Cardiovascular Revascularization Medicine 20 (2019) 663–668

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Long-Term Outcomes of Left Main Bifurcation Double Stenting in Patients with STEMI and Cardiogenic Shock

Gianluca Rigatelli [a,*], Marco Zuin [b], Huy Dinh [c], Sara Giatti [d], Van Tan Nguyen [e], Neha Maddali [f], Fabio Dell'Avvocata [a], Ramesh Daggubati [f]

[a] Cardiovascular Diagnosis and Endoluminal Interventions, Rovigo General Hospital, Rovigo, Italy
[b] Section of Internal and Cardiopulmonary Medicine, Department of Medical Science, University of Ferrara, Ferrara, Italy
[c] Department of Interventional cardiology, Tam Duc Heart Hospital, Ho Chi Minh City, Viet Nam
[d] Division of Cardiology, Rovigo General Hospital, Rovigo, Italy
[e] Department of Interventional Cardiology, Thong Nhat Hospital, Ho Chi Minh City, Viet Nam
[f] Department of Medicine, NYU Winthrop Hospital, Mineola, NY, USA

ARTICLE INFO

Article history:
Received 17 August 2018
Received in revised form 17 September 2018
Accepted 27 September 2018

Keywords:
Left main
PCI
Cardiogenic shock

ABSTRACT

The contribution of different left main (LM) bifurcation stenting techniques on long-term CV mortality has been poorly investigated. We evaluated the 3-year outcomes of revascularization of unprotected complex bifurcation LM in patients with cardiogenic shock (CS) with LM bifurcation/distal disease as culprit lesion. We analyzed 752 consecutive patients with STEMI admitted to our centre from 1 January 2014 to 1 March 2018, searching for patients with CS and complex distal/bifurcation LM disease as culprit lesion who received, at operators' discretion, LM double stenting by means of Culotte, T-stenting/TAP or Nano-crush technique. Fifty-seven patients (23 females, mean age 62.3 ± 10.5 years) with CS and STEMI with distal/bifurcation LM as culprit lesion were identified: 20 patients (35.0%) received Culotte, 16 patients (28.0%) received T-stenting/TAP and 20 (35.0%) received Nano-crush technique. At 3-year follow-up, clinical-driven target lesion revascularization, and mortality rate for all-causes were comparable among different stenting techniques. Conversely, considering 3-year CV mortality as outcome, a statistically significant difference was observed favoring Nano-crush when compared to patients treated with T stenting. Nano-crush obtained a larger improvement of ejection fraction on serial echocardiograms. CS with complex distal/bifurcation LM disease can be treated with acceptable rate of complication and short-term mortality using double stenting techniques. Techniques that minimize rewiring and kissing steps and shorten ischemic time should probably be preferred.

1. Introduction

Nowadays, cardiogenic shock (CS) remains the leading cause of cardiovascular mortality in patients with acute myocardial infarction (AMI) and unstable angina complicating about 5% to 10% of cases and leading to a higher and unacceptable mortality rate of 30% in the short-term period [1]. As well known, the early revascularization of the culprit lesion remains the therapeutic cornerstone in patients with ST-elevation myocardial infarction (STEMI) [2,3] and in non-ST elevation acute coronary syndrome when cardiac surgery is not available in the very short term. In this setting, percutaneous coronary intervention (PCI) of unprotected distal left main (LM) bifurcation as culprit lesion is relatively uncommon in daily clinical practice and always represents a challenge for interventional cardiologists [4]. Indeed, in these subjects, the optimal stenting technique should decrease, as much as possible, the procedural and the ischemic time, as well the amount of metal jackets inside the bifurcating and should be applicable to any diameter-ratio and bifurcation angle between the main (MB) and side (SB) branches. To date, no data have been provided regarding the interventional management and outcome of such challenging subset of patients.

