Four-Year Outcomes of Unprotected Left Main Lesion PCI with Self-Apposing Stents versus Balloon-Expandable Stents

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Abstract

Background: Left main percutaneous coronary intervention (PCI) has been established as an effective and safe treatment option for left main coronary artery disease. There are data suggesting that different stent platforms can impact the outcomes after left main PCI. The aim of current study was to compare the four-year outcomes of patients with left main stenosis treated by PCI with a balloon-expandable stent or a self-apposing stent.

Methods and Results: A total of 146 patients with left main stenosis treated by PCI were included, of which 84 (57.5%) had balloon-expandable stents (Group A) and 62 (42.5%) had self-apposing stents (Group B). Baseline SYNTAX scores were higher in Group A than in Group B. Proximal optimization technique was used more often in Group A (45.2% in Group B vs 81.4% in Group A, p<0.001). The same observations were made for kissing balloon postdilation (30.6% Group B vs 62.7% in Group A, p<0.001). Procedural success with TIMI 3 flow was achieved in similar proportions in both groups. Mortality rate and MACE rates at 4-year follow-up were higher in Group B compared to Group A but have not reached statistical significance in univariable or multivariable analysis. Implantation of a self-apposing stent has been an independent predictor for target lesion revascularization rate (TLR) in multivariable analysis (HR 0.06, CI – 1.11-11.7, =0.03).

Conclusions: In our study, TLR rate was significantly higher in patients with left main lesion treated by PCI with self-apposing stents.

Keywords

percutaneous coronary intervention, left main coronary artery disease, balloon-expandable stent, self-apposing stent.

Abstract

Introducere: Intervenția coronariană percutană (PCI) pentru leziunile de trunchi comun reprezinta o opțiune eficientă și sigură de tratament. Există date care sugerează că diferite platforme de stent pot afecta rezultatele după angioplastia de trunchi comun. Scopul studiului actual a fost de a compara rezultatele la 4 ani ale pacienților cu stenoză de trunchi comun tratați prin PCI cu un stent balon expandabil sau cu un stent autoexpandabil.

Metode și rezultate: Au fost incluși 146 de pacienți cu leziune de trunchi comun tratați prin PCI, dintre care 84 (57,5%) cu stent balon expandabil (grupul A) și 62 (42,5%) cu stenturi autoexpandabile (grupul B). Scorurile SYNTAX au fost mai mari în grupul A decât în grupul B. Tehnica de optimizare proximală a fost utilizată mai des în grupul A (45,2% în grupul B vs 81,4% în grupul A, p <0,001). Aceleași observații au fost făcute pentru post-dilatarea prin kissing balloon (30,6% grupul B vs 62,7% în grupul A, p <0,001). Succesul procedural a fost atins în proporții similare în ambele grupuri. Rata mortalității și rata MACE la urmărirea pe 4 ani au fost mai mari în grupul B comparativ cu grupul A, dar nu au atins semnificația statistică în analiza univariabilă sau multivariabilă. Implantarea unui stent autoexpandabil a fost un predictor independent pentru rata de revascularizare a leziunilor țintă (TLR) în analiza multivariantă (HR 0,06, CI - 1,11-11,7, = 0,03).

Concluzii: În studiul nostru, rata TLR a fost semnificativ mai mare la pacienții cu leziune de trunchi comun tratați prin PCI cu stenturi autoexpandabile

Cuvinte cheie

intervenție coronariană percutană; leziune de trunchi comun; stent balon expandabil; stent auto-expandabil.

Introduction

Percutaneous coronary intervention (PCI) in unprotected left main coronary artery disease (ULMCAD) has become a safer and more efficient treatment method. Although coronary artery bypass grafting (CABG) was the standard treatment for complex left main lesions, an increasing number of patients with ULMCAD are treated by PCI [1-3]. Here we can include both patients with low or intermediate syntax scores and more and more patients with high syntax scores who have contraindications for surgery due to comorbidities or due to local surgical expertise [2, 4-6].

Developments in stents have made it possible to address complex cases of left main stenosis [7, 8]. The introduction of the self-apposing stent (Stentys) made it possible to treat left main lesions in which there were aneurysms or significant dilatations of the coronary arteries – large discrepancies between the diameter

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of the main proximal vessel and the distal proximal vessel – due to the special properties of this stent. The stent Stentys (Stentys, France) is a self-apposing device constructed of nickel and titanium alloy characterized by the ability to push externally, increasing its dimensions only upon reaching the vessel wall, or a predictable maximal diameter dependent on the size of the device used [9].

