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Long-term outcome after the V stenting technique in *de novo* bifurcation lesions using drug-eluting stents

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KEYWORDS
Angioplasty, drug eluting stent, stent thrombosis

Abstract

Aims: To report long-term outcome data on the V technique using drug-eluting stents.

Methods and results: From April 2002 to December 2006, 31 consecutive patients were successfully treated with V stenting of a *de novo* bifurcation lesion. The technique involves the deployment of two stents in the two branches of a bifurcation, the proximal edges of the stents just touching one another. Patients exclusively received either sirolimus- (10), paclitaxel- (20) or biolimus-eluting (one) stents. On average, 1.5±0.8 stents with a total length of 26.6±17.2 mm and 1.1±0.4 stents with a total length of 18.3±7.6 mm were deployed in the distal main vessel and side branch respectively. Mean duration of follow-up was 853±553 days. Within 30 days, three patients died; two other patients had definite stent thrombosis involving the V stents, both requiring re-PCI. Beyond 30 days and within one year, there was one death and three cases of target vessel revascularisation, including one target lesion revascularisation. There were a further three deaths (one cardiac) beyond one year. Eleven patients (35.5%) had angiographic follow-up, exhibiting a binary restenosis rate of 9.1% at 203±33 days.

Conclusions: In this real-world cohort, late clinical events stand in accord with studies on competitive techniques, but early outcome was less encouraging, probably due to the baseline risks.

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Introduction

The optimal technique for treating bifurcation lesions with percutaneous coronary intervention (PCI) has not been clearly established. There is particularly little outcome data on V stenting in the current drug-eluting stent (DES) era. The V stenting technique scaffolds both distal limbs of a bifurcation lesion from the carina onwards and is only suitable when the lesion spares the proximal main vessel (PMV)[1]. In treating bifurcation lesions, optimal coverage without any un-stented gaps is essential for optimal scaffolding and drug delivery to mitigate the restenotic process[2-4]. Recently, various groups have described the Simultaneous Kissing Stents (SKS) technique – the simultaneous deployment of the distal main vessel (DMV) and side branch (SB) stents so that the new apposing struts from the two adjacent stents extended proximally from the carina[5-7] for 8±5 mm[5] or 8.9±2.5 mm[6]. Preliminary angiographic[6] and histologic[7] results showed that a new carinal membrane developed on these struts. While this technique can handle proximal disease close to the carina, the PMV receiving the two stents is often over-dilatated with its attendant risks[5]. A newer approach is to implant in the PMV a conical self-expandable Axxess (Devax, Irvine, CA, USA) stent with a "flared" distal part covering the outer rim of the bifurcation and two stents distally with V technique to scaffold the inner rim. To facilitate progress in this field, noting the possible dreaded complication of late stent thrombosis[8], we reviewed the long-term outcome of V stenting using DES from April 2002[9] to December 2006.

Methods

Study population

On April 16, 2002, our institution began to use sirolimus-eluting stents (SES, Cypher, Cordis Corporation, Warren, NJ, USA) as the default strategy for every PCI, until Feb 16, 2003 when paclitaxel-eluting stents (PES, Taxus, Boston Scientific, Natick, MA, USA) became our default strategy. Data were recorded in the Rapamycin-Eluting Stent Evaluated at Rotterdam Cardiology Hospital (RESEARCH) registry[10] and the Taxus Stent Evaluated AT Rotterdam Cardiology Hospital (T-SEARCH) registry[11]. From April 2002 to December 2006, 656 procedures involving treatment of *de novo* bifurcation lesions were performed in 638 patients. Out of this cohort, and after reviewing the angiographic films, we identified 31 consecutive patients, who had one bifurcation lesion successfully treated with V stenting; none of them had a second procedure involving this technique. Written informed consent was obtained from all patients prior to the procedure.

Procedure

V stenting is defined as the delivery and implantation of two stents in the two branches of a bifurcation; one stent is deployed in the DMV and the other one in the SB[12]. The stents can be deployed either concurrently or in a successive mode[13]. The latter is presumably an acceptable alternative, provided that the second stent is deployed concurrently with a balloon inflated in the first stent, to protect this from being crushed; systematic post-dilation with kissing balloons should be performed. To differentiate from the SKS technique, we defined V stenting as the proximal edges of the stents just touching one another without any significant overlap, protruding into the PMV by no more than 5 mm[12] (Figure 1).

