported in all age groups including pediatric population, young adults, and elderly individuals. There are differing reports from various studies. In another observational Indian study, there were a large number of patients belonging to the younger age group (between ages 20 and 40 years) indicating the high incidence of CKD in young Indian population. However, in our study, we were looking for a specific population of CKD patients who had a cephalic vein diameter ≤2 mm and our sample size was relatively small ($n = 60$ patients). Hence, we got a larger number of elderly patients rather than the young population with CKD.

There was a male preponderance in our study with 76.7% males in the HD group and 70% males in the PBA group. There were 23.3% and 30% females in the HD group and PBA group, respectively. There are contradictory reports available in the literature regarding male and female differences in AVF. Women usually have smaller arteries and veins, and therefore, may do worse compared with men. Moreover, this may be the reason for poorer maturation and survival rates of vascular access. Miller et al. reported

**Table 2: Comparison of re-intervention between hydrostatic dilatation and primary balloon angioplasty groups**

| Re-intervention | Group HD | Group PBA | $P$  |
|----------------|----------|-----------|------|
| No             | 19 (63.3)| 28 (93.3) | 0.010|
| Yes            | 11 (36.7)| 2 (6.7)   |      |
| Total          | 30 (100) | 30 (100)  |      |

HD: Hydrostatic dilatation, PBA: Primary balloon angioplasty

**Table 3: Comparison of primary patency rates between hydrostatic dilatation and primary balloon angioplasty groups**

| Primary patency (6 months) | Frequency (%) | $P$  |
|----------------------------|---------------|------|
| No                         | 11 (36.7)     | 0.010|
| Yes                        | 19 (63.3)     |      |
| Total                      | 30 (100)      |      |

HD: Hydrostatic dilatation, PBA: Primary balloon angioplasty

![Figure 6: Comparison of fistula maturation times between HD and primary balloon angioplasty groups](image)

![Figure 7: Comparison of working arteriovenous fistula at 6 months between HD and primary balloon angioplasty groups](image)
worse primary failure among women compared to men (68% vs. 50%), but Caplin et al. found no difference (28% vs. 23%) when preoperative ultrasound was used. Another study by the same author states that arterial and venous diameters were not significantly different between men and women and functioning fistulae were created in 72% of the female and 77% of the male patients.[14,15] In a meta-analysis of radiocephalic fistula, women had similar maturation and 1-year patency rates as men.[16] In our study also, there was no significant difference in patency rates and maturation time between the two sexes.

Different comorbidities such as hypertension, diabetes, hyperlipidemia, tobacco use, heart disease, peripheral vascular disease, and chronic pulmonary disease were equally distributed in the two groups. These values are consistent with several studies done on CKD patients in the past. It is a known fact that these patients have multiple comorbidities and are very high-risk candidates for any form of surgical intervention. This is all the more reason why we must try to salvage their AVFs because each intervention comes with a high incidence of morbidity and sometimes, mortality.

In our study, nine patients (15%) belonged to CKD Stage IV, whereas 51 (85%) belonged to CKD Stage V. At the time of fistula creation, 80% of patients were already on dialysis in the HD group, whereas in PBA group, 83.7% patients were on dialysis. In comparison to a study by Veroux et al.,[17] only 68% patients were on dialysis therapy at the time of fistula creation, whereas 32% had reported much before dialysis was initiated. This was consistent with the KDOQI guidelines which state that patients should have a functional permanent access at the initiation of dialysis therapy. A fistula should be placed at least 6 months before the anticipated start of hemodialysis. This timing allows for access evaluation and additional time for revision to ensure that a working fistula is available at initiation of dialysis therapy. This points out to the fact that in our country, strict adherence to guidelines is lacking and we need to implement several measures to motivate the CKD patients and also physicians in this regard.

In our study, the mean arterial diameter of patients in HD group was 1.90 ± 0.22 mm (range 1.60–2.2 mm) whereas in PBA group, it was 1.80 ± 0.25 mm (range 1.4–2.2 mm). As regards the average cephalic vein diameter, it was 1.77 ± 0.15 mm (range 1.5–2 mm) in patients belonging to HD group and 1.80 ± 0.14 mm (range 1.6–2 mm) in patients belonging to PBA group. According to several studies, AVF success definitely depends on the size of artery and vein. This is an important factor because there are technical difficulties in making the anastomosis when the vessel size is very small. This has been analyzed by various authors; however, the results are variable. In one series, it was reported that the artery and vein size were the predominant factors determining the success of radiocephalic AVF. Artery size <0.21 mm had a very high failure rate (80%) compared to a size of 0.23–0.25 mm (8% failure rate). The probable explanation for failure of AVF in small-sized artery is a small radius which would limit the flow through the fistula. The primary patency rates also depend on the size of the vein.

In our study, we included patients with radial/brachial arteries having normal DUS parameters (normal triphasic flow with the absence of turbulent flow). We did not exclude patients according to smaller diameter of the artery. Moreover, all our patients had vein sizes ≤2 mm and we have randomized them into two groups according to the technique used for dilating the vein at the time of fistula creation (hydrostatic dilatation vs. PBA).

It was found that following creation of fistula, immediate success with good palpable thrill was achieved in 100% patients in the PBA group, whereas in the HD group, only 73.3% cases achieved immediate success. This was due to early thrombosis of the AVF in eight patients belonging to the HD group. There is an Italian study conducted by Veroux et al.[17] where they had an even higher immediate failure rate in AVFs made from hydrostatic dilatation of small cephalic veins (33%). This shows that hydrostatic dilatation is not a very effective method in those AVFs that have small diameter cephalic veins (≤2 mm). There is a significantly high rate of immediate thrombosis and failure.

In HD group, 36.7% patients underwent re-intervention over a follow-up period of 6 months (26.7% underwent immediate revision of AVF for thrombosis whereas 10% underwent late intervention for stenosis), whereas in PBA group, only 6.7% patients underwent re-intervention for stenosis. It is clearly evident from these results that re-intervention rates are very low in the PBA group as compared to the HD group. De Marco Garcia et al.[18] had described an interesting technique of ballooning of a short segment of cephalic vein (from mid-forearm to the wrist, length from 4 cm to 12 cm) at the time of fistula creation, in a subgroup of patients with a cephalic vein diameter <3 mm. However, 53 of 62 patients needed repeated PBA under fluoroscopy at 2, 4, and 6 weeks after AVF creation: failure in AVF maturation was probably related to the high resistances of the distal nondilated small cephalic vein (from the mid-forearm to the elbow).

Although the concept of multiple ballooning during the maturation time can be appealing, patients are exposed to the risk of multiple angiograms, renal function deterioration, and embolism. Repeated ballooning may also cause intimal injury, which increases the risk of restenosis and thrombosis. Finally, this technique is highly expensive and not comfortable for the patients. In our study, we performed PBA of a longer segment of cephalic vein from the wrist to elbow (for radiocephalic AVF) and elbow to upper arm (for brachiocephalic AVF) to achieve a low
resistance venous outflow. This probably led to a very low rate of re-intervention in these patients.

The average fistula maturation time for patients in HD group was 52.53 ± 3.45 days (minimum 46 days and maximum 61 days) and primary patency of the fistula at 6 months was 63.3%, whereas in PBA group, the average fistula maturation time was 32.83 ± 3.16 days (minimum 29 days and maximum 40 days) and primary patency at 6 months was 93.3%. Moreover, a working AVF rate of 90% was found in patients belonging to HD group, as compared to a working AVF rate of 100% in PBA group at 6 months. This showed a favorable result for PBA group. In patients belonging to the HD group, the key factor affecting the primary patency and maturation time of AVF was the high resistance venous outflow because there were no reported technical defects at the level of the anastomosis. In a similar study conducted by Veroux et al.,[17] even poorer 6-month primary patency rates (57%) were reported for forearm AVFs made from hydrostatic dilatation of small cephalic veins, whereas they reported an excellent 6-month primary patency and working AVF rates of 95% and 100%, respectively, for radiocephalic AVFs, in which they had done PBA at the time of fistula creation.

Overall, this technique of PBA of cephalic veins with a preoperative diameter of ≤2 mm at the time of fistula creation has the great potential to maximize the number of patients with autogenous AV access for hemodialysis by including those patients who have been previously discarded due to small cephalic veins. However, there are certain shortcomings of this study which need to be highlighted. First of all, the sample size was very small. Second, a 6-month follow-up did not allow us to reach definitive conclusions because a longer follow-up is required to detect future stenosis/occlusions. Third, the selection criteria of this study were very stringent, and this prevented us from using this technique on a larger number of patients.

In conclusion, PBA of very small cephalic veins (≤2 mm) performed before the creation of AVF for hemodialysis is a safe and feasible procedure. The technique is associated with excellent primary patency rates and decreased maturation time, significantly decreases the need for re-intervention, and is superior to the standard hydrostatic dilatation technique.

Conclusions

After analyzing the various factors involved in the study, we would like to conclude that:

- PBA of small cephalic veins (≤2 mm) performed before the creation of AVF for hemodialysis is a safe and feasible procedure
- It markedly improves the immediate success rate of fistula surgery as compared to the standard technique of hydrostatic dilatation (HD)
- It significantly reduces the re-intervention rates over a period of 6 months as compared to hydrostatic dilatation technique. This reduces the total cost burden as well as the morbidity and mortality associated with repeated interventions
- The fistula maturation time is significantly reduced in the PBA group of patients as compared to HD group, thereby allowing earlier initiation of dialysis
- It is associated with a much higher primary patency rate at 6 months as compared to hydrostatic dilatation technique
- It has a higher rate of working AVF at 6 months in comparison to hydrostatic dilatation technique
- Overall, it is superior to the standard hydrostatic dilatation technique.

In short, this technique of PBA of cephalic veins with a preoperative diameter of ≤2 mm at the time of fistula creation has the great potential to maximize the number of patients with autogenous AV access for hemodialysis by including those patients who have been previously discarded due to small cephalic veins.

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Conflicts of interest
There are no conflicts of interest.

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