Drug coated balloon for failing vascular access

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Disclosure

Speaker name:

Skyi Yin Chun Pang

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

✓ I do not have any potential conflict of interest
Background

- Failing vascular access is a common problem in dialysis patients
- Percutaneous transluminal angioplasty is well recognized as the mainstay of treatment
  - 12 month primary patency of percutaneous transluminal angioplasty is only 46%
    - Increase workload as a burden to vascular surgeon or interventional radiologist.
    - Increase morbidities
    - Increase vascular catheter used → central vein problem

Different endovascular tools

• Bare metal stent
  • Primary patency at 6-month 39.3%

• Cutting balloon
  • primary patency at 6-month 47.9%

• Covered stent
  • The 6-month primary patency rate of PTFE grafts was enhanced to 51% after stent graft implantation in venous outflow stenoses
Drug coated balloon in dialysis access

- Promising result shown on Katsanos study
  - 6-month primary patency 70% (PCB) vs. 25% (POBA) p=0.001

Observational study in juxta anastomosis of radiocephalic fistula

- 6-month patency rate
  - DCB 70% vs POBA 0% $p < 0.01$
- 12-months patency rate
  - DCB 20% vs POBA 0% $p > 0.05$

Multicentre, randomised, blinded, control trial of drug-eluting balloon vs Sham in recurrent native dialysis fistula stenoses

Jan “John” Swinnen¹, Kerry Hitos², Lukas Kairaitis³,⁴, Simon Gruenewald⁵, George Larcos⁵, David Farlow⁵, David Huber⁶, Gabriel Cassorla⁷, Christopher Leo⁸, Laurencia M Villalba⁶, Richard Allen¹, Farshid Niknam⁶ and David Burgess⁹
132 recurrent AVF stenosis
(48% in BMS)
Significant less late lumen loss 0.12mm in DCB group at 12th month (p=0.0003)
Significant longer freedom from intervention at 12th month
Effect persists in both stented and unstented group

John Swinnen, Kerry Hitos, Lukas Kairaitis, Simon Gruenewald, George Larcos, David Farlow, David Huber, Gabriel Cassorla, Christopher Leo, Laurencia M Villaba, Richard Allen, Farshid NikNam, David Burgess. The Journal of Vascular Access 2018; 1-10
Hemodialysis Arteriovenous Fistula and Graft Stenoses: Randomized Trial Comparing Drug-eluting Balloon Angioplasty with Conventional Angioplasty

Farah Gillan Irani, MBBS, FRCR • Terence Kiat Beng Teo, MBBS, FRCR • Kiang Hiong Tay, MBBS, FRCR, FAMS • Win Htet Yin, MBBS, BSc (Hons) • Hlaing Hlaing Win, MBBS, MSc • Apoorva Gogna, MBBS, FRCR, FAMS • Ankur Patel, MBBS, MRCS, FRCR • Chow Wei Too, MBBS, FRCR • Shaun Xavier Ju Min Chan, MBBS, FRCR • Richard Hoau Gong Lo, MBBS, FRCR, FAMS • Luke Han Wei Toh, MBBS, FRCR, FAMS • Siew Ping Chng, MBBS, MRCS, FAMS • Hui Lin Choong, MBBS, MMed, FAMS • Bien Soo Tan, MBBS, FRCR, FAMS

From the Departments of Vascular and Interventional Radiology (F.G.I., K.H.T., W.H.Y., H.H.W., A.G., A.P., C.W.T., S.X.J.M.C., R.H.G.L., L.H.W.T., B.S.T.), Vascular Surgery (S.P.C.), and Renal Medicine (H.L.C.), Block 2 Level 1, Singapore General Hospital, Outram Rd, Singapore 169608; and Department of Radiology, Mount Elizabeth Hospital, Singapore (T.K.B.T.). Received April 16, 2017; revision requested June 27; revision received May 10, 2018; accepted May 21. Address correspondence to F.G.I. (e-mail: farah.gilan.irani@singhealth.com.sg).

Supported by the National Medical Research Council (NMRC/1296/2011).

1Deceased.

Conflicts of interest are listed at the end of this article.