All procedures were performed according to current interventional standards at the time. The use of predilation, post-procedure kissing balloon inflation and the use of glycoprotein IIb/IIIa inhibitors was left to the operators' discretion. During the procedure, intravenous heparin was administered, in order to maintain an activated clotting time above 250 seconds. All patients were prescribed 80 mg of aspirin lifelong and were pretreated with 300 mg clopidogrel followed by 75 mg clopidogrel for at least six months.

Clinical definitions and follow-up

Angiographic success was defined as residual stenosis <30% by visual estimation in the presence of Thrombolysis In Myocardial Infarction (TIMI) grade 3 flow. Clinical success was defined as angiographic success without the occurrence of death, myocardial infarction or repeat revascularisation of the target lesion during the hospital stay. Myocardial infarction was diagnosed by an increase in creatine kinase-MB fraction of three times the upper limit of normal, according to American Heart Association / American College of Cardiology guidelines[14]. Target lesion revascularisation (TLR) and target vessel revascularisation (TVR) were defined according to the Academic Research Consortium (ARC) recommendations[15]; they were adjudicated as clinically indicated, only if driven by symptoms/objective signs of ischaemia and a percent diameter stenosis exceeding 50% on follow-up angiography. Clinical events were recorded in two ways: firstly, as composite major adverse cardiac events (MACE), including all-cause death, nonfatal myocardial infarction and TVR and secondly, in the form of the ARC recommended device-oriented composite, including cardiac death, myocardial infarction (not clearly attributable to a non-target vessel) and TLR.

We applied ARC recommendations to adjudicate stent thrombosis. Angiographically defined thrombosis with TIMI grade 0 or 1 flow or the presence of a flow-limiting thrombus accompanied by acute symptoms was considered as definite stent thrombosis. Unexplained death was adjudicated as probable stent thrombosis if occurring within 30 days, and as possible stent thrombosis if after 30 days[15]. Stent thrombosis was further categorised according to the timing of the event into acute (within 24 hours), subacute (24 hours-30 days), late (30 days-1 year) and very late (beyond one year). We retrieved electrocardiographic (ECG) information on patients with myocardial infarction for adjudication.

Data sources for both registries included municipal civil registries for survival status, information from health questionnaires, medical records, and information from local physicians on repeat coronary interventions (surgical or PCI), myocardial infarction and medication usage [10, 11].

Angiographic evaluation

The bifurcation lesions were adjudicated according to the Medina classification[16] after reviewing the pre-procedure images. Quantitative coronary angiographic (QCA) analysis was performed by means of dedicated bifurcation QCA software (CAAS 5.4,