The aim of single-center study is to evaluate, retrospectively, the impact of different stenting techniques on the mid-term outcome of CS patients with an unprotected distal LM bifurcation culprit lesion, treated with PCI.

2. Methods

We retrospectively analyzed the procedural and medical records of 752 consecutive STEMI patients admitted to Rovigo General Hospital from the 1st January 2014 to the 1st March 2018. Our institution is a tertiary-hub center for cardiovascular disease, encompassing a population of about 250,000 inhabitants and inserted in a network with three spoke

* Corresponding author at: Cardiovascular Diagnosis and Endoluminal Interventions, Santa Maria della Misericordia Hospital, Viale Tre Martiri 140, 45100 Rovigo, Italy.
E-mail address: jackyheart@libero.it (G. Rigatelli).

https://doi.org/10.1016/j.carrev.2018.09.017
1553-8389/

hospitals in the province. To diminishing possible bias coming from a different clinical and prognostic entities, only patients with STEMI due to LM bifurcation culprit lesion were included in the study. Moreover patients should be treated by PCI, using at the operator's discretion, one of the following stent techniques: very minimal crush technique (Nano-crush), Culotte stenting, T-stenting/TAP or provisional cross-over stenting technique. The preoperative characteristics, clinical profile and medications, intraoperative data, and postoperative outcomes were retrieved from a computerized database. The ejection fraction was rarely recorded during CS, so we considered as baseline the values at the first recorded echo-scan in the intensive coronary care unit after revascularization procedure.

In addition, patient charts were reviewed to confirm the diagnosis and time onset of CS and to acquire relevant laboratory data. Clinical cardiovascular risk factors, Canadian Cardiovascular Score class (CCS), EUROSCORE [5]) and angiographic characteristics (lesion/s location and severity according to the SYNTAX score [6] and MEDINA classification [7]) as well the complexity of the Bifurcation disease, were assessed using the DEFINITION trial criteria [8]. Written informed consent was obtained from all patients before the procedure and the Hospital Department Board approved the study. Due the retrospective design of the study, individual patient informed consent was waived.

2.1. Clinical definitions

AMI was defined as a rise of cardiac biomarker values (creatine kinase-MB or troponin) with at least 1 value >99th percentile of the upper reference limit was detected in patients with symptoms of ischemia, new significant ST-segment/T-wave changes, new left bundle-branch block, or echocardiographic evidence of new regional wall motion abnormality [9].

Presence of CS, which was entered into our database for every patient at the time of catheterization was defined as a systolic blood pressure <90 mmHg for at least 30 min with a severe reduction in cardiac index (<1.8 $L \cdot min^{?1} \cdot m^{?2}$ without support or <2.0–2.2 $L \cdot min^{?1} \cdot m^{?2}$ with support) and elevated left or right ventricular (RV) filling pressures; the need for inotropes/intra-aortic balloon pump (IABP)/extracorporeal membrane oxygenation (ECMO) to maintain a systolic blood pressure? 90 mmHg; or inadequate peripheral or end-organ perfusion (pH <7.3, serum lactate >2 mmol/L, cool extremities, urine output <30 mL/h, altered mental status), acute pulmonary congestion, or edema; and a heart rate >90 bpm or the need for cardiopulmonary resuscitation [10]. Patients developing CS during the catheterization procedure have been excluded.

Unprotected complex LM bifurcation disease was defined as: (1) a stenosis with a diameter of >50% involving the mid-shaft/distal main vessel with significant involvement (≥50% luminal narrowing and ≥ 10 mm length by visual estimation) of the Left anterior descending coronary artery (LAD) and Left Circumflex artery ostia (diameter ≥ 2.5 mm by visual estimation) and, (2) without any patent graft to the left anterior descending artery or left circumflex artery.

Angiographic success was defined as residual stenosis 30% by QCA 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, (2) non-fatal myocardial infarction (MI), or (3) target lesion revascularization (TLR). All deaths were considered to be of cardiac origin unless a noncardiac origin was established clinically or at autopsy.

