Percutaneous Endovascular Treatment to Salvage Non-Maturing Arteriovenous Fistulas in a Multiethnic Asian Population

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Abstract

Introduction: An arteriovenous fistula (AVF) is the preferred method for haemodialysis in patients with end-stage renal failure. Previous studies have shown value in attempting percutaneous transluminal angioplasty (PTA) to salvage AVFs that fail to mature, but they are relatively small in size and mainly reported in Western populations. We reviewed our data of PTA in non-maturing AVFs to establish whether this technique is translatable to our local multiethnic population. Materials and Methods: We retrospectively reviewed the medical records and procedural images of 105 patients who had PTA for non-maturing AVFs performed at our department from January 2008 to January 2011. Technical success was defined as ≤30% residual stenosis after angioplasty. Clinical success was defined as at least 1 successful haemodialysis session within 4 weeks after PTA. Results: All 105 patients underwent angioplasty for at least 1 haemodynamically significant stenosis. Six (5.7%) had additional embolisation of accessory veins. Technical success was achieved in 95.2% of cases. The clinical success rate was 76.2%. Primary patency rates at 3, 6 and 12 months were 83%, 45% and 28%, respectively. Secondary patency rates at 3, 6 and 12 months were 90%, 79% and 70%, respectively. The minor complication rate was 18.1%. No major complications were encountered. An average of 1.7 interventions per access-year was required to maintain AVF patency. Patients with a preoperative vein size >2.0 mm and age <55 years were more likely to achieve clinical success, although not statistically significant. Conclusion: PTA is a viable option to help salvage non-maturing AVFs in a multiethnic Asian population.

Key words: Angioplasty, Chronic renal disease, Haemodialysis, Interventional radiology

Introduction

End-stage renal failure (ESRF) is an important global cause of morbidity and mortality. A 2008 World Health Organization (WHO) bulletin estimated the number of people requiring renal replacement therapy (RRT) at 1.4 million with an estimated 8% increase per annum. In Singapore, the number of patients with ESRF requiring RRT has steadily increased with an estimated prevalence of 4895 patients in December 2011 compared with 3565 in 2005. Haemodialysis is the mainstay of RRT with good evidence that dialysis via arteriovenous fistula (AVF) is associated with lower mortality, complication rate and overall cost when compared with other options such as arteriovenous graft (AVG) or haemodialysis catheters (HC). Up to 28% to 60% of autologous AVFs will fail to mature adequately to allow effective dialysis with reported associations to female sex and previous tunnelled catheter use. The characteristics of a mature AVF are summed up by the United States’ National Kidney Foundation in the Kidney Disease Outcome Quality Initiative (KDOQI) “rule of 6s” (6 mm vein, <6 mm under the skin and ≥600 mL/min flow). AVFs that fail to mature are small, non-palpable or have inadequate blood flow for dialysis.

There is growing literature on the efficacy of percutaneous transluminal angioplasty (PTA) to salvage AVFs that fail to mature. The techniques include angioplasty to assist AVF
maturation and embolisation of collateral veins to channel blood flow through a single outflow vein. However, most of these studies have focused on Western populations who have larger vessel sizes.\textsuperscript{8-15} Those studies done in Asian populations have small sample sizes.\textsuperscript{16-20} As a tertiary interventional centre which performs a significant number of cases, we performed a retrospective analysis to see if PTA of non-maturing AVF is a viable option in our patient population and to determine the factors that influence a successful outcome.

Materials and Methods

For this retrospective study, approval was obtained from our Institutional Review Board. Informed consent was waived. From our computerised database of 1968 PTA’s for AVFs performed between January 2008 and January 2011, we found that 105 angioplasties were for salvage of non-maturing AVFs. We retrospectively reviewed the medical records and procedural images of all 105 procedures. The cases were performed or supervised by interventional radiologists with >5 years of experience.