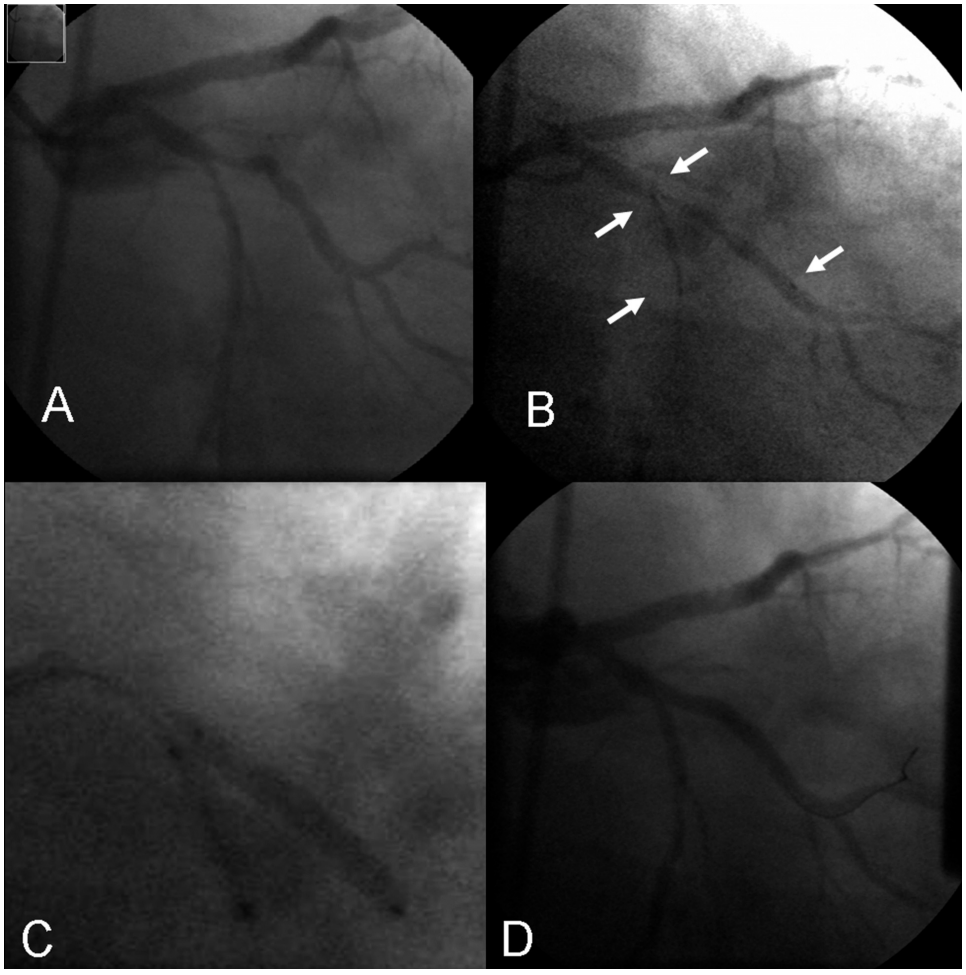

Figure 1. Illustration of V stenting technique. A. Typical 0,1,1 bifurcation lesion involving the left circumflex (LCX) and the obtuse marginal (OM) branch (distal main vessel). B. Two sirolimus-eluting, Cypher, stents have been advanced into position. The 3.0 x 23 mm stent is in the OM, the 2.5 x 13 mm stent is in the LCX. Arrows point at the stents' markers; the proximal markers barely touch each other, not protruding into the proximal main vessel. C. Both stents are simultaneously deployed. D. Final result.

Maastricht, PIE Medical software, The Netherlands) (Figure 2); the relevant methodology employing a ten-segment model for the bifurcation lesion has already been described[17]. Angiographic parameters, namely minimal lumen diameter (MLD), interpolated reference vessel diameter (RVD) and percentage diameter stenosis (DS), were independently determined both within the stent(s) and within the segment(s). These parameters were measured pre-procedure, post-procedure and, when available, at follow-up. In the case of a chronic total occlusion (CTO), the MLD equals 0 mm, %DS equals 100% and RVD cannot be determined. Late lumen loss (LLL) was calculated as the difference in MLD between post-procedure and follow-up. Angles between the PMV and SB (proximal bifurcation angle) and between DMV and SB (distal bifurcation angle) were automatically determined. Binary angiographic restenosis was defined as DS ≥50% at follow-up.

Statistical analysis

Categorical variables are presented as counts and percentages, whereas continuous variables are expressed as mean ± standard deviation. A comparison of angiographic variables both between pre and post and between post and follow-up was performed with a Wilcoxon signed rank test. A p- value of <0.05 was considered significant. Statistical analysis was performed using commercially available software (SPSS 12.0 for Windows, SPSS, Chicago, IL, USA).

Results

The baseline demographics and procedural characteristics in the 31 patients are reported in Tables 1 and 2. PCI was performed in 20 (64.5%) patients for an acute coronary syndrome (22.6% with ST elevation myocardial infarction and 41.9% with unstable angina or non-ST elevation myocardial infarction). Twenty-three patients (74.2%) had multivessel disease and 12 of them (38.7%) had interventions to at least one additional major epicardial vessel beyond the target vessels. All patients received exclusively one type of DES; Taxus and Cypher stents were implanted in 20 and 10 cases respectively. There was a single patient who received exclusively biolimus-eluting stents (BES, Biomatrix, Biosensors, Singapore); he was recruited in a research study and had no clinical event during the follow-up period. The average number of stents was 3.5±1.5 per patient with a total stent length 64.1±32.6 mm. However, regarding

