Evaluation of the safety and efficacy of the Cobra PzF NanoCoated Coronary Stent (NCS) in 1,000 all-comers, consecutive, prospective, high-risk patients: The e-Cobra Registry

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Déclaration de liens d'intérêt avec la présentation

Intervenant : Luc Maillard, Aix en Provence

☑ Consultant for Celonova
High Bleeding Risk Patients (HBR)

Mostly excluded from device and APT trials
Never specifically studied

Current guideline recommendations:
- BMS + one month DAPT
- DES + “shortened” DAPT

Approximately 20% are HBR
Cobra PzF
NanoCoated Coronary Stent (NCS)
COBRA PzF™

CeloNova’s New Generation Coronary Stent

Thin Strut Cobalt-Chromium Coronary Stent

Polyzene®-F Surface Modification

COBRA PzF Coronary Stent System
Mechanism of Polyzene®-F

Stent design

"Biologically invisible stent"

SECONDS
Fibrinogen Resistance

MINUTES
Albumin Binding

DAYS
Rapid Endothelialization
The Balance of Safety vs. Efficacy

**NCS**
- **Benefits:**
  - 1 month DAPT Or Less
  - Lower Late Stent Thrombosis (LST)
  - Lower TLR and MACE rates
  - Lower Late Loss

**BMS**
- **Limitations:**
  - Higher TLR and MACE rates
  - Higher Late Loss (LL)
- **Benefits:**
  - Only 1 month
  - Dual Antiplatelet Therapy (DAPT)
  - Lower Late Stent Thrombosis (LST)

**DES**
- **Limitations:**
  - Late Stent Thrombosis (LST)
  - Long Term (12 months or greater)
  - Dual Antiplatelet Therapy (DAPT)
- **Benefits:**
  - Lower TLR and MACE rates
  - Lower Late Loss
Design

- All comers Prospective, French, Multicentric, observational registry (17 sites en France)
- Consecutive: Non indicated patients to receive a DES for any reasons
- e-CRF (Electronic Clinical Research Form)
- Independent publications of the results
- Sponsor: Celonova Biosciences
- CRO: Alpin ARC (association de recherche clinique d’Annecy)
- CEC (independent Clinical Events committee)
Inclusion Criteria

- All patients undergoing treatment of “de novo” lesions in native coronary vessels, saphenous vein graft and/or arterial bypass conduits with the COBRA PzF™ coronary stent system
- Non indicated patient to receive a DES for any reason
Endpoints

- **Primary Registry Objectives:** To assess the rate of MACE at twelve months:
  - cardiac death: Any death due to proximate cardiac cause
  - myocardial infarction: peri-procedural, Spontaneous
  - clinically driven target lesion revascularization

- **Secondary Registry Objectives:**
  - Definite and probable stent thrombosis (according to ARC definition)
  - Clinical driven target vessel and lesion revascularization
  - Mean length of dual antiplatelet therapy
  - Proportion of patients treated with mono antiplatelet therapy
Exclusion Criteria = NONE
Complex lesions and Patients Included with:

- Life expectancy < 1 yr
- Serum creatinine clearance < 30 ml/min
- Documented or suspected systemic and/or infectious disease
- Antithrombotic drug intolerance
- Documented cardiac and/or extracardiac disease requiring surgical repair
- Pulmonary hypertension
- Recent (< 6 months) PCI or CABG
- In-stent restenosis
- Extreme vessel tortuosity
- Diffuse, severe coronary calcifications
Cobra 3.0x18
Cobra 3.5x15
Cobra 3.5x30 / 3.5x24
Cobra 3.0x24 / 2.5x24 / 2.5x15
Clopidogrel alone 3 weeks
Then Aspirin 1 week
Surgery
## Baseline and Angiographic Characteristics
(900 pts / 1260 stents)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age</td>
<td>73.3</td>
</tr>
<tr>
<td>Male gender</td>
<td>71 pts (%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>15.6 (%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>55.5 (%)</td>
</tr>
<tr>
<td>Past Smoker</td>
<td>23.6 (%)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>38 (%)</td>
</tr>
<tr>
<td>AF</td>
<td>6.9 (%)</td>
</tr>
</tbody>
</table>
Clinical Presentation (900 pts)

- Stable Angina: 45%
- Acute MI: 23%
- Unstable Angina: 32%
Past History (900 pts)

- PTCA: 17.8 (%)
- CABG: 3.6 (%)
- Previous MI: 9.8 (%)

Status (900 pts)

- Ejection fraction: 53.8 +/- 12.9 %
- Vessel diseased (1/2/3): 84/13/2 %
Cobra Target Lesion (900 pts)
Cobra Lesion type (ABC) (900 pts)

- **A**: 17%
- **B1**: 52%
- **B2**: 20%
- **C**: 11%
Recommended Anti Coagulant Regimen (900 pts)

**Pre PTCA**
- Aspirin
- Clopidogrel
  - 1-2 mg/kg/d
  - 10 mg/kg/d

**Per PTCA**
- Aspirin IV
- Heparin IV
  - 500 mg
  - 5000 IU

**Post PTCA**
- Aspirin
- Clopidogrel
  - 1-2 mg/kg/d
  - 1 mg/kg/d
  - one month

**Bi therapy for one month or less**
Technical success

Device Success: Stent delivery to the target lesion

896 pts (99.5 %)
1256 stents (99.7 %)

(4 failures)

Procedural success

Attainment of < 30% final residual stenosis of the target lesion and no in-hospital MACE.
Conclusions

- High risk of both bleeding and thrombotic patients non indicated to receive a conventional DES
- Very severe population at high risk of complications
- Excellent preliminary results
- Current events are pending for adjudication
### BioFreedom (DCS) vs COBRA PzF (NCS)

<table>
<thead>
<tr>
<th></th>
<th>BioFreedom</th>
<th>Cobra PzF</th>
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</thead>
<tbody>
<tr>
<td><strong>Stent material</strong></td>
<td>Stainless steel</td>
<td>CoCr</td>
</tr>
<tr>
<td><strong>Struts thickness</strong></td>
<td>120um</td>
<td>71um</td>
</tr>
<tr>
<td><strong>Crossing profile</strong></td>
<td>1.1mm</td>
<td>0.89mm</td>
</tr>
<tr>
<td><strong>Coating</strong></td>
<td>No coating</td>
<td>&lt; 0.05um PzF</td>
</tr>
<tr>
<td><strong>Drug</strong></td>
<td>Biolimus A9</td>
<td>No drug</td>
</tr>
<tr>
<td><strong>Min DAPT</strong></td>
<td>1 month</td>
<td>1 month (or less )</td>
</tr>
<tr>
<td><strong>TLR @ 12M</strong></td>
<td>5.1%</td>
<td>5%</td>
</tr>
<tr>
<td><strong>ST at 12M</strong></td>
<td>2% (LEADERS Free)</td>
<td>0% (all comers)</td>
</tr>
</tbody>
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Thank you for your attention
And to all e-Cobra investigators

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