

# DEB versus POBA for postdilatation after SFA stenting – the FREEWAY trial

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# Disclosure

Speaker name:

Johannes Lammer

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Lecture honorarium from Eurocor GmbH
  
- I do not have any potential conflict of interest

# Study Design & Methods

- Multicenter, prospective randomized study
- 200 patients with symptomatic lesions of the SFA and PI-segment
- Randomization 1:1
- 15 German & Austrian centers
- Independent, blinded corelab

# Endpoints

## *Primary endpoint*

- Clinically driven TLR at 12 months follow-up

## *Secondary endpoints*

- Change in Rutherford clinical improvement at 6 and 12 months
- Change of ABI at 6 and 12 months
- Primary patency rate at 6 and 12 months
- Major adverse events at 1, 6 and 12 months

# Main Study Criteria

## *Inclusion criteria*

- SFA and PI stenosis or occlusion
- Rutherford 2 – 5
- Lesion length  $> 4$  and  $\leq 15$  cm

## ➤ *Exclusion criteria*

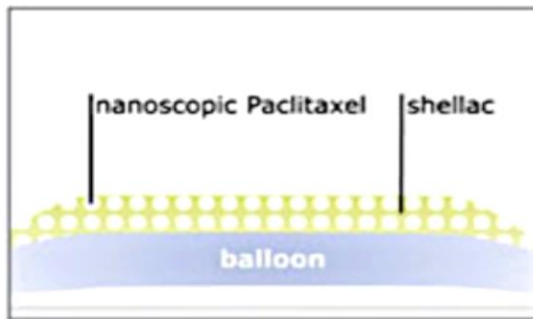
- Previous bypass or stenting of target vessel
- Significant inflow to the target vessel treated in last 6 months
- No patent outflow vessel

## Study device:

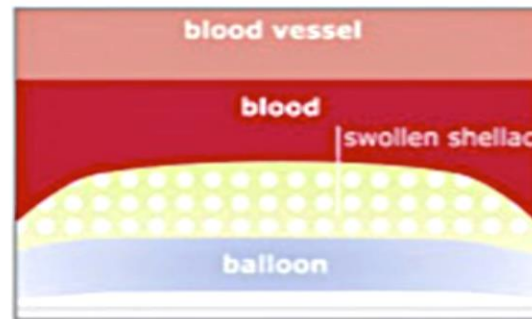
FREEWAY<sup>®</sup> 035" Paclitaxel eluting balloon (Eurocor GmbH).

Balloon coating: shellac matrix composed of shellolic and alleuritic acid. In contact with body liquid the hydrophilic shellac-network swells and opens for the pressure-induced release of Paclitaxel.

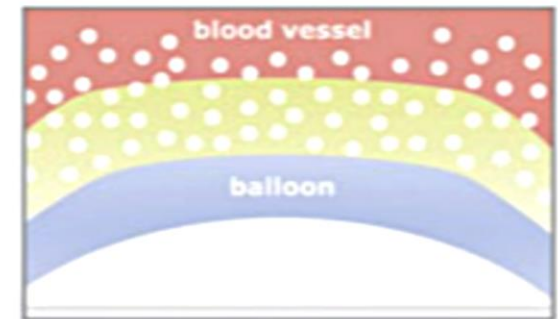
Drug: Paclitaxel 3  $\mu\text{g}/\text{mm}^2$ .



