IN.PACT Admiral DCB
In Upper Limb Arteriovenous Fistulae/Grafts
A South African Single Unit Audit

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Collaborators
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Disclosure

Speaker name: Dirk le Roux

I have the following potential conflicts of interest to report:
• Compare patency intervals between POBA and DCB.
• Cost Saving?
• Time (workdays) Saving?
• Comparison to RCT’s
• Overall, 40% of fistulas (AVF) fail within a year of creation & grafts (AVG) fare worse.\(^1\)

Our Practice

• From 01 Jan 2016: All AVF PTA’s
  - Sample 28 random Patient Files were drawn.
  - 90 interventions - 45 in each treatment modality
  - Retrospective from 2013 onwards
Inclusion Criteria

• Intervention in:
  – Upper arm AVF / AVG
Indication for interventions

• Decreased dialysis and Physical Examination
  – PE at each HD session provides a simple, cost effective, bedside tool - the “backbone” of screening programme
  – Prolonged bleeding from needle site
  – Difficulty with needling & aspiration of clots
  – Provide equivalent benefit to surveillance but should be complementary
  – Flow >25% drop threshold 400ml/min

• Oedema of arm
Indication for interventions

- Occluded / thrombosed AVF or AVG
- DDoppler –
  - A significant stenosis of >70% defined on the basis of reduction in diameter as compared to an adjacent normal segment,
  - doubling of peak systolic velocity or
  - absolute minimum diameter of 2.7mm.
- 3 to 4 monthly follow up if possible.
Patency Definition

• Primary Patency – Index procedure until occlusion.
• POBA and DCB - Between intervention days.
• Patent or non – patent at demise.
• Until abandonment of access with new access.
• Until 31 August 2018.
Procedural Steps

- **DCB** 2 min inflation – primary dilation catheter unless not able to pass then pre-dilatation with 3-4 mm balloon catheter.
- **POBA** 2 min inflation.
- All patients received Clopidogrel 75mg daily and immediately post op for 6 weeks.
- Aspirin 81mg.
- Continue with chronic meds.
Case Example 12/7/2016

POBA + Thrombectomy
Case Example 30/08/2018

DCB + Thrombectomy
• PP Index 36 months
• POBA patency 2 months
• 1st DCB Patency 4 months
• 2nd DCB Patency 19 months
Index Procedure

- 50% median PP at 1 year
- 16 month mean patency
Comparative Patency POBA vs DCB
Primary Patency Through 12 Months

Kaplan-Meier Curve for Primary Patency

% Patency
0.0% 10.0% 20.0% 30.0% 40.0% 50.0% 60.0% 70.0% 80.0% 90.0% 100.0%

Months
0 1 2 3 4 5 6 7 8 9 10 11 12

POBA
DCB
## Results and Analysis

### T-tests; Grouping: POBA or DCB (DEB VS POBA)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean DCB</th>
<th>Mean POBA</th>
<th>t-value</th>
<th>df</th>
<th>p</th>
<th>Valid N DCB</th>
<th>Valid N POBA</th>
<th>Std.Dev DCB</th>
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</thead>
<tbody>
<tr>
<td>Patency Days</td>
<td>214.5333</td>
<td>118.6000</td>
<td>2.763555</td>
<td>88</td>
<td>0.000302</td>
<td>45</td>
<td>45</td>
<td>149.5772</td>
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<tr>
<td>Patency Months</td>
<td>7.0532</td>
<td>3.8992</td>
<td>3.763555</td>
<td>88</td>
<td>0.000302</td>
<td>45</td>
<td>45</td>
<td>4.9176</td>
</tr>
</tbody>
</table>

### T-tests; Grouping: POBA or DCB (DEB VS POBA)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Std.Dev POBA</th>
<th>Mean 1 - Mean 2</th>
<th>Confidence -95.000%</th>
<th>Confidence +95.000%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patency Days</td>
<td>82.85623</td>
<td>95.93333</td>
<td>45.27715</td>
<td>146.5895</td>
</tr>
<tr>
<td>Patency Months</td>
<td>2.72404</td>
<td>3.15397</td>
<td>1.48856</td>
<td>4.8194</td>
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</tbody>
</table>
Patency Rates

- **Index procedure**: 489 days or 16 months mean PP.
- **POBA**: 118 days or 3.9 months mean Patency
- **DCB**: 215 days or 7.1 months mean Patency

{We assessed each intervention as a new index event until the next event (thrombosis or dialysis problem)}
Compared to RCT’s?

• At 6 months, cumulative target lesion primary patency was significantly higher after PCB application (70% in PCB group vs. 25% in BA group, p<0.001; HR 0.30, 95% CI 0.12 to 0.71, p<0.006).\(^2\)

• (52% DCB(PCB) vs 22% POBA (BA) in our audit)

\(^2\) Paclitaxel-Coated Balloon Angioplasty vs. Plain Balloon Dilation for the Treatment of Failing Dialysis Access: 6-Month Interim Results From a Prospective Randomized Controlled Trial Konstantinos Katsanos J et al ENDOVASC THER 2012;19:263–272
• At 1 year, cumulative target lesion primary patency was significantly higher after DEB application (35% vs. 5% after BA, p < 0.001). Overall, median primary patency was 0.64 years in case of DEB vs. 0.36 years in case of BA (p = 0.0007)\(^3\)

• Audit – Median patency at .56 years for DCB vs .32 years in case of POBA

Costs?

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>POBA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of Balloon</td>
<td>R10100 (US$ 666)</td>
<td>R3400 (US$ 224)</td>
</tr>
<tr>
<td>Hospital Cost /Event*</td>
<td>R38100 (US$ 2514)</td>
<td>R31400 (US$ 2072)</td>
</tr>
<tr>
<td>Cost per year</td>
<td>R64394 (US$ 4250)</td>
<td>R99157 (US$ 6545)</td>
</tr>
</tbody>
</table>

- **US$: R 1:15,15**
- **Cost saving per year R 34763 (US$ 2295)**
- *Including Theatre Cost, High Care 2 days and 1 acute dialysis session and balloon dilation catheter.*
- **Days off work: DCB 5 / year vs POBA 9 / year**
Conclusion

• Intervals for lesions treated with DCB patent for longer on average.
• Mean patencies 7.1 months for DCB vs 3.9 months for POBA (+-22% 6 month) P=.0003
• Patencies are poor with POBA and DCB almost doubles patency rates.
• Compares well to RCT’s data.
Future Questions?

• Role of Vessel Prep with scoring, HPB?

• Is there a trend for longer intervals between DCB treatments- Thus longer Assisted PP or Secondary Patency? We think so – working on study protocol.

• Protocol to do routine intervention before occlusion of access.
  – Day procedure. Monetary and Social cost savings?
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