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Patients At High Risk Of Bleeding, A Forgotten Population In DES Trials? Insights From The Ongoing LEADERS FREE Trial

Philip Urban[1], Alexandre Abizaid[2], Ian T. Meredith[3], Marie-Claude Morice[4], Samantha Greene[5], Pedro Eerdmans[5]

[1]Hôpital de la Tour, Geneva, Switzerland, [2]Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil, [3]Monash University, Melbourne, Australia, [4]Cardiovascular European Research Center, Massy, France, [5]Biosensors Europe, Morges, Switzerland

Background: A sizeable proportion of patients treated with PCI are unable to take dual antiplatelet therapy (DAPT) for the guideline-recommended period of 6-12 months. Optimal treatment of patients at high bleeding risk thus remains uncertain. The BioFreedom™ drug-coated stent (DCS) (Biosensors Europe SA, Morges, Switzerland) is polymer- and carrier-free, releases Biolimus A9 into the vessel wall over a period of 28 days, and then technically becomes a BMS.
Methods: 2465 patients at high bleeding risk from 68 centers in Europe, Asia, and Canada were enrolled from Dec 2012 to May 2014 in a double-blinded randomized 1:1 comparison of Gazelle™ BMS (Biosensors Europe SA, Morges, Switzerland) vs. BioFreedom DCS with a 1 month course of DAPT only, in both arms. The 2 primary endpoints at 1 year are a composite of cardiovascular death, MI and stent thrombosis for safety and the rate of ci-TLR for efficacy. The DSMB is monitoring all safety data at 4 months.
Results: In the overall trial population, the most frequently used inclusion criteria were: advanced age (64%), need for long term oral anticoagulation (36%), anemia, recent bleeding or transfusion (21%), renal insufficiency (19%), planned surgery (15%) and concomitant cancer (9%). When compared to those included in "all-comer" trials, patients were markedly older (76±9.4 years), and had more co-morbidities (diabetes 33%, atrial fibrillation 34%, peripheral vascular disease 16%, heart failure 13%, prior stroke 10%, COPD 11%). 1.7 stents/patients were implanted for a total stent length of 32 mm/patient. Technical procedure success was high at 96%. 66% of patients were discharged on DAPT alone, 30% on DAPT + oral anticoagulation, and 2% on a single antiplatelet agent + oral anticoagulation. Current data are preliminary; Data from all recruited patients will be available at time of presentation.
Conclusions: The trial is a first in 3 ways: it focuses on a never previously studied high bleeding risk population, characterized by advanced age and more comorbid conditions. It is the first evaluation of a DCS with clinical endpoints and it comprises the shortest ever DAPT course with an active stent to be evaluated for both safety and efficacy.

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Risk of stent thrombosis with 6 vs. 12 months dual antiplatelet therapy after new generations drug-eluting stents implantation: final results of the multicenter prospective ESTROFA-DAPT study

Jose M. De la Torre Hernandez[1], Juan F. Oteo Dominguez[2], Felipe Hernandez[3], Tamara Garcia Camarero[4], Omar Abdul-Jawad Altisent[5], Fernando Rivero-Crespo[6], Jose D. Cascon[7], German Zavala[8], Federico Gimeno[9], Antonio L. Arrebola-Moreno[10], Leire Andraka[11], Antonio Gomez Menchero[12], Francisco Bosa[13], Xavier Carrillo[14], Angel Sanchez-Recalde[15], Fernando Alfonso[16], Armando Pérez de Prado[17], Ramon Lopez Palop[18], Juan Sanchis[19], José A. Diarte de Miguel[20], Rocio De Lemos[21], Luz Muñoz[22], Antonio Ramirez Moreno[23], Helena Tizon-Marcos[24]

[1]Hospital Universitario Marques de Valdecilla, Santander, Spain, [2]Hospital Puerta de Hierro, Madrid, Spain, [3]Hospital 12 de Octubre, Madrid, Spain, [4]H. Marques de Valdecilla, Santander, Spain, [5]MutuaTerrassa Hospital, Terrassa, Spain, [6]Hospìtal Universitario de la Princesa, Madrid, Spain, [7]Hospital Santa Lucia, Cartagena, Spain, [8]Hospital Vall de Hebron, Barcelona, Spain, [9]Hospital Clinico de Valladolid, Valladolid, Spain, [10]Hospital Universitario Virgen de las Nieves, Granada, Spain, [11]Hospital de Basurto, Bilbao, Spain, [12]Hospital Juan Ramón Jimenez, Huelva, Spain, [13]H. Clinico de Tenerife, Santa Cruz de Tenerife, Spain, [14]HU Germans Trias i Pujol, Badalona, Barcelona, [15]H. Universitario La Paz, Madrid, Spain, [16]Hospital Universitario Clinico San Carlos. Madrid, Madrid, Spain, [17]HemoLeon, Fundación Investigación Sanitaria en León, Leon, Leon, [18]Hospital San Juan de Alicante, Alicante, Alicante, [19]Hospital Clinico de Valencia, Valencia, Spain, [20]Miguel Servet University Hospital, Zaragoza, Zaragoza, [21]Hospital Virgen de la Victoria de Malaga, Malaga, Spain, [22]Hospital Carlos Haya, Malaga, Spain, [23]Hospiten Estepona, Marbella-Málaga, Spain, [24]Hospital del Mar, Barcelona, Spain

