A prospective Randomized Study Comparing the use of Plain PTA Balloon Catheters for Primary Balloon Angioplasty (PBA) Versus Hydrostatic Dilatation to prepare the Cephalic Vein Prior to Creation of Radio-cephalic Arteriovenous for Dialysis

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ABSTRACT

Aim: *To compare the immediate technical success, maturation time, and the need for further balloon assisted maturation for radio-cephalic arteriovenous fistulas to render them ready for hemodialysis.* ***Patients & methods:*** *Fifty-seven (57) patients with ESRD in need for vascular access for whom a radio-cephalic arteriovenous fistula was of choice, with a cephalic vein ≤ 3 mm. They presented to us from the period of November 2014 till January 2017, were randomized into two groups. The cephalic vein was prepared in group. (A) using hydrostatic dilatation prior to creation of the fistula, while in group (B) the vein was prepared using a PTA balloon catheter for primary balloon angioplasty prior to the creation of the fistula.* ***Results:*** *The technical success rate was 96.5%, 100% in both groups respectively. The reintervention rate was 35.7%, 7.1% in both groups respectively. The mean maturation time was 43days , 32.1 days in both groups respectively.* ***Conclusion:*** *Using primary balloon dilatation during creation of a radiocephalic arteriovenous fistula leads to a decreased maturation time and less reintervention rate, but still these results are statistically insignificant may be due to small number of study sample.*
Key words: *Radiocephalic arteriovenous fistula, fistula maturation, primary balloon angioplasty (PBA).*

INTRODUCTION

Most of patients in Egypt with end stage renal disease (ESRD) are on hemodialysis because of the low rate of kidney transplantation due to legal, religious, and financial issues.

While in the United States, it is estimated that 65% of ESRD patients were on hemodialysis, 30% underwent transplantation, and 5% on peritoneal dialysis.[1]

That is why maintenance of the hemodialysis access is of utmost importance because most of hospital admissions or ESRD patients is due to access site complications. Therefore, creating a natural functioning arteriovenous fistula is a top priority in our practice.

Native arteriovenous fistulas are recommended but on the other hand these types of fistula fail to mature at higher rates than do arteriovenous grafts.[2-5]

For native arteriovenous fistula, the KDOQI guidelines identified a fully mature arteriovenous fistula suitable for cannulation by the rule of 6s, which include a 6 mm diameter vein, 6mm access depth from skin, with an access flow rate of 600ml/min.[6]

PATIENTS AND METHODS

This study was conducted over patients attending the vascular outpatient clinic or referred from the nephrology department at Ain Shams University hospitals. This was a prospective randomized study done upon 57 patients with ESRD (patients already on hemodialysis, or patients scheduled to have hemodialysis within 6 months) presenting for vascular access creation to have regular hemodialysis sessions from. The study sample presented to the outpatient clinic in the period from November 2014 till January 2017.

The inclusion criteria of these patients were:

1. Male Patients having ESRD aging 15 to 55 years old.
2. Patients were not known to have Diabetes Mellitus.
3. Patients were not known to have cardiac disease.
4. Patients with well felt radial pulsation in the designated side.

5. Patients with no recent history of cannulation or intravenous sampling from the cephalic vein of the designated side and the cephalic vein is ≤ 3mm in diameter by duplex ultrasound.
6. Patient's approval to be included in the study.

The exclusion criteria were:

1. Patients who are younger than 15 or older than 45.
2. Patients known to have diabetes Mellitus and / or cardiac disease.
3. Patients with non-felt radial pulsations.
4. Patients with recent history of cannulation or intravenous sampling of the designated side.
5. Patients refusal to be included in the study.

Every patient was subjected to:

1. History taking with special emphasis on the past history of diabetes Mellitus and / or cardiac disease.
2. Clinical examination with attention to radial pulsations, signs of cannulation of the cephalic vein, thrombophlebitis of the cephalic vein.
3. Duplex Scanning to detect the presence of stenotic segment within the course of the radial artery, and to measure the diameter of the cephalic vein.

After that the patients were randomized into two groups.

