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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.**

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

J Vasc Access. 2016 Mar 9;17(2):103-10.



APERTO
ITALIAN
REGISTRY
2014- 2017

Centres involved

4 centres:



D. Savio
Radiology
Torino



M. Tozzi
Vascular Surgery
Varese



L. Carbonari
Vascular Surgery
Ancona



F. Benedetto
Vascular Surgery
Messina



APERTO[®] OTW

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0,1 μm
invisible nano small
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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

follow-up efficacy



COHORT: 217 pts (sept. 2014- dic 2017)

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:

male	121 (55,7%)
age, (years \pm SD)	68 \pm 13
Risk factors	(%)
CVD	60.5
hypertension	38.3
diabetes	34.6
smoking	23.5
IHD	34.6
COPD	17.3

results

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

aVA: 93 (42.8%)

venous side: 45 (48.3%)

perianastomotic: 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%)

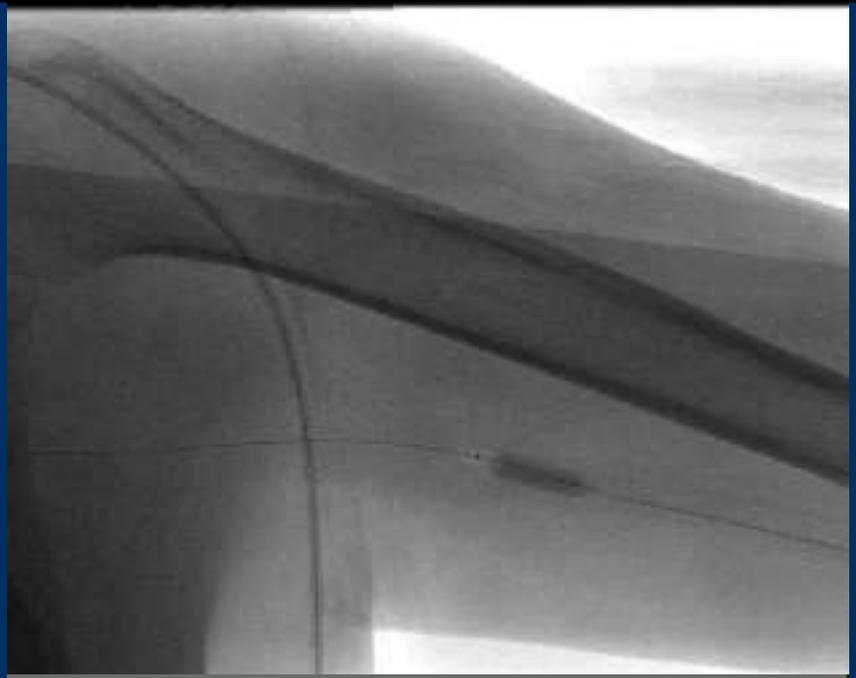
Ninety-eight (49.0%) VA were created more than 1 year before stenosis treatment.

