"SUPERSUB Trial: 1-yr outcomes of SUPERa®SUBintimal stenting in CLI Patients"

Dr. L.M. Palena, MD
Interventional Radiology Unit
Foot & Ankle Clinic
Policlinico Abano Terme (PD), ITALY
Disclosure

I have the following potential conflicts of interest to report:

[ ] Consulting: “ABBOTT”
Focus of **SUPERSUB** Trial

- Diabetic Patients with CLI
- Long Femoro-popliteal, calcified CTO's (TASC C–D)
- Multilevel, multivessel arterial disease
- Poor surgical candidates or s/p failed surgery.

*The Sickest Patients*
EVT OUTCOMES in CLI:

Historical-matched cohort treated with PTA.

26.4% @ 12 m
Can we do better?

**SUPERSUB** Trial Objectives:
To assess long-term outcomes of subintimal **Supera®** Stenting for long FEM-POP CTO’s in CLI patients.
Long (>15 cm), calcified, fem-pop CTO’s are difficult to cross intraluminally.

Crossing through the subintimal space creates a "NEOLUMEN", which lacks the luminal and intimal disease burden.

HOWEREVER,

Calcified intimal and medial boundaries make the neolumen resistant to PTA and lead to frequent recoiling.

Which is addressed by

Proper, progressive and aggressive vessel Preparation, prior to SUPERA® Stenting.
82 y-o male with CLI, RF 5, DM, s/p TMA. TcPO2=12mmHg. Non-healing surgical incision.
1-year DUS Follow up
1-year Follow up
**SUPERSUB: 1-yr Endpoints**

- **Primary Efficacy:**
  - Stent patency \((PSVR < 2.0)\).
  - Freedom from TLR.

- **Primary Safety:**
  - Composite rate of freedom from death from any cause, major amputations, and TLR.

- **Secondary:**
  - Stent integrity.
  - Rutherford class shift.
  - AFS.
  - QoL improvement.
  - Cost-efficiency analysis.

- **Follow up:** Scheduled visit and DUS at 1, 3, 6, 9 & 12 months.
## SUPERSUB: Demographics

<table>
<thead>
<tr>
<th>Previous Coronary Revascularization</th>
<th>11/34 (32.4%)</th>
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<tbody>
<tr>
<td>PTCA + Stent</td>
<td>3/34 (8.8%)</td>
</tr>
<tr>
<td>CABG</td>
<td>8/34 (23.5%)</td>
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</tbody>
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<tr>
<th>Previous Surgical Vascular Revascularization (Target Limb)</th>
<th>12/34 (35.3%)</th>
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<tbody>
<tr>
<td>Aorto-Femoral Bypass</td>
<td>1/34 (2.9%)</td>
</tr>
<tr>
<td>Femoro-popliteal Bypass</td>
<td>5/34 (14.1%)</td>
</tr>
<tr>
<td>Endarterectomy</td>
<td>4/34 (11.8%)</td>
</tr>
<tr>
<td>Endarterectomy + Femoro-popliteal Bypass</td>
<td>2/34 (5.9%)</td>
</tr>
</tbody>
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<tr>
<th>Previous EVT (PTA)</th>
<th>31/34 (91.2%)</th>
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<tbody>
<tr>
<td>Target Limb</td>
<td>16/34 (47.1%)</td>
</tr>
<tr>
<td>Contralateral limb</td>
<td>15/34 (44.1%)</td>
</tr>
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</table>
34 consecutive diabetic, CLI patients (mean age 76.4 ± 7.5 years; 32 men)

- TASC D: 24/34 (70.6%)
- TASC C: 10/34 (29.4%)
- RF 5: 24/34 (70.6%)
- RF 6: 8/34 (23.5%)

Moderate to severe calcification: 85.3%.
 SUPERSUB: Results

- 0 to 1 tibial Runoff: 76.5%.
- 85.3% of patients underwent concomitant treatment of BTK arteries.
- Lesion length: 27.9 ± 10.2 (range 15-53) cm.
- Implanted stent length: 30.6 ± 11 (range 17-58) cm.
- Number of implanted stents: 2.2 ± 0.9 (range 1-4).
- Retrograde access in 12/34 (35.3 %) to re-enter in the “Ideal Landing Zone”.
Primary Efficacy

OUTCOMES AT 1 YEAR:

PRIMARY PATENCY RATE: 94.1%

FREEDOM FROM CDTLR: 97.1%
Primary Safety

- Freedom from intraprocedural complication rate: 85.3%.
- 5 patients (14.7%): SFA pseudoaneurysm after vessel preparation.
- Treatment: Supera® Stenting
- F/U: US surveillance (1 day, 1 Wk, 1, 3, 6, 9, 12 months).
- Mortality: 1 patient @ 7-months (Not procedure-related).
- No Major amputations (Limb salvage rate: 100%).
Secondary End-Points

**Rutherford Class Shift**

P < 0.0001

<table>
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<tr>
<th>% of Patients</th>
<th>baseline</th>
<th>3-M FU</th>
<th>6-M FU</th>
<th>9-M FU</th>
<th>12-M FU</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>RC6</td>
<td>RC5</td>
<td>RC4</td>
<td>RCO</td>
<td></td>
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Graph showing the % of Patients across different time points (baseline, 3-M FU, 6-M FU, 9-M FU, 12-M FU) with different categories (RC6, RC5, RC4, RCO).
No stent fractures were identified at any of the follow up points.

Amputation free survival rate: 82.4%.

6 Patients (17.6%) underwent PRE-PLANNED minor amputations.
Secondary End-Points (*Cost Efficiency*)

Costs (Index procedure + TLR within 390 days)

Historical cohort vs Study cohort

$p < 0.0001$

4427.3

9564.9

Costs of DRG (Euros)
Freedom from TLR

Freedom From TLR (Within 390 days)

- Log Rank (p<0.0001)
- Patients Populations
  - Study Group
  - Historical Group

Cumulative Survival Rate vs TIME (Days)
Primary Efficacy Objective:

- **Primary Patency Rate**: 94.1% was superior to the 66% VIVA performance goal (p < 0.0001)

Modified Primary Safety Objective:

- Freedom from death from any cause, TLR and Major amputation: 91.2% was not different from the 88% VIVA performance goal (p=0.132).
Conclusions

- **SUPERA®** Stenting after **SUB** intimal Crossing of long (TASC C-D) Fem-pop CTOs in CLI patients is superior to current efficacy and modified safety performance goals (set for patients with IC).

- **SUPERSUB** provides superior Patency rates, Freedom from TLR, improvement in Rutherford Class, QoL, and Limb Salvage.

- **SUPERSUB** is a cost-effective (cost saving = reduction of repeated procedures and hospitalization time) therapeutic strategy.

- Larger, multicenter studies of this strategy with longer follow-up are warranted to determine the generalizability of these results. **SUPERSUB 2: (Currently enrolling…)**
SUPERSUB 2:

- Multicenter, prospective study of Supera Stenting after Subintimal Crossing of TASC C-D SFA-Pop lesions in CLI patients.
- Will enroll and follow up 100 CLI pts.

SUPERSUB 2 Investigators:

Thank you for your attention
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