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Comparison of plaque prolapse in consecutive patients treated with Xience V and Taxus Liberte stents

Zhu Jun Shen · Salvatore Brugaletta · Hector M. Garcia-Garcia · Jurgen Ligthart · Josep Gomez-Lara · Roberto Diletti · Giovanna Sarno · Karen Witberg · Patrick W. Serruys

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Abstract The purpose of this article is to investigate the prevalence of plaque prolapse (PP) after Xience V and Taxus Liberte stent implantation. During the study period 2006–2007, 200 consecutive patients underwent coronary revascularization for de novo lesions and received an intravascular ultrasound (IVUS) post-stenting evaluation, ($n = 124$ patients with Taxus Liberte and $n = 76$ with Xience V) (227 stent segments). Cross-sectional and longitudinal 3D IVUS images were analyzed in a blind fashion, evaluating the prevalence of PP and calculating its depth and angle. The angulation degree of the coronary artery at the lesion site pre-stent implantation was also evaluated by angiography. The prevalence of PP was 23.9% in Xience V versus 38.1% in Taxus Liberte ($P = 0.025$). The depth and angle of PP were greater in Taxus Liberte stent than Xience V stent (0.4 ± 0.1 mm versus 0.5 ± 0.2 mm, $P = 0.004$; and $32.0 \pm 8.9°$ versus $44.6 \pm 27.6°$, $P = 0.044$, respectively). The angulation degree of the coronary artery at the lesion site was higher in presence of plaque prolapse than in its absence ($48.2 \pm 29.3°$ vs. $38.2 \pm 28.1°$, $P = 0.013$). By multivariate analysis, stent type was independently associated with incidence of plaque prolapse. Xience V stent has less plaque prolapse than Taxus Liberte stent. Stent design may play a role in the prevalence of plaque prolapse.

Keywords Plaque prolapse · IVUS · Drug eluting stent · Xience V stent · Taxus Liberte stent

Z. J. Shen · S. Brugaletta · H. M. Garcia-Garcia · J. Ligthart · J. Gomez-Lara · R. Diletti · G. Sarno · K. Witberg · P. W. Serruys (✉)
Thoraxcenter, Erasmus Medical Center, Ba-583, 's-Gravendijkwal 230, 3015, CE, Rotterdam, The Netherlands
e-mail: p.w.j.c.serruys@erasmusmc.nl

H. M. Garcia-Garcia
Cardialysis, BV, Rotterdam, The Netherlands

Introduction

Plaque prolapse (PP) is commonly defined as tissue extrusion through the stent strut post-procedure and is observed more frequently by IVUS than coronary angiography [1, 2]. Several investigators have raised concerns (i.e. stent thrombosis and restenosis) about PP after implantation of bare metal stents and first generation drug eluting stents (DES) [3, 4].

Compared to bare metal stents, drug eluting stents are associated with lower rates of restenosis. [5]. However, late stent thrombosis became the fundamental Achilles' heel of DES. Although not firmly established, PP and incomplete stent apposition have been considered to play a role in the pathogenesis of late stent thrombosis [6].

The platform changes of Taxus Liberte stent were intended to improve device delivery and drug release

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versus the Taxus Express 2 [7]. A second generation DES, the Xience V stent, was also shown to reduce restenosis rates and long-term MACE events compared to BMS and some first and second generation DES [8, 9]. There are, however, no studies to date examining the relationship between PP and second generation DES.

Thus, the aim of the present study was two-fold: (1) to compare the prevalence of PP, as assessed by cross-sectional and three dimensional volumetric IVUS imaging, in patients treated with Xience V and Taxus Liberte implantation and (2) to identify patient or procedural factors associated with PP.