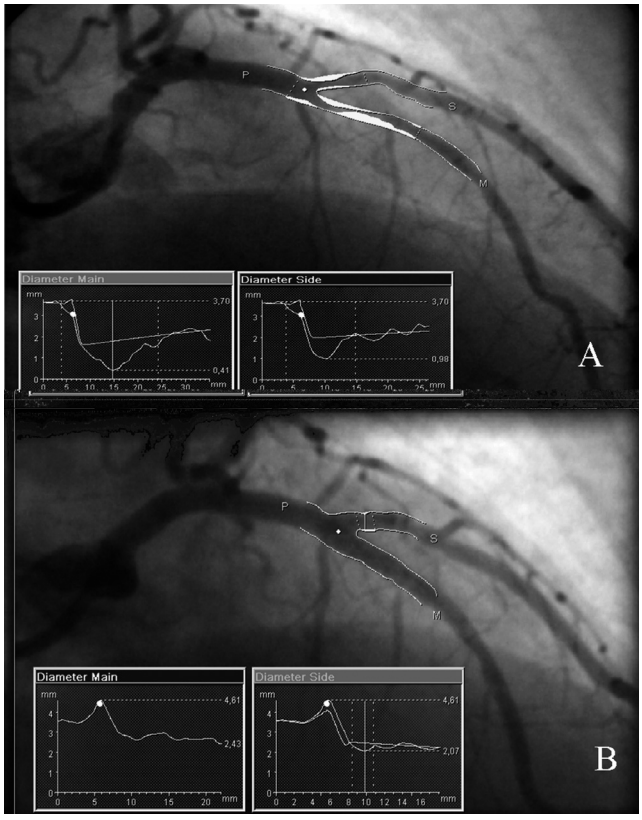

Figure 2. Quantitative coronary angiography of a bifurcation lesion involving the left anterior descending (LAD) and the diagonal branch (side branch). Automatic contour detection pre-procedure (A) and post-procedure (B). Images include the corresponding diameter plots for the main branch and the side branch (CAAS 5.4, Maastricht, PIE Medical software, The Netherlands).

the bifurcation lesion itself, 1.5±0.8 stents with a mean total length of 26.6±17.2 mm and 1.1±0.4 stents with a mean total length of 18.3±7.6 mm were deployed in the DMV and SB respectively. All patients had Medina bifurcation lesion classification of 0,1,1 for the lesion receiving V stenting. The left main bifurcation was the location of the lesion in the majority of the cases (16 cases-51.6%); the lesion involved the left anterior descending (LAD)/diagonal bifurcation in eight cases, the left circumflex (LCX)/obtuse marginal bifurcation in six cases and the distal right coronary artery (RCA) bifurcation in one case. Stents were deployed simultaneously at all times, whereas post-dilation with kissing balloons was performed in 10 cases (32.3%); glycoprotein IIb/IIIa inhibition was employed in 13 cases (41.9%).

Thirty-day outcome

Within 30 days, three patients died (patients 1, 2 and 3 in Table 3). The first death was regarded as non-cardiovascular, since the patient succumbed to hospital acquired pneumonia after a stroke, whereas patient 2 was adjudicated to have probable stent thrombosis. Patient 3 could not be saved despite a rescue procedure for cardiogenic shock after failed thrombolysis, and died of heart failure. Two other patients had definite stent thrombosis and required emergency PCI, one on day 0 and one on Day 5. The latter (patient 4 in Table 3), a 78-year old man suffering a heart attack five days after a prostate operation, had a cerebral haemorrhage on day 4 and therefore aspirin and clopidogrel were discontinued; the stents occluded the very next day. Finally, another patient who had the V stents placed at the left main bifurcation, and also had intervention on a sub-totally occluded venous graft to his right coronary artery, had a myocardial infarction on the same day; ECG changes pointed to the treated graft as the culprit.

Table 1. Patient demographics and clinical characteristics (n = 31).

Age (years)	65.9±11.4
Male gender (%)	22 (70.9)
Diabetes mellitus (%) -all NIDDM	5 (16.1)
Hypertension (%)	10 (32.3)
Hypercholesterolaemia (%)	15 (48.4)
Current smoker (%)	6 (19.4)
Previous myocardial infarction (%)	12 (38.7)
Previous PCI (%)	4 (12.9)
Previous CABG (%)	2 (6.5)
Clinical presentation	
Stable angina (%)	11 (35.5)
Unstable angina or non-ST elevation myocardial infarction (%)	13 (41.9)
ST elevation myocardial infarction (%)	7 (22.6)
Glycoprotein IIb/IIIa inhibitors periprocedural usage (%)	13 (41.9)

NIDDM: non insulin dependent diabetes mellitus; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft surgery

Table 2. Baseline angiographic and procedural characteristics (n = 31).