These properties of the Stentys stent have removed, at least in theory, several problems of left main angioplasty:

- the difference in diameter between left main and left anterior descending artery (LAD), making the use of proximal optimization technique (POT) unnecessary
- opening the stent struts to the side branch
- the use of kissing balloon is not mandatory due to the ability of the stent to conform to the anatomy of the left main bifurcation [9].

Many of these assumptions made at the introduction of the stent have been tested, some being refuted, and others confirmed [10, 11]. Leaving aside the above, the left main angioplasty technique must remain standardized according to the recommendations in use.

The aim of current study was to compare the four-year outcomes of patients with ULMCAD treated by PCI with a balloon expandable stent or a self-apposing stent (Stentys stent), including both elective patients and patients presenting with acute coronary syndrome (ACS).

MATERIALS AND METHODS

1. Study Population

All patients with ULMCAD treated by PCI between January 2014 and December 2018 were selected from the electronic hospital records at the Prof. Dr. C.C. Iliescu Institute for Cardiovascular Diseases, Bucharest, Romania. Patients with a history of CABG and occluded grafts and patients presenting with ACS were included. Only patients with complete data were included in the study. This resulted in a total of 146 patients for which demographic, clinical, angiographic, procedural, post-procedural and outcome data were extracted from the hospital electronic records. Life status was verified using the National Insurance Agency Platform in June 2019 to identify possible out-of-hospital deaths. Data analysis was performed with the approval of the institutional ethics committees of the hospital involved.

2. Study Outcomes

Major adverse cardiac events (MACEs) were defined as the occurrence of death, myocardial infarction (MI) or target lesion revascularizations (TLRs). ACS was defined as either unstable angina, non-ST segment elevation MI (NSTEMI) or ST segment elevation MI (STEMI). TLR was defined as repeated PCI for restenosis of the entire segment involving the implanted stent and the 5-mm distal and proximal borders adjacent to the stent. Angiographic success was defined as residual stenosis of <30% by visual estimation in the presence of thrombosis in myocardial infarction (TIMI), flow grade 3. Complete revascularization was defined as any attempt to revascularize all diseased segments (≥2.5 mm in diameter).

3. Statistical Analysis

Frequencies are given as numbers and percentages, continuous values as median (inter-quartile range or minimum-maximum values). Population characteristics were compared using the Mann-Whitney U test, Kruskall Wallis test and Fisher's exact test. Patients were divided into two main groups based on the type of stent used during PCI: Group A used a balloon-expandable stent, while Group B used a self-apposing stent.

Early outcomes (mortality, stent thrombosis, need for intra-aortic balloon pump (IABP), access site complications) are based on known status at 30 days and presented as percentages. Late outcomes are estimated using the Kaplan Meier method. Late outcomes of interest are: mortality, TLR and MACE.

Predictors of early outcomes were identified using univariable linear regression adjusted by acute coronary syndrome at the time of procedure. Multivariable analysis was not possible due to only 12 early events. Predictors of late outcomes (death, TLR) were identified using a combination of backward and forward stepwise multivariable Cox regression, including all variables with a univariable regression p value of less than 0.1 and less than <10% missing values. The statistically significant variables left in the final model were considered independent predictors. The Group A vs Group B variable was always kept in the model, as a variable of interest. Statistical analyses were done with STATA/SE 12.0 (StataCorp LP, College Station, TX).

RESULTS

A total of 146 patients undergoing left main PCI were included, age ranging from 33 to 86 years (median of 63 years). Group A consisted of n=84 (57.5%), Group B of the remaining n=62 (42.5%). Detailed demographic and baseline clinical characteristics by group are presented in Table 1. We found few significant differences among the two groups, namely more patients with peripheral artery disease in Group A (25% Group A vs 6.6% Group B, p=0.004).

SYNTAX, SYNTAX II (PCI and CABG, with respective predicted mortality) and EuroSCORE II scores for the two groups are detailed in Table 2. SYNTAX scores are higher in patients treated with balloon-expandable stents compared to patients treated with self-apposing stents.

