Long term results of >200 patients with the Aperto® DCB from the Italian Aperto registry

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Disclosure

Speaker name: Matteo Tozzi

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
Systematic review of drug eluting balloon angioplasty for arteriovenous haemodialysis access stenosis.

Khawaja AZ, Cassidy DB, Al Shakarchi J, McGrogan DG, Inston NG, Jones RG

Six studies reported on 254 interventions in 162 participants.

At 6 months TL PP was reported between 70% to 97% for DeBs in the RCTs and cohort studies, and 0% to 26% for non-DeBs.

TLs treated with DeBs were associated with a higher primary patency at 6 months as compared to non-DeB balloons.

APERTO
ITALIAN
REGISTRY
2014- 2017
Centres involved

4 centres:

- M. Tozzi, Vascular Surgery, Varese
- L. Carbonari, Vascular Surgery, Ancona
- F. Benedetto, Vascular Surgery, Messina
- D. Savio, Radiology, Torino
APERTO® OTW
THE NEW GENERATION OF PACLITAXEL COATED
HIGH PRESSURE SHUNT BALLOON DILATATION CATHETER

0.1 μm
invisible nano small
PTX particle size.

CARDIONOVUM®
Life deserves the best
APERTO ITALIAN REGISTRY

# ETHIC COMETEE: 7924352

STUDY DESIGN: registry, nonrandomized prospective clinical trial

OBJECTIVE: demonstrate efficacy of the DCB in a real – world scenario

PRIMARY END-POINT: primary patency TL, critical restenosis TL 12-24

SECONDARY END-POINT: secondary patency

COHORT: all critical stenosis detected during surveillance (according to NKF) aVA and pVA, stenosis with malfunctioning of Vascular access during HD

mean follow-up: 21+/- 8 months (range 2 – 37).
mean follow-up index*: 0.86

Clinical & DUS evaluation: 3-mth

*Completeness of Follow-Up Determines Validity of Study Findings: Results of a Prospective Repeated Measures Cohort Study
Von Allmen RS, Weiss S, Tevaearai HT, Kuemmerli C, Tinner C, Carrel TP, Schmidli J, Dick
PLoS One. 2015;10(10):e0140817

INDEX OF FOLLOW-UP = FOLLOW-UP COVERED BY STUDY / POTENTIAL FOLLOW-UP DURATION
Demographic Data and Risk factors:

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>(%)</th>
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<tbody>
<tr>
<td>CVD</td>
<td>60.5</td>
</tr>
<tr>
<td>hypertension</td>
<td>38.3</td>
</tr>
<tr>
<td>diabetes</td>
<td>34.6</td>
</tr>
<tr>
<td>smoking</td>
<td>23.5</td>
</tr>
<tr>
<td>IHD</td>
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<tr>
<td>COPD</td>
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<table>
<thead>
<tr>
<th>male</th>
<th>121 (55.7%)</th>
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<tbody>
<tr>
<td>age, (years ± SD)</td>
<td>68± 13</td>
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results

Tot: 328 DCB angioplasty – 217 stenosis – 111 restenosis during the follow-up

aVA: 93 (42.8%)
  venous side: 45 (48.3%)
  perianastomotyc: 48 (51.7%)

pVA: 124 (57.2%)
  venous anastomosis: 65 (52.4%)
  venous outflow: 43 (34.6%)
  prosthesis: 12 (9.6%)
  arterial anastomosis: 4 (3.2%)

Ninety-eight (49.0%) VA were created more than 1 year before stenosis treatment.

Fifty-one (25.5%) lesions had been treated yet with conventional angioplasty during the previous year.

Complication: Acute circuit thrombosis 4 (1.2%); vein rupture 3 (0.9%)
VA abbandonment: 15 (6.9%)
Mortality rate: 7.2 %
Kaplan – Meier estimator of free from restenosis (TL PP) after DEB angioplasty

Estimation of the survival documented that 88.0%, 64.2%, 40.6% of the lesions treated were free from restenosis at 6, 12, 24 months respectively.
Kaplan – Meier estimator of Secondary Patency (TL)

TL patency considering multiple angioplasty was 99.2%, 92.5%, 84.8% at 6, 12, 24 and 36 months respectively.
Kaplan – Meier estimator of risk of restenosis
Recurrent vs Denovo stenosis

P < 0.001
Kaplan – Meier estimator of free from restenosis (TL PP)

Recurrent vs Denovo stenosis

DCB shall not be a second option, but first line treatment for all VA stenosis
Recurrence of NH > 36 m is irreversible……..

BUT……. WITH DCB

Low % restenosis

Saving Vessel assets

Prolong Life of VA

Low number retreatment Endovasc/Surg
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