Press Release

Eurocors Valentines Trial II published in EuroIntervention

The Valentines Trial II: results of the worldwide multicenter enrollment trial, evaluating the real world usage of the second generation DIOR® paclitaxel drug-coated balloon for treatment of de novo coronary lesions.

Bonn, Germany, 15. November 2013 – Eurocor announced the publication of the Valentines Trial II in the Scientific Journal EuroIntervention (Volume 9, Number 5, Sep. 2013) with the title *Drug-coated balloons for de novo coronary lesions: results from the Valentines II trial.* The registry was conducted with an objective to assess the efficacy of the second-generation Paclitaxel-coated balloon DIOR for *de novo* lesions at 6-9 months follow-up. 103 patients suffering from *de novo* lesions were enrolled by 38 Investigators from 16 countries starting between February 14th and March 31st2011.Overall 109 lesions were treated. A follow-up rate of 99 % was reached with a 50.5% on-site Clinical Monitoring. Three Principal Investigators carried out the trial: Dr. Antonio Serra,(Barcelona, Spain), Dr. Alfredo Rodriguez (Buenos Aires, Argentina) and Prof. Dr. Fazila Malik (Dhaka, Bangladesh).

Dr. AntoninoLaudani, COO at Eurocor GmbH says: “The results of the Valentines Trial II show, that the usage of DCB shouldbewidelyextendedto*de novo*lesions, particullaryforpatientswhere DES is not an option.“

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The Results: The follow-up results convincingly show that the DIOR DCB is a safe and effective treatment for cases of *de novo* lesions. The treatment with DIOR DCB resulted in a very low overall target lesion revascularization (TLR) rate of 2.9% and a target vessel revascularization (TVR) rate of 6.9%. Also, the overall major adverse cardiac event (MACE) rate of 8.7% was remarkably low. The preliminary late lumen loss (LLL) upon angiographic follow-up of a small subset of patients was 0.30 ±

0.36 mm and 0.33 ± 0.37 mm for the in-DCB segment and in-segment analyses, respectively. A subgroup analysis of the patients suffering from diabetes (28.2%) show that the DIOR DCB is effective in this population with a single digit TLR rate of 6.9% and a TVR rate of 13.8% at 6-9 months follow-up post treatment. The non-diabetic group of patients shows a TLR rate of 1.4% and a TVR rate of 4.1% at 6-9 months follow-up.

Conclusion

The results demonstrate that, in elective percutaneous coronary intervention, the adjunctive use of DCBs may be a feasible alternative to stenting in lesions that respond favorably to POBA. This may prove valuable in the subset of patients who are unsuitable for DES implantation.

Please see the publication: http://www.pcronline.com/eurointervention/64th_issue/98/

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Eurocor is a rapidly growing European Life Sciences Technology Corporation specializing in the research, development and manufacture of cardiovascular and endovascular products. Eurocor provides interventional physicians with innovative coronary stent technologies and special cardiovascular and endovascular devices, manufactured in Europe. Products are indicated for minimally invasive cardiovascular and peripheral surgery and comply with biological and biomechanical principles to offer highly flexible, adaptable solutions. Extensive research and development, close clinician collaboration, outstanding quality standard philosophy and global scientific alliances lead to optimization of clinically effective technologies. Eurocor has designed an innovative method for balloon catheter drug delivery with high patient compliance. One heartbeat ahead® – with innovative products such as DIOR® and FREEWAY™.

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