- Group A: patients in this group were subjected to vein preparation by hydrostatic dilation using a 16-gauge cannula.
- Group B: patients in this group were subjected to vein preparation by PTA balloon catheter (PBA) 4mm in diameter, 120 mm in length

Procedure:

1. The procedure was done under local infiltration anesthesia.
2. A 3cm skin incision was made in the distal forearm midway between the radial artery and the cephalic vein.
3. Dissection and exposure of a good length of the cephalic vein (to facilitate its transposition to the artery) and radial artery (sufficient for vascular clamp placement) was done.
4. The cephalic vein was transacted and spatulation was done:
   - Group (A): we introduced a 16-gauge cannula in the cephalic vein with gentle dilatation by injection of saline-heparin solution while applying compression to the cephalic vein proximally using the ultrasound probe.
   - Group (B): through the venotomy we introduced a 0.035 J shaped guide wire under ultrasound guidance over which we introduced a 4mm diameter, 120 mm in length PTA balloon with the proximal one cm of the balloon hanging of the venotomy, then we used an inflator inflating the balloon to a pressure midway between its nominal and burst pressure, as shown in figure (1).
5. Using 6/0 proline, the cephalic vein was anastomosed to the radial artery in an end to side fashion.
6. Technical success was considered when there is thrill over the cephalic vein, or bruit at auscultation.
7. Skin wound was closed with 3/0 prolene.
8. The procedure was followed up every 2 weeks till 6 months using duplex ultrasound looking for vein diameter along its length, flow inside the vein and to detect the presence of any stenotic segment in the cephalic vein needing further balloon dilation (more than 50 % reduction in diameter) to render the fistula ready for dialysis.
9. Maturation time was considered from the time of creation till successful hemodialysis use.

RESULTS

This study was conducted on 57 patients for radiocephalic arteriovenous fistula. The study sample presented to the outpatient clinic in the period from November 2014 till January 2017. In group A, 29 patients were included, while in group B, 28 patients were included.

The following table shows the demographic data of the studied sample and showed no significant difference between both groups.

Table (1): Description of the studied patients

		Group A	Group B	P value
Age		31.41379 ±13.72567	31.89286 ±12.76958	0.798104 Fisher's exact
Side of the AV graft	Right	11	5	0.97266 Fisher's exact
	Left	18	22	

The following table shows patients' co-morbid factors, and there is no significant difference between booth groups.

Table (2): Co-morbid factors of both studied groups

		Group A	Group B	P value
Hypertension	Yes	24	22	0.7414 Fisher's exact
	No	5	6	

Patients were randomized into two groups in group A we used hydrostatic dilatation while in group B we used balloon dilatation and the technical success was shown in table (3).

Table (3): Technical success.

	Group A	Group B	P value
Thrill	28 (96.5%)	28 (100%)	1.0000 Fisher's exact

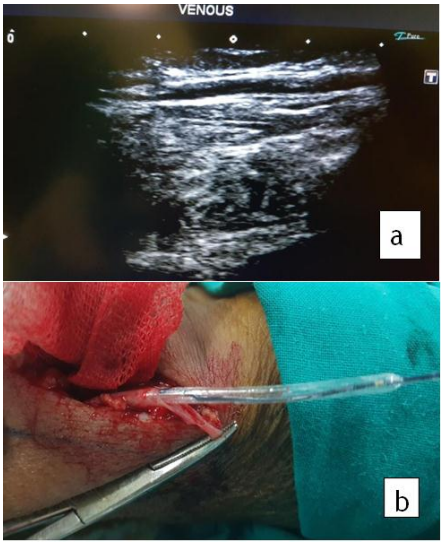

Fig. (1): A patient in group B. (a): duplex ultrasound of the balloon in the cephalic vein. (b): the balloon in the cephalic vein in group B patients.

During follow up, duplex ultrasound was done to detect the presence of stenotic segments within the cephalic vein which showed more than 50 % reduction in the lumen diameter. These stenotic segments were dealt with balloon dilatation to aid in maturation of the fistula. The following table (4) shows these results.

Table (4): Reintervention rate in both groups.

	Group A	Group B	P value
2 weeks	4	0	1.000 Fisher's exact
4 weeks	3	1	
6 weeks	3	1	
Total	10 (35.7 %)	2 (7.1 %)	12

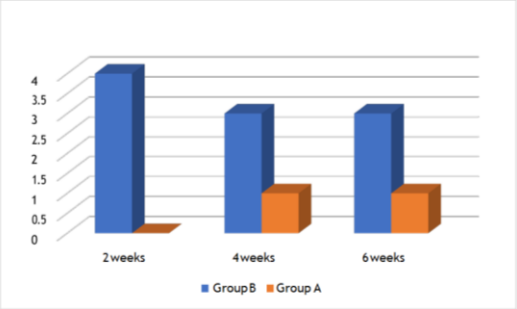

Fig. (2): Reintervention rate in both groups.