Target vessel revascularization (TVR) was 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. 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 [11].

2.2. Interventional protocols

A 6F right radial approach has been selected whenever possible. During PCI, patients were anticoagulated with unfractionated heparin (a bolus of 40 U/kg and additional heparin to achieve an activated clotting time of 250–300 s). Additional significant lesions in other vessels were treated with staged procedures and a routine last generation drug eluting stent (DES) at the operator's discretion (Promus Premier, Boston Scientific, Galway, Ireland; Orsiro, Biotronik, Bulack, Switzerland, Resolute Integrity or Onyx, Galway, Ireland). Size of LM stent has been selected on the basis of Finet law calculation upon angiographic QCA as previously described [12], IVUS being difficult to use due to the emergent setting of the procedure. Twelve-month Ticagrelor or Prasugrel treatment and life-long aspirin were recommended to all patients.

2.2.1. Nano-crush technique

The technique was used for any angles as already described [13]. The Orsiro stent has been chosen when calculated diameter of the proximal LM was <5 mm, whereas Onyx stent has been selected when proximal LM diameter was ≥5 mm.

2.2.2. Culotte technique

The Culotte technique was performed when angle between LAD and LCx was <60° and the LCx diameter equalized the LAD diameter on QCA with a maximal difference of 0.5 mm [14]. Resolute or Onyx or Promus Premier has been used depending on the LM diameter.

2.2.3. T-stenting/TAP or cross-over

The rest of the other techniques include the TAP/T-stenting and cross-over stenting performed as suggested by the European Bifurcation Club [15].

2.2.4. Procedural measurements

Quantitative coronary angiographic (QCA) analysis at baseline, post-stenting and at follow-up were performed using edge detection techniques (CAAS II 5.0 version; Pie Medical, Maastricht, Netherlands). Radiological equipment was the GE Medical System Innova 3100 30"-30" Flat Panel in all cases. An estimation of the effective dose has been obtained from the measurements of the dose-area product (DAP). DAP was recorded automatically by the radiological equipment during the procedures. Fluoroscopy and procedural time and contrast volume were analyzed as well.

2.3. Follow-up

Per our institutional protocol, follow-up was conducted by physical examination at 1, 6, and 12 months and then yearly. Transthoracic echocardiography (TTE) was scheduled at 6 months and yearly with routine ejection fraction measurements following Lang et al. [16]. Angiographic with intravascular ultrasound control was eventually performed at the time of additional vessel treatment or driven by clinical symptoms or instrumental evidence of myocardial ischemia. 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. Post-discharge survival status was obtained from the Municipal Civil Registries. Information on 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.

Table 1
General characteristics of the population enrolled.

	All N = 57	Culotte N = 21	T stent N = 16	Nano-crush N = 20	p
Demographics					
Age (years)	62.3 ± 10.5	64.1 ± 10.5	61.3 ± 5.2	61.4 ± 13.6	0.65
Female (%)	23 (40.4)	8 (38.1)	6 (37.5)	9 (45.0)	0.73
Hemodynamic status					
SBP (mmHg)	80.0 ± 4.1	81.1 ± 5.2	80.0 ± 4.1	82.8 ± 5.0	0.23
HR	128.2 ± 15.4	128.5 ± 4.7	131.5 ± 9.9	125.3 ± 10.5	0.49
SI	1.58 ± 0.2	1.59 ± 0.3	1.64 ± 0.1	1.52 ± 0.1	0.27
Comorbidities					
HT (%)	19 (33.3)	6 (28.6)	4 (25.0)	9 (45.0)	0.36
Familiar CAD (%)	12 (21.1)	4 (19.0)	3 (18.8)	5 (25.0)	0.77
Current Smoking (%)	9 (15.8)	3 (14.3)	2 (12.5)	4 (20.0)	0.71
Diabetes (%)	13 (22.8)	4 (19.0)	3 (18.8)	6 (30.0)	0.58
Dyslipidemia (%)	17 (29.8)	6 (18.6)	5 (31.2)	6 (30.0)	0.94
Previous PCI (%)	11 (19.2)	3 (14.3)	4 (25.0)	4 (25.0)	0.98

SBP: Systolic blood pressure; HR: heart rate; SI: shock index; HT: Hypertension; TTE: Transthoracic echocardiography; LVEF: Left ventricular ejection fraction; FW: Follow up: LAD: left anterior descending; LCX: left circumflex; RCA: Right coronary artery: TLR: Target lesion revascularization; TVR: Target vessel revascularization.

2.4. Statistical analysis

Continuous variables are described as mean ± standard deviation while categorical variables as proportions. Analysis of variance with the Bonferroni's post-hoc correction was used to compare grouped continuous variables while Pearson's Chi^2 test to compare the prevalence of categorical ones. Mantel-Cox analysis was used to analyze difference in cardiovascular mortality among groups as well as multivariate Statistical analysis was performed using a statistical software package (SAS for Windows, version 8.2; SAS Institute; Cary, NC). A probability value of <0.05 was considered statistically significant.

3. Results

Fifty-seven patients (7.5%) with distal/bifurcation LM culprit lesion and CS (23 females, mean aged 62.3 ± 10.5 years), received LM stenting. The general characteristic of the population enrolled is showed in Table 1. Specifically, 21 (36.8%) patients received Culotte, 16 (28.0%) T-stenting and 20 (35.0) Nano-crush. None of the subjects enrolled underwent cross-over stenting.

Ten patients (17.5%) had complete distal LM occlusion with TIMI 0. Post-operative success was achieved in 100% of cases with a relatively low incidence of procedural complications (21%) (Table 2). Mean final diameter and length of the implanted stents were 4.3 ± 0.8 mm and 28.2 ± 7.1 mm in LM to LAD and 3.5 ± 0.8 mm and 22.6 ± 0.8.6 mm in LM to LCx in the Culotte group of patients, 4.2 ± 0.8 mm and 20.2 ± 9.3 mm in LM to LAD and 3.5 ± 0.8 mm and 12.3 ± 0.7.1 mm in LM to LCx in T-stenting, and finally 4.4 ± 0.8 mm and 27.1 ± 8.7 mm in LM-LAD and 3.1 ± 0.9 mm and 22.1 ± 0.7.1 mm in LCx in Nano-Crush patients.

Nano-crush patients group showed lower contrast medium volume and X-ray exposure, and shorter fluoroscopy and procedural times compared to other patients' groups (Table 2) suggesting a faster procedure execution.

Additional staged PCI in other vessels has been accomplished in 14/57 (24.5%) patients: 6 patients in Culotte group and 7 patients in T-stenting

Table 2
Procedural data comparison among the three different double stenting techniques. IABP: intraortic balloon pump; LAD: Left anterior descending coronary artery; LCx: Left circumflex coronary artery; RCA: right coronary artery.