Radiology 2018; 289:238–247 • https://doi.org/10.1148/radiol.2018170806 • Content codes: VA IR
Favorable result in DCB group

- 119 participants
  - AVF(98) & AVG(21)
- DCB 81% Vs POBA 61% at 6 months (p=0.03)
- DCB 51% Vs POBA 34% at 1 year (p=0.04)

Radiology 2018; 289:238-247
## Quick Comparison for the RCTs

<table>
<thead>
<tr>
<th></th>
<th>Australian Study (Swinnen)</th>
<th>Singapore (Farah)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target population</strong></td>
<td>Recurrent Fistula</td>
<td>Failing AVF/AVG</td>
</tr>
<tr>
<td></td>
<td>~50% prior stenting</td>
<td>17.6% AVG</td>
</tr>
<tr>
<td><strong>Type of DCB</strong></td>
<td>IN.PACT Admiral/Pacific™</td>
<td>IN.PACT Admiral™</td>
</tr>
<tr>
<td><strong>Vessel prep</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Blinding</strong></td>
<td>Patients and assessors</td>
<td>No blinding</td>
</tr>
<tr>
<td><strong>Follow up</strong></td>
<td>Sonographic assessment at 12 month Index trial area &amp; fistula flow</td>
<td>Angiographic at 6month clinical at 12 month</td>
</tr>
<tr>
<td><strong>Sponsor</strong></td>
<td>Medtronic Australia</td>
<td>National Medical Research Council Singapore</td>
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</tbody>
</table>
Other large scale studies

• **Lutonix AV Global Registry N = 324**
  • Lutonix 035 DCB
  • 75% AVF 25% AVG; 11.1% ISR
  • 52.9% recurrent lesion
  • 73.5% Target lesion primary patency at 6 month

• **IN.PACT™ AV Access IDE Study N=330**
  • IN.PACT Admiral 035DCB
  • AVF Only
  • 69.7% recurrent lesion
  • 6 Month primary patency result will be available in Autumn 2019
Hong Kong situation

- PD still as the first-line of RRT
- Public awareness on vein preservation
- Follow up or surveillance of vascular access
- Variability for the intervention service availability
- Re-imbursement issue
  - Drug device is not yet included for even well-established femoro-popliteal disease
Paclitaxel-eluting balloon versus plain angioplasty balloon for dysfunctional dialysis access: a prospective double-blinded randomized controlled trial

Department of Surgery, Department of Medicine & Department of Radiology, Pamela Youde Nethersole Eastern Hospital
Hong Kong

Australian New Zealand Clinical Trials Registry
ANZCTR12616000789460
Objective

To compare the target lesion primary patency rate at 12 months between paclitaxel-eluting balloon (DEB) versus plain balloon angioplasty (BA) for the treatment of the dysfunctional vascular access.
Study design

• A prospective, single center, double-blind, randomized intervention study
  • Study site:
    • A general hospital in the Eastern part of Hong Kong Island, Hong Kong SAR, China
  • Study population:
    • Patients with end-stage renal failure on haemodialysis with dysfunctional vascular access

• Non-sponsored trial
• Intervention is performed by Vascular surgeon
• Assessment and follow up by Renal physician, Sonographers and Nurses
Study description

• **Primary Outcome**
  - target lesion primary patency rate at 12 months
    (functional dialysis access with <50% re-stenosis and without any repeat interventional procedures)

• **Secondary outcomes:**
  - Technical success (final residual stenosis <30%)
  - Clinical success (smooth haemodialysis for 3 consecutive sessions)
  - Median days of patency
Dysfunctional AVF/AVG detected at HD center

Reviewed by renal physicians

USG duplex by Sonographers within 4 weeks

Vascular clinic

Proceed to intervention

Exclude from study
Randomization and Blinding

• Randomization
  • At operation theatre after lesion crossing

• Blinding
  • Patients
  • Assessors (renal physicians and nurses/sonographers)
Paclitaxel-eluting balloon arm