Multivessel disease (%)	23 (74.2)
Multivessel intervention (%)	21 (67.7)
Angiographic success (%)	31 (100)
Clinical success (%)	25 (80.6)
Target bifurcation lesion location	
LMS (%)	16 (51.6)
LAD / diagonal (%)	8 (25.8)
LCX / obtuse marginal (%)	6 (19.4)
RCA bifurcation (%)	1 (3.2)
CTO within the target bifurcation lesion	5 (16.1)
In the distal main vessel	4 (12.9)
In the side branch	1 (3.2)
Mean number of stents per patient	3.5±1.5
Mean total length of stents (mm)	64.1±32.6
Mean number of stents in the main vessel	1.5±0.8
Mean total length of stents in the main vessel (mm)	26.6±17.2
Mean number of stents in the side branch	1.1±0.4
Mean total length of stents in the side branch (mm)	18.3±7.6
DES implanted	
Patients receiving SES (%)	10 (32.3)
Patients receiving PES (%)	20 (64.5)
Patients receiving BES (%)	1 (3.2)
Post-dilation with kissing balloons (%)	10 (32.3)

LMS: left main stem; LAD: left anterior descending; LCX: left circumflex; RCA: right coronary artery; CTO: chronic total occlusion; DES, SES, PES, BES: drug-, sirolimus, paclitaxel and biolimus- eluting stents respectively

Table 3. All-cause death: patient characteristics and procedural details.

Patient	Gender/Age	Index PCI indication	Treated vessels	V stents location	Stent type	GP IIb/IIIa Inhibitor use	Kissing balloon inflation	Stent thrombosis by ARC definitions	Time to TLR/TVR, days	Time to Death, days	Remarks
1	M/64 yrs	Unstable angina	LCX, intermediate	LCX-intermediate	PES	Yes	Yes	No	No	11	Stroke on day 4, died of hospital acquired pneumonia
2	F/63 yrs	Unstable angina	LAD, LCX	LAD-LCX	PES	Yes	Yes	Probable	No	11	Pulmonary embolism, hence anti-coagulated. Sudden death preceded by generalised convulsion
3	M/78 yrs	ST elevation myocardial infarction	LAD, LCX	LAD-LCX	SES	No	No	No	No	14	Index PCI was rescue procedure for cardiogenic shock. Died of heart failure
4	M/78yrs	ST elevation myocardial infarction	LAD, diagonal	LAD-diagonal	PES	No	No	Definite	LAD stent thrombosis Day 5	42	Cerebral haemorrhage on day 4; cessation of aspirin and clopidogrel on the same day; LAD and LM stented on re-PCI with moderate result Sudden death during recovery
5	F/80yrs	Unstable angina	LAD, LCX, OM	LCX-OM	SES	No	No	No	No	450	Sepsis after amputation
6	M/74yrs	Unstable angina	LAD, LCX	LAD-LCX	SES	No	No	No	Ostial LCX restenosis Day 189	1058	Ischaemia-driven TLR, day 189. Succumbed to end-stage heart failure
7	M/66yrs	Stable angina	LAD, LCX	LAD-LCX	SES	Yes	No	No	No	1206	Sepsis due to pneumonia

PCI: Percutaneous coronary intervention; TLR: Target lesion revascularisation; TVR: Target vessel revascularisation; ARC: Academic Research Consortium; LCX: Left circumflex; LAD: Left anterior descending; OM: Obtuse Marginal branch; LM: Left Main coronary artery; SES/PES: sirolimus-/paclitaxel-eluting stents