	Culotte N = 21	T-stent N = 16	Nano-crush N = 20	p
6F Radial access	10 (47.6)	16(100)	12(60.0)	**0.78**
7-in-6F radial access	1(4.7)	0(0)	8 (40.0)	0.64
7F femoral access	9(42.8)	0(0)	0 (0)	0.66
Angiographic appearance				
Medina 1,1,1	16 (76.1)	12(75)	17(85.0)	0.81
Syntax score I	35.6 ± 7.7	33.4 ± 5.8	36.8 ± 6.3	0.72
TIMI 0	3 (14.2)	3 (18.7)	4(20)	0.68
TIMI 1–2	2 (9.5)	1(6.25)	3(15)	0.71
TIMI 3	16(76.1)	12(75)	13(65)	0.67
LAD stenosis >50%[a]	4 (19.0)	4 (25.0)	6 (30.0)	0.67
LCX stenosis >50%[a]	2 (9.5)	3 (18.8)	4 (20.0)	0.70
RCA stenosis >50%	3 (14.3)	2 (12.5)	3 (15.0)	0.86
Procedure				
Orsiro	7(33.3)	5(31.2)	14(70)	0.60
Resolute/Onyx	8(38.0)	7(43.7)	6(30)	0.76
Promus premier	6(28.5)	4(25)	0(0)	0.62
Fluoroscopy time (minutes)	23.8 ± 7.7[†]	21.4 ± 6.4	16.4 ± 8.4[*]	0.03
Contrast medium volume (ml)	208 ± 46.7[†]	188 ± 48.2	170 ± 55.7[*]	0.02
Dose area product (cGy/cm^2)	16,177 ± 4331[†]	15,008 ± 5227	11,422 ± 4687[*]	0.03
IABP[b]	4 (19.0)[†]	4 (25.0)	6 (30.0)	0.55
Intraprocedural complications	5 (23.8)	7(43.7)	0(0)	0.05
Abrupt vessel occlusion	1(4.7)	6(28.6)	0(0)	0.64
Access hematoma/occlusion	4(19.0)[†]	1(6.25)	0(0)	0.02

[a] Stenosis not accounted in the first 10 mm in the mid or distal vessel segment.
[b] As per institutional protocol, IABP was used only as back up if TIMI 3 flow restoration was not achieved in the first 10 min from arterial puncture.
[*] $p < 0.05$ between Nano-crush and T-stent.
[†] $p < 0.001$ between Culotte and T-stent.

