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Impact of different final optimization techniques on long-term clinical outcomes of left main cross-over stenting☆

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ABSTRACT

Background: The optimal final optimization technique to be used in patients after Cross Over Left main stenting remainsdebatable.
Aim: We evaluate the impact of the post-optimization technique (POT), kissing balloon (KB) and the POT-side-POT techniques on both cardiovascular mortality and event-free survival in patients receiving left main (LM) cross-over stenting for an isolated/distal bifurcation LM disease.
Methods: Clinical and instrumental records of 128 consecutive patients (102 males, mean age 73.39 ± 9.54 years old) with isolated distal/bifurcation LM disease and bypass surgery contraindications or refusal enrolled to receive LM cross-over stenting between the 1st January 2012 and the 1st January 2017 at two institutions: the Rovigo General Hospital (Rovigo, Italy) and the Alexandrovka Hospital University School of Medicine (Sofia, Bulgaria). Patients has been divided into three groups (POT, KB and POT-side-POT) according the optimal final optimization technique used while the 5-year cardiovascular mortality has been evaluated using the log-rank (Mantel-Cox) analysis.
Results: Baseline angiographic characteristics of the LM disease were mostly equivalent among the three groups. Over a global follow-up of 61.03 ± 0.92 months, the rates of target vessel revascularization, acute myocardial infarction, and stent thrombosis, were not different among groups. Patients treated with POT had a slightly better long-term survival.
Conclusions: None of these optimization techniques appeared to have clearly better long-term outcomes after LM Cross-over stenting in our retrospective study. POT resulted in a slightly better survival compared to Pot-sid-POT and KB.

1. Introduction

Single cross-over stent implantation (provisional stent or cross-over stent) is the preferred technique to treat left main (LM)distal/bifurcation disease when clinically indicated [1]. However, the optimal final optimization technique to be used in these patients remains matter of speculation. Indeed, despite proximal optimization technique (POT) has been proved to correct both the proximal main vessel (MV) malapposition and optimize the side branch (SB) ostium strut opening for proper wire re-crossing in the distal cell [2,3], the kissing balloon (KB) technique has been thought to be most effective in order to secure and reduce SB stenosis patency, removing jailed struts, particularly important in a huge, vital bifurcation such as the LM bifurcation [4,5]. From an operative point of view, the former technique appears simpler and faster, whereas the latter requires SB rewiring, impacting on procedural time and contrast use. Finally the POT-side-POT sequence has been conceived to improve results of POT achieving a great ostial opening for the LCx [6]. While bench studies with different type of stents are available but of scarce clinical utility, the real clinical impact of these techniques in terms of long-term outcomes remains still unknown.

The present study is aimed to evaluate in real clinical practice the impact of these three techniques on both cardiovascular mortality and event-free survival in population submitted to LM cross-over stenting for an isolated distal/bifurcation LM disease.

2. Methods

We retrospectively evaluated the clinical and instrumental records of patients with isolated distal/bifurcation LM disease and bypass surgery contraindications or refusal as determined by the local Heart Team who were enrolled to receive Intravascular Ultrasound (IVUS)-guided cross-over stenting from 1° January 2012 to 1° January 2017 at two institutions: the Rovigo General Hospital, Rovigo, Italy and the

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Alexandrovka Hospital University School of Medicine, Sofia, Bulgaria. All patients signed an informed consent and the Hospital Department Board approved the study.

Patients were analysed on the basis of clinical (cardiovascular risk factors, Canadian Cardiovascular Score class, EUROSCORE [7]) and angiographic characteristics (lesion/s location and severity according to the SYNTAX score [8] and MEDINA classification [9]) as well.

Patients with any of the following were excluded from the analysis: 1) Primary PCI during acute ST-elevation myocardial infarction 2) significant (>50%) disease of RCA, LCx and Left anterior descending (LAD) coronary artery assessed by QCA which required stent implantation at the time of LM intervention;

3) In adherence to any of the procedural steps of optimization (as described below) as withdrawn by the angiographic films and reports review.

4) Discontinuation of dual antiplatelet regimen during the first 12 month after the procedure.

All cases were reviewed by two independent external interventional cardiologists with at least 10 years' experience. All conflictual cases were collegially reviewed and resolved by discussion: agreement was 98.6%.

2.1. Percutaneous coronary intervention

Second and Third generation DES of the operator's choice including Resolute Integrity (Medtronic Inc., Galway, Ireland), Promus Premier (Boston Scientific, Galway, Ireland), and Orsiro (Biotronik, Bulack, Switzerland), have been implanted following EBC recommendations [10] including: 1) Predilation of MV 1:1 with non-compliant balloon; 2) Stenting of MV with stent diameter according to the distal MV reference diameter as currently recommended. Optimization techniques including one of the following:

1) Proximal optimization technique (POT) only, using a NC balloon (any brand) matching the proximal LM diameter on IVUS. The balloon distal tip was positioned in front of the carena on fluoroscopy magnification and expanded at high pressure (14 to 22 atm) for at least 5 to 10 s.
2) Classical kissing balloon technique: simultaneous inflation starting with the LCx balloon at high pressure (12 to 22 atm) for at least 5 to10 s using two NC balloons (any brand), LM to LAD and LM to LCx with a size matching the proximal LAD and LCx diameters. Deflation should start with the LCx balloon.
3) POT-side-POT sequence: after initial POT, a NC balloon (any brand) with a diameter matching the proximal LCx was inflated at high pressure (12 to 22 atm), followed by a final POT.

2.2. Antiplatelet regimen

Twelve-month Ticagrelor or Prasugrel treatment and life-long aspirin were recommended to all patients.

2.3. IVUS protocol

Intravascular Ultrasound examination would be performed following current guidelines [11] using the 3 F Opticross coronary IVUS catheter (Boston Scientific, Fremont, CA, USA) and automatic pull-back system (0.5 mm/s). On-line ultrasound assessment was performed in diastole. IVUS images were recorded after administration of 100–200 mg of nitroglycerin. The ultrasound catheter was advanced 0.5 mm beyond the lesion/stent and was pulled back to.5 mm proximal to the lesion/stent using motorized transducer pullback at 0.5 mm/s IVUS was performed and interpreted by the treating physician and at least one experienced IVUS technician. The lumen cross-sectional area (CSA) at the stent level was assessed by planimetry at the interface of the blood and the stent, at multiple levels (at least three), and the smallest area was chosen. The proximal and distal reference lumen areas and diameters were also measured by manual planimetry. The reference segments were selected as the most normal-looking cross section within 10 mm proximal and distal to the stent [12]. AVIO criteria have been used for area and stenosis evaluation [13].To reduce the variability, all IVUS measurements were repeated, and the average of the two values was used in the analysis. Routine measurements were recorded pre- and post-stent implantation.

2.3.1. Definitions

Quantitative coronary angiographic (QCA) analysis at baseline, post-stenting and at follow-up was performed using edge detection techniques (CAAS II 5.0 version; Pie Medical, Maastricht, Netherlands). Angiographic success was defined as residual stenosis 30% by visual analysis in the presence of Thrombolysis in Myocardial Infarction (TIMI) 3 flow grade. Binary restenosis was defined as stenosis ≥50% of the luminal diameter in target lesions. Angiographic measurements included the stented segment as well as the margins 5-mm proximal and distal to the stent.

Major adverse cardiac events (MACE) were defined as (1) cardiovascular death, and (2) nonfatal myocardial infarction (MI), and Target Vessel Revascularization (TVR), defined as a repeated intervention (surgical or percutaneous) to treat a luminal stenosis within the stent or in the 5-mm distal or proximal segments adjacent to the stent, including the ostium of the left anterior descending artery (LAD) and/or circumflex artery. All deaths were considered to be of cardiac origin unless a noncardiac origin was established clinically or at autopsy. Q-wave MI was defined as an elevation in Troponin I level in the presence of new Q-waves on the electrocardiograph in >2 contiguous Leads, as measured at baseline and at 12 and 24 h and daily if increased 2× the baseline level, following Thygesen K et al. [14]. Stent thrombosis was classified according to the Academic Research Consortium (ARC) definitions as definite, probable or possible, as early (0–30 days), late (31–360 days) or very late (>360 days).In-stent restenosis (ISR) was classified as focal (<10 mm long), diffuse (>10 mm long), proliferative (>10 mm long and extending outside the stent edges), or totally occluded [15].Information about in-hospital outcomes was obtained from an electronic clinical database for patients maintained at our institution and by review of hospital records for those discharged to referring hospitals.

2.3.2. Clinical follow-up

Per our institutional protocol, follow-up was conducted by physical examination at 1, 6, and 12 months and then yearly. Induced ischemia test by means of an ergometric test, nuclear stress test or stress echocardiography was scheduled at 6/8 months. Similarly, transthoracic echocardiography (TTE) was scheduled at 6 months. Angiographic and intravascular ultrasound control was performed at the time of additional vessel treatment or driven by clinical symptoms or instrumental evidence of myocardial ischemia. Information about the in-hospital outcome was obtained from an electronic clinical database for patients maintained at our institution and by review of hospital records for those discharged to referring hospitals. Post-discharge survival status was obtained from the Municipal Civil Registries. Information on the occurrence of AMI or repeated interventions at follow-up was collected by consulting our institutional electronic database and by contacting referring physicians and institutions and all living patients.

2.4. Statistical analysis

Continuous variables are described as mean ± standard deviation (SD) while categorical variables as proportions. Specifically, analysis of variance (ANOVA) with the Bonferroni's post -hoc correction was used to compare grouped continuous variables while the Chi-square or Fisher exact test were used, where appropriated, to compare the prevalence of categorical variables. Multivariate Cox regression analysis was performed to evaluate the independent predicotors of mortality during the follow-up period. Cardiovascular mortality during the

Table 1
Comparison of patients by post stenting optimization technique.

	KB N = 38	POT-S-POT N = 34	POT N = 56	p
Demographics				
Age (years)	72.79 ± 10.33	73.65 ± 6.00	73.64 ± 10.78	0.90
Males, n (%)	30 (78.9)	24 (70.6)	48 (85.7)	0.01
Risk factors				
Dyslipidemia, n (%)	10 (26.3)	8 (23.5)	19 (33.9)	0.06
Arterial hypertension, n (%)	8 (21.1)	15 (44.1)	17 (30.4)	0.18
Diabetes, n (%)	13 (34.2)	7 (20.6)	11 (19.6)	0.40
COPD, n (%)	10 (26.3)	8 (23.5)	17 (30.4)	0.07
Previous smokers, n (%)	5 (13.2)	3 (3.8)	3 (5.4)	0.69
Current smokers, n (%)	6 (15.8)	5 (14.7)	3 (5.4)	0.60
Obesity, n (%)	4 (10.5)	3 (8.8)	7 (12.5)	0.39
Clinical presentation				
Unstable angina	13 (34.2)	11 (32.3)	21 (37.5)	0.80
NSTEMI	25 (65.7)	23 (67.6)	35 (62.5)	0.92
CCS	2.1 ± 0.6	2.2 ± 0.5	2.1 ± 0.4	0.87
Angiographic and procedural data				
SINTAX score	21.1 ± 2.4	22.4 ± 2.5	20.8 ± 2.3	0.75
Medina 1,0,1	22 (57.8)	20 (58.8)	32 (57.1)	0.68
Medina 1,0,0	13 (34.2)	11 (32.3)	18 (32.1)	0.78
Medina 1,1,0	2 (5.2)	2 (5.8)	4 (7.1)	0.96
Medina 1,1,1	1 (2.6)	1 (2.9)	2 (3.5)	0.98
Lesion Type A	5 (13.1)	4 (11.7)	9 (16.0)	0.59
Lesion Type B	13 (34.2)	12 (35.2)	19 (33.9)	0.88
Lesion Type C	20 (52.6)	18 (52.9)	28 (50.0)	0.91
IVUS-guidance	26 (68.4)	21 (61.7)	36 (64.2)	0.86
Stent geometries				
Resolute Integrity	20 (52.6)	18 (52.9)	31 (55.3)	0.91
Promus Premier	7 (18.4)	9 (26.4)	12 (21.4)	0.76
Orsiro	10 (26.3)	7 (20.5)	13 (23.2)	0.74
Diameter[a], (mm)	3.46 ± 0.79	3.45 ± 0.59	3.5 ± 0.43	0.91
Length[a], (mm)	20.47 ± 7.27	21.82 ± 7.63	22.75 ± 8.72	0.87
MACE				
TVR	3 (7.8)	1 (2.9)	0	0.06
AMI	2 (5.2)	0	0	0.58
Stent-thrombosis, n (%)	3 (7.8)	1 (1.7)	0	0.06
CV-death (5-years follow-up)	6 (15.8)	4 (11.7)	1 (1.7)	0.04

[a] Mean diameter and length of the stent at implantation before optimization.

follow-up period was analysed with the log-rank (Mantel-Cox analysis). A p-value < 0.05 was considered to be statistically significant. Statistical analysis was performed using a statistical software package (SAS for Windows, version 8.2; SAS Institute; Cary, NC).

3. Results

One hundred and twenty-eight patients (Table 1) fulfilled the enrollment criteria and resulted comparable for main demographic and clinical characteristics. The angiographic characteristics of the LM disease were mostly equivalent among the three groups. IVUS usage was quite high and homogenously distributed into the different groups as well the different type of stents used: angiographic and IVUS measurements did not differ significantly among the techniques (Table 2). All procedures were successful with no intra-hospital death or major complications (including aortic or vessel dissection, vessel perforation, cardiogenic shock or intraprocedural AMI) excepted troponin increase >2× the baseline level in 6 patients (4.6%, 2 patients in the POT-S-POT group, 4 in the KB group). Patients were discharged after a mean hospitalization time of 3.5 ± 2.5 days (Table 3). Multivariate Cox regression analysis demonstrated that in patients treated with POT, mortality was independently predicted by complex bifurcation lesion (evaluated through the Medina classification) HR (1.86, 95% CI 1.12–2.01), age > 65 years (HR 1.78, 95% CI 1.43–1.98) and COPD (HR 1.52, 95% CI 1.12–1.76) (Table 4). Similarly, cardiovascular mortality in patients treated with POT-side-POT was independently predicted by age > 65 years old (HR 1.61, 95% CI 1.40–1.86), presence of a complex bifurcation lesion (HR 1. 78, 95% CI 1.42–1.99) and arterial hypertension (HT) (HR 1.84, 95% CI 1.51–2.03) (Table 5). Conversely, in patients

Table 2
Procedural quantitative coronary angiography (QCA) and intravascular ultrasound (IVUS) measurements. CSA: cross sectional area; LM: left main; MLD: minimal lumen diameter. QCA and IVUS measurement have been taken at the confluency polygon of LM.

Distal LM	Baseline		Post-stent	
	MLD (mm)	% stenosis	MLD (mm)	CSA (mm^2)
POT	1.9 ± 1.2	85.2 ± 6.6	4.5 ± 0.4	14.0 ± 0.9
POT-S-POT	1.8 ± 1.1	86.1 ± 5.2	4.4 ± 0.3	13.7 ± 0.9
KB	1.8 ± 1.2	85.6 ± 5.4	4.5 ± 0.3	13.8 ± 1.0
p	ns	ns	ns	ns

Table 3
Mortality difference among different optimization techniques.

	Chi-square	HR	95% CI	p (Log-rank Mantel-Cox)
KB vs POT-S-POT	0.34	0.62	0.46–0.91	0.55
POT-S-POT vs POT	3.64	0.93	0.86–1.04	0.05
KB vs POT	6.86	2.92	1.78–3.22	0.009

Table 4
Multivariate Cox regression analysis demonstrating the independent predicots of cardiovascular mortality in patients treated with POT.

	HR	95% CI	p
Medina classification (complex bifurcation)	1.86	1.12–2.01	0.002
Age >65 years	1.78	1.43–1.98	0.01
COPD	1.52	1.12–1.76	0.03

Table 5
Multivariate Cox regression analysis demonstrating the independent predicots of cardiovascular mortality in patients treated with POT-S-POT.

	HR	95% CI	p
Age >65 years	1.61	1.40–1.86	0.01
Medina classification (complex bifurcation lesions)	1.78	1.42–1.99	0.001
Arterial hypertension	1.84	1.51–2.03	0.03

Table 6
Multivariate Cox regression analysis demonstrating the independent predicots of cardiovascular mortality in patients treated with KB.

	HR	95% CI	p
Age >65 years	1.54	1.25–1.78	0.002
Diabetes	1.32	1.12–1.48	0.01

receiving KB as post-optimization technique, CV mortality was independently predicted only by age > 65 years old (HR 1.54, 95% CI 1.25–1.78) and diabetes (HR 1.32, 95% CI 1.12–1.48) (Table 6). In all multivariate analysis, adding gender did not modify the model. Over a global follow-up of 61.03 ± 0.92 months, the rates of TVR, AMI, and stent thrombosis, as shown in Table 1, were not significantly different among the techniques. The mortality difference among patients treated with KB, POT-S-POT and POT was 54.39 ± 2.26, 56.74 ± 1.67 and 63.69 ± 0.29 months, respectively, with a cumulative survival favouring POT over POT-S-POT and KB (Fig. 1). Obviously, also due to the low number of events and the good equivalence of the groups, diabetes, gender, stent type, stent diameter, stent length and IVUS usage resulted not impacting the overall results after the corrected Mantel- COX analysis.

4. Discussion

Our retrospective study suggests that POT technique had slightly better long-term outcomes compared to KB and POT –S-POT when applied to LM Cross-over stenting in our retrospective study. Difference in CV events were not statistically significant.

