Conventional vs cutting balloon angioplasty for treatment of arterio-venous fistula stenosis

Poster No.: C-2644
Congress: ECR 2018
Type: Scientific Exhibit
Authors: M. Salsano\(^1\), S. Matthew\(^2\), R. ross\(^2\), A. Khawaja\(^1\), J. Weir-McCall\(^2\), G. Houston\(^2\); \(^1\)Birmingham/UK, \(^2\)Dundee/UK
Keywords: Interventional vascular, Kidney, Veins / Vena cava, Fluoroscopy, Percutaneous, Ultrasound-Colour Doppler, Angioplasty, Catheters, Venous access, Dilatation, Fistula, Obstruction / Occlusion
DOI: 10.1594/ecr2018/C-2644

Any information contained in this pdf file is automatically generated from digital material submitted to EPOS by third parties in the form of scientific presentations. References to any names, marks, products, or services of third parties or hypertext links to third-party sites or information are provided solely as a convenience to you and do not in any way constitute or imply ECR's endorsement, sponsorship or recommendation of the third party, information, product or service. ECR is not responsible for the content of these pages and does not make any representations regarding the content or accuracy of material in this file. As per copyright regulations, any unauthorised use of the material or parts thereof as well as commercial reproduction or multiple distribution by any traditional or electronically based reproduction/publication method ist strictly prohibited. You agree to defend, indemnify, and hold ECR harmless from and against any and all claims, damages, costs, and expenses, including attorneys' fees, arising from or related to your use of these pages. Please note: Links to movies, ppt slideshows and any other multimedia files are not available in the pdf version of presentations.

www.myESR.org
Aims and objectives

The failure of haemodialysis access, in particular autogenous fistulas (AVFs) and prosthetic grafts (AVGs), increases morbidity and healthcare costs in patients with end stage renal disease (1). One of the main causes of this failure is the development of venous stenosis and subsequent thrombosis of the access. The development of a stenosis involves similar mechanisms in both AVFs and AVGs (cellular proliferation, microvessel formation, and cytokine expression) with neointimal hyperplasia as final result (1)(2). Native AVFs are the recommended option for permanent vascular access as they have relatively low rates of thrombosis and infection, and require fewer interventions to maintain patency (3)(4). Costs for creation and maintenance of AVF are lower than other types of vascular access (VA) and the overall life-span is longer compared to other kind of VA (3) (5). Percutaneous transluminal angioplasty (PTA) is the recommended treatment of choice for stenosis (6) (7). Some stenoses can prove resistant to conventional PTA, due to the presence of dense fibrous strands incorporated into the venous neointimal layer, or from scar tissue resulting from recurrent puncture trauma to the venous wall (8). An alternative to standard balloon PTA is the use of cutting balloon, incorporated with 3 or 4 fine cutting blades capable of cutting and disrupting the fibroelastic continuity of this ring of neointimal hyperplasia. They can prevent elastic recoil and enable dilation to occur by separating the intact plates of intima with little or no barotrauma (9). Recent literature has shown conflicting results concerning the patency rates of native access after treatment with conventional and cutting balloon PTA (10)(11) (12).
Methods and materials

Study design

This retrospective study was approved by the local ethics committee. We reviewed all PTAs performed on upper limb dialysis access at our center in the period between August 2011 and March 2017.

These totalled 436 interventions out of which 114 were excluded from the analysis because these were abandoned during the procedure (VA considered failed/not salvageable or technical failure as unable to cross lesion). Angioplasty performed on the arterial side of the access were also excluded (n=2). Sixteen PTA were excluded (two missing DSA data or report not available and 14 cases with ultrasound data not recorded). Four PTA procedures were excluded because of the use of drug eluting balloons. Post-thrombectomy PTA were included (n=13).

Only patients followed up at the local hospital (Ninewells, Dundee - UK) were included.

Twenty PTAs on 10 PTFE fistulas were excluded due to the well-established differences in patency profiles of AVGs requiring more frequent interventions to maintain patency.

A total of 138 fistulas were studied, 88 treated with standard balloon only and 50 with cutting balloon PTA.

A systematic US assessment was performed before the surgery, the day after the procedure and again at 6, 12, 24 and 52 weeks. When abnormal results were observed, fistulography was performed.

On the basis of clinical, hemodynamic or US changes, patients were referred to our angiography unit for diagnostic fistulography and treatment as appropriate.

Technique

Written consent was obtained from all patients before the procedure. The intervention was performed under local anesthesia, with sedation when required, and the use of vascular sheaths. The direction of the access was chosen according to the location of the stenosis previously defined on US (retrograde for perianastomotic stenosis; antegrade for proximal venous, mid/upper-arm, and cephalic arch stenosis).

Arterial access was used only for imaging in complex stenoses in XX cases. After the stenosis had been crossed using a combination of guidewires and catheters depending on its morphology, a 4 or 5 Fr sheath for standard balloon and a 7 Fr sheath for cutting balloon was inserted.
Both antegrade and retrograde access were performed if needed (ex: presence of multiple stenoses in different locations).

All cases had heparin administered during procedure - this ranged between 3000 and 5000 IU at the dependent on the individual Radiologist/practitioner. Different sizes of balloon were used, ranging from 4 to 12 mm, depending on the stenosis and on the operator's discretion, usually 10%- 15% oversized compared with the adjacent normal vein.

With the use of an inflation device with a pressure gauge, the angioplasty balloon was gradually inflated until the stenosis was eliminated, reaching and passing the rated burst pressure (rbp) if necessary. Standard balloon was used as a first attempt.