We extracted information on patient and AVF characteristics, possible factors contributing to non-maturation, procedure details and treatment outcomes. Patient demographic data included age, gender and ethnicity. For the AVFs, we looked at the date of creation, type of AVF and calibre of anastomosed vessels. To determine possible factors contributing to non-maturation, we recorded information on the number and location of any stenoses, the presence of competing collateral veins and whether these were treated. For each procedure, we noted the date it was performed, angioplasty balloon characteristics, complications, technical success and any residual stenosis. Outcomes measured include clinical success, primary and secondary patency rates, as well as number and type of secondary interventions.

AVF Evaluation

In our institution, all AVFs were reviewed by a surgeon 4 to 6 weeks after creation. If there was clinical suspicion that the AVF was not maturing, further evaluation was performed with duplex ultrasound. Patients with significant stenosis on ultrasound examination were referred to our department for fistulography and assisted maturation.

Intervention

For each case, the AVF was initially assessed using ultrasound and/or fistulography. The fistulography was performed by injecting contrast through a 21G butterfly needle or 19 to 22G cannula inserted into the juxta-anastomotic segment of the AVF. In cases where spontaneous reflux of contrast into the feeding artery was not seen, we inflated a blood pressure cuff around the upper arm during contrast injection to achieve contrast reflux opacification of the anastomosis. When there was difficulty in puncturing the juxta-anastomotic segment, we performed the fistulography via a brachial artery approach.

After fistulography and documentation of the underlying lesions, interventions were performed using a venous approach. The draining vein was punctured, either antegrade or retrograde as appropriate, and a vascular sheath inserted to obtain access. In a few cases, both approaches were required to treat all the lesions. When the stenosis could not be crossed via the venous approach, brachial artery access was used. After externalisation of the guidewire through the venous sheath, the angioplasty balloon was advanced from the venous approach to treat the stenosis.

Anastomotic and juxta-anastomotic stenoses were treated using angioplasty balloons with a diameter of 3 mm to 6 mm (Fig. 1). Stenoses in the draining vein were treated using angioplasty balloons with a diameter of 5 mm to 8 mm (Fig. 2). Central vein stenoses were treated using angioplasty balloons with a diameter of 10 mm to 14 mm.

Fig. 1. Percutaneous angioplasty of a non-maturing radiocephalic AVF. A) Venogram obtained after insertion of a 5F sheath in the cephalic vein shows a 3 cm tight stenosis (arrow) in the juxta-anastomotic cephalic vein. B) A 4F catheter and 0.035 guidewire were manipulated across the stenosis into the proximal radial artery. C) Images obtained during inflation of a 4 mm x 40 mm conventional angioplasty balloon show balloon “waisting” at 6 atm, and full effacement of the balloon waist at 12 atm. D) Post-angioplasty angiogram obtained by injection of contrast through a 4F catheter in the radial artery. No residual stenosis is seen.
We used conventional angioplasty balloons (Powerflex; Cordis, Miami, FL, USA or Sterling; Boston Scientific, Natick, MA, USA) as the first-line treatment option. High-pressure balloons capable of inflation pressures up to 26 atmospheres (Conquest; BARD, Tempe, AZ, USA) were utilised when conventional balloons did not achieve satisfactory effacement.

Six patients had embolisation of accessory veins performed to assist AVF maturation (Fig. 3). Three of the patients had embolisation with coils performed during the initial angioplasty. The others were done post-angioplasty at 14, 17 and 26 weeks, respectively when their AVFs did not mature. An additional patient had surgical ligation of an accessory collateral vein performed 12 weeks after initial angioplasty.

**Definitions**

Technical success was defined as ≤30% residual stenosis on angiographic images for all treated lesions which follows the recommendations of the Society of Interventional Radiology (SIR).\(^{21}\) For embolisation of competing collateral veins, technical success was defined as successful occlusion of competing collateral flow on angiographic images.