Single stent-Provisional or cross over stenting is the most widely used techniques to treat LM bifurcation in the real world. This techniques showed good long-term outcomes in both past and recent trials [16,17]. However, how to perform and which is the ideal post-dilating technique are still being hotly debated. In the past, the classic final KB inflation represented the “mantra” of the interventional cardiologist in the optimization of LM stenting. More recently, the POT and its modified techniques such as the POT-S-POT, showed high potential of correcting the KB drawbacks in bench tests while achieving a great ostial opening for the SB.

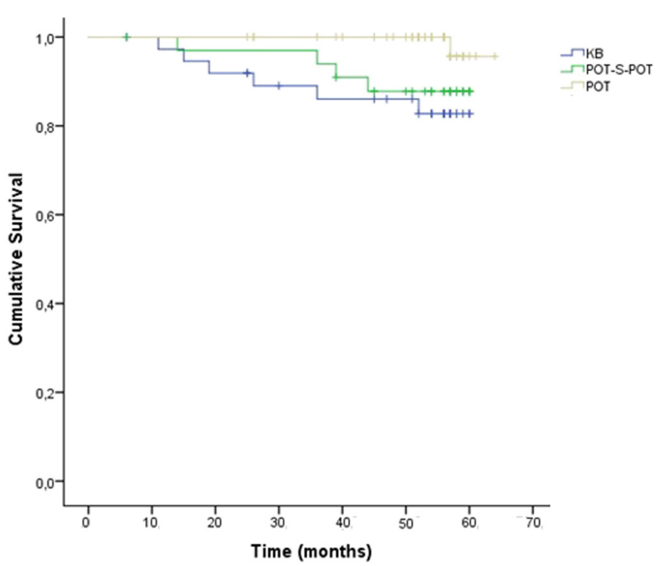

Fig. 1. Cumulative survival comparison (Mantel-Cox analysis) among POT, POT-S-POT and KB groups of patients.

Many bench and clinical studies showed that KB restores the MV stent volume, area, and symmetry loss after SB dilation in the bifurcation segment at the cost of some zones of struts malapposition due to the effect and a certain proximal elliptical deformation [18,19]. On the contrary, POT promotes full proximal stent apposition and conferred a more natural circular shape to the proximal segment of the MV [6]. POT also increases the size of opening of the SB ostium and by that, facilitated a distal wire re-crossing, independently which stent type was used.

As suggested recently by computed flow dynamic study [20], in cross-over stenting, KB performed better than POT at the carina site leaving higher wall shear stress (WSS) forces, while at the wall opposite to the carina, POT provided smaller area of lower WSS compared to all the other techniques. In the past, other studies confirmed these bench study results [5,6]: POT alone impacted mostly on the proximal part of the MV and at the wall of the SB opposite to the carina, POT increased the apposition of struts: but it doesn't the same effect at the carina itself, where KB and POT-S-POT seem more efficient. Indeed, KB only induced a bottleneck effect with lower WSS at the carina and this problem could only be corrected with a second POT. That would probably explain why POT and POT-S-POT resulted slightly more effective in the long-term than KB. However, from a mechanical point of view, our observations suggest that a better strut apposition rather than a more complete coverage produced a beneficial effect in respect to restenosis and more importantly thrombosis.

5. Limitations

Obviously, our study suffers of different potential confounders and bias including the small sample size, the retrospective and non-randomized design of the study, the different stents used and potential unreported or doubtful adherence to the optimization protocols used. More specifically, since the optimization technique was not randomized, different patient- or lesion-related confounding factors may have influenced our result. For this reason, we kept attention to include only patients with LM disease in order to minimize the inference on long-term outcomes of other diseased vessels (this explains also the relatively low Syntax score) and a multivariate Cox regression analysis was performed to add some adjustments in order to improve the statistical analysis. Moreover, the KB group had a quite longer follow-up (3 months); this aspect could have lead to some bias in the final analysis.

6. Conclusions

Although retrospective, our study for the first time in literature evaluated the impact of different optimization technique in Cross-Over stenting of LM on long-term follow-up. None of these optimization techniques appeared to have clearly better long-term outcomes after LM Cross-over stenting in our retrospective study. POT resulted in a slightly better survival compared to POT-S-POT and KB and for its simplicity probably would be preferable in cross-over stenting.

Larger randomized clinical trials, although difficult to conceive, are needed to assess the real contribution of all these techniques on the long-term outcomes of LM cross-over stenting and in general, in coronary bifurcation lesions.

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