International Journal of Cardiology 175 (2014) 261–267

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Comparison of frequency and severity of longitudinal stent deformation among various drug-eluting stents: An intravascular ultrasound study

Hideaki Ota, Hironori Kitabata, Marco A. Magalhaes, Anh Bui, Karina Kardenas, Caitlin H. Thomas, Fang Chen, Rebecca Torguson, Lowell F. Satler, Augusto D. Pichard, Ron Waksman *

Interventional Cardiology, MedStar Washington Hospital Center, Washington, DC, United States

ARTICLE INFO

Article history:
Received 4 February 2014
Received in revised form 2 May 2014
Accepted 11 May 2014
Available online 16 May 2014

Keywords:
Longitudinal stent deformation
Drug-eluting stent
Intravascular ultrasound

ABSTRACT

Background: Longitudinal stent deformation (LSD) in drug-eluting stents (DES) has been described as a disruption of stent structure. This study aimed to compare first- versus second-generation DES with respect to their actual stent length post deployment.

Methods: A total of 617 DES for de novo coronary lesions in 552 patients were analyzed. Intravascular ultrasound (IVUS) was utilized to compare the degree and rate of LSD among six different DES types. IVUS-measured stent length was compared to the labeled length for calculation of absolute difference in stent length and relative absolute difference (absolute difference divided by the labeled length).

Results: The baseline characteristics were comparable between groups, except for higher calcification in the sirolimus-eluting stent (SES) group ($p = 0.037$). The absolute and relative difference in length showed the lowest degree in the SES group and the highest degree in the Endeavor zotarolimus-eluting stent group ($p = 0.085$ and 0.078, respectively). The percentage of more than 5% relative absolute difference was the lowest in the SES group compared to the other groups ($p = 0.018$). However, the percentage of significant (>15%) relative absolute difference was similar among groups ($p = 0.99$). In multivariate linear regression analysis, labeled stent length and stent diameter, but not stent type, were identified as independent correlates to the absolute and relative difference in the actual stent length post-deployment.

Conclusion: This IVUS analysis confirms that among second-generation DES, there is overall similar frequency and severity of LSD when deploying in common coronary lesions.

1. Introduction

Coronary stent design and materials have undergone significant improvements over the past decades [1,2]. Early stents were manufactured from thick stainless steel struts, which lead to poor deliverability and conformability, and various clinical complications [3,4]. In contrast, modern coronary stents are mainly composed of cobalt–chromium (CoCr) and platinum-chromium (PtCr), which allow for high radial force while using thinner struts and fewer connectors between hoops [5]. Thinner struts and fewer connectors can improve stent flexibility, deliverability, conformability to the artery, and side-branch accessibility. Accordingly, a new concern was raised that these novel stent designs (with improved transport) may be the cause of lower longitudinal strength [6–9].

Longitudinal stent deformation (LSD) is a recently reported complication of coronary intervention, with the occasional association with adverse clinical events [10–16]. Recent bench testing has revealed that the incidence of LSD is higher in stents with fewer connectors between hoops (e.g. PtCr-everolimus-eluting stents [PtCr-EES] and zotarolimus-eluting stents [ZES]) as compared to stents with more connectors (e.g. sirolimus-eluting stents [SES]) [17–19]. On the other hand, a clinical study showed no stent deformation or significant differences in the stent length ratios (defined as the stent length by quantitative coronary angiography [QCA] divided by labeled stent length) between CoCr-EES and PtCr-EES [20]. In addition, we have previously reported that axial integrity among first-generation drug-eluting stents (DES) and second-generation DES was similar [21]. As can be seen from the previous results, there remains a discrepancy of aspects between the studies. Furthermore, to date, this complication has not been systematically examined using objective criteria, and in the real world, there are several unanswered questions, including the frequency of LSD, difference in LSD rates among stent types, and the possible association of LSD with clinical events.

The objectives of the present study were therefore to assess the degree and rate of LSD through intravascular ultrasound (IVUS),

* Corresponding author at: Division of Cardiology, MedStar Washington Hospital Center, 110 Irving Street, NW, Suite 4B-1, Washington, DC 20010, United States. Tel.: 202 877 2812; fax: 202 877 2715.
E-mail address: ron.waksman@medstar.net (R. Waksman).

http://dx.doi.org/10.1016/j.ijcard.2014.05.015
0167-5273/

Table 1
Baseline patient characteristics.