Clinical success was defined as at least 1 successful haemodialysis session within 4 weeks after PTA using the treated AVF without creation of a new haemodialysis access (AVF or AVG), surgical revision or insertion of a peritoneal or vascular dialysis catheter. This reflects the standard practice at our institution where the patient is reviewed 4 weeks post-procedure to assess the treatment result.

Primary patency was defined as the interval between the initial salvage procedure and the next thrombosis or repeat intervention (surgical or radiological).

Secondary patency was defined as the lifetime of the AVF from the initial salvage procedure, including its maintenance by PTA, until it is surgically revised or abandoned for any reason.

Complications were categorised into minor and major complications according to the SIR classification system.\(^{21}\)

**Statistical Analysis**

We used the chi-square test to determine if any of the variables mentioned earlier showed association with clinical success. Primary and secondary patency rates were measured with Kaplan-Meier survival analysis based on the time of the initial intervention to the last known status of the AVF. The 7 patients that underwent embolisation or surgical ligation of accessory veins were not included in our analysis of patency rates. Multivariate analysis was performed using the Cox regression model. A P value of <0.05 was taken as the threshold value for statistical significance. We performed the statistical analysis with SPSS 16.0 software.
Results

Within the study period, a total of 105 patients had PTA for non-maturing AVF. The mean age was 63 years (range, 33 to 84 years) with 57.1% (n = 60) of them being male. The majority were of Chinese ethnicity (68%) while the rest were of Malay (31%) and Indian (6%) ethnicity. Most AVFs (74.3% [n = 78]) were radiocephalic, 21.9% (n = 23) were brachiocephalic, and 3.8% (n = 4) were brachio basilic vein transposition.

The time interval between AVF creation to PTA ranged from 0.9 to 17.6 months (mean 4.6 months; median 3.9 months).

Thirteen patients (12.4%) had PTA of the AVF attempted more than 6 months after creation. In 7 cases, the decision was made to try an alternate option first. Of these 7 patients, 3 had tunnelled dialysis catheters inserted for long-term haemodialysis. Another 3 had a second AVF created on the opposite arm and only after this failed were they referred for PTA of the first non-maturing AVF. The last patient had surgical ligation of an accessory vein to aid maturation before being referred for PTA.

Of the remaining 6 patients, 4 had AVFs created in preparation for dialysis but PTA was delayed as renal function did not deteriorate as quickly as expected. Two patients were referred for PTA but initial fistulography did not reveal a stenosis. Repeat fistulography after 6 months showed significant stenosis for which PTA was performed.

Altogether, 156 stenoses of ≥50% were found, with a mean of 1.5 stenoses per patient (range, 1 to 4). In 59.0% of cases (n = 62), an isolated stenosis was present. In the rest, 34.3% (n = 36) had 2 stenoses, 5.7% (n = 6) had 3 stenoses, and 1.0% (n = 1) had 4 stenoses. The locations of the stenoses are shown in Table 1.

Technical success was attained in 95.2% (n = 100) of angioplasties and 100% of coil embolisations.

In all cases, a venous approach was first attempted. The majority of the cases (90.5%, n = 95) were treated via a standard venous approach, retrograde and/or antegrade as appropriate. Arterial access was required in 9.5% (n = 10) of patients. In 14.3% (n = 15) of cases, a 0.018” (versus a standard 0.035”) platform was needed to cross the stenosis. Three cases were done using an arterial approach while the other 12 through standard venous access.

In 93.3% (n = 98) of cases, angioplasty was successful in using conventional balloons while the other 6.7% (n = 7) necessitated the use of high-pressure balloons.

Minor complications were seen in 18.1% (n = 19) of cases. In 10 cases, angioplasty resulted in vein rupture which was successfully controlled by manual external compression and/or prolonged balloon inflation, with maintenance of AVF patency. Dislodgement of a coil occurred during one of the embolisation procedures and was retrieved with a snare. Other complications included puncture site haematoma in 6 patients, pseudoaneurysm formation in 1 patient and non-flow-limiting dissection in another. All these complications were managed conservatively. There were no major complications.