Methods

Population

A total of 410 consecutive patients were evaluated with IVUS after percutaneous coronary intervention (PCI) for de novo lesions in our cath lab between January 2006 and December 2007. We excluded patients with acute myocardial infarction (AMI) within the preceding 2 weeks. During the study period, 80% of patients were implanted either with the Xience V (polymer-based, everolimus-eluting, Abbott Vascular, Santa Clara, CA, USA) or Taxus Liberte (polymer-based, paclitaxel-eluting, Boston Scientific Corporation, Natick, MA, USA) stent. Patients treated with other stents were excluded. Thus, we analyzed the data of 200 patients with 227 stented segments (with newly implanted stents) that were associated with good quality IVUS images.

Coronary stent procedure

Coronary angioplasty was performed according to standard practice. When multi-segment or multi-vessel treatment was performed, all implanted stents were of the same type.

All patients were treated with oral aspirin indefinitely (100–300 mg/daily) and clopidogrel (300 mg loading dose and 75 mg/daily maintenance dose for 1 year).

Quantitative coronary angiographic analysis

Vessel curvature (i.e. angulation) at the lesion site was measured in Rubo Dicom viewer system (Rubo Medical Imaging BV, Aerdenhout, The Netherland) both pre- and post-stenting [10]. The measurement was done on a still frame at end diastole in the same angiogram view selected by the interventional cardiologist, who was blinded to stent type, pre and post-stenting (Fig. 1) Angulation measurements were performed by an analyst who was blind to the stent type. Diameter stenosis, lesion length, minimal lumen

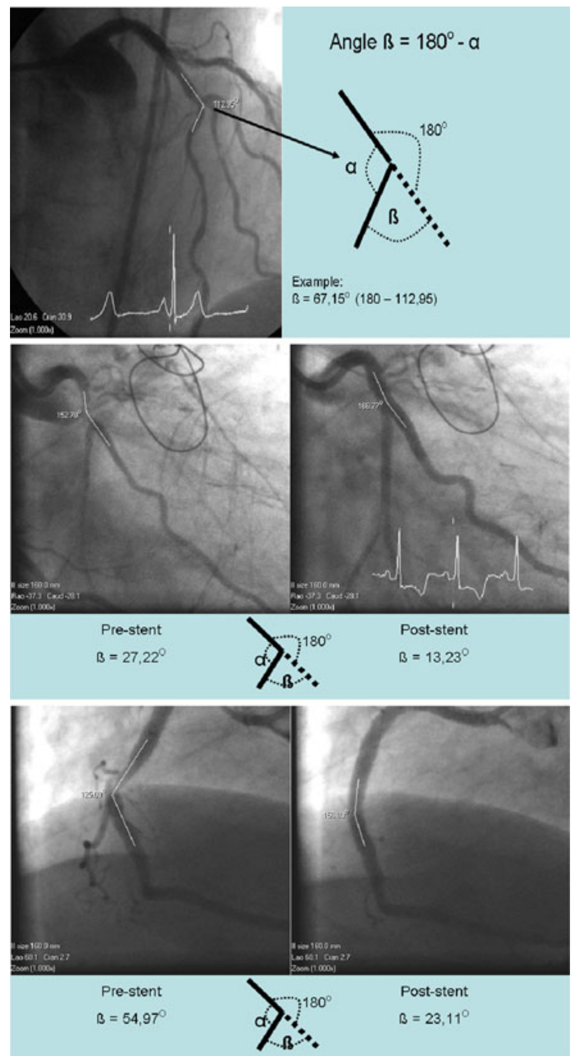

Fig. 1 This illustration shows the methodology of defining the vessel curvature angle pre-stenting and post-stenting. *Upper* In Rubo DicomViewer, we can only measure the angle α with two tangents to the proximal and distal parts of the stenosis/stents at the end-diastolic angiographic frame. We calculate the angle β to represent the angulation of the vessel. *Middle* An example of Xience V stent pre and post-stent angle changes in LCX. *Lower* An example of Taxus Liberte stent pre and post-stent angle changes in RCA

diameter, and reference vessel diameter before and after intervention were analyzed off-line (CAAS II, Pie-Medical, Maastricht, The Netherlands).