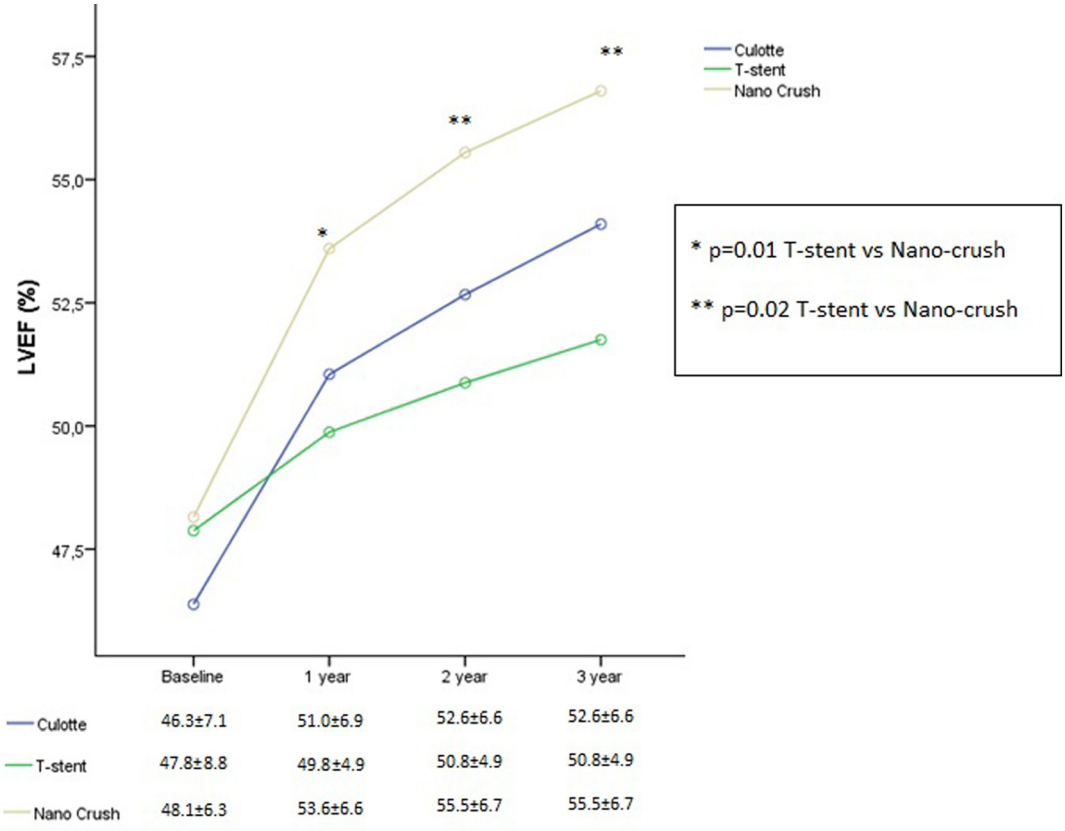

Fig. 1. Improvement of ejection fraction on serial echocardiograms during the follow-up. Comparison among the three groups of patients.

and 5 patients in Nano-crush group, respectively): distal LAD in 8 patients, Right Coronary artery PCI in 6 patients.

At 30–day CV mortality was 8.7%: two patients with Culotte and three patients with T stenting died during the hospital recovery for ventricular fibrillation.

Clinical follow-up was available in all the alive 52 patients: EF on TTE at demonstrated a trend in favor of a larger improvement for patients treated by Nano-crush compared to the other two groups (Fig. 1). At three-year follow-up TLR, TVF and three-year mortality-rate for all-causes were not statistically different among the three groups (Table 3). Conversely, considering 3-year CV mortality as outcome, a statistically significant difference was observed favoring Nano-crush when compared to patients treated with T stenting (Table 4 and Fig. 2).

4. Discussion

Our brief study suggests that in emergent settings such as CS with distal/bifurcation LM disease as culprit lesion, double stenting achieved in general good results with an acceptable rate of procedural complications and mid-terms mortality-rates. Our retrospective analysis suggested that Nano-crush stenting technique might have some advantages in terms of speed of handling and contrast volume compared to either T-stenting or Culotte. Nano-crush showed similar survival of Culotte and a slight better survival compared to T–stenting with a global better recovery of the left ventricle EF on mid–term follow-up.

Double stenting technique in LM distal bifurcation revascularization seems to be able, as demonstrated in recent studies, to provide a benefit when compared to cross-over provisional stenting in terms of MACE during the mid–term follow-up [17]. DK-Crush has been suggested with some criticisms to be superior to Culotte [18] and also provisional stenting [19]. On the other hand Ferenc et al. [20] found in Left main bifurcation higher long-term risk of MACE driven by a higher incidence of TLR in single compared to dual stenting, but similar risk of death, MI, or stent thrombosis.

Recently Pavani et al. [21] found no difference in long-term outcomes in patients treated with Culotte, minicrush or T-stenting in a

Table 3
Follow-up echocardiography and clinical outcomes comparison of the survivors.
CV: cardiovascular; LVEF: left ventricle ejection fraction; TLR: target lesion revascularization; TVR: target vessel revascularization.

	All N = 52	Culotte N = 19	T stent N = 13	Nano-crush N = 20	*p*
TTE					
LVEF baseline[a] (%)	47.4 ± 6.3	46.3 ± 7.1	47.8 ± 4.9	48.1 ± 6.6	0.64
LVEF at 1 year (%)	51.6 ± 6.4	51.5 ± 6.9	49.8 ± 4.9	53.6 ± 6.6	0.20
LVEF at 2 years (%)	53.1 ± 6.4	52.6 ± 6.6	50.8 ± 4.9	55.5 ± 6.7	0.80
LVEF at 3 years (%)	54.3 ± 6.2	54.1 ± 6.5	51.7 ± 5.9	56.8 ± 6.1	0.50
3-year follow-up					
TLR (%)	6 (11.5)	2 (10.5)	3 (23.0)	1 (5.0)	0.62
TVR (%)	2 (3.8)	1 (5.2)	1 (7.8)	0 (0)	0.78
Mortality for all-causes (%)	10 (19.2)	3 (15.7)	5 (38.6)	2 (10.0)	0.82
CV mortality (%)	7 (13.4)	2 (10.5)	4 (30.8)	1 (5.0)	0.64

[a] Baseline values referred to the first echo-scan in the intensive coronary care unit after revascularization not to the EF during Cardiogenic shock.