Clinical success was achieved in 76.2% of patients (n = 80). A preoperative anastomotic vein diameter of ≥2.0 mm was found to be a significant positive predictor for clinical success (PR = 1.29; 95% CI, 1.03 to 1.62; P = 0.024), while an age of ≥55 years was a negative predictor for clinical success (PR = 0.78; 95% CI, 0.65 to 0.94; P = 0.043) (Table 2).

The mean follow-up period was 356 days. During this time, 134 further interventions were performed (120 angioplasties, 10 thrombolysis procedures, 3 collateral vein embolisations and 1 surgical ligation of an accessory vein). From the 80 patients who had clinical success, 50% (n = 40) required further interventions to maintain AVF patency. There was an average of 1.7 interventions per access-year. The mean interval from the initial angioplasty to the next intervention was 5.8 months (range, 1.6 to 17.8 months). None of the patients underwent renal transplantation during the period of follow-up.

The primary patency rates following angioplasty at 3 months, 6 months and 1 year were 83%, 45% and 28%, respectively (Fig. 4A). The corresponding secondary patency rates were 90%, 79% and 70%, respectively (Fig. 4B). The mean duration of primary patency was 9.0 months with a median of 5.8 months. For secondary patency, this was 20.8 months and 29.5 months, respectively.

We found that patients with a preoperative vein size of ≥2.0 mm tend to have better long-term patency (Fig. 5). At 3, 6, and 12 months’ post-intervention, they showed primary patency rates of 92%, 53%, and 40% and secondary patency rates of 95%, 88%, and 83%, respectively. This is compared to primary patency rates of 75%, 39%, and 26% and secondary patency rates of 84%, 73% and 60%, respectively, for patients with a preoperative vein size of ≥2.0 mm (Table 2).
Table 2. Factors Affecting Clinical Success

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total n (%)</th>
<th>Clinical Success n (%)</th>
<th>Prevalence Ratio</th>
<th>(95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>105 (100.0)</td>
<td>80 (76.2)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>&lt;55 years’ old</td>
<td>24 (22.9)</td>
<td>22 (91.7)</td>
<td>1.00</td>
<td>(reference)</td>
<td>-</td>
</tr>
<tr>
<td>≥55 years’ old</td>
<td>81 (77.1)</td>
<td>58 (71.6)</td>
<td>0.78</td>
<td>(0.65 – 0.94)</td>
<td>0.043</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Male</td>
<td>60 (57.1)</td>
<td>49 (81.7)</td>
<td>1.00</td>
<td>(reference)</td>
<td>-</td>
</tr>
<tr>
<td>Female</td>
<td>45 (42.9)</td>
<td>31 (68.9)</td>
<td>0.84</td>
<td>(0.67 – 1.06)</td>
<td>0.128</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
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<tr>
<td>Chinese</td>
<td>68 (64.8)</td>
<td>51 (75.0)</td>
<td>1.00</td>
<td>(reference)</td>
<td>-</td>
</tr>
<tr>
<td>Malay</td>
<td>31 (29.5)</td>
<td>24 (77.4)</td>
<td>1.03</td>
<td>(0.82 – 1.31)</td>
<td>0.794</td>
</tr>
<tr>
<td>Indian</td>
<td>6 (5.7)</td>
<td>5 (83.3)</td>
<td>1.11</td>
<td>(0.76 – 1.63)</td>
<td>0.648</td>
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<tr>
<td><strong>Time from AVF creation to PTA angioplasty</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6 months</td>
<td>84 (80.0)</td>
<td>66 (78.6)</td>
<td>1.00</td>
<td>(reference)</td>
<td>-</td>
</tr>
<tr>
<td>≥6 months</td>
<td>21 (20.0)</td>
<td>14 (66.7)</td>
<td>0.85</td>
<td>(0.62 – 1.17)</td>
<td>0.252</td>
</tr>
<tr>
<td><strong>Type of AVF</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Forearm (RC)</td>
<td>78 (74.3)</td>
<td>58 (74.4)</td>
<td>1.00</td>
<td>(reference)</td>
<td>-</td>
</tr>
<tr>
<td>Upper arm (BC, BBT)</td>
<td>27 (25.7)</td>
<td>22 (81.5)</td>
<td>1.10</td>
<td>(0.88 – 1.37)</td>
<td>0.454</td>
</tr>
<tr>
<td><strong>Preoperative size of artery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤2.0 mm</td>
<td>24 (22.9)</td>
<td>16 (66.7)</td>
<td>1.00</td>
<td>(reference)</td>
<td>-</td>
</tr>
<tr>
<td>&gt;2.0 mm</td>
<td>68 (64.8)</td>
<td>52 (76.5)</td>
<td>1.15</td>
<td>(0.84 – 1.57)</td>
<td>0.347</td>
</tr>
<tr>
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<td>13 (12.4)</td>
<td>12 (92.3)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Preoperative size of vein</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤2.0 mm</td>
<td>48 (45.7)</td>
<td>32 (66.7)</td>
<td>1.00</td>
<td>(reference)</td>
<td>-</td>
</tr>
<tr>
<td>&gt;2.0 mm</td>
<td>50 (47.6)</td>
<td>43 (86.0)</td>
<td>1.29</td>
<td>(1.03 – 1.62)</td>
<td>0.024</td>
</tr>
<tr>
<td>No information</td>
<td>7 (6.7)</td>
<td>5 (71.4)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Number of sites stenosed</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single stenosis</td>
<td>62</td>
<td>47</td>
<td>1.00</td>
<td>(reference)</td>
<td>-</td>
</tr>
<tr>
<td>Multiple stenoses</td>
<td>43</td>
<td>33</td>
<td>1.01</td>
<td>(0.82 – 1.26)</td>
<td>0.912</td>
</tr>
</tbody>
</table>

