The BATTLE Trial

Comparing Bare Metal to Drug Eluting Stents for Intermediate Length Lesions of the SFA

BATTLE RCT investigators:

BATTLE ClinicalTrials.gov number, NCT02004951
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Disclosure
Speaker name: Yann Gouëffic

I have the following potential conflicts of interest to report:

Receipt of grants/research support
Details: Abbott; Bard; Medtronic; Terumo; WL Gore

Receipt of honoraria and travel support
Details: Abbott; Bard; Boston Sc; Cook; Medtronic; Perouse; Spectranetics

Employment in industry
Details: /

Shareholder in a healthcare company
Details: /

Owner of a healthcare company
Details: /

I do not have any potential conflicts of interest to report
Previous and recent RCTs compared to POBA

VIENNA, RESILIENT, ZILVER PTX, INPACT SFA, LEVANT 2, ILLUMINATE…

POBA is not the standard of care anymore

BATTLE trial

French multicentric randomized clinical trial comparing MISAGO vs. ZILVER PTX for the treatment of intermediate femoropopliteal lesions
(from February 2014 to September 2018)

10 centers: Clinique d'Antony (Jean-Marc PERNES); CHU de Besançon (Simon RINCKENBACH); CHU de Bordeaux (Eric DUCASSE); CHU de Clermont Ferrand (Eugenio ROSSET); AP-HP, Hôpital Henri Mondor (Pascal DESGRANGES); CHU de Lyon (Patrick FEUGIER); CH de Bourgouin (Patrick LERMUSIAUX); Clinique Ollioules (Philippe COMMEAU); CHU de Rennes (Alain CARDON); Clinique Pasteur (Antoine SAUGUET); CHU de Nantes (Yann GOUËFFIC)

Sponsor Nantes University Hospital
BATTLE ClinicalTrials.gov number, NCT02004951
**BATTLE trial protocol**

*Sponsor Nantes University Hospital - BATTLE ClinicalTrials.gov number, NCT02004951*

- Investigator initiated study
- RCT multicenter and controlled
- Sample size calculation: 186 patients
- Rigorous data collection process, independent
- Adjudication by:
  - *Duplex ultrasound core laboratory*
  - *Clinical events committee*
  - *Data safety monitoring board*
- Follow-up includes
  - 1, 6, 12, and 24-month clinical assessment
  - 1, 12 and 24-month stent x-ray
- Monitoring with 100% source data verification
BATTLE objective

To demonstrate the clinical superiority of primary stenting using Zilver PTX stent system versus bare metal self-expandable stenting in the treatment of intermediate length femoropopliteal lesions in patients with symptomatic peripheral arterial disease (Rutherford 2-5).

BATTLE primary endpoint

Freedom from in-stent restenosis @ 1 year

*Defined by restenosis of >50% and by a peak systolic velocity index >2.4 at the target lesion. Assessment by an independent core laboratory*
Study devices
(BATTLE interim analysis)

Zilver PTX® (Cook)
- Self expendable nitinol stent with a polymer-free paclitaxel coating
  - Paclitaxel, a cytotoxic drug
  - Over-the-wire system

Misago® (Terumo)
- Flexible stent design
- Moderate radial force
  - RX system
- One hand operation
- Accurate deployment
Key eligible criteria
(BATTLE 6-month outcomes interim analysis)

Main inclusion criteria
- Rutherford stages 2-5
- De novo atherosclerotic lesions (stenosis and/or occlusion) of the SFA, the proximal popliteal artery (P1), or both
- Target lesion has a length $\geq$2-cm and $\leq$14-cm
- RVD 4 to 7-mm

Main exclusion criteria
- Asymptomatic lesion
- Restenosis
- No atheromatous disease
186 were included
  5 not randomized
    -2 have exclusion criteria
    -3 were doubleloon error

181 underwent randomization

Group A (91)
  84 underwent assigned intervention
  80 completed 6-month follow-up

Group B (90)
  85 underwent assigned intervention
  82 completed 6-month follow-up
### Demographic Data

(BATTLE 6-month outcomes interim analysis)

<table>
<thead>
<tr>
<th></th>
<th>Group A (N= 84)</th>
<th>Group B (N=85)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (y)</strong></td>
<td>67±12</td>
<td>70±12</td>
</tr>
<tr>
<td><strong>Sex ♂, n (%)</strong></td>
<td>61 (73)</td>
<td>61 (72)</td>
</tr>
<tr>
<td><strong>Smoking, n (%)</strong></td>
<td>28 (33)</td>
<td>20 (24)</td>
</tr>
<tr>
<td><strong>Hypertension (%)</strong></td>
<td>51 (61)</td>
<td>58 (68)</td>
</tr>
<tr>
<td><strong>Diabetes mellitus (%)</strong></td>
<td>22 (26)</td>
<td>40 (47)</td>
</tr>
<tr>
<td><strong>Dyslipidemia (%)</strong></td>
<td>60 (71)</td>
<td>54 (63)</td>
</tr>
<tr>
<td><strong>Renal failure (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CAD (%)</strong></td>
<td>34 (40)</td>
<td>27 (32)</td>
</tr>
<tr>
<td><strong>Statines (%)</strong></td>
<td>60(71)</td>
<td>57(67)</td>
</tr>
<tr>
<td><strong>Antiplatelet drug (%)</strong></td>
<td>73(87)</td>
<td>71(84)</td>
</tr>
<tr>
<td><strong>ACE inhibitors (%)</strong></td>
<td>26(31)</td>
<td>18(21)</td>
</tr>
</tbody>
</table>