4. Angiographic characteristics

Table 3 shows the main angiographic findings by type of stent used. Self-apposing stents were implanted more often in patients with distal left main lesions compared to balloon-expandable stents (69% in balloon-expandable group vs 87.1% in self-apposing group, p=0.009). Self-apposing stents were used more often in Medina 0/1/0 lesions compared to balloon-expandable stents (15.1% in balloon-expandable group vs 41.9% in self-apposing group, p=0.01).

As expected, true bifurcation lesions (Medina 1/1/1) were more frequent in Group A (30.1% in Group A vs 19.4 in Group B, p=0.01).

Table 1 - Demographic and baseline clinical characteristics according to the type of the implanted stent in patients with unprotected left main coronary artery disease (ACS – acute coronary syndrome; NSTEMI – non-ST segment elevation myocardial infarction; STEMI – ST segment elevation myocardial infarction; PCI – percutaneous coronary intervention; TIA – transient ischemic attack; COPD - chronic obstructive pulmonary disease; PAD – peripheral artery disease; LBBB – left bundle branch block; RBBB – right bundle branch block; LVEF – left ventricular ejection fraction; HB – hemoglobin)

	Balloon-expandable stents	Self-apposing stents	Total	p value
Age, y (median, IQR)	63 (56-72)	62 (52-70)	63 (55-71)	0.2
Male	58 (69.1)	44 (71)	102 (69.9)	0.8
Cardiovascular risk factors				
Hypertension	71 (84.5)	51 (83.6)		0.5
Dyslipidemia	73 (86.9)	53 (86.9)	126 (86.9)	0.6
Diabetes	25 (29.8)	17 (27.9)	42 (29)	0.8
Obesity	21 (25)	17 (27.4)	38 (26)	0.8
Smoking status				
Active smoker	25 (30.1)	18 (29.5)	43 (29.9)	0.8
Former smoker	16 (19.3)	10 (16.4)	26 (18.1)	0.8
Patient history				
ACS	32 (38.1)	26 (42.6)	58 (40)	0.6
Unstable angina	3 (9.4)	3 (11.5)	6 (10.3)	
NSTEMI	11 (34.4)	5 (19.2)	16 (27.6)	
STEMI	18 (56.2)	18 (69.3)	36 (62.1)	0.4
PCI	20 (23.8)	14 (22.6)	34 (23.3)	0.5
Atrial fibrillation	11 (13.1)	8 (13.1)	19 (13.1)	0.6
Stroke/TIA	10 (11.9)	5 (8.1)	15 (10.3)	0.6
Bleeding	2 (2.4)	3 (4.9)	5 (3.4)	0.6
COPD	1 (1.2)	1 (1.6)	2 (1.4)	0.7
PAD	21 (25)	4 (6.6)	25 (17.2)	0.004
Neoplasm	9 (10.7)	0 (0)	9 (6.2)	0.01
Clinical presentation				
Stable angina	40 (47.6)	30 (48.4)	70 (47.9)	
Unstable angina	19 (22.6)	11 (17.7)	30 (20.5)	
NSTEMI	9 (10.7)	7 (11.3)	16 (11)	
STEMI	10 (11.9)	8 (12.9)	18 (12.3)	
ACS with cardiogenic shock	6 (7.2)	6 (9.7)	12 (8.2)	0.9
Atrial fibrillation	7 (8.6)	5 (8.1)	12 (8.4)	0.6
LBBB	6 (7.4)	3 (4.8)	9 (6.3)	0.4
RBBB	7 (8.6)	4 (6.4)	11 (7.7)	0.4
Ventricular tachycardia	0 (0)	2 (3.2)	2 (1.4)	0.2
LVEF, % (median, IQR)	50 (35-55)	50 (38-60)	50 (35-57.5)	0.6
LV systolic disfunction				
None (>=50%)	42 (50.6)	32 (52.5)	74 (51.4)	
Mild (40-49%)	16 (19.3)	13 (21.3)	29 (20.1)	
Moderate (30-39%)	15 (18.1)	10 (16.4)	25 (17.4)	
Severe (<30%)	10 (12)	6 (9.8)	16 (11.1)	0.9
Diastolic disfunction	71 (92.2)	49 (84.4)	120 (88.9)	0.2
Regional wall motion abnormality	58 (71.6)	38 (62.3)	96 (67.6)	0.3
LV aneurysm	5 (6.1)	4 (6.6)	9 (6.3)	0.6
LV thrombus	2 (2.4)	0 (0)	2 (1.4)	0.5
LV hypertrophy	31 (41.3)	14 (24.6)	45 (30.1)	0.06
Dilated cardiomyopathy	4 (4.8)	3 (4.9)	7 (4.9)	0.6
Mitral regurgitation				
None/Trivial	12 (14.5)	2 (3.3)	14 (9.8)	
Mild	51 (61.4)	45 (75)	96 (67.1)	
Moderate	12 (14.5)	10 (16.7)	22 (15.4)	
Severe	8 (9.6)	3 (5)	11 (7.7)	0.09
Aortic regurgitation				
None/Trivial	61 (73.5)	40 (66.7)	101 (70.6)	
Mild	15 (18.1)	20 (33.3)	35 (24.5)	
Moderate	7 (8.4)	0 (0)	7 (4.9)	
Severe	0 (0)	0 (0)	0 (0)	0.01
Ascending aorta diameter, mm (median, IQR)	32 (30-34)	34 (31-37)	32 (30-35)	0.02
Moderate/severe aortic stenosis	3 (3.6)	0 (0)	6 (4.2)	0.3
Tricuspid regurgitation	50 (60.2)	40 (65.6)	90 (62.5)	0.6
Pulmonary hypertension	15 (20)	4 (7)	19 (14.4)	0.04
Blood samples pre-PCI				
HB, g/dl (median, IQR)	13.4 (12.2-14.4)	13.9 (12.5-15)	13.5 (12.3-14.7)	0.1
CK-MB, U/L (median, IQR)	25 (18-63)	22 (16-37)	22 (17-50)	0.2
Troponin, ng/ml (median, IQR)	0.24 (0.03-1.3)	1 (0.07-4.8)	0.3 (0.03-2.9)	0.2
Creatinine, mg/dl (median, IQR)	0.9 (0.8-1.2)	0.9 (0.8-1.2)	0.9 (0.8-1.2)	0.9
Creatinine clearance, ml/min/1.73m2 (median, IQR)	80 (62-97)	80 (65-95)	80 (64-96)	0.9