Late clinical outcome

Survival status was available in every patient for ≥ 12 months after the initial PCI. The mean duration to the last follow-up or to death was 853±553 days. Beyond 30 days, and within a year, there was one more death (Table 4). Patient number 4 in Table 3 died on day 42 while recovering from the cerebral haemorrhage; this sudden death was adjudicated as possible stent thrombosis. Three patients required a target vessel revascularisation, but in only two were the bifurcation V stents the targets for re-intervention. One patient underwent repeat coronary angiography and subsequently reintervention on day 160 upon referral for unstable angina. He had a mid-LAD in-stent restenosis of 70% and a borderline 50% (by visual estimation) ostial LAD restenosis, involving the V stents implanted at the LAD-LCX bifurcation. The former lesion was deemed the culprit lesion and was re-stented with a DES, whereas the latter was also treated with a DES deployed in the distal left main into the proximal LAD, fenestrated to the LCX; the procedure was completed with a kissing balloon inflation. However, QCA analysis ascribed a 43.9% stenosis to the ostial LAD restenotic lesion; thus this was not adjudicated as an ischaemia-driven revascularisation. Another patient with LAD-LCX V stents, had a re-study on day 189 revealing ostial LCX in-stent restenosis, which was treated with balloon dilatation. No patients had reinfarction beyond 30 days (Table 4). There were a further three deaths on days 450, 1058, 1206; the causes of death were respectively sepsis, end-stage heart failure and sepsis and none was adjudicated as having stent thrombosis (Table 3). The patient who died of heart failure was actually the single ischaemia-driven TLR case. The overall rates of mortality and other clinical endpoints within 30 days and 1-year (cumulative) are summarily reported in Table 4.

Quantitative angiographic analysis

Analysis of the baseline procedure could be done for 30 out of the 31 patients (Table 5); we could not retrieve post-procedure images for one case. Out of the 30 baseline procedures analysed, there were five cases involving a CTO, therefore the preprocedure RVD and the bifurcation angulation parameters could not be determined. In 11 cases, there was minimal stent protrusion into the PMV (2.23±0.72 mm), however never exceeding 5 mm or the respective RVD of the PMV; in three cases the protrusion was actually less than half the respective RVD. Angiographic follow-up (at a period of 203±33 days) was available for 11 patients (35.5%); data are presented in Table 6. Out of this group, eight patients underwent routine control coronary angiography and presented no binary angiographic restenosis of the target bifurcation lesion; out of the three patients who were referred for anginal symptoms (two with stable angina and one with unstable angina), one patient had binary in-stent restenosis. Thus, this cohort exhibited a restenosis rate of 9.1% (1/11). The LLL in the DMV and SB was 0.17±0.53 mm and

Table 4. Clinical outcome over the follow-up period.

	Within 30 days	At one year (cumulative)
All-cause mortality	3 (9.7%)	4 (12.9%)
Cardiac mortality	2 (6.5%)	3 (9.7%)
Non-cardiovascular mortality	1 (3.2%)	1 (3.2%)
Non-fatal myocardial infarction	2 (6.5%)	2 (6.5%)
Target lesion revascularisation (ischaemia driven)	2 (6.5%)	3 (9.7%)
Target vessel revascularisation (ischaemia driven)	2 (6.5%)	5 (16.1%)
MACE-Mortality or non-fatal ST elevation myocardial infarction or target vessel revascularisation	6 (19.4%)	9 (29.0%)
Device oriented composite-cardiac mortality or target vessel related myocardial infarction or target lesion revascularisation	4 (12.9%)	5 (16.1%)
Stent thrombosis according to Academic Research Consortium definitions	Acute	Subacute / Late
Definite	1 (3.2%)	1 (3.2%) / 0 (0%)
Probable	0 (0%)	1 (3.2%) / 0 (0%)
Possible	0 (0%)	0 (0%) / 1 (3.2%)

MACE: Major Adverse Cardiac Events

Table 5. Angiographic parameters for the baseline procedure (n=30).

	Pre	Post	P-value
Proximal main vessel			
MLD (mm)	1.73±0.55	2.45±0.46	<0.01
RVD (mm)	2.69±0.92	2.90±0.65	0.73
%DS	26.2±16.0	13.8±6.8	<0.01
Distal main vessel			
In segment			
MLD (mm)	0.96±0.59	2.13±0.43	<0.01
RVD (mm)*	2.10±0.47	2.69±0.46	<0.01
%DS	54.8±25.9	19.5±10.1	<0.01
In stent			
MLD (mm)	0.96±0.59	2.39±0.37	<0.01
RVD (mm)*	2.10±0.47	2.70±0.45	<0.01
%DS	54.8±25.9	11.0±7.9	<0.01
Side branch			
In segment			
MLD (mm)	0.99±0.41	1.91±0.47	<0.01
RVD (mm)**	2.04±0.49	2.41±0.44	<0.01
%DS	50.3±19.1	21.6±10.5	<0.01
In stent			
MLD (mm)	0.99±0.41	2.10±0.43	<0.01
RVD (mm)**	2.04±0.49	2.45±0.44	<0.01
%DS	50.3±19.1	14.4±6.0	<0.01
Distal bifurcation angle (degrees)	60.7±21.0	51.1±18.3	0.01

MLD: minimal lumen diameter; RVD: reference vessel diameter; DS: diameter stenosis. * 26 patients (4 pre-procedure chronic total occlusions). ** 29 patients (1 pre-procedure chronic total occlusion).