Maturation time was calculated from the time of creation of the fistula till reaching a 6 mm diameter vein for a length of 6 cm. In group A 5 (17.85%) fistulas failed to reach our goal in comparison to one (3.57%) fistula in group B. The mean maturation time for group A was 43 days in comparison to 32.1 days in group B patients.

After maturation, 23 patients in group A had had adequate hemodialysis from their fistulas in comparison to 27 patients in group B. Those patients were followed up for 6 months.

We also measured the blood flow rate in both groups and table 5 shows these results.

Table (5): Blood flow rate

Flow rate	Group A	Group B	P value
250 – 300 ml/min	9 (39.13 %)	16 (59.26 %)	0.2563
200 – 250 ml/min	14 (60.87%)	11 (40.75%)	Fisher's exact
Total	23	27	

During the follow up period of 6 months, a patient from group B died from a cardiac event, 5 (21.7%) patients in group A had anastomotic stenosis that needed balloon angioplasty, a patient (3.8%) in group B had anastomotic stenosis to which angioplasty was done.

Furthermore, 3 patients in group A had balloon angioplasty for a stenosis other than anastomotic versus non in group B.

In addition to a patient in group A who had thrombosis of the fistula and did not function after angioplasty as same as group B. And the following table summarize these results.

Follow up	Group A	Group B
Died	0	1
Anastomotic stenosis	5	2
Stenosis other than anastomotic	3	0
Thrombosed	1	1

Primary patency was calculated from the time of complete maturation (start of having dialysis from the access) till thrombosis of the access or reintervention. Primary patency for group A is 60.87% (n=14), while in group B it is 88.46% (n=23).

DISCUSSION

In our study, a radio cephalic arteriovenous fistula was done for 57 patients, in 29 of them the cephalic vein was prepared intra-operative with hydrostatic dilatation, while the other 28 the cephalic vein was prepared by balloon dilatation using a 4mm diameter plain PTA balloon catheter.

The technical success rate was 96.5% in the hydrostatic group in comparison to 100% in the balloon group, which was a statistically non-significant result between both groups.

The rate of reintervention in the form of balloon assisted maturation (BAM) was in the hydrostatic group 35.7% in comparison to only 7.1% in the balloon group. Though statistically non-significant, but there is decreased rate of reintervention in the balloon group.

The mean maturation time was decreased in the balloon group as it was 32.1days in comparison to 43 days in the hydrostatic group.

Overall 20.69% of patients in the hydrostatic group (one technical failure and five failed to mature) versus 3.57% (one failure to mature) in the balloon group failed to have a functioning arteriovenous fistula.

The use of smaller vein diameter in creation of arteriovenous fistulas led to the increase in number of revisions due to non-maturity of the access.[7]

In the study by De Marco Garcia et al., they used PBA associated with BAM to attain maturation of > 90% of autogenous arteriovenousfistula.[8]

In the study by by Veroux et al., the Immediate success rate was 100% for Primary balloon angioplasty and 67% for Hydrostatic dilatation groups respectively. They performed their study on vein diameter $\leq$ 2mm.[9]

In the study by Khan et al., they achieved a technical success rate of 100% in PBA group compared to 73.3 % in the hydrostatic group. While the maturation time for patients in hydrostatic group

was 52.53 ± 3.45 days whereas in PBA group, the average maturation time was 32.83 ± 3.16 days which was a statistically significant ($P < 0.001$) result.[10]

In the same study by Khan et al., the reintervention rate in 6 months, in the hydrostatic group was 36.7%, while the reintervention in the primary balloon angioplasty was 6.7%.[10]

Effective hemodialysis plays an important role in decreasing morbidity and mortality in patients, 11 and ineffective dialysis is one of the factors causing mortality of these patients.[12]

In the study by Kim and his colleagues , increasing the blood flow rate by 15- 20% in patients with low efficiency dialysis results in increase of efficiency of dialysis.[13]

the study by Borzou et al., showed that the efficiency of dialysis is related to the blood flow rate.[14]

CONCLUSION

Creating a native functioning arteriovenous fistula offers a lot of benefits for patients of chronic renal failure, radio-cephalic fistulas are the first choice for an access in our practice. That is why attaining a functioning one is of utmost importance. Primary balloon angioplasty gave us an excellent technical success rate with decreased reintervention rate, and a decreased maturation time in comparison to the ordinary way of hydrostatic dilatation inspite of statistically insignificant results which may be explained by low sample size and larger samples may be needed to verify these results.

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