Table 2 - SYNTAX, SYNTAX II (for PCI and CABG, with respective predicted mortality) and EuroSCORE II scores of patients with unprotected left main coronary artery disease according to the stent strategy

	Balloon-expandable stents	Self-apposing stents	Total	p value
SYNTAX	23.5 (16.5-30.5)	17.5 (11-25.5)	21 (13-29)	0.004
SYNTAX-2 PCI	34.1 (25.6-45.4)	28.9 (22.1-40.7)	32.2 (23.6-43.6)	0.04
Estimated PCI mortality	9.8 (4.9-22.7)	6.2 (3.6-15.9)	8.3 (4.1-19.9)	0.03
SYNTAX-2 CABG	31.5 (23.3-40.9)	25.3 (16.4-33.6)	28.9 (19.4-38)	0.01
Estimated CABG mortality	7.7 (3.9-16.2)	4.6 (2.2-10.3)	6.2 (2.9-13.6)	0.01
EUROSCORE II	1.6 (1-3.3)	1.1 (0.8-2.5)	1.3 (0.9-2.8)	0.1

Table 3 - Angiographic findings of patients with unprotected left main coronary artery disease according to the type of implanted stent (LM – left main; LAD – left anterior descending artery; LCX – left circumflex artery; RCA – right coronary artery)

	Balloon-expandable stents	Self-apposing stents	Total	p value
Arterial access site				
Radial	16 (19.1)	18 (29)	34 (23.3)	0.2
Femoral	68 (80.9)	44 (71)	112 (76.6)	0.2
Left main lesion localization				
Ostial	10 (11.9)	0 (0)	10 (6.9)	
Middle segment	1 (1.2)	0 (0)	1 (0.7)	
Distal	58 (69)	54 (87.1)	112 (76.7)	
Ostial and distal	1 (1.2)	3 (4.8)	4 (2.7)	
Whole length	14 (16.7)	5 (8.1)	19 (13)	0.009
Bifurcation	63 (75)	52 (83.9)	115 (78.8)	0.2
Trifurcation	21 (25)	10 (16.1)	31 (21.2)	0.2
Other lesions				
None	24 (28.6)	25 (40.3)	49 (33.6)	
One vessel	27 (32.1)	17 (27.4)	44 (30.1)	
Two vessels	23 (27.4)	16 (25.8)	39 (26.7)	
Three vessels	10 (11.9)	4 (6.5)	14 (9.6)	0.4
Chronic total occlusion	17 (20.2)	14 (22.6)	31 (21.2)	0.8
LAD ostium involved	45 (53.6)	50 (80.6)	95 (65.1)	0.001
LCX ostium involved	36 (42.9)	24 (38.7)	60 (41.1)	0.7
LAD non-ostial lesion	41 (48.8)	23 (37.1)	64 (43.8)	0.2
LCX non-ostial lesion	27 (312.1)	13 (21)	40 (27.4)	0.2
RCA lesion	28 (33.3)	20(32.3)	48 (32.9)	0.5
Left main lesion characteristics				
Diffuse lesion	49 (5.3)	27 (43.5)	76 (52.1)	0.09
Eccentric lesion	64 (76.2)	43 (69.4)	107 (73.3)	0.4
Calcified lesion	29 (34.5)	14 (22.6)	43 (29.4)	0.1
Ulcerated lesion	21 (25)	15 (24.2)	26 (25.7)	0.5
Carina involved	4 (4.8)	5 (8.1)	9 (6.2)	0.5
Medina classification (only distal Left main lesions)				
1/1/1	22 (30.1)	12 (19.4)	34 (25.2)	
1/0/0	17 (23.3)	6 (9.7)	23 (17.1)	
1/1/0	10 (13.7)	6 (9.7)	16 (11.9)	
1/0/1	6 (8.2)	3 (4.8)	6 (6.7)	
0/1/0	11 (15.1)	26 (41.9)	37 (27.4)	
0/1/1	4 (5.5)	6 (9.8)	10 (7.4)	
0/0/1	3 (4.1)	3 (4.8)	6 (4.4)	0.01
True bifurcation (1/1/1, 0/1/1)	26 (35.6)	18 (29)	44 (32.6)	0.5
Left main take-off angle $>70^0$	22 (32.8)	22 (37.9)	44 (35.2)	0.6
Bifurcation angle				
>90 degrees	5 (8.1)	7 (12.1)	12 (10)	
70-90	24 (38.7)	24 (41.4)	48 (40)	
45-69	11 (17.7)	10 (17.2)	21 (17.5)	
<45	22 (35.5)	17 (29.3)	39 (32.5)	0.8
LM stenosis, % (median, IQR)	67 (45-89)	30 (11-57)	55 (20-80)	<0.001
LAD stenosis, % (median, IQR)	83 (58-90)	86 (71-93)	85 (66-92)	0.006
LCX stenosis, % (median, IQR)	71 (43-84)	63 (18-86)	70 (30-86)	0.4

5. Procedural characteristics

Six patients (4.1%) were on mechanical support system with IABP prior to the PCI procedure [12, 13]. Radial access was used more often with self-apposing stents (19.4% in self-apposing Group vs 3.6% in balloon-expandable Group, p=0.004).

Minicrush technique was used more often with balloon-expandable stents (16% in self-apposing Group vs 43.7% in balloon-expandable Group, p=0.03) and Cullotte technique with self-apposing stents (40% in self-apposing Group vs 9.4% in balloon-expandable Group, p=0.03).

POT was used more often with balloon-expandable stents (45.2% in self-apposing Group vs 81.4% in balloon-expandable Group, p<0.001). The same observations were made for KBPD

Table 4 - Procedural characteristics according to the type of implanted in patients with unprotected left main coronary artery disease (PCI – percutaneous coronary intervention; IABP – intra-aortic balloon pump; LAD – left anterior descending artery; LCX – left circumflex artery; POT – proximal optimization technique; KBPD – kissing balloon post dilatation; TKBPD – triple kissing balloon post dilatation; MV – main vessel; SB – side branch; iFR - instantaneous wave-free ratio; IVUS – intravascular ultrasound)