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

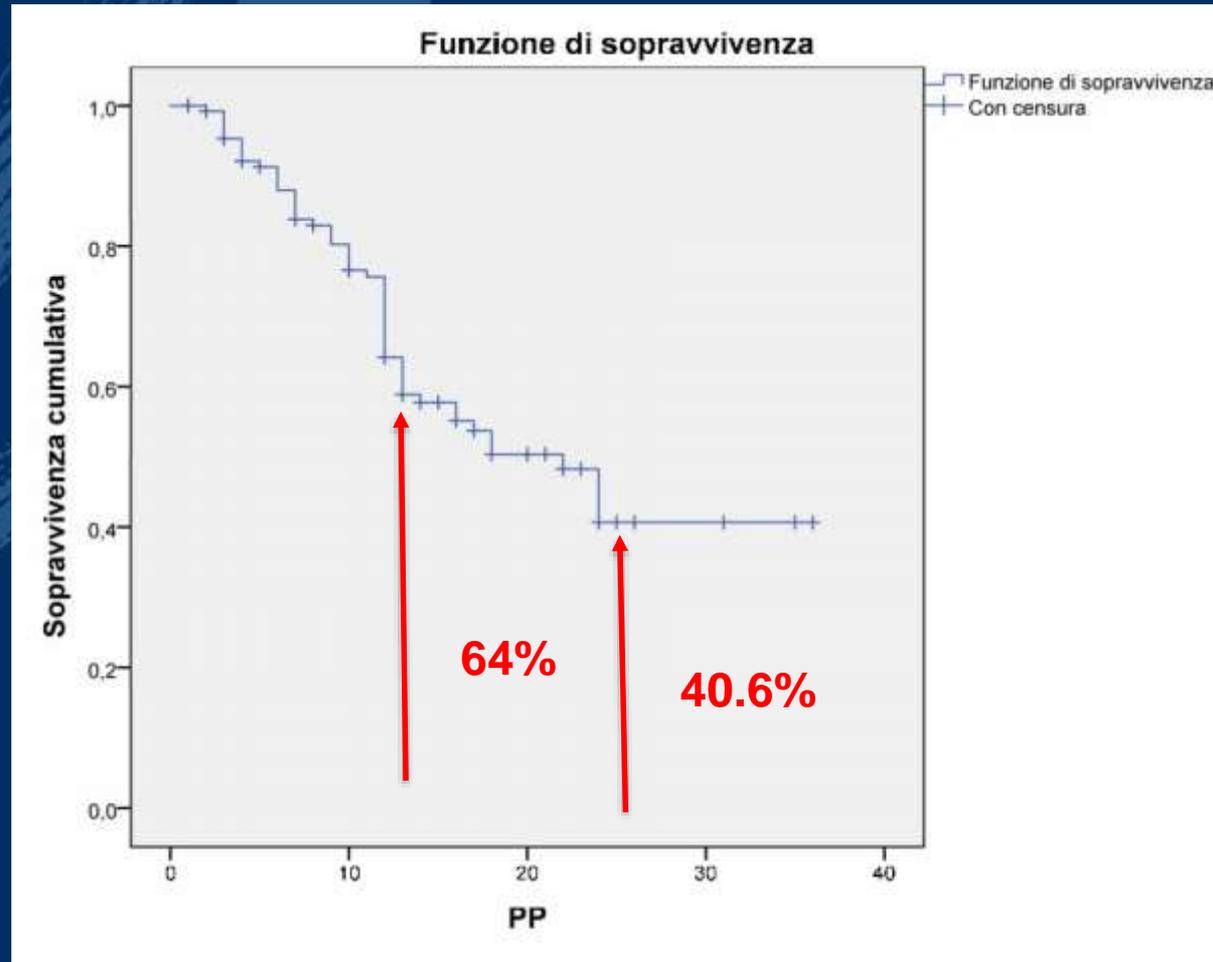
Complication: Acute circuit thrombosis 4 (1.2%); vein rupture 3 (0.9%)

VA abandonment: 15 (6.9%)

