LONG-TERM OUTCOMES OF DRUG-ELUTING STENTS FOR OFF-LABEL INDICATIONS: A REPORT FROM THE NHLBI DYNAMIC REGISTRY

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Background: Off-label use of drug-eluting stents (DES) is highly prevalent in routine clinical practice. Uncertainty still remains, however, as to their long-term safety when used under these circumstances. Therefore, we sought to evaluate the effect of off-label use of DES as compared to bare metal stents (BMS) on 3-year outcomes after PCI.

Methods: Three thousand nine hundred and eighty patients enrolled in the National Heart, Lung, and Blood Institute (NHLBI) Dynamic Registry who received at least one stent and had complete 3-year follow-up were included in this analysis. Patients were then divided into those receiving BMS only (n=1291) and those receiving DES only (n=2689), and within each group, stent use was categorized as standard or off-label. All patients were followed-up for the occurrence of death, myocardial infarction (MI), CABG or repeat PCI.

Results: Off-label use was common (54.6% of BMS and 48.7% of DES). DES use was associated with more co-morbidities regardless of indication of use. At three years, off label use of DES was associated with a lower rate of need for CABG (8.2% vs. 3.9%, p<0.001), without an increased hazard of death (10.4% vs. 12.8%, p=0.06) or MI (7.7% vs. 9.8%, p=0.07), as compared to BMS. Similar findings were seen after multivariate adjustments (figure).

Conclusions: Our study shows that off-label use of DES is not associated with a long-term increased hazard of death or MI as compared with BMS, while resulting in lower rates of CABG.