Thrombosed fistulae were not excluded. Following thrombolysis (Arrow-Trerotola Percutaneous Thrombolytic Device), if an underlying stenosis was discovered a standard or cutting balloon angioplasty was performed. The decision as to whether the fistula was salvageable was based on standard criteria, which included the duration of thrombosis, amount of thrombus, and presence or absence of aneurysmal dilatation of the fistula.

If the appearances were satisfactory the sheath was removed after the application of a hemostatic purse-string suture.

**Data recorded and definitions**

The target lesion and the presence of any eventual further stenoses were evaluated at diagnostic fistulography.

The diameter of the vessel before and after the venoplasty was recorded and compared to the diameter of the balloon to define the recoil of the stenosis after the procedure. Anatomic measurements were made with the use of a calibrated reference marker.

Patency was defined using standardised published criteria (13).

This study aimed also to assess the procedural success (defined as a residual stenosis #50%), number of repeat interventions on the same vascular access and degree of residual stenosis of the vessel in comparison with the inflating balloon diameter (stenosis recoil).

**Statistical Analysis**

Comparisons were made between the two groups with respect to demographic, fistula, and intervention characteristics. Non-normally distributed continuous variables were compared by using the Mann-Whitney U and Pearson chi-Square tests. Statistical analysis of the postintervention primary and secondary patency patency were performed
with the Kaplan Meier method. A P value of less than .05 was indicative of statistical significance.

All statistical analyses were performed with SPSS statistical software (IBM SPSS Statistics, version 20.0.0).
Results

A total of 281 PTA procedures were recorded, 207 performed using standard balloons and 74 using cutting angioplasty balloons.

The demographic characteristics of the population are presented in Table 1. There were no significant differences in characteristics between the two treatment groups. The characteristics of the fistulas are presented in Table 2.

Cutting balloon showed a better PP, SP and APP compared to standard balloons (p=0.046; 0.002 and 0.001 respectively).

Kaplan-Meier graphs of PP, SP and APP are provided in Figure 1.

Technical success was reached in 240 over 264 procedures, 171 over 194 treated with standard balloon, 69 over 70 treated with cutting balloon (p=0.009 Pearson Chi-Square).

Median recoil for standard balloon venoplasty was 40% (±15.9 SD), whereas cutting balloon suffered minor recoil 25.6% (±17.1 SD; p<0.001).

Considering the single treatment, the patency rates at the intervention, 6, 13, 26 and 52 weeks were respectively 93%, 79%, 77%, 70%, 69% for the standard balloon group and 100%, 89%, 88%, 70%, 58% for the cutting balloon group (table 3).

In keeping with literature, cutting balloon showed a better secondary patency at 6 months compared to standard balloon angioplasty (p=0.029 - Pearson Chi-Square)(14).

According to the US follow-up, cutting balloon showed a significant improvement in the patency of the fistula only after the intervention (p=0.005), with no significant difference at the following scans at 6, 13, 26 and 52 weeks (0.067, 0.09, 0.992 and 0.315 respectively).

Linear regression analysis showed a strong correlation between the outcome and the stenosis recoil, wherein a better outcome was found in procedures with less stenosis recoil. A direct correlation was found between the kind of balloon and the stenosis recoil (p<0.001), showing that the use of cutting balloon has a reduced stenosis recoil percentage.

Table 1

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Standard Balloon (n)</th>
<th>Cutting balloon (n)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native</td>
<td>207</td>
<td>74</td>
<td></td>
</tr>
</tbody>
</table>
Table 2

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Standard balloon</th>
<th>Cutting balloon</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native fistulas</td>
<td>88</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Secondary patency</td>
<td>268±297</td>
<td>433±375</td>
<td>0.001</td>
</tr>
<tr>
<td>mean days ±SD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of fistulas</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>bb</td>
<td>75</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>bc</td>
<td>95</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>rc</td>
<td>37</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Left side</td>
<td>141</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>Right side</td>
<td>66</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>124</td>
<td>41</td>
<td></td>
</tr>
</tbody>
</table>

Table 3

<table>
<thead>
<tr>
<th>Patency of the AVF (n)</th>
<th>Standard balloon</th>
<th>Cutting balloon</th>
</tr>
</thead>
<tbody>
<tr>
<td>After the procedure</td>
<td>188/202</td>
<td>72/72</td>
</tr>
<tr>
<td>6 weeks</td>
<td>153/194</td>
<td>63/71</td>
</tr>
<tr>
<td>13 weeks</td>
<td>110/142</td>
<td>51/58</td>
</tr>
<tr>
<td>26 weeks</td>
<td>71/101</td>
<td>33/47</td>
</tr>
<tr>
<td>52 weeks</td>
<td>40/58</td>
<td>15/26</td>
</tr>
</tbody>
</table>
Fig. 1: Kaplan-Meier analysis of primary patency of the entire vascular access circuit.

© University of Dundee
Fig. 2: Kaplan-Meier analysis of assisted primary patency of the entire vascular access circuit.

© University of Dundee
**Fig. 3:** Kaplan-Meier analysis of secondary patency of the entire vascular access circuit.

© University of Dundee
Conclusion

Vorwerk et al. reported the first use of a cutting balloon, in 1995 for coronary dilation, for the treatment of venous hemodialysis fistulas.

From then, several studies have been published comparing the primary and secondary outcome of cutting and standard balloon venoplasty.

A recent meta-analysis by Agarwal et al, aiming to assess the safety and efficacy of cutting balloon angioplasty in comparison with conventional and high pressure balloon angioplasty in the treatment of vascular access stenosis, showed a significantly higher patency rate of cutting balloon compared to standard balloon at 6 months (10).

The better outcome of cutting balloon could be explained by their capacity to reduce the barotrauma due to the inflation, resulting in less neointimal hyperplasia and less restenosis (9).
References