IVUS imaging protocol

Intravascular ultrasound images were acquired using a motorized pullback at a constant speed of 0.5 mm/s (30 frames). Images were recorded on high-resolution CD for off-line analysis. Two types of IVUS catheter were used during the study period: (1) Eagle Eye 20 MHz (Volcano Corporation, Rancho Cordova, USA) in 29 patients (14.5%) and (2) Atlantis pro 40 MHz (Boston Scientific/Cardiovascular Imaging System, Maple Grove, Minnesota) in the remaining 171 patients (85.5%). Two independent experienced investigators reviewed the IVUS images and were blinded to stent type. As definition of plaque prolapse was evaluated as qualitative variable in previous reports [3, 4, 11, 12], we defined PP as quantitative variable as a tissue protrusion into the vessel lumen measuring at least 0.15 mm passed the boundary of the stent area. Intra and inter-observer variabilities were calculated for PP identification. As the strut thickness of the first generation DES is approximately 0.15 mm, this threshold was used in our definition. The stent area was defined by planimetry of the area bounded by stent struts. In Rubo Dicom viewer system, we measured (1) the maximum depth of PP across the stent (2) the angle of PP using the center of the vessel as a reference point and (3) the percentage of depth of PP relative to stent diameter (Fig. 2).

Quantitative 3D IVUS analysis was performed using a dedicated quantitative IVUS analysis system (Curad IVUS Analysis 4.1.8, Wijk bij Duurstede, The Netherlands). The quantitative IVUS analysis system enables semiautomatic contours detection of the lumen, vessel, and stent as well as quantitative analysis of their dimensions in longitudinal and cross-sectional views. The resulting cross-sectional Bezier contours can be visualized immediately superimposed on a running video loop and may be edited manually. The mathematical description consists of a connected series of Bezier curves. Lumen, stent areas were measured along the entire target segment. This system has been validated and used in previous clinical studies [13]. The volume of PP was automatically calculated by subtracting lumen volume from stent volume.

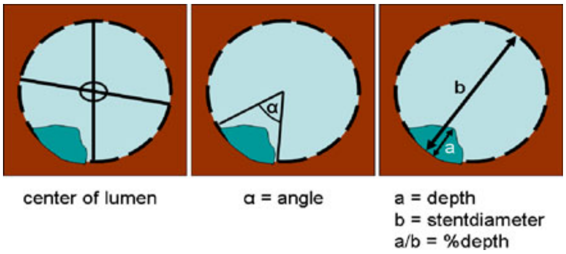

Fig. 2 This figure depicts defining the center of the lumen, measurement of PP angle, depth and percentage of depth. The center of gravity utilise intersection of the *shortest* and *longest* diameter

Statistical analysis

All normally distributed data were expressed as % or mean ± SD. Normal distribution of the variables was tested by Kolmogorov–Smirnov test. Group differences of categorical variables were compared using Pearson chi-squared tests. A kappa co-efficient was estimated to evaluate the inter-observer agreement of identification of plaque prolapse. Comparison of means was done using independent-samples *t* test. Multivariate logistic regression analysis was performed to identify independent factors of PP. An exploratory univariate analysis was used to identify the variables to included in the multivariate model (only the variables with a P value of <0.15 and the pre-stenting lesion angle, as possible confounding factor, were included). A P value of <0.05 was considered significant, and all tests were two-tailed. Data were analyzed with SPSS version 16.0 software (SPSS Inc., Chicago, IL).

Results

The baseline patient characteristics were similar between the Xience V and Taxus Liberte groups (Table 1). The mean age of the patients was 64 years old. The majority were male (70%) and the most frequently treated vessel was left anterior descending (54.5%). At pre-stenting, the angle at site lesion was significant lower in Xience V group compared to Taxus Liberte group (34.8 ± 24.2° vs. 45.7 ± 30.7°, $P = 0.003$); the change in angulation from pre- to post-stenting was larger in Taxus Liberte stent compared to Xience V (16.3 ± 18.6° vs. 10.8 ± 11.5°, $P = 0.006$) (Table 1).

