TITAX AMI TRIAL & TITAN STENT

The latest results of the multicenter prospective Randomized Controlled Trial TITAX AMI have been presented at the occasion of the Late Coronary Breaking Trials during EuroPCR 2009 Wednesday the 20th in Barcelona by the co-Principal Investigator Pasi Karjalainen, MD, PhD, from the Satakunta Central Hospital, Pori Finland.

The aim of this non inferiority study was to compare the effectiveness of the Titanium-Nitride-Oxide coated stent with the Paclitaxel Eluting stent in patients presenting with Acute Myocardial Infarction (STEMI & NSTEMI).

425 consecutive patients were randomized between the TiTAN2 Bio Active Stent (Hexacath, Paris, France) and the TAXUS Liberté (Boston Scientific, Natick, MA, USA) Drug Eluting Stent. The primary end point was the rate of Major Adverse Cardiac Events (MACE) at 12 & 24 months.

Baseline patients characteristics were comparable between both groups, except a higher incidence of previous PCI in the TiTAN2 BAS group (10% vs 5%, *p=0.04*). The procedural and lesion characteristics were also similar between the TiTAN2 BAS and TAXUS groups: stent length: 17.4mm vs. 17.7mm, *p=0.48*, stent diameter: 3.16mm vs. 3.11mm, *p=0.19*, Type C lesions: 16% vs. 11%, *p=0.16*.

At 12 months, the cumulative incidence of primary endpoint was 10.3% in the TiTAN2 BAS group vs. 12.8% in the TAXUS group (*p=0.5*). The only significant difference was the rate of stent thrombosis higher in the TAXUS group (3.3% vs.0.5%, *p=0.031*).
At 24 months the clinical follow up was obtained from 100% of the patients and a significantly lower rate of primary end point was observed in the TiTAN2 BAS group compared with the TAXUS group (11.2% vs. 21.8%, *P*=0.004). This difference was driven by a reduced rate of MI (5.1% vs. 15.6%, *P*<0.001) and cardiac death (0.9% vs. 4.7%, *P*=0.02) in favour of the TiTAN2 group. Definite stent thrombosis occurred in 0.5% and 6.2% of the patients (*P*=0.001), respectively. Only the rates of TLR were similar in both groups at follow up (9.3% vs. 10%, *P=NS*). Interestingly, the outcomes of patients presenting with NSTEMI and STEMI were similar at follow up confirming the fact that despite NSTEMI and STEMI are usually considered to be different entities, the prognosis of either subgroup of MI is similar. Noteworthy, this study was initiated by the investigators with no industrial sponsor and was conducted according to the declaration of Helsinki.

The TITAX AMI trial provides new additional data confirming the efficacy and safety of the TITAN2 BAS in one of the highest risks patient population: NSTEMI and STEMI.
The TiTAN2 BAS from Hexacath France is a new category of stent coated with Titanium-Nitride-Oxide, a compound which has demonstrated unique mechanisms of action such as inhibiting platelet and fibrin deposition, promoting re-endothelialisation and minimizing inflammation. Today, the TiTAN2 BAS is the only new innovation outside DES, with proven records of both efficacy and safety backed up by 10 years of clinical R&D in coatings, 8 years of BAS market history, 8 international publications (3 about randomized studies) and more than 15 registries.

HEXACATH was established in 1994 in Rueil-Malmaison - France, with the goal of developing, manufacturing and distributing innovative cardiovascular therapies. Today,

Hexacath is strongly dedicated to innovation and is working on different pathways and new technologies to improve patient treatment and PCI procedures.