	SES (n = 100)	PES (n = 100)	E-ZES (n = 100)	CoCr-EES (n = 98)	PtCr-EES (n = 77)	R-ZES (n = 77)	p value
Age (yrs)	66.6 ± 13.3	63.6 ± 12.0	66.0 ± 11.2	65.4 ± 11.9	64.2 ± 9.9	65.9 ± 11.9	0.59
Male gender	64 (64.0)	68 (68.0)	63 (63.0)	67 (68.4)	55 (71.4)	55 (71.4)	0.76
Hypertension	86 (86.0)	91 (90.1)	87 (86.1)	83 (83.8)	62 (80.5)	66 (85.7)	0.62
Diabetes mellitus	41 (41.0)	38 (37.6)	31 (30.7)	27 (27.3)	35 (45.5)	22 (28.6)	0.064
Family history	46 (46.5)	51 (52.0)	49 (48.5)	45 (45.5)	31 (40.3)	33 (42.9)	0.70
Hyperlipidemia	93 (93.0)	96 (95.0)	83 (82.2)	75 (75.8)	59 (76.6)	62 (80.5)	<0.001
Smoke	49 (49.0)	48 (47.5)	51 (50.5)	57 (57.6)	33 (42.9)	40 (51.9)	0.51
Previous MI	22 (22.7)	15 (15.8)	13 (12.9)	22 (22.2)	17 (23.0)	17 (22.4)	0.34
Previous CABG	16 (16.0)	9 (9.0)	8 (7.9)	14 (14.1)	13 (16.9)	10 (13.0)	0.33
Previous PCI	37 (38.1)	36 (38.7)	16 (16.3)	29 (29.6)	23 (30.3)	25 (32.5)	0.010
History of CRF	16 (16.0)	6 (5.9)	10 (9.9)	14 (14.4)	10 (13.0)	11 (14.3)	0.28
Body mass index	31.0 ± 7.5	29.2 ± 6.1	29.5 ± 6.4	30.2 ± 6.8	30.0 ± 6.2	30.0 ± 6.5	0.52
LVEF	0.51 ± 0.15	0.50 ± 0.15	0.53 ± 0.14	0.52 ± 0.11	0.44 ± 0.21	0.45 ± 0.21	0.004

Data are presented as mean ± SD or n (%). Hypertension is defined as blood pressure > 140/90 mm Hg or the use of antihypertensive drug. Hyperlipidemia is defined as fasting total cholesterol > 250 mg/dl or the use of lipid-lowering drug. MI, myocardial infarction; CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; CRF, chronic renal failure; and LVEF, left ventricular ejection fraction.

comparing six commercially available DES, and to detect the correlate factors for LSD.

2. Methods

2.1. Study design and patient population

The study was a single-center registry, which included patients with de novo coronary artery lesions undergoing first- or second-generation DES implantation with post-implantation IVUS assessment. Moreover, the present study extends our previous research, including more than a two-fold greater number of patients and stents [21]. The patients were classified into six groups according to SES (Cypher; Cordis Corporation, Miami Lakes, FL); paclitaxel-eluting stents (PES, TAXUS-Express; Boston Scientific Corporation, Natick, MA); E-ZES (Endeavor; Medtronic, Minneapolis, MN); CoCr-EES (XienceV/Abbott Vascular, Santa Clara, CA, or PROMUS/Boston Scientific Corporation); PtCr-EES (PROMUS-Element; Boston Scientific Corporation); and R-ZES (Resolute Integrity; Medtronic). Patients in the PtCr-EES arm were prospectively and retrospectively enrolled. The other five cohorts (SES, PES, E-ZES, CoCr-EES and R-ZES arms) were retrospectively included in each group. The retrospective cohorts consisted of percutaneous coronary intervention (PCI) cases from 2003 to 2013, and were obtained from medical record review.

We excluded patients who received >1 stent within the same lesion during the implantation procedure or were treated for in-stent restenosis. Patients without post-implantation IVUS or automatic pullback IVUS were also excluded. Additionally, stents were excluded if the IVUS image quality prevented the detection of both stent edges.

The study was conducted according to the principles of the Declaration of Helsinki and was approved by the institutional review board of MedStar Washington Hospital Center (Washington, DC). Written, informed consent was obtained from the prospectively-enrolled patients.