Table 1 Baseline clinical ($n = 200$) and lesion characteristics ($n = 227$) as to different type of stent

Baseline clinical characteristics	Xience V $N = 76$	Taxus Liberte $N = 124$	*P*
Age (years)	64 ± 9.74	63 ± 10.35	0.378
Male (%)	71.1	69.4	0.799
Diabetes (%)	18.4	16.1	0.675
Hypertension (%)	50	46.8	0.658
Dyslipidemia*(%)	52.6	62.9	0.152
Smoking (%)	36.8	50.8	0.052
Family history (%)	44.7	48.4	0.616
No. of coronary arteries narrowed > 50% (*n*)			0.089
1 vessel	39	59	
2 vessel	23	53	
3 vessel	14	12	
Clinical presentation (*n*)			0.913
Stable angina	49	79	
Unstable angina	27	45	
Lesion characteristics	Xience V ($n = 88$)	Taxus ($n = 139$)	
Target vessel (*n*)	0.307		
LAD	52	72	
LCX	19	26	
RCA	13	34	
LM	2	6	
Intermediate	2	1	
Lesion characteristics (*n*)			0.174
Type A	30	33	
Type B1	44	69	
Type B2	9	26	
Type C	5	11	
Maximum angle (°)	34.4 ± 23.7	40.6 ± 24.3	0.056
Pre-stenting angle (°)	34.8 ± 24.2	45.7 ± 30.7	0.003
Post-stenting angle (°)	24.4 ± 19.5	29.7 ± 22.4	0.060
Angle change (°)	10.8 ± 11.5	16.3 ± 18.6	0.006
MLD pre (mm)	0.75 ± 0.39	0.82 ± 0.53	0.269
Vessel size (mm)	3.12 ± 0.51	3.25 ± 0.59	0.094
Lesion length (mm)	29.8 ± 15.1	30.5 ± 15.8	0.722

* Total cholesterol ≥ 5.0 mmol/l or treatment with a lipid-lowering drug. *LAD* left anterior descending artery, *LCX* left circumflex artery, *RCA* right coronary artery, *LM* left main, *MLD pre* minimal lumen diameter pre-intervention

In total, there were 74 (32.6%) PP sites as assessed by IVUS (Figs. 3, 4). PP was observed more commonly in Taxus Liberte (53/139, 38.1%) than Xience V (21/88, 23.9%) ($P = 0.025$). The depth and angle of PP were significantly larger in Taxus Liberte than Xience V (0.54 ± 0.20 mm vs. 0.40 ± 0.11 mm, $P = 0.004$ for PP depth; and 44.66 ± 27.60° vs. 32.05 ± 8.97°, $P = 0.044$ for the angle) (Table 2). Intra- and inter-observer variabilities for PP evaluation yielded good concordance ($\kappa = 0.90$ and $\kappa = 0.84$, respectively).

At pre-stenting, sharper angles were found in patients with PP compared to those without PP (48.2 ± 29.3° vs. 38.2 ± 28.1°, $P = 0.013$) (Table 3). Lesions characteristics in patients with PP tended to be more complex compared to those in patients without PP ($P = 0.06$). The pre-stent angle between Xience V and Taxus Liberte was not significant different among patients without PP, while was significantly different among patients with PP (35.9 ± 21.8° versus 53.4 ± 31.8°, $P = 0.010$) (Fig. 5).