Pre-dilatation

In.Pact Admiral drug eluting balloon

Plain angioplasty balloon arm

Plain balloon angioplasty

High pressure balloon for residual stenosis if needed

Bare-stent/ covered stent as bailout in case of dissection/rupture

Post-intervention angiogram
Trans radial approach for brachial axillary AVG stenosis

Antegrade brachial approach with bailout stent at RCF

Retrograde approach for juxta anastomosis stenosis of RCF

Diffuse severe stenosis of forearm AVG

Calcified Juxta and arteriovenous anastomosis stenosis

Cannulation zone stenosis

Trans radial approach for brachial axillary AVG stenosis
Follow up

• Post procedure sonographic assessment by two experienced sonographers
  • 1 week, 3, 6, 9 & 12 month
  • Location, degree of stenosis and length of lesion
  • Definition of degree of stenosis determined by the diameter of target lesion
• Clinical assessment performed during haemodialysis sessions
Pre-intervention

Post-intervention

3 months

6 months
### Result

40 patients recruited from June 2016 – April 2018

<table>
<thead>
<tr>
<th></th>
<th>DEB ( n=20)</th>
<th>POBA ( n=20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>58.1+/8.93</td>
<td>57.4+/6.9</td>
<td>0.78</td>
</tr>
<tr>
<td><strong>Sex (female)</strong></td>
<td>5</td>
<td>3</td>
<td>0.31</td>
</tr>
<tr>
<td><strong>(male)</strong></td>
<td>15</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td><strong>Smoking history</strong></td>
<td>6</td>
<td>10</td>
<td>0.26</td>
</tr>
<tr>
<td><strong>Hyperlipidaemia</strong></td>
<td>12</td>
<td>12</td>
<td>0.31</td>
</tr>
<tr>
<td><strong>hypertension</strong></td>
<td>20</td>
<td>18</td>
<td>0.31</td>
</tr>
<tr>
<td><strong>Ischaemia heart disease</strong></td>
<td>11</td>
<td>11</td>
<td>0.28</td>
</tr>
<tr>
<td><strong>Diabetes Mellitus</strong></td>
<td>6</td>
<td>4</td>
<td>0.41</td>
</tr>
<tr>
<td><strong>AVF</strong></td>
<td>13</td>
<td>15</td>
<td>0.31</td>
</tr>
<tr>
<td><strong>AVG</strong></td>
<td>7</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><strong>History of intervention</strong></td>
<td>16</td>
<td>14</td>
<td>0.33</td>
</tr>
</tbody>
</table>
## Target lesion characteristics

<table>
<thead>
<tr>
<th></th>
<th>DEB (n=20)</th>
<th>POBA (n=20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target lesion location</td>
<td></td>
<td></td>
<td>0.20</td>
</tr>
<tr>
<td>Juxta and arteriovenous anastomosis</td>
<td>6</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Cannulation zone</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Venous outflow</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>graft</td>
<td>4</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Venous graft anastomosis</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Target lesion % stenosis</td>
<td>69.8% +/- 15.8</td>
<td>69.5% +/- 13.6</td>
<td>0.95</td>
</tr>
<tr>
<td>Target lesion length (mm)</td>
<td>45.8 +/- 38.4</td>
<td>50.2 +/- 33.5</td>
<td>0.70</td>
</tr>
</tbody>
</table>
Result at 6-month

• Technical success 90%
• Clinical success 100% in DCB group; 95% in POBA group
  • Patient developed acute thrombosis 1 week after intervention require with open thrombectomy performed
• Primary patency at 6-month
  • DCB group 90% Vs POBA group 55% (p= 0.008)
• Secondary patency at 6 months
  • DCB group 95% vs POBA group 80% (p=0.034)
Preliminary 6-month result in our study

• Drug balloon angioplasty 1\textsuperscript{st} approach may provide better circuit patency at 6-month as shown in our non-sponsor double blinded randomized trial

• Cost effectiveness evaluation may provide more evidence to support the re-imbursement policy
Conclusion

• Drug eluting balloon provides better outcome in failing vascular access
  • DCB 1st approach for both failing AVG/AVF
  • For recurrent AVF stenosis
  • For stented or unstented fistula

• Regular surveillance of vascular access is essential
Drug coated balloon for failing vascular access

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