	Balloon-expandable stents	Self-apposing stents	Total	p value
Time from coronary angiogram to PCI, days (median, IQR)	2 (0-22.5)	2.5 (0-20)	2 (0-20)	0.8
Arterial acces site				
Femoral	81 (96.4)	50 (80.6)	131 (89.7)	0.004
Radial	3 (3.6)	12 (19.4)	15 (10.3)	0.004
Pre-PCI IABP	5 (5.9)	1 (1.6)	6 (4.1)	0.2
Guide catheter				
6F	47 (55.9)	31 (50)	78 (53.4)	
7F	37 (44.1)	29 (46.8)	66 (45.2)	
8F	0 (0)	2 (3.2)	2 (1.4)	0.2
Rotational atherectomy	2 (2.4)	1 (1.6)	3 (2.1)	0.6
Two stent technique	35 (41.7)	25 (40.3)		0.5
Provisional stenting	1 (3.1)	0 (0)	1 (1.7)	
TAP	10 (31.2)	10 (40)	20 (35.1)	
Minicrush	14 (43.7)	4 (16)	18 (31.6)	
DK-Crush	3 (9.4)	0 (0)	3 (5.3)	
Cullotte	3 (9.4)	10 (40)	13 (22.8)	
V-stenting	1 (3.1)	1 (4)	2 (3.5)	0.03
MV predilatation	62 (78.5)	49 (79)	111 (78.7)	0.5
SB predilatation*	29 (40.9)	19 (30.7)	48 (36.1)	0.4
Predilatation at nominal pressure**	21 (30.4)	24 (46.1)	40 (36)	0.3
Dissection	19 (26.4)	9 (17.3)	26 (23.4)	0.2
POT*	57 (81.4)	28 (45.2)	87 (64.4)	<0.001
POT after first stent***	46 (78)	22 (78.6)	68 (50.4)	0.6
POT after KBPD***	32 (54.2)	6 (21.4)	38 (28.2)	0.005
POT balloon diameter*, mm (median, IQR)	4 (4-4.5)	4 (4-4.5)	4 (4-4.5)	0.9
KBPD*	42 (62.7)	19 (30.6)	62 (45.9)	<0.001
TKBPD*	5 (7.2)	0 (0)	5 (3.7)	0.03
MV stent diameter				
3	14 (16.7)	18 (29.3)	32 (21.9)	
3.5	53 (63.1)	44 (71)	97 (66.4)	
4	17 (20.2)	0 (0)	17 (11.6)	<0.001
MV stent length, mm (median, IQR)	24 (16-29)	22 (18-25)	22 (18-28)	
SB stent diameter, mm (median, IQR)	3 (3-3.5)	3.5 (3-3.5)	N/A	0.5
SB stent length, mm (median, IQR)	19 (13-23)	22 (18-27)	N/A	0.06
Under expansion of >30%	6 (7.1)	8 (12.9)	14 (9.6)	0.3
IFR used pre-PCI	2 (2.4)	4 (6.5)	6 (4.1)	0.4
IFR used post-PCI	0 (0)	4 (6.5)	4 (2.8)	0.03
IVUS used pre-PCI	2 (2.4)	0 (0)	2 (1.4)	0.5
IVUS used post-PCI	12 (14.3)	14 (22.6)	26 (17.8)	0.3

**Excluding ostial lesions*
***only when predilation was used*
****only when POT was used*

(30.6% in self-apposing Group vs 62.7% in balloon-expandable Group, p<0.001) (table 4).

Procedural success with TIMI 3 flow was achieved in similar proportions in both groups (Table 5). Instantaneous wave-free ratio (iFR) was performed before the PCI in 6 cases (4.4%) and after in 4 cases (3%). In 2 cases (1.5%) intravascular ultrasound (IVUS) was used before the procedure, while in 26 (19.3%) it was used after the procedure [14].

Technical outcomes and post-procedural complications by strategy group are summarized in Table 5. There were no differences between the two groups in term of peri-procedural complications.

6. Early outcomes

There was an 8.2% early mortality (30 days mortality) (n=12), with a 2% peri-procedural mortality (n=3). Most deaths occurred in patients presenting with ACS (n=11) and mostly in patients complicated with cardiogenic shock (n=8). As such, early mortality in non-ACS patients was 1.4% with no peri-procedural deaths [14].

30-days mortality was 11.29% in patients treated with self-apposing stents and 5.95% in patients treated with balloon-expandable stents, but without statistically significant difference.

7. Late outcomes

Mortality, TLR and MACE at 4 years were 21.9%, 14% and 32.5% overall, 9.6%, 15% and 24.1% in non-ACS patients and 33.3%, 12.8% and 40.1% respectively in ACS-patients, respectively. Unadjusted comparisons of mortality, TLR and MACE at 4 years between Group A and Group B are shown in Figure 1. Mortality rate and MACE rates at 4-year follow up were higher in Group B compared to Group A but have not reached statistical significance in univariable or multivariable analysis.

Table 5 - Procedural outcomes and post-procedural complications according to the type of implanted stent in patients with unprotected left main coronary artery disease (LM – left main; SB – side branch; TIA – transient ischemic attack; PCI – percutaneous coronary intervention; CIN – contrast induced nephropathy)

	Balloon-expandable stents	Self-apposing stents	Total	p value
Unaffected LM ostium covered by implanted stent	12 (14.3)	6 (9.7)	18 (13.3)	0.4
LM lesion covered	84 (100)	60 (96.8)	133 (98.5)	0.2
SB residual stenosis				
None	50 (67.5)	36 (58.1)	83 (62.4)	
<50%	17 (23)	21 (33.9)	38 (28.6)	
>50%	7 (9.5)	5 (8)	12 (9)	0.4
Procedural success	81 (96.4)	57 (91.9)	138 (94.5)	0.3
Complete revascularization	63 (75)	46 (74)	109 (74.7)	0.5
TIMI flow at the of the procedure				
1	1 (1.2)	3 (4.8)	4 (2.7)	
2	3 (3.6)	1 (1.6)	4 (2.7)	
3	80 (95.2)	58 (93.6)	138 (94.5)	0.4
Peri-procedural complications				
Hematoma	3 (3.6)	3 (4.8)	6 (4.1)	0.7
Stroke/TIA	1 (1.2)	0 (0)	1 (0.7)	0.6
MI	1 (1.2)	3 (4.8)	4 (2.7)	0.2
Afib	1 (1.2)	1 (1.6)	2 (1.5)	0.8
Need for external electric shock	1 (1.2)	3 (4.8)	4 (2.7)	0.3
Bradi-arrhythmia	3 (3.6)	7 (11.3)	10 (6.9)	0.1
Death during PCI	1 (1.2)	2 (3.2)	3 (2)	0.6
CIN*	9 (16.4)	5 (13.2)	14 (15.1)	0.8

**Not including 11 ostial lesion and 2 missing values*
***in 93 patients with pre- and post-PCI creatinine measurements*

Implantation of a self-apposing stent has an independent predictor for TLR in multivariable analysis (HR 0.06, CI – 1.11-11.7, =0.03).

DISCUSSION

The study included an unselected population of patients with ULMCAD treated by PCI. Thus, patients who presented with acute coronary syndrome were not excluded from the study, considering in the analysis also severe patients with cardiogenic shock. The aim of this study was to highlight the results obtained after left main angioplasty performed with different stent platforms in an interventional cardiology center with a large volume of cases, both in elective patients and in priority or urgent patients. The study included 146 patients with ULMCAD PCI, of whom 52.06% had acute coronary syndrome. The study population was divided into 2 groups depending on the type of stent used for left main PCI: group A – balloon-expandable stents and group B - self-apposing stents. There is little data on the comparison of the two types of stents in current practice in both elective and acute coronary patients.

A first significant difference is that patients treated with self-apposing stents had lower risk scores, both anatomical and combined, than patients treated with balloon-expandable stents. Thus, we could say that self-apposing stents are implanted in less complex cases. This is since the implantation of a self-apposing stents requires the most appropriate predilation of the lesion and the passage of the stent through the lesion is more difficult due to the higher profile than the balloon-expandable stents [9, 10].

There is a preference for a particular type of stent depending on the location of the lesion in the left main. Patients with ostial and mid-segment lesions were not treated using a self-apposing stent. Self-apposing stents are considered to have a lower radial force than balloon-expandable stents. This makes their use in aorto-ostial lesions lower, due to the high resistance of this area and the greater tendency to “recoil” of the implanted stent. The self-apposing stent was preferred in distal left main lesions, especially in patients with LAD ostial lesion, Medina 0/1/0 [9].

POT and KBPD were performed much more frequently in the case of balloon-expandable stents. This is due to the properties of the self-apposing stents to self-appose to the vessel wall (hence