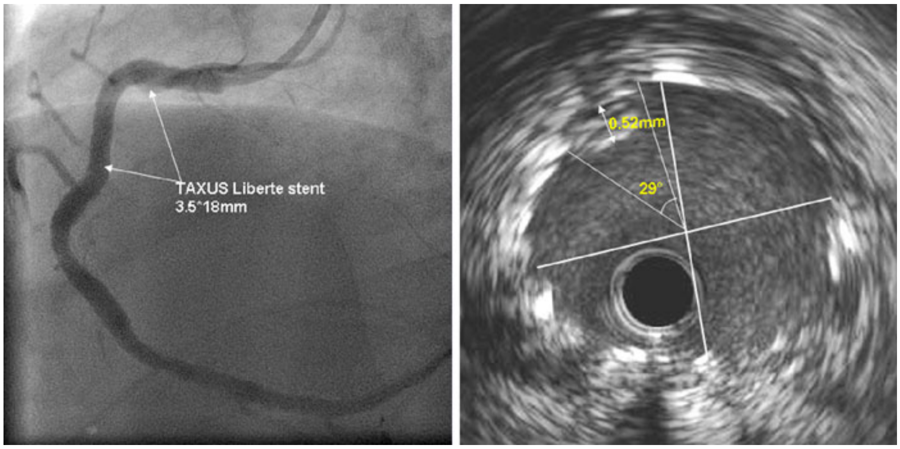

Fig. 3 *Left panel* Right coronary artery (RCA) angiogram post-stent. Proximal RCA TAXUS Liberte stent 3.5*18 mm (between white arrows). *Right panel* plaque prolapse in IVUS (40 mHz Atlantis Pro), with plaque depth 0.52 mm and angle 29°

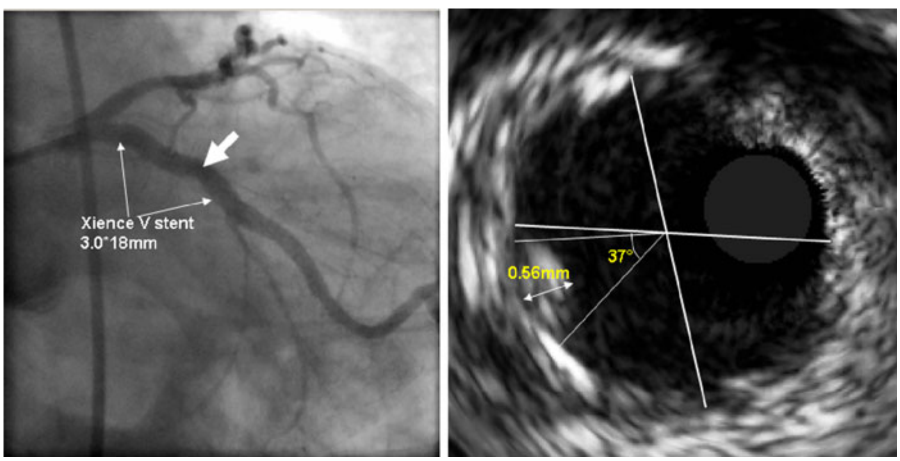

Fig. 4 *Left panel* Left circumflex (LCX) angiogram post-stent, mid-LCX has a Xience V stent 3.0*18 mm (between two *white arrows*). *Big white arrow* indicated the approximate angiographic location of the plaque prolapse seen in the IVUS. *Right panel* plaque prolapse in IVUS (20 mHz *Eagle Eye*), with plaque depth 0.56 mm and angle 37°

Table 2 IVUS characteristics of plaque prolapse between Xience V and Taxus Liberte

Variables	Xience V ($n = 21$)	Taxus Liberte ($n = 53$)	P
Plaque volume (mm^3)	0.33 ± 0.42	1.06 ± 2.23	0.145
Depth (mm)	0.40 ± 0.11	0.54 ± 0.20	0.004
Depth (%)	13.7 ± 3.87	15.8 ± 5.50	0.115
Angle (°)	32.05 ± 8.97	44.66 ± 27.60	0.044
Length (mm)	1.10 ± 1.48	1.46 ± 1.30	0.305

In the multivariate analysis, including all variables with $P < 0.15$ in univariate analysis, only the type of stent implanted was the independent predictor of plaque prolapse (Table 4).