Claudication: group A: 82% / group B: 80%
Baseline angiographic data  
(BATTLE 6-month outcomes interim analysis)

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N= 84)</td>
</tr>
<tr>
<td>Mean lesion length (cm)</td>
<td>70 ± 40</td>
</tr>
<tr>
<td>Reference vessel diameter (mm)</td>
<td>5.7 ± 0.6</td>
</tr>
<tr>
<td># of patent run-off vessel</td>
<td></td>
</tr>
<tr>
<td>...1</td>
<td>13 (15)</td>
</tr>
<tr>
<td>...2</td>
<td>12(14)</td>
</tr>
<tr>
<td>...3</td>
<td>59 (70)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N=85)</td>
</tr>
<tr>
<td>Mean lesion length (cm)</td>
<td>65 ± 35</td>
</tr>
<tr>
<td>Reference vessel diameter (mm)</td>
<td>5.8 ± 0.7</td>
</tr>
<tr>
<td># of patent run-off vessel</td>
<td></td>
</tr>
<tr>
<td>...1</td>
<td>11 (13)</td>
</tr>
<tr>
<td>...2</td>
<td>27 (32)</td>
</tr>
<tr>
<td>...3</td>
<td>47 (55)</td>
</tr>
</tbody>
</table>
# Procedural characteristics

* (BATTLE 6-month outcomes interim analysis)

<table>
<thead>
<tr>
<th></th>
<th>Group A (n= 84)</th>
<th>Group B (n=85)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-dilatation performed (%)</td>
<td>70 (83)</td>
<td>68 (80)</td>
</tr>
<tr>
<td>Number of implanted stents (%)</td>
<td>101</td>
<td>116*</td>
</tr>
<tr>
<td>...1</td>
<td>67 (80)</td>
<td>56 (65)</td>
</tr>
<tr>
<td>...2</td>
<td>17 (20)</td>
<td>27 (32)</td>
</tr>
<tr>
<td>...3</td>
<td>0(0)</td>
<td>2(2)</td>
</tr>
<tr>
<td>Stents localisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>...Proximal SFA</td>
<td>14</td>
<td>10</td>
</tr>
<tr>
<td>...Mid SFA</td>
<td>54</td>
<td>56</td>
</tr>
<tr>
<td>...Distal SFA</td>
<td>44</td>
<td>45</td>
</tr>
<tr>
<td>...P1</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Mean stent length (per stent)</td>
<td>91±41 (40-150)</td>
<td>72±26 (40-150)</td>
</tr>
<tr>
<td>Mean stent length (per patient)</td>
<td>90,7±38,2 (40-150)</td>
<td>70,4±22,1 (40-105)</td>
</tr>
<tr>
<td>Diameter 6</td>
<td>74</td>
<td>86</td>
</tr>
<tr>
<td>Post dilatation performed</td>
<td>72(86)</td>
<td>79 (93)</td>
</tr>
<tr>
<td>Concomitant ipsilateral endo repair (%)</td>
<td>16(19)</td>
<td>19(22)</td>
</tr>
<tr>
<td>Intraoperative complications (%)</td>
<td>8(10)</td>
<td>5(6)</td>
</tr>
</tbody>
</table>
Cumulative safety data @ 6 months
*(BATTLE 6-month outcomes interim analysis)*

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death (%)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Rehospitalization (%)</td>
<td>12 (2)</td>
<td>12(6)</td>
</tr>
<tr>
<td>Major amputation (%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Reintervention of the target lesion (%)</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
Clinical outcomes @ 6 months
(BATTLE 6-month outcomes interim analysis)

Baseline

Group A
- CLI: 18%
- Rutherford 0%: 65%
- Rutherford 1%: 17%
- Rutherford 2%: 4%

Group B
- CLI: 20%
- Rutherford 0%: 61%
- Rutherford 1%: 19%
- Rutherford 2%: 7%

6 months

Group A
- CLI: 1%
- Rutherford 0%: 9%
- Rutherford 1%: 24%
- Rutherford 2%: 9%

Group B
- CLI: 2%
- Rutherford 0%: 13%
- Rutherford 1%: 20%
- Rutherford 2%: 13%

CLI: 18% / 20%
CLI: 1% / 2%
Cumulative morphological data @ 1 month
(BATTLE 6-month outcomes interim analysis)

In-stent restenosis: N=8
- Group A: n=6
- Group B: n=2

Thrombosis: N=13
- Group A: n=6
- Group B: n=7

*In-stent restenosis is defined by restenosis > 50% and by a peak systolic velocity (PSV) ratio > 2.4 at the lesion site.
Hemodynamic outcomes @ 6 month

(BATTLE interim analysis)

ABI at baseline:
- Group A 0.71 ± 0.21
- Group B 0.68 ± 0.18

ABI at M6:
- Group A 0.96 ± 0.18
- Group B 0.90 ± 0.17
BATTLE take home message
(6 months outcomes interim analysis)

- BATTLE enrolment is completed: the assigned number of patients has been reached (N=186)
- Follow-up and monitoring are undergoing
- Primary endpoint results will be released this year
- BATTLE trial completion date (2 years FU) : September 2018
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