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Vascular Healing After Endothelial Progenitor Cell Capturing Stent Implantation at 30 days
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Background: As an alternative to DES, a novel antibody-coated endothelial progenitor cell capturing (EPC) Genous (OrbusNeich Medical GmbH, Wiesbaden, Germany) stent has been developed, which has shown good results in unselected patients. The capture of circulating endothelial progenitor cells promotes rapid endothelialization of the stent, which in turn allows shorter duration of dual-antiplatelet treatment. Optical coherence tomography (OCT) has become the method of choice for evaluating stent endothelialization and vascular healing.

Methods: We analyzed the percentage of stent strut endothelial cell coverage (binary strut coverage) and stent apposition using optical coherence tomography (OCT) and evaluated the reactivity of the microcirculation using coronary flow reserve (CFR) by transhoracic echocardiography after implantation of EPC stents. A total of 20 patients with a lesion in LAD were enrolled and OCT and CFR were performed at 30 days after stent implantation.

Results: The binary strut coverage was 94.8%. No thrombi were detected and the percentage of malapposed stent struts was 2.4%. The mean NIH thickness was 108±96 μm and NIHs 8.9±7.4 μm. Mean CFR was 2.5±0.2. Two patients had abnormal CFR < 2.0 (1 restenosis and 1 de novo lesion in the target vessel).

Table. Optical tomographic measurements

|               | Before Ac. | 30 Days | GENIOUS (20) | DEB (10) | No. of Cross Sections | 10 | 20 | 30 | 40 | 50 | 60 | 70 | 80 | 90 | 100 | 110 | 120 |
|---------------|------------|----------|--------------|----------|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| EVENTS        |            |          |              |          |                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| No. of Events | 10         | 20       | 30           | 40       | 50                   | 60 | 70 | 80 | 90 | 100| 110| 120|    |    |    |    |    |    |    |
| No. of Struts | 100        | 100      | 100          | 100      | 100                  | 100| 100| 100| 100| 100| 100| 100|    |    |    |    |    |    |    |

Conclusion: Evaluated with OCT and CFR, the Genous stent showed favorable healing properties with rapid endothelialization, low NIHs area, few malapposed struts and adequate vasodilation response at 30 days excluding patient with restenosis.

TCT-235
Evaluation of Neointimal Healing of EPC-Capturing Sirolimus-Eluting COMBO Stent by Optical Coherence Tomography: The EGO-COMBO Pilot Study (interim results)

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Background: COMBO Stent (OrbusNeich Medical, FL, USA) is a hybrid version of the endothelial progenitor cell (EPC) capturing GENIOUS Stent, with an additional abluminal 5 ng/mm sirolimus coating, about ½ the dose of current sirolimus-eluting stent but with a similar release profile (about 90% of the drug released by 35 days) via a Surmodics SynBiosys™ bio-degradable polymer, aiming at optimal neointimal suppression similar to other DES while retaining the EPC capturing benefit (envisaged better endothelialization and less late stent thrombosis) as reported in animal models. Such combined benefits were evaluated clinically in this Study.

Methods: In this prospective, single center, pilot study, 60 patients treated by COMBO Stent were randomised to 4 monthly groups (in 1:2:2:1 ratio); OCT was performed sequentially at baseline post-stenting, at early follow-ups in 4 groups at 2nd, 3rd, 4th, and 5th month (for early neointimal healing), and at 9 months (for OCT late loss). Independent OCT core laboratory performed the covered strut % and neointima analyses, while in-house analyses further stratified the early strut coverage into 6 categories.

Results: To date, all 60 patients (30% diabetic, 87 COMBO stents implanted) were enrolled; 40 had the first OCT follow up. A total of 7004 frames and 60069 struts were analyzed. The mean percentage of covered struts (with proper apposition) was 74.4%, 84.0%, 87.4% & 95.6%, p<0.014, 0.226, & 0.046, from 2nd to 5th monthly group, respectively (refer to Figure). No MACE was recorded. Study Limitations: (1) no other DES control arm & (2) OCT classification of early strut coverage requires further validation.

Conclusion: These early OCT follow-up data suggest the possible healing profile of the new EPC-capturing COMBO DES, with near 100% strut coverage by 140 days. Nine months follow-up data are pending. Clinical data on larger patient population are needed to verify these promising imaging results.