Discussion

The main observations of this study were the following: (1) plaque prolapse was more commonly

Table 3 Comparison of patients having prolapse and their counterparts

Variable	PP(+) $N = 74$	PP(−) $N = 153$	*P*
Age (years)	63 ± 11.4	64 ± 9.7	0.542
Men (%)	67.6	71.2	0.571
Diabetes (%)	17.6	17.0	0.914
Hypertension (%)	48.6	49	0.958
Dyslipidemia* (%)	60.8	53.6	0.305
Smoking (%)	51.4	41.2	0.148
Family history (%)	47.3	45.8	0.827
Stent type (%)			0.013
Xience V	27.0	44.5	
Taxus Liberte	73.0	55.5	
No. of coronary arteries narrowed > 50% (*n*)			0.783
1 vessel	37	69	
2 vessel	27	62	
3 vessel	10	22	
Clinical presentation (*n*)			0.147
Stable angina	41	100	
Unstable angina	33	53	
Target vessel (*n*)			0.179
LAD	40	84	
LCX	13	32	
RCA	24	27	
LM	0	8	
Intermediate	1	2	
Lesions characteristics ((*n*, (%))			0.06
Type A	15 (20)	48 (31)	
Type B1	35 (47)	78 (51)	
Type B2	16 (21)	19 (12)	
Type C	8 (12)	8 (6)	
Direct stenting (%)	30.5	69.5	0.527
Post-dilatation (%)	15	20	0.785
Max post-dilatation balloon pressure, mean ± SD	17.1 ± 2.2	16.9 ± 2.3	0.716
Pre-stenting angle (°)	48. 2 ± 29.3	38.2 ± 28.1	0.013
Post-stenting angle (°)	31.9 ± 22.6	25.6 ± 20.6	0.037
Angle change (°)	16.4 ± 19.2	12.6 ± 15.3	0.115
Lesion length (mm)	32.7 ± 15.3	29.0 ± 15.5	0.092
Vessel size (mm)	3.17 ± 0.49	3.21 ± 0.48	0.607
MLD pre (mm)	0.72 ± 0.47	0.83 ± 0.49	0.093

* Total cholesterol ≥ 5.0 mmol/L or treatment with a lipid-lowering drug. *PP* plaque prolapse, *LAD* left anterior descending artery, *LCX* left circumflex artery, *RCA* right coronary artery, *LM* left main, *MLD pre* minimal lumen diameter pre-intervention

observed in the Taxus Liberte group than in the Xience V group; (2) presence of plaque prolapse was associated with sharper angle at the lesion site; (3) geometrical characteristics of plaque prolapse were different between the two stent groups.

Plaque prolapse was first reported in 1994 using coronary angiography and described as residual stenosis and haziness [14]. IVUS technology confirmed the suspicions of plaque prolapse noted by angiography. Studies of BMS and first generation DES (sirolimus-eluting Cypher and paclitaxel-eluting Taxus stent) documented PP rates between16.6 to 41% [3]. In this retrospective observational study, approximately one third of patients were identified with PP by IVUS.

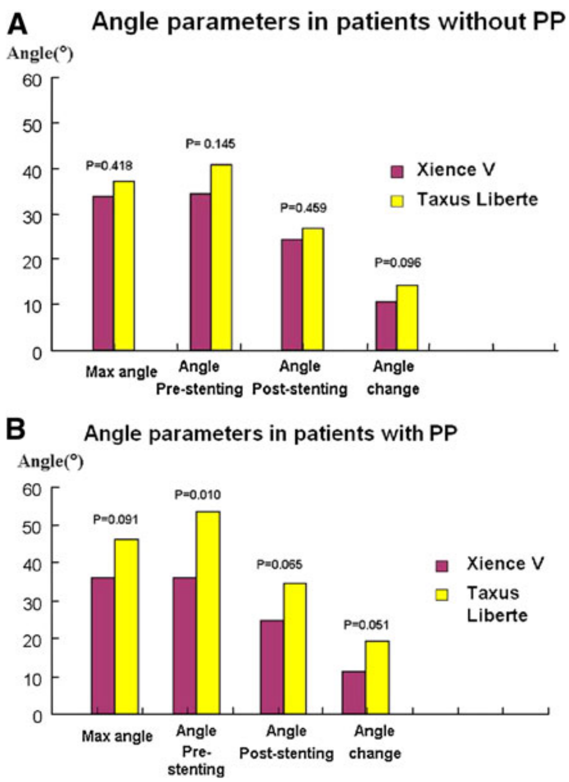

Fig. 5 Vessel curvature parameters in patients without plaque prolapse (*panel A*) and in patients with plaque prolapse (*panel B*)

Table 4 Univariate and multivariate analysis of independent predictors of plaque prolapse

Variables	Univariate analysis	Multivariate analysis
Clinical setting	$P = 0.05$	$P = 0.05$
Lesion length	$P = 0.54$	
Stent type	$P = 0.04$	$P = 0.03$
Pre-stenting MLD	$P = 0.54$	
Pre-stenting lesion angle	$P = 0.28$	$P = 0.17$
Angle change after stenting	$P = 0.50$	
Lesion characteristics, according to AHA/ACC classification	$P = 0.11$	$P = 0.06$
Maximum balloon pressure	$P = 0.34$	

MLD minimum lumen diameter

Lesion characteristics may contribute to the plaque prolapse. Previous studies have demonstrated that plaque prolapse may occur with greater frequency in the setting of long lesions, chronic total occlusions, positive remodeling and thrombus [3, 12]. In the present study, we found that the pre-stenting angulation at the lesion site was higher in the lesions with plaque prolapse. As vessel curvature at the lesion site has been demonstrated as a predictor of major adverse cardiac events [15], an increased frequency of plaque prolapse in those patients could represent a link between vessel curvature and clinical outcomes.

Procedural characteristics may also play a role in the prevalence of PP. In our study, all the procedures were performed by the same group of interventional cardiologists using similar techniques. No obvious differences in procedural characteristics were observed between the two stent types groups.

Although most stent designs can adequately cover atherosclerotic plaques, PP may also be related to struts' geometry and design. Previous studies have shown similar rates of plaque prolapse between Taxus and Cypher stents [3]. In our analysis, we found a greater incidence of prolapse in the Taxus Liberte stent than Xience V stent (38.2% vs. 23.9%, $P = 0.025$). The difference in type of metal or design between these two stent could be accounted for the higher incidence of plaque prolapse. In particular, previous studies and data from manufactures have shown that the maximum cell opening and the metal artery wall ratio (percentage of artery wall covered by the outer surface of the stent) between Taxus Liberte and the Xience V were different (Table 5) [16]. However, despite an higher metal artery wall ratio, Taxus exhibits a higher plaque prolapse incidence. For this reason, difference in stent design could be probably more important in determining plaque prolapse. Taxus Liberte is a stainless steel platform and open cell design [17]. On the other side, the Xience V stent is a multi-link vision cobalt chromium stent platform and is also an open cell concept with two designs for small and larger vessels [8]. Although there was a different angiographic vessel curvature between Xience V with Taxus Liberte groups, at multivariate regression analysis, stent type was still an independent predictor of plaque prolapse (OR 1.86, 95%CI 1.00, 3.47, $P = 0.050$).

Limitations

This study suffers from the inherent limitations of any small size, retrospective, non-randomized study. Coronary segment angle degree measured by 2D software suffers from the limitation of 2D

Table 5 Metal artery ratio between Xience V and Taxus Liberte

	Xience V				Taxus Liberte		
Stent diameter (mm)	2.5	3.0	3.5	4.0	2.5	3.0	4.0
MAR (%)	13.3	10.7	14.3	12.2	20.1	17.0	18.0

MAR metal artery ratio

measurement. The limitation of IVUS to differentiate PP tissue characteristics and the limited sensitivity of IVUS to identify small plaque prolapse may have also confounded the observed rate of plaque prolapse after stenting.

In addition, it has been reported that using optical coherence tomography technology, which is associated with greater resolution, plaque prolapse can be observed in more than 70% of patients [18]. Thus, the true prevalence of plaque prolapse is still unclear and can vary depending on the imaging modality and definition used.

Conclusion

Plaque prolapse rate is higher after Taxus Liberte stent implantation compared to Xience V stent implantation. The importance of stent design and lesion characteristics in the pathogenesis of plaque prolapse need further elucidation.

Conflict of interest There are no conflicts of interest.

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