Background: Drug eluting stents (DES) have been associated to an increased risk of late stent thrombosis. The recommendation for dual antiplatelet therapy (DAPT) is for 12 months, nevertheless this strategy is expensive and associated to a variable bleeding risk. Recent limited in size trials have suggested that 6 months DAPT could be safe but large real practice registries are still lacking.
Methods: We enrolled prospectively consecutive patients treated with new generation DES from 18 Spanish centers that were discharged with a 6 month DAPT prescription. Patients to include should meet at least one of the following criteria: silent ischemia, stable angina, low risk acute coronary syndrome (ACS) or any ACS with no-low bleeding risk. The adherence to the 6 months DAPT period was verified at follow up. In order to compare outcomes with a 12 months DAPT strategy we performed a propensity score matched analysis with the large cohort of patients from the multicenter prospective ESTROFA-2 database (4,354 patients treated with second generation DES and at least 12 month DAPT).
Results: A total of 2,572 matched patients were included (1,286 in each group) with well balanced baseline clinical, angiographic and procedural characteristics. Admission diagnose was ACS in 40-41% of the patients in both groups. The incidence of definite stent thrombosis at 12 months follow up was 0.4% in 6 month-DAPT group and 0.6% in 12 months-DAPT group (p=0.4) and the incidence of definite/probable thrombosis was 0.7% in 6 month-DAPT group and 1.5% in 12 months-DAPT group (p=0.09). The incidence of definite/probable thrombosis between 6 and 12 months after DES implantation was 0.2% in the 6 months-DAPT group and 0.3% in the 12 months-DAPT group (p=0.7).
Conclusions: A DAPT period of 6 months compared to 12 months after implantation of new generation DES resulted safe in the selected patients of this multicenter study.

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Association of Dual Antiplatelet Therapy Cessation with Ischemic and Bleeding Events Following Cobalt-Chromium Everolimus-Eluting Stent Implantation in Chinese Population: First Two-Year Reports of the Prospective Multicenter SEEDS Study

Yelin Zhao[1], Bo Xu[1], Yaling Han[2], Bao Li[3], Qiang Liu[4], Junyu Cui[5], Lang Li[6], Shuzheng Lu[7], Yuejin Yang[1]

[1]Fu Wai Hospital, National Center for Cardiovascular Diseases, Beijing, China, [2]General Hospital of Shenyang Military Region, Shenyang, China, [3]Shanxi Provincial Cardiovascular Institute, Taiyuan, China, [4]Shenzhen Sun Yat-Sen Cardiovascular Hospital, Shenzhen, China, [5]Beijing Military General Hospital, Beijing, China, [6]First Affiliated Hospital of Guangxi Medical University, Nanning, China, [7]Affiliated Anzhen Hospital of Capital Medical University, Beijing, China

Background: Appropriate duration of dual antiplatelet therapy (DAPT) after drug-eluting stent implantation is still controversial. We sought to assess the associations between DAPT cessation, ischemic events and bleeding risks following PCI in patients with complex lesions treated with the cobalt-chromium (CoCr) everolimus-eluting stent (EES).
Methods: 1900 patients with small vessel (reference diameter < 2.75 mm), long lesion (length >25 mm), or multivessel (>2 target vessels) disease who underwent PCI with EES (Xience V, Abbott Vascular, Santa Clara, CA, USA) in the prospective SEEDS study were categorized into 4 groups according to DAPT duration (1-6 months, 6-12 months, 12-24 months after PCI and no DAPT cessation). All events were classified into "on DAPT" or "off DAPT" group according to the DAPT status at the time of event occurred. Clinical follow-up data at 2 years were analyzed for all. The major outcomes were ischemia-driven target vessel failure (ID-TVF), a composite of cardiac death, target vessel myocardial infarction, or ischemia-driven target vessel revascularization, definite/probable stent thrombosis (ST), and BARC bleeding II-V at 2 years.
Results: DAPT cessation after 12 months following the index PCI decreases the risks of ID-TVF, but not ST compared to no DAPT cessation group. Among the 13 definite/probable ST events, 12 (92.9%) of them occurred on DAPT and 1 occurred off DAPT. On the other hand, use of DAPT was a strongly independent predictor of BARC bleeding (HR [95%CI]: 9.82 [4.64,20.80], p< 0.0001) at 2 years. However, adverse events occurred on DAPT was increased overtime (table).

Table. Clinical Outcomes at 24 Months According to DAPT Duration and DAPT Status at The Time of Event

Events	a DAPT Cessation at 1-6 Months N=41	b DAPT Cessation at 6-12 Months N=538	c DAPT Cessation at 12-24 Months N=648	d No DAPT Cessation N=673	*p*-value			
					a *vs.* d	b *vs.* d	c *vs.* d	All Groups
ID-TVF	2.4 (1)	7.43 (40)	4.63 (30)	9.21 (62)	0.25	0.27	0.001	0.007
DAPT-on	0 (0)	87.5 (35)	86.7 (26)	100.0 (62)				
DAPT-off	100.0 (1)	12.5 (5)	13.3 (4)	0 (0)				
Def/Pro ST	0 (0)	0.74 (4)	0.77 (5)	0.6 (4)	1.00	0.74	0.75	0.91
DAPT-on	-	75.0 (3)	100.0 (5)	100.0 (4)				
DAPT-off	-	25.0 (1)	0 (0)	0 (0)				
Bleeding (≥ type II)	24.39 (10)	4.28 (23)	2.93 (19)	1.49 (10)	<0.0001	0.003	0.07	<0.0001
DAPT-on	70.0 (7)	78.3 (18)	94.7 (18)	100.0 (0)				
DAPT-off	30.0 (3)	21.7 (5)	5.3 (1)	0 (0)				
Data are presented as % (n)								

Conclusions: The present study demonstrated that DAPT cessation was not associated with an increase in adverse ischemic events and might suggest that shorter DAPT duration is reasonable to decrease bleeding complications in Chinese patients receiving a CoCr EES. (ClinicalTrials.gov identifier: NCT 01157455)