

ESTATE Protocol

DoES the design of the sTent ends influence the Acute and long TErm clinical result?

An observational study on two different versions of the same stent

Background

There is only little information available on the influence of the end-design of coronary stents on the clinical outcome. Voigt et al. found out, that with the NIR stent there is 22,9 % restenosis within the stent and 0 % restenosis pre- and post-stent, where with the Multi-Link 6,1 % are in-stent, 7,3 % pre-stent and 4,8 % post-stent stenosis. Strupp et al. observed an extremely non-symmetrical opening of the InFlow Gold stent, which is related with a high rate of restenosis. It is postulated, that the expansion characteristic might increase the injury to the vessel wall.

Generally, all stents open first at the ends. In order to obtain a more uniform stent expansion, it would be necessary to modify the balloon or to increase the amount of metal at the ends of the stent. There exist two hypotheses:

1. The stent should open first at the ends to be fully embedded into the vessel wall avoiding any flow turbulences. Further, the interface between stent ends and the non-stented vessel is critical and should show a minimum gradient on flexibility. With a relatively stiff stent end, the moving vessel will be affected with an increased damage at the interface.

Further it is known, that emboli are produced during stent implantation resulting in a CK elevation. Opening of the stents first at the ends should better trap these emboli.

2. The stent should open uniformly or first in the mid-part, followed by the stent ends. This will reduce the damage to the vessel wall at the ends of the stent. A lower degree of dissections and restenosis should result from this design.

Type of Packaging

The Coroflex stent will be available in two versions. One is the standard configuration, which opens first at the ends (at 3 bar), followed by complete expansion (at 4 bar) and a modified version with shorter ring elements at both ends of the stent. The reduced length of 1,28 mm (compared to 1,38 mm with the standard configuration) at the proximal and distal elements requires an increased force for expansion. This results in more uniform expansion characteristics. Both versions will be available only as a 16 mm version (with CE mark) and will

be packaged with different article numbers. The investigator will know, which version he will be using. On each package is a serial number, which also identifies the stent version. This number will be found on each Case Report Form.

Study Design

The study is a registry-based survey, aimed at estimating the overall event rate (as defined in the primary endpoint section). Data collection will be prospective in a selected patient's population treated with two versions of the same stent.

At a significance level of 0.05, and with a power of 0.90, the sample size required to estimate the true event rate as about 0.04 (with precision of 0.03 absolute percentage points) is 450 patients.

Univariate exploratory and descriptive analysis will be performed on data collected. Registry quality and completeness will be evaluated.

Estimation of the probability of an event will be based on a binomial model adjusted for potentially confounding factors.

Primary endpoint is the overall event rate in terms of MACE (all-causes death, Myocardial Infarction) and any revascularization at any time (acute and follow-up)

Secondary endpoint are the acute angiographic dissections, CK elevations and TVR (Target Vessel Revascularization). Restenosis (treadmill test optional) will be checked, after 6 months in a subgroup of patients in the Centers performing control angiography on a routine basis.

Center policy: each center is asked to enroll at least 20 patients. After this number and up to the completion of the study the enrollment will be on a competitive basis.

Patient inclusion/ exclusion criteria:

- The study will be performed in a „real world“ situation
- No other type of stent should be implanted into the same vessel
- Excluded is SVG stenting, the high degree of thrombus in these lesions could influence the results
- Excluded are chronic total occlusions and restenotic lesions
- In case of direct stenting, the generally accepted precautions have to be taken into consideration. Exclusion criteria for direct stenting are:
 - age >75 y
 - chronic occlusions
 - angina >6 mo.
 - any sign of calcification
 - vessel diameter <2,6 mm
 - bifurcation lesions
 - extreme tortuosity

CRF - Sending instructions

- ✓ Pages A and B to be sent by fax (+39 0432 478686) within 2 days since discharge
- ✓ Pages C and D to be sent by fax (+39 0432 478686) at conclusion of F.U. (6 months)
- ✓ All CRFs (original copy) to be sent by mail at the end of the study

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Contact Point

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