Is 6 Months DAPT Post Coronary Stenting Non Inferior To 24 Months? The Italic/Italic+ Randomized Trial. Results of the One Year Primary Endpoint

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Background. The currently recommended duration of DAPT in DES recipients is 12 months to reduce the risk of late stent thrombosis. However, DAPT is associated with increased bleeding which may affect the outcome of patients especially those with co-morbidities or requiring surgical treatment.

It was hypothesized that antiplatelet treatment with aspirin alone 6 months after DES implantation may be non-inferior to DAPT in aspirin non resistant pts

Methods. A multicenter, all comer randomized study was set up to assess the non-inferiority of aspirin as a single treatment vs. DAPT with clopidogrel and aspirin after 6 months and for 24 months after DES in pts tested for non resistance to aspirin. The primary end-point is a composite of death, MI, TLR, stroke and major bleeding at 12 months post PCI. Secondary endpoints are the components of the primary endpoint and minor bleeding at 24 months.

Results. From Nov 2008 to Dec 2010 (ITALIC Trial) and from Jan 2012 to Nov 2013 (ITALIC PLUS Trial), 2031 pts were enrolled in 70 centers in Europe and the Middle East. 80.1% were men, mean age: 61.6±11.0 yrs. 941 pts were randomized to DAPT for 24 months followed by aspirin and 953 pts to DAPT for 6 months followed by aspirin alone, 137 pts were resistant to aspirin (treatment left to the physicians’discretion)

Risk factors: hypertension (64.9%) dyslipidemia (67.0%) diabetes (37.2%), family history (35.3%), current smoker (23.0%), all well balanced between the 2 groups.

Procedural results: Pts had 1.04 procedures and mean no. of stents implanted per procedure was 1.9 ±0.16.

Procedural success was obtained in 98.6%. In hospital, 10 pts experienced at least 1 of the composite endpoint including no death, 2 MI (0.05%), no CABG, 4 repeat PCI (0.2%), 1 stroke (0.05%) and 4 major bleeding( 0.2%). 6-month follow-up was obtained in (95.8 %) of pts 109 (5.4%) pts experienced at least 1 of the composite endpoint events including 13 deaths (0.7%) 6 MI (0.3%), 2 CABG (0.1%), 76 repeat PCI for restenosis (4.0%) and 7( 0.4%) major bleeding.

Conclusion: The risk benefit ratio (bleeding/stent thrombosis) of short/ long DAPT requires randomized trials. The primary endpoint of the ITALIC trial will be available at the meeting. ITALIC is the 1st randomized trial comparing 2 DAPT regimens in pts non resistant to aspirin.
DISCLOSURE: