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CRT-156

Current Perspectives on Stent Deformation: Trends, Characteristics and Outcomes From the Food and Drug Administration Manufacturer and User Facility Device Experience Database

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Background: Newer generation DES has been associated with thinner stent struts and fewer connectors. We aimed to assess the contemporary incidence and clinical implications of stent deformation (SD). The FDA Manufacturer and User Facility Device Experience (MAUDE) database is an electronic system which aims to capture voluntary reported device-related safety issues.
Methods: MAUDE database was searched from 2002-2013 for "stent deformation", "longitudinal deformation" and "longitudinal stent deformation". We reviewed 1727 reports and identified 704 reports with SD.
Results: A total of 704 reports were identified with SD. There were 473 reports of SD due to failure of stent implantation and stents were subsequently removed. The majority for these cases involved lesions with at least moderate calcification and moderate tortuousity. Most of this SD occurred in the Resolute platform (66.2%), followed by Endeavor platform (29.4%), Element (3.4%), Cypher and Taxus Liberte (1%). The remaining 231 reports were SD in successfully implanted stents. These include 66 reports with at least moderate tortuosity, 64 reports with at least moderate calcifications, 45 reports involving bifurcations and 33 reports involving ostial lesions. Most of this SD occurred in the Element platform (86.1%). The majority of SD was in the LAD (40.3%), followed by RCA (22.5%), LCX (14.3%), vein graft (10%) and left main (5.2%). The primary mechanisms for SD were associated with post-dilatation balloon (25.7%), guide catheter (13.7%) or imaging device (13.6%). The majority of patients was stable and was treated with another stent implantation (46.8%) or balloon angioplasty (39.0%).
Conclusions: Majority of reported SD occurs in the newer generation DES. Adequate lesion preparation and careful usage of device through stents are essential to prevent incidence of SD.

Mechanism for SD in implanted stents	N=241
SD associated with post-dilatation balloon	62 (25.7%)
SD associated with IVUS catheter	31 (12.9%)
SD associated with OCT catheter	1 (0.4%)
SD associated with guide catheter/guide extension	33(13.7%)
SD associated with thrombectomy device	23 (9.5%)
SD associated with another undeployed stent	18(7.5%)
SD associated with bifurcation stenting	13 (5.4%)
SD noted after post-dilatation	10 (4.1%)
SD due to complex lesion anatomy	9 (3.7%)
SD due to withdrawal of trapped wire	8 (3.3%)
SD after removal stent balloon	5 (2.1%)
SD due to passing of unknown device	5 (2.1%)
Unknown mechanism	23 (9.5%)

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Impact of Glycosylated Hemoglobin (HbA1C) Levels in Patients with Diabetes Mellitus Undergoing Percutaneous Coronary Intervention with Second Generation Drug-Eluting Stent Implantation

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Background: The impact of optimal glycemic control on the long term cardiovascular outcomes in diabetic patients is a subject of ongoing controversy that may be especially pertinent in patients undergoing percutaneous coronary intervention (PCI).
Objective: This study aimed to determine the prognostic value of peri-procedural glycosylated hemoglobin (HbA1C) levels in diabetic patients undergoing PCI with 2nd-generation drug-eluting stent (DES) implantation.
Methods: From July 2008 to May 2012, a cohort of 586 consecutive diabetic patients that underwent PCI with implantation of 2nd generation DES at our center were analyzed. Patients were stratified in to two groups based on HbA1C [A1C<7(n=216) and A1C≥7 (n=370)]. One-year rate of major adverse cardiovascular events (MACEs) including death, Q-wave myocardial infarction, and target vessel revascularization was indexed.
Results: Baseline clinical and procedural characteristics were similar between groups, except patients in A1C≥7 group were younger (64±11 vs. 68±10, p<0.001), had higher insulin treated diabetes (55% vs. 26%, p<0.001), and higher body mass index (33±7 vs. 31±6, p=0.002). On the other hand patients in A1C<7 group had higher baseline creatinine (1.8±2.1 vs. 1.4±1.6, p=0.04) and higher dialysis (8% vs. 3%, p=0.006). The rates of one year MACEs (18% vs. 13%, p=0.12), mortality (6.8% vs. 7.4%, p=0.76) and revascularization (7.6% vs. 4.3%, p=0.12) were similar in the high A1C and normal A1C groups. By multivariate analysis, age, renal failure, and type C lesion were independently associated with MACEs. In contrast, neither HbA1C nor fasting plasma glucose were associated with outcome.
Conclusions: Peri-procedural HbA1C is no longer a correlate of cardiac events at one year in diabetic patients with coronary artery disease undergoing PCI with 2nd-generation DES.