coated balloon deflated

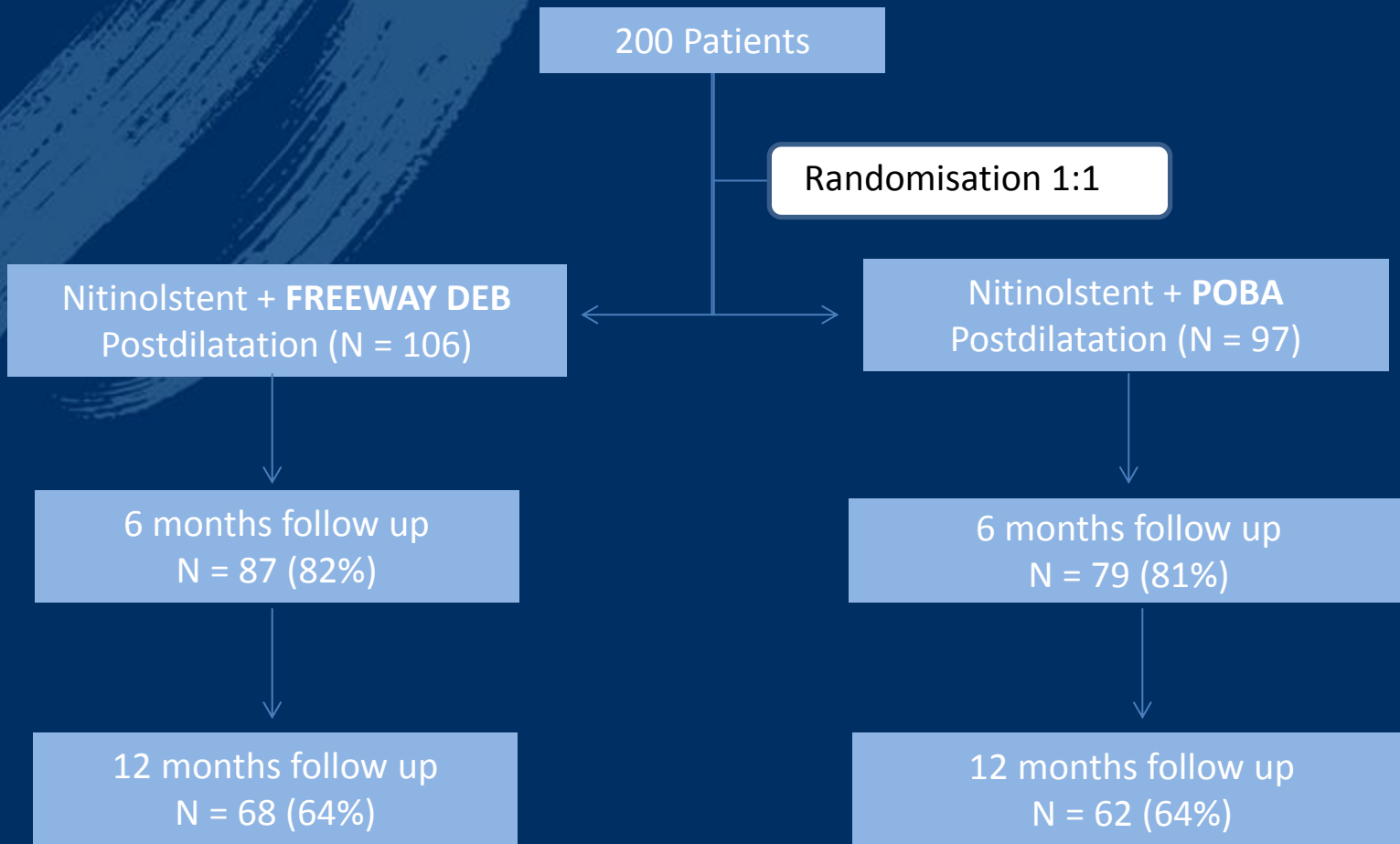


in contact with blood



inflated balloon allows freed Paclitaxel to enter the vessel wall

# Flow Chart



# Baseline Demographics

	<b>FREEWAY DCB</b>	<b>POBA</b>	<b>p-value</b>
	<b>N = 106</b>	<b>N = 97</b>	<b>(ns &gt; 0.05)</b>
<b>Male</b>	<b>78.3 %</b>	<b>76.3 %</b>	<b>ns</b>
<b>Age</b>	<b>64.9 ± 9.5 yrs</b>	<b>64.3 ± 9.8 yrs</b>	<b>ns</b>
<b>Diabetes Mellitus</b>	<b>25.5 %</b>	<b>25.8 %</b>	<b>ns</b>
<b>History of PAD</b>	<b>36.8 %</b>	<b>44.3 %</b>	<b>ns</b>
<b>History of CAD</b>	<b>24.5 %</b>	<b>23.7 %</b>	<b>ns</b>
<b>Smoking</b>	<b>86.8 %</b>	<b>81.4 %</b>	<b>ns</b>
<b>Hyperlipidemia</b>	<b>59.4 %</b>	<b>59.8 %</b>	<b>ns</b>
<b>Hypertension</b>	<b>73.6 %</b>	<b>72.2 %</b>	<b>ns</b>



# Baseline Clinical Status

		<b>FREEWAY DCB</b> N = 102/106	<b>POBA</b> N = 94/97	<b>p-value</b> (ns > 0.05)
<b>ABI</b>	<b>1.0-&gt;1.2</b>	<b>4.9 %</b>	<b>4.2 %</b>	<b>ns</b>
	<b>0.9 – 1.0</b>	<b>3.9 %</b>	<b>1.1 %</b>	<b>ns</b>
	<b>0.5 – 0.9</b>	<b>69.6 %</b>	<b>73.4 %</b>	<b>ns</b>
	<b>&lt; 0.5</b>	<b>21.6 %</b>	<b>21.3 %</b>	<b>ns</b>
<b>Rutherford</b>	<b>2</b>	<b>25.5 %</b>	<b>28.9 %</b>	<b>ns</b>
	<b>3</b>	<b>67.9 %</b>	<b>64.9 %</b>	<b>ns</b>
	<b>4</b>	<b>1.9 %</b>	<b>2.1 %</b>	<b>ns</b>
	<b>5</b>	<b>4.7 %</b>	<b>2.1 %</b>	<b>ns</b>

# Baseline Lesion Characteristics

		<b>FREEWAY DCB</b> N = 106	<b>POBA</b> N = 97	<b>p-value</b> (ns > 0.05)
Lesion location	SFA prox	4.7 %	4.1 %	ns
	SFA mid	50.0 %	47.4 %	ns
	SFA distal	43.4 %	48.5 %	ns
	PI	1.9 %	0.0 %	ns
<b>Lesion length</b>	<b>8.2 ± 3.7 cm</b>	<b>8.3 ± 4.3 cm</b>	<b>ns</b>	
Diameter stenosis	94.4 %	95.5 %	ns	
<b>Total occlusion</b>	<b>63.2 %</b>	<b>66.0 %</b>	<b>ns</b>	
Ref. vessel diameter	5.2 ± 0.8 mm	5.1 ± 0.7 mm	ns	
Infrapopliteal patent vessels	1	8.5 %	14.4 %	ns
	2	24.5 %	33.0 %	ns
	3	67.0 %	52.6 %	0.045

# Baseline Procedural Data

	<b>FREEWAY DCB</b> N = 106	<b>POBA</b> N = 97	<b>p-value</b> (ns > 0.05)
<b>Predilatation</b>	<b>74.5 %</b>	<b>69.1 %</b>	<b>ns</b>
<b>Stent</b>			
<b>Length</b>	<b>9.8 ± 3.7 cm</b>	<b>9.8 ± 3.5 cm</b>	<b>ns</b>
<b>Diameter</b>	<b>6.2 ± 0.7 mm</b>	<b>6.3 ± 0.6 mm</b>	<b>ns</b>
<b>Postdilatation study balloon</b>			
<b>Length</b>	<b>87.5 ± 27.3 mm</b>	<b>78.9 ± 24.5 mm</b>	<b>ns</b>
<b>Diameter</b>	<b>5.3 ± 0.6 mm</b>	<b>5.4 ± 0.6 mm</b>	<b>ns</b>
<b>Inflation time total procedure</b>	<b>163.6 ± 65.9 sec</b>	<b>114.2 ± 54.4 sec</b>	<b>&lt; 0.001</b>
<b>Inflation time study device</b>	<b>108.4 ± 65.9 sec</b>	<b>78.1 ± 54.4 sec</b>	<b>&lt; 0.001</b>
<b>Inflation pressure study device</b>	<b>9.0 ± 2.1 atm</b>	<b>8.7 ± 1.7 atm</b>	<b>ns</b>
<b>2nd study balloon used</b>	<b>50.9 %</b>	<b>45.4 %</b>	<b>ns</b>

# Primary patency rate

	<b>FREEWAY DEB</b>	<b>POBA</b>	<b>p-value</b>
<b>6-month</b>	<b>N = 85</b>	<b>N = 77</b>	
	<b>89.4 %</b>	<b>72.7 %</b>	<b>0.008</b>
<b>12-month</b>	<b>N = 62</b>	<b>N = 60</b>	
	<b>74.2 %</b>	<b>68.3 %</b>	<b>ns*</b>

\* Preliminary result because incomplete follow-up (64%)

# Clinically driven -TLR

	<b>FREWAY DCB</b>	<b>POBA</b>	<b>p-value</b>
<b>6-month</b>	<b>N = 87</b> <b>4.6 %</b>	<b>N = 79</b> <b>10.1 %</b>	<b>ns*</b>
<b>12-month</b>	<b>N = 70</b> <b>8.6 %</b>	<b>N = 61</b> <b>16.4 %</b>	<b>ns*</b>

\* Preliminary result because incomplete follow-up (64%)

# Rutherford clinical improvement 12-Month

Shift in Rutherford from baseline	Freeway DCB N = 68	POBA N = 62	p-value (ns > 0.05)
-1	0.0 %	12.9 %	0.002
0	5.9 %	12.9 %	ns
+1	10.3 %	9.7 %	ns
+2	30.9 %	24.2 %	ns
+3	48.5 %	38.7 %	ns
+4	2.9 %	1.6 %	ns
+5	1.5 %	0.0 %	ns
≥ 1	94.1 %	74.2 %	0.003

# Conclusion

The preliminary 12-month data (64% follow-up) demonstrated in TASC A+B SFA lesions:

- A significant higher patency rate at 6-month for the DEB (89.4%), however, currently not at 12-month
- No significant difference in TLR (DEB 8.6%, POBA 16.4%)
- A significant higher improvement of  $\geq 1$  of Rutherford clinical category in the DEB arm (94.1% vs. 74.2%)

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