AVF: Arteriovenous fistula; BBT: Brachiobasilic vein transposition; BC: Brachiocephalic; CI: Confidence interval; PTA: Percutaneous transluminal angioplasty; RC: Radiocephalic

≤2.0 mm. However, this difference was not statistically significant (Kaplan-Meier log rank test: $P = 0.591$ for primary patency rate and $P = 0.099$ for secondary patency rate). The average secondary patency for patients with a preoperative vein size of >2.0 mm was 685 days (95% CI, 572 to 798), as compared to 517 days (95% CI, 407 to 627) for patients with a preoperative vein size of ≤2.0 mm ($P = 0.099$).

**Discussion**

This is a large retrospective study looking at the results of PTA to salvage non-maturing AVF in a multiethnic Asian population. The ethnic distribution of our patients is reflective of that seen in HD prevalence for our local population, which in 2011 stood at 67.6% Chinese, 24.3% Malay and 7% Indian. This distribution has been generally stable since 1999, with a similar pattern seen in the incidence of patients starting HD and incidence of chronic kidney disease stage 5.3 The technical success rate for PTA was high at 95.2%, with clinical success achieved in 76.2% of cases. While our technical success rates are comparable to prior studies which showed technical success rates of between 87% to 97%, our clinical success rates are slightly lower compared to those of other studies (83% to 98%).8,10-15,18-20 Our overall primary and secondary patency rates were 28% and 70% at 12 months, respectively. These values are marginally lower than those obtained in previous Western studies of 34% to 39 % primary patency and 68% to 79 %
secondary patency.\textsuperscript{8,10,12,14,22} We postulate that our results could be attributable to factors such as vessel (artery and vein) size, age and diabetes prevalence that are known to affect clinical success and AVF patency.\textsuperscript{23,24}