Table 6. Angiographic parameters from the patients having angiographic follow-up (n=11).

	Post	Follow-up	P-value
Proximal main vessel			
MLD (mm)	2.56±0.48	2.29±0.38	0.09
RVD (mm)	3.03±0.53	2.85±0.36	0.16
%DS	15.9±7.1	19.7±8.2	0.42
LLL (mm)		0.27±0.44	
BAR		0	
Distal main vessel			
In segment			
MLD (mm)	2.24±0.46	2.07±0.44	0.35
RVD (mm)	2.74±0.51	2.65±0.41	0.37
%DS	1.6±1.0	23.0±9.5	<0.01
LLL (mm)		0.17±0.53	
BAR		0	
In stent			
MLD (mm)	2.39±0.41	2.08±0.45	0.04
RVD (mm)	2.74±0.54	2.66±0.42	0.45
%DS	12.1±8.4	22.0±10.3	0.03
LLL (mm)		0.31±0.43	
BAR		0	
Side branch			
In segment			
MLD (mm)	1.96±0.46	1.78±0.49	0.33
RVD (mm)	2.42±0.49	2.44±0.59	0.65
%DS	19.0±7.4	27.1±14.0	0.11
LLL (mm)		0.18±0.60	
BAR		0	
In stent			
MLD (mm)	2.12±0.55	1.83±0.49	0.16
RVD (mm)	2.46±0.50	2.46±0.55	0.79
%DS	14.8±5.9	25.9±14.5	0.04
LLL (mm)		0.29±0.57	
BAR		1 (9.1%)	
Distal bifurcation angle (degrees)	45.6±13.2	50.9±17.7	0.29

MLD: minimal lumen diameter; RVD: reference vessel diameter; DS: diameter stenosis; LLL: late lumen loss; BAR: binary angiographic restenosis

0.18±0.60 mm in-segment and 0.31±0.43 mm and 0.29±0.57 mm in-stent respectively. Sixteen cases exhibited a Y anatomical configuration regarding the bifurcation treated, whereas nine were T-shaped; the distal bifurcation angle was smaller than 70 degrees in the former and larger in the latter.

Discussion

This paper reports a real-world experience on V stenting technique using DES. The paucity of outcome data after V stenting reflects that this technique is rarely performed[9]; the current series of 31 patients were collected over nearly five years. A percentage of 13.7% has been reported[18] regarding the frequency of the type 4 bifurcation lesion according to the ICPS classification system, which is the equivalent of the 0,1,1 lesion in the Medina classification. Even if this is per definition, the ideal lesion configuration for the implementation of V stenting, similar techniques such as Simultaneous Kissing Stents claim a great share of those procedures, accounting for the rarity of V stenting.

Many techniques have been described to treat bifurcations, reflecting the lack of a perfect solution. Although the proposed strategy would be stenting the main branch with provisional stenting of the side branch, this would not apply in this setting; a bifurcation lesion involving a large side branch with a long stenosis certainly calls for a two-stent strategy. With the Crush technique, bench studies revealed that stent deployment even after kissing balloon inflation is often suboptimal and associated with malapposition[4,19], findings corroborated by intravascular ultrasound studies[20]. Stent under-expansion could predispose to higher restenosis rate and thrombotic risk[21,22]. Less data has accumulated for Culotte stenting in the current DES era, but this technique has attracted renewed attention[23,24].

Early outcome

The admittedly less than desirable early outcome (MACE rate of 19.4%) should be interpreted in the context of unstable clinical presentation, extensive coronary disease and a multitude of aggravating factors. This series bears the highest rate (64.5%) of acute coronary syndrome as the clinical presentation compared to other relevant studies in the DES era (13.3-62.0%)[2,3,6,7,24,25]; moreover the rates of multivessel disease (74.2%), multivessel intervention (67.7%), intervention on additional major epicardial vessels beyond the target vessels (38.7%) and the rate of left main stem stenting (51.6%) rank high among the corresponding studies. Out of the three deaths occurring within 30 days, none was clearly attributable to the PCI itself, even though two of them were adjudicated as cardiac. One was due to cardiogenic shock, not reversed by a rescue procedure after failed thrombolysis, and the other one had to be adjudicated as probable stent thrombosis, recent pulmonary embolism notwithstanding; an autopsy was not performed.