Mortality rate: 7.2 %

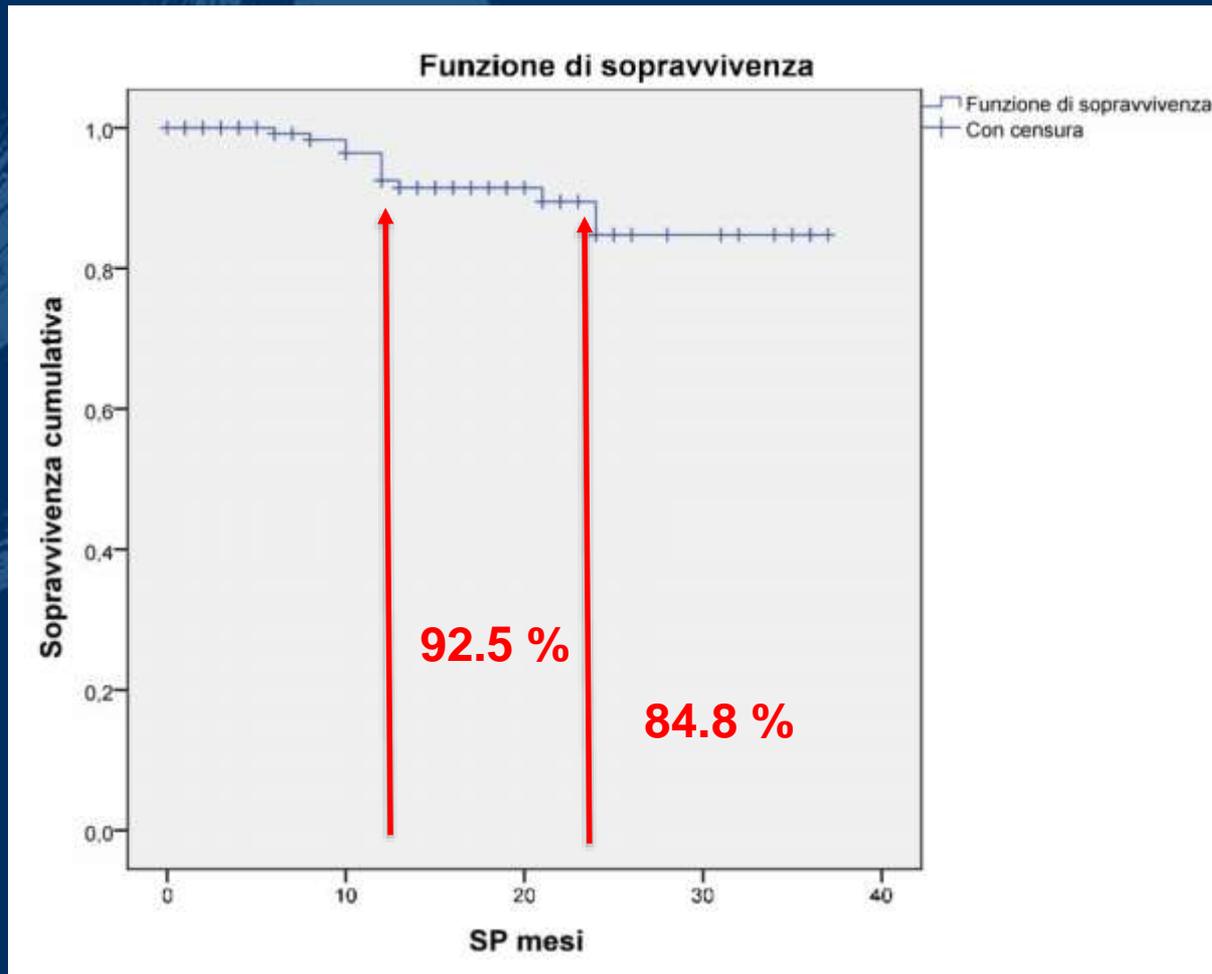


Kaplan – Meier estimator of free from restenosis (TL PP) after DEB angioplasty



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

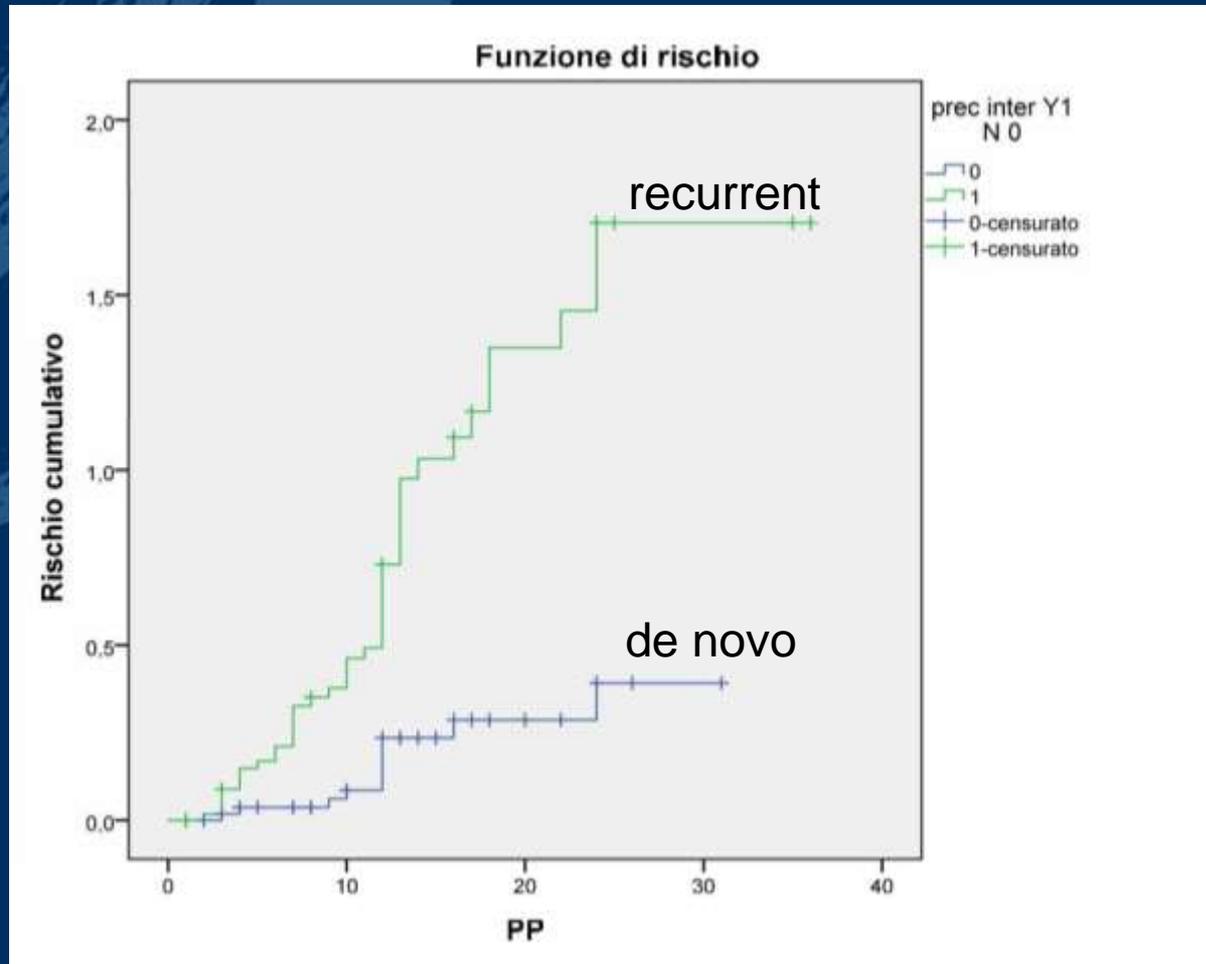
Kaplan – Meier estimator of Secondary Patency (TL)



TL patency considering multiple angioplasty was 99.2%, 92.5%, 84.8% at 6, 12, 24 and 36 months respectively.

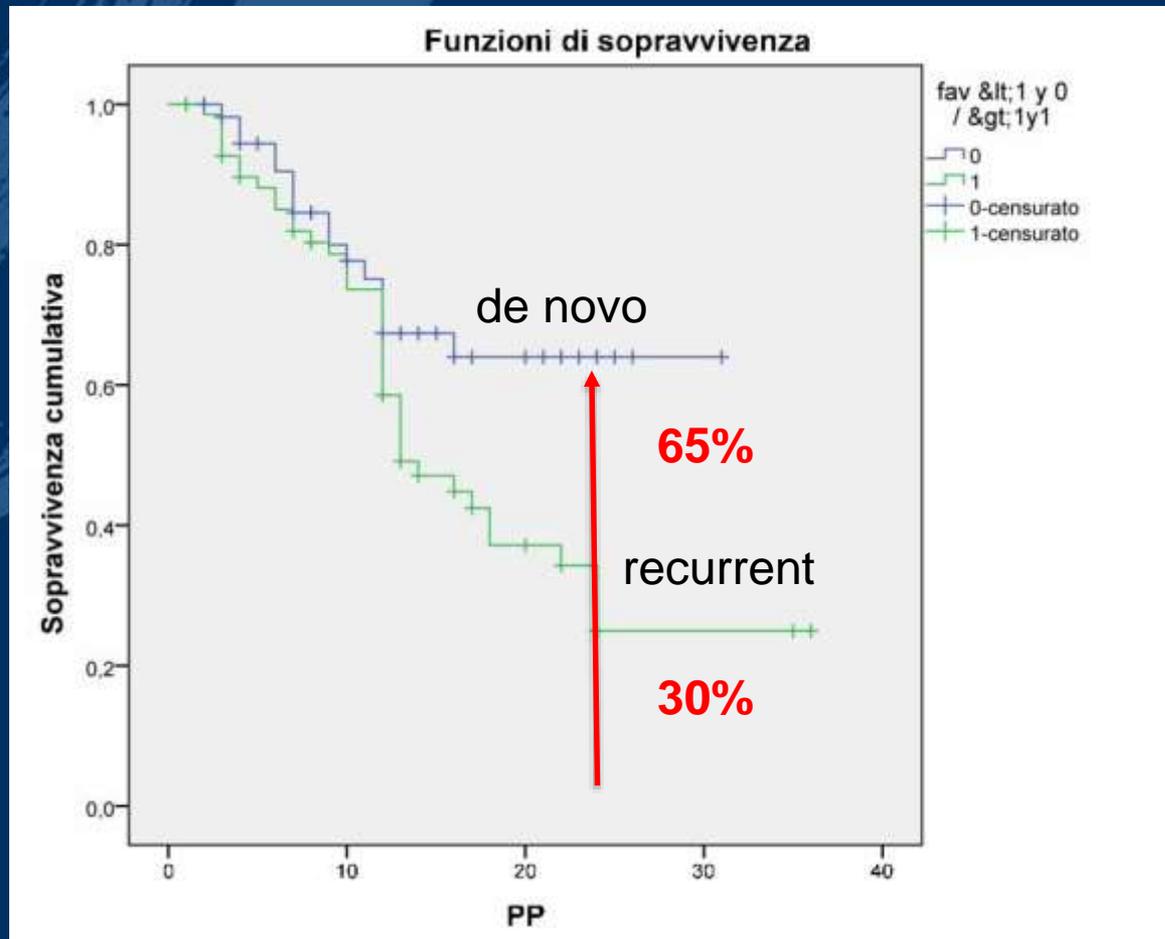
Kaplan – Meier estimator of risk of restenosis

Recurrent vs De novo stenosis



$P < 0.001$

Kaplan – Meier estimator of 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

final remarks:

Recurrence of NH > 36 m is irreversible.....



BUT..... WITH DCB

Low % restenosis

Low number
retreatment
Endovasc/Surg

Saving Vessel assets

Prolong Life of VA



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