

# Two year mortality post DEB and plain balloon angioplasty: pooled primary data analysis of 4 RCTs

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# Disclosure

Speaker name:

Thomas Albrecht

I have the following potential conflicts of interest to report:

- Consulting: B. Braun, Boston Scientific, Med Alliance, Olympus
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I  not have any potential conflict of interest

# Background

SYSTEMATIC REVIEW AND META-ANALYSIS



## Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

Konstantinos Katsanos, MD, PhD, MSc, EBIR; Stavros Spiliopoulos, MD, PhD; Panagiotis Kitrou, MD, PhD; Miltiadis Krokidis, MD, PhD; Dimitrios Karnabatidis, MD, PhD

2 year mortality, 12 studies, 2316 pat.:

DEB/DES (Paclitaxel): 101 / 1397 (7.2%)

Control (no Paclitaxel): 35 / 919 (3.5%)  $p < 0.05$

# Purpose

To investigate the 2 year mortality post Paclitaxel-DEB and plain balloon angioplasty based on a pooled *primary data analysis* of 4 RCTs: THUNDER, FEMPAC, PACIFIER, CONSEQUENT

ORIGINAL ARTICLE

## Local Delivery of Paclitaxel to Inhibit Restenosis during Angioplasty of the Leg

Gunnar Tepe, M.D., Thomas Zeller, M.D., Thomas Albrecht, M.D., Stephan Heller, M.D., Uwe Schwarzwälder, M.D., Jean-Paul Beregi, M.D., Claus D. Claussen, M.D., Anja Oldenburg, M.D., Bruno Scheller, M.D., and Ulrich Speck, Ph.D.

## Paclitaxel-Coated Balloons Reduce Restenosis After Femoro-Popliteal Angioplasty

### Evidence From the Randomized PACIFIER Trial

Michael Werk, MD; Thomas Albrecht, MD; Dirk-Roelfs Meyer, MD; Mohammed Nabil Ahmed, MD; Andrea Behne, MD; Ulrich Dietz, MD; Götz Eschenbach, MD; Holger Hartmann, MD; Christian Lange, MD; Beatrix Schnorr, DVM; Heiner Stiepani, MD; Giuseppe Biondi-Zoccai, MD; Enrique Lopez Hänninen, MD

## Inhibition of Restenosis in Femoropopliteal Arteries Paclitaxel-Coated Versus Uncoated Balloon: Femoral Paclitaxel Randomized Pilot Trial

Michael Werk, MD; Soenke Langner, MD; Bianka Reinkensmeier, MS; Hans-Frank Boettcher, MD; Gunnar Tepe, MD; Ulrich Dietz, MD; Norbert Hosten, MD; Bernd Hamm, MD; Ulrich Speck, PhD; Jens Ricke, MD

## Two-Year Clinical Outcomes of the CONSEQUENT Trial: Can Femoropopliteal Lesions be Treated with Sustainable Clinical Results that are Economically Sound?

Thomas Albrecht<sup>1</sup> · Matthias Walliszewski<sup>2,3</sup> · Catherine Roca<sup>4,5</sup> · Ulf Redlich<sup>6</sup> · Jörg Tautenhahn<sup>6</sup> · Maciej Pech<sup>7</sup> · Zuhir Halloul<sup>8</sup> · Özlem Gögebakan<sup>1</sup> · Dirk-Roelfs Meyer<sup>9</sup> · Ines Gemeinhardt<sup>10</sup> · Thomas Zeller<sup>11</sup> · Stefan Müller-Hülsbeck<sup>12</sup> · Ilka Ott<sup>13</sup> · Gunnar Tepe<sup>14</sup>

# Methods

- Analysis of mortality based original data of 2 year follow-up of THUNDER, FEMPAC, PACIFIER and CONSEQUENT
- Causes of death
- Logistic regression of predictors of 2 year mortality (dependent variable)

# Patients with clinical 2 year follow-up

Study	N pat. included		N pat. with 2 year FU	
	Control	DCB	Control	DCB
THUNDER	54	46	49	43
FEMPAC	36	37	29	32
PACIFIER	44	41	42	39
CONSEQUENT	75	78	65	70
<b>Pooled</b>	<b>209</b>	<b>202</b>	<b>185</b> 88.5%	<b>184</b> 91.1%

# 2 year Mortality

Study	Control		DEB	
	Died	Mortality	Died	Mortality
THUNDER	5 / 49	10%	6 / 43	14%
FEMPAC	3 / 29	10%	6 / 32	19%
PACIFIER	4 / 42	10%	2 / 39	5%
CONSEQUENT	1 / 65	2%	2 / 70	3%
<b>Pooled</b>	<b>13 / 185</b>	<b>7.0%</b>	<b>16 / 184</b>	<b>8.7%</b>

**NS (p = 0.55)**

# Causes of death

	<b>Control</b>	<b>DEB</b>
Heart failure	3	3
Cardiac arrhythmia	1	1
Acute MI	1	1
Malignancy	2	3
Sepsis	2	0
Other	2	5
Unknown	2	3
All	13	16



# Logistic regression of possible predictors of mortality

Variable in logistic regression model	p-value
Treatment group DEB vs. control	0,53
Age $\geq$ 75 years	0,03
Gender	0,12
Diabetes	0,86
Hypertension	0,27
Smoking	0,75
Hypercholesteremia	0,75
Coronary artery disease	0,70
Cerebro-vascular disease	0,97
Critical limb ischemia	0,18
Occlusion	0,33
Lesion calcification	0,50
Lesion length	0,94

# Conclusion

- No significant difference in mortality between DEB and control in pooled primary data analysis of 4 RCTs
- No obvious patterns of causes of death
- The only predictor of mortality in regression analysis was patient age ( $P = 0.03$ ).
- The use of DEB was no predictor of mortality ( $p = 0.53$ )

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