As to the two definite stent thrombosis cases, both of them presented with ST elevation myocardial infarction; neither of them was treated with glycoprotein IIb/IIIa inhibitors at index procedure, most probably due to old age; cessation of both antiplatelet agents in the second case was undoubtedly the major contributor to the stent thrombosis within 24 hours. Interestingly, in these two cases, stent protrusion by QCA was either trivial on non-existent. The remaining case of myocardial infarction was related to the concomitant intervention on the sub-totally occluded saphenous vein graft. Applying the ARC recommended device-oriented composite, the event rate substantially drops (12.9%), not adjusting however for the aforementioned circumstances.

Late outcome

Contrary to the early outcome, event rates at one year excluding the first 30 days, are close to the corresponding values reported in the vast majority of the relevant literature. As a matter of fact, cumulative 1-year TVR and TLR rates (16.1% and 9.7% respectively) compare favourably to DES studies employing Crush (11.0% TVR and 9.7% TLR at nine months)[25], Culotte (11.1% TVR and 8.9% TLR at nine months)[24], T stenting (TVR and TLR 27.3% at nine months)[24], SKS (TLR 4.0-13.9%)[5,6] and mixed cohorts (TLR 4.3-9.5 at six months)[2,3,9]. Equally amenable are the angiographic features (low LLL in both branches and low binary restenosis rate), despite the increased average number of stents and total stent length implanted. Of note, in the RESEARCH and T-SEARCH registries[10,11], the average stent length was 38.7±23.7 mm and 42.9±31.2 mm respectively. The Nordic Bifurcation Study stands out due to its strikingly low rates of events (3.4% MACE and 1.0% TLR at six months in the two stent arm); however, this is offset by leaving the much higher angiographic restenosis (16.0%) unattended[26]. Over an average of 853 days of follow-up, there was only one case of possible late stent thrombosis.

Unlike the Crush or Culotte techniques, the V stenting technique does not deform conventional tubular stents. It allows the operator to preserve access to both branches throughout the procedure, without the need to rewire. However, this has to be traded against the possibility of using a smaller guiding catheter, since a guiding catheter of at least 7 Fr for the Taxus stent or even 8 Fr for the Cypher stent, is required for simultaneous stent deployment[12]. Moreover, great precision is required for accurate positioning of the stents, in order to avoid geographic miss or protrusion into the PMV. When the PMV is also involved (i.e. Medina classification 1,1,1), usage of dedicated devices such as the Devax stent to deal with the proximal lesion in the main vessel combined with V stenting of the bifurcation should provide full coverage of the lesion with minimal overlapping of the stent struts. The recent multicentre Axxess Plus trial[27] on 139 patients receiving the Axxess (Devax) stent, reported satisfactory outcome at 6-months with a TLR rate of 7.5% and angiographic in-stent LLL of 0.09 mm. However, only 77.7% of patients were regarded as having "true" bifurcation lesions involving both the PMV and SB and only 41.9% had stenting of both DMV and SB[27]. Future studies with V stenting, plus a proximal dedicated device for more challenging bifurcation lesions, are eagerly awaited.

Limitations

An obvious limitation to this analysis is the small number of patients involved. This precluded us from performing any kind of subgroup analysis; we could not compare events in the DMV and the SB or study the influence of variables, such as the type of DES, the clinical indication, the number of stents and total stented length, the location of the bifurcation lesion and last, but not least, the impact of angulation on the short- and long-term outcome. Even more limited was the rate of angiographic follow-up (35.5%), which was not routinely acquired. Regrettably, IVUS images were not available; in this setting they would have verified complete and accurate lesion coverage and adequate stent struts apposition. Finally, this is a retrospective, single-centre study, with no control arm. This does not allow us to favour or discredit the technique at hand.

Conclusions

We provided long-term outcome data on an unselected cohort who had V stenting of *de novo* bifurcation lesions with drug-eluting stents. It is a technique dedicated to a distinct anatomic dataset. Early outcome looks less than encouraging, but on closer scrutiny could appear circumstantial and endpoint-dependent; late outcome, on the other hand, stands in accord with competitive techniques and merits further evaluation.

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