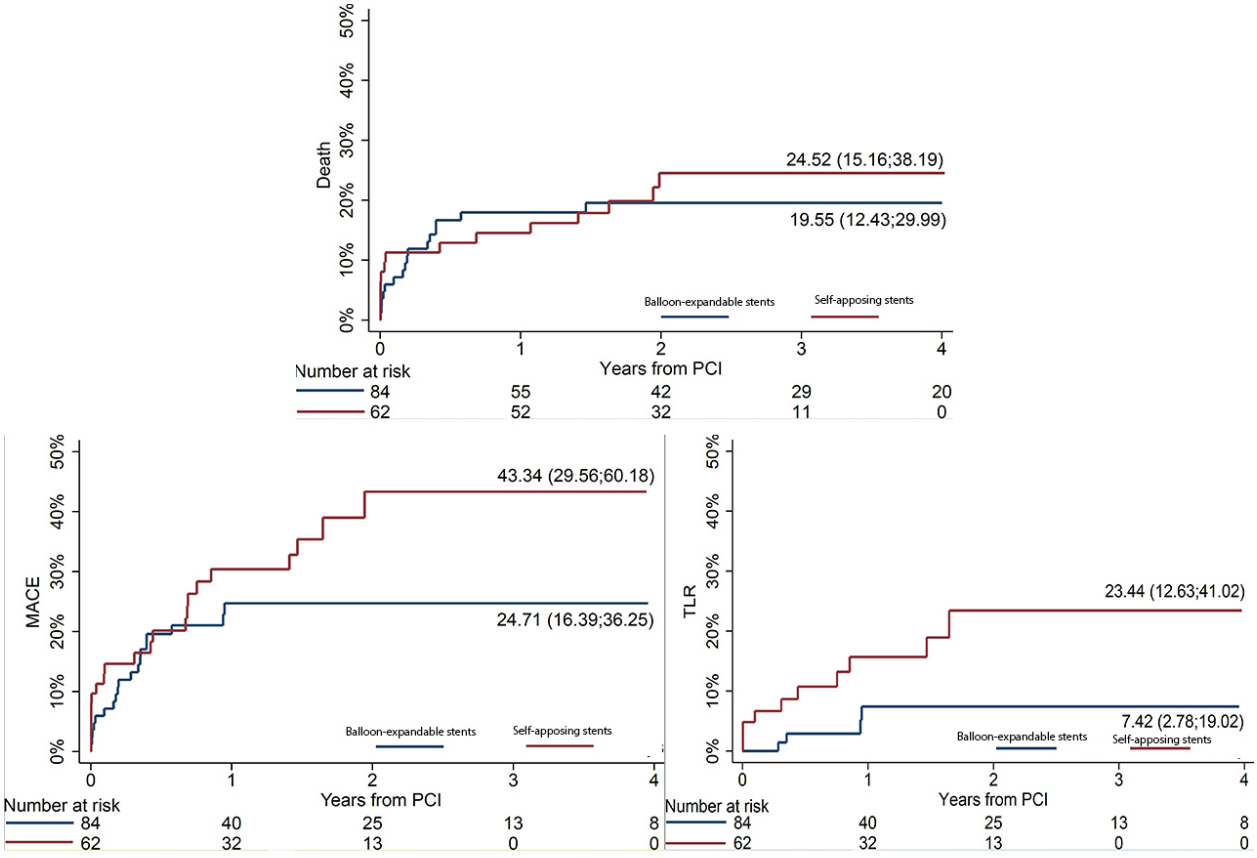


Figure 1 - Unadjusted comparisons of mortality, TLR and MACE at 4 years according to the type of the stent in patients with unprotected left main coronary artery disease. Curves represent Kaplan-Meier failure function.

the theoretical lack of the need for proximal optimization) and minimal deformation when the struts to the side branch are opened (hence the theoretical lack of the need for kissing balloon) [10, 11].

There was no difference in mortality rate and 4-year MACE rate between the two groups. However, the rate of revascularization of the target lesion was significantly higher when a self-apposing stent was used. Although there is no evidence from studies of ex-vivo models, self-apposing stents tend to narrow the ostium of the secondary vessel over time, precisely because of their properties of continuing to expand over time.

STUDY LIMITATIONS

This study was a nonrandomized study in which operator bias may have influenced the final conclusion. Although it might have offered more data on restenosis, routine angiographic reevaluation is no longer recommended and was not performed. The small number of early events prevented multivariable analyses, so the results are subject to confounding. The use of various types of stents introduces a degree of heterogeneity.

CONCLUSIONS

Although there are differences in the technique of angioplasty between patients treated with self-apposing stents compared to those treated with balloon-expandable stents, the mortality and MACE rates at 4 years did not differ between the two types of stents. However, TLR was significantly higher in patients with left main lesion treated by PCI with self-apposing stents.

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Disclosures

The authors declare that there is no conflict of interest.

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