The primary end point was to assess the overall difference in stent length post-deployment via IVUS among the six stent arms. The secondary end points were to detect the occurrence of >5%, 10%, and 15% differences in stent length by IVUS as compared to the labeled stent length.

2.2. Coronary angiography and intervention

PCI was performed using standard techniques, and the choice of procedure and the type of stent were at the discretion of the operator. All patients received oral administration of 325 mg of aspirin before the procedure and a clopidogrel loading dose of 300–600 mg or prasugrel 60 mg during or just after the procedure. During coronary intervention, patients received anticoagulation with bivalirudin (0.75 mg/kg bolus followed by a 1.75 mg/kg/hour infusion) or unfractionated heparin (40 U/kg bolus, with an additional dose to achieve an active clotting time of 250–300 s). Glycoprotein IIb/IIIa inhibitors were also used at the operator's discretion.

2.3. Quantitative coronary angiography analysis

Standard image acquisition was performed at the clinical site using ≥2 angiographic projections of the stenosis, intracoronary nitroglycerine to provide maximum coronary vasodilation, and repetition of identical angiographic projections of the lesion at baseline and final angiography. All images were sent to the MedStar Health Research Institute Core Laboratory at MedStar Washington Hospital Center (Washington, DC).

QCA was conducted blindly by independent laboratory technicians with a validated automated edge-detection program (CAAS 5.9.2, Pie Medical Imaging BV, Maastricht, The Netherlands). The angiographic projection that minimized stent foreshortening was used for analysis. Collected angiographic data included stent length, in-stent minimal lumen diameter, degree of angulation, calcification and legion location.

Table 2
Lesion characteristics.

	SES (n = 112)	PES (n = 108)	E-ZES (n = 112)	CoCr-EES (n = 109)	PtCr-EES (n = 93)	R-ZES (n = 83)	p value
Target vessel							
Left main	4 (3.6)	2 (1.9)	2 (1.8)	3 (2.8)	3 (3.2)	1 (1.2)	0.88
LAD	61 (54.5)	47 (43.5)	52 (46.4)	55 (50.5)	35 (37.6)	40 (48.2)	0.23
LCx	16 (14.3)	3 4 (31.5)	28 (25.0)	25 (22.9)	29 (31.2)	11 (13.3)	0.004
RCA	29 (25.9)	23 (21.3)	29 (25.9)	25 (22.9)	24 (25.8)	30 (36.1)	0.29
Lesion location							
Ostial	5 (4.5)	3 (2.8)	5 (4.5)	5 (4.6)	0 (0.0)	3 (3.6)	0.46
Proximal	31 (27.9)	45 (41.7)	35 (31.3)	35 (32.4)	31 (33.3)	24 (28.9)	0.33
Mid	51 (45.9)	49 (45.4)	48 (42.9)	42 (38.9)	39 (41.9)	32 (38.6)	0.85
Distal	24 (21.6)	6 (5.6)	23 (20.5)	24 (22.2)	22 (23.7)	24 (28.9)	0.002
Pre DS	0.84 ± 0.08	0.83 ± 0.09	0.85 ± 0.10	0.86 ± 0.09	0.87 ± 0.09	0.86 ± 0.08	0.007
Pre MLD	0.98 ± 0.49	0.99 ± 0.45	0.95 ± 0.44	0.88 ± 0.49	0.89 ± 0.51	1.01 ± 0.49	0.31
Pre RVD	2.72 ± 0.46	2.69 ± 0.45	2.85 ± 0.49	2.67 ± 0.51	2.80 ± 0.51	2.91 ± 0.53	0.003
Pre lesion angle	26.4 ± 17.0	31.2 ± 23.4	25.3 ± 21.4	26.2 ± 18.8	27.5 ± 19.8	27.9 ± 19.9	0.38
Calcified lesion[a]	15 (14.2)	5 (5.2)	4 (3.9)	8 (7.9)	4 (4.6)	4 (5.0)	0.037
Tortuosity lesion	2 (1.9)	5 (5.1)	2 (1.9)	1 (1.0)	6 (6.8)	0 (0.0)	0.004

Data are presented as mean ± SD or n (%).
LAD, left anterior descending; LCx, left circumflex; RCA, right coronary artery; DS, diameter stenosis; MLD, minimal lumen diameter; and RVD, reference vessel diameter.
[a] Severe calcified lesion was only defined as calcified lesion in this study.