In this study, 45.7\% of the preoperative veins were less than 2 mm, which is well researched and below the widely accepted cut-off vein size associated with a lower chance of AVF maturation.\textsuperscript{25-27} Our study findings are also consistent with the prevailing evidence, showing that patients having a preoperative vein size of <2 mm had a significantly reduced chance of clinical success (66.7\% vs 86.0\%). They also tended to have lower primary and secondary patency rates although this did not attain statistical significance. Population studies have shown that Caucasians tend to have larger vein sizes compared with other races, and this is probably a contributing factor to better outcomes in the Western studies.\textsuperscript{28,29}

In addition, 22.9\% of our patients had a preoperative artery size of <2 mm which is the minimum recommended diameter for successful creation of radiocephalic (RC) AVF.\textsuperscript{30}

Our patients were also of slightly older age – mean of 63 years, compared with mean of 58 to 60 years in previous studies.\textsuperscript{8,10,14} A meta-analysis of RC AVFs in elderly patients found increased primary failure rate and poorer patency rates at all time points.\textsuperscript{31} This could be due to the increased burden of atherosclerotic disease or other comorbidities such as diabetes. Our analysis revealed that an age of ≥55 years was also associated with a reduced chance of clinical success (71.6\% vs 91.7\%), which is in agreement with the previous meta-analysis. However, there are also studies which dispute the finding of age as a significant factor with
regard to AVF maturation. Based on current information, we do not feel that age should be a determining factor in patient selection for PTA.

Finally, a possible reason could be the higher prevalence of diabetes in our study population. The estimated prevalence of diabetes in Singapore is 12.8% compared with 10.0% in Taiwan and 9.1% in Europe. The incidence of local patients on haemodialysis due to diabetic nephropathy stands at 64.9% in 2014, an increase from 36.9% in 1999. There is evidence that diabetics with AVFs have poorer patency rates. However, this is still largely speculative, given that we did not track the prevalence of diabetes in our study population.

Our rates are also slightly lower compared with the study by Liang et al, the clinical success rate was slightly lower for patients in whom intervention was performed later than 6 months (although this did not achieve statistical significance). One possible explanation could be related to the time from AVF creation to intervention. Our mean time was 4.6 months (range, 0.9 to 17.6), compared with just 7.9 weeks (range, 3 to 12). Therefore, our patients had a generally longer interval between AVF creation and intervention which could impact our success rate. In our study and another by Renaud et al', the clinical success rate was slightly lower for patients in whom intervention was performed later than 6 months (although this did not achieve statistical significance). One reason for the relative delay in intervention was that some AVFs had been created earlier in anticipation for dialysis; as a result, the surgeon was willing to take a more conservative approach to management.

We did not find any correlation between successful salvage rates and gender although previous studies have suggested female sex to be a negative predictive factor for AVF maturation.

Our study had a few limitations. Firstly, it was a retrospective study, with data collection limited to what can be gleaned from clinical notes and procedure reports. For example, preoperative artery and vein sizes were missing in 12.4% (n = 13) and 6.7% (n = 7) of our cases. Given that the surgeon would be more inclined to mention a small vessel in his report, we had probably overestimated the actual proportion of patients with small vessels in our study population. Secondly, we did not compare our results with any alternative treatment options for non-maturing AVFs, such as surgical revision. However, surgical revision would inevitably result in loss of available vessel for future access, unlike PTA where the original AVF is still salvaged.

Conclusion

Increased population longevity and a rising prevalence of diabetes will result in an ever larger number of patients developing ESRF requiring RRT. AVFs are the preferred option for haemodialysis but a significant number of AVFs fail to mature after creation. Our institution has a policy of creating an AVF first for haemodialysis, and veins of small calibre are utilised by our surgeons to create a lower arm AVF rather than resorting to an AVF in the upper arm or an AVG. This strategy has the advantage of preserving the patient’s arm veins for future access creation. Despite the smaller vein sizes, we have shown that in our multiethnic Asian population, PTA is a viable method for salvaging non-maturing AVFs and it should be attempted before abandoning any non-maturing AVFs.

REFERENCES