Table 4
Survival analysis for different clinical and angiographic outcomes. CV: Cardiovascular; TVR: Target vessel revascularization; TLR: Target lesion revascularization.

	Chi square	P Log-rank (Mantel Cox)
3-year all-cause mortality		
Culotte vs T-stent	3.17	0.75
T-stent vs Nano-crush	0.62	0.23
Culotte vs Nano-crush	0.03	4.69
3-year CV mortality		
Culotte vs T-stent	3.20	0.73
T-stent vs Nano-crush	5.01	0.02
Culotte vs Nano-Crush	0.33	0.56
3-year TVR		
Culotte vs T-stent	1.08	0.29
T-stent vs Nano-crush	2.45	0.11
Culotte vs Nano-Crush	2.45	0.11
3-year TLR		
Culotte vs T-stent	0.24	0.62
T-stent vs Nano-crush	1.18	0.12
Culotte vs Nano-Crush	1.19	0.15

registry of stable patients: obviously in CS patients the capability of the technique to diminishing the global ischemic time plays a different role, compared to stable patients scenario. That seems to be confirmed by a small study showing that in STEMI due to occlusion of LM, DK Crush can offer acceptable results with a similar rate of re-infarction of NSTEMI patients [22] with an acceptable mortality.

There are no real-world data about the outcomes of double stenting technique in primary PCI, neither about the use of such technique in distal/bifurcation LM and STEMI. Even data about outcome of LM revascularization in STEMI setting are lacking or outdated.

In 2004 in a series of 1736 patients with an acute MI who underwent primary PCI, only 2.2% of these could be associated with an obstruction of the left main artery causing TIMI flow grade ?2.7 Primary PCI was performed in all of them, with an in-hospital mortality rate of 55%. Cardiogenic shock complicated 74% of the cases, 47.1% among the survivors and 95.2% among the patients that did not survive. PCI was successful in 100% versus 57.1%, respectively. In-hospital mortality reached a mean of 55%, 71.4% among patients with shock and 10% among those without [23]. The main findings seem no changes 7 years later as in a series of 2014, despite performance of primary PCI, patients with AMI due to LMCA occlusion were associated with >50% in-hospital mortality [24].

Apparently, our retrospective study focused on an unexplored field: 30-day mortality of revascularization of patients with shock complicating LM occlusion, taking into account the very challenging setting, was quite low and survival at three years was remarkable.

Several reasons for these unexpected good outcomes should be taken into account. First, the small percentage of patients with complete occlusion, only 17.5% had actually a complete TIMI 0 flow occlusion of the LM. Secondly, the mean age of patients was 62.3 years, relatively low for such challenging subset of patients and in favor of a prompt recovery. Finally, the moderate global extent of the disease that is suggested by a relatively low SYNTAX score, despite the LM bifurcation disease resulted complex by using the Definition study score. The low percentages of patients who need IABP confirmed that the sample has somewhat favorable characteristics.

The specific stenting techniques used to achieve revascularization and TIMI 3 flow probably played a secondary role: the most important factor as always in STEMI remains flow restoration as faster as possible and short ischemic time. For this purpose, the Nano-crush, being applicable to a variety of angles and eventual MB and SB diameter mismatch seems to have a slight advantage over Culotte. Moreover, number of rewiring and kissing steps are minimized in such techniques compared to Culotte, something to consider in an emergent setting as cardiogenic shock. TAP or T-stenting use reflects the attempt to use a provisional strategy, which in such setting probably leaves a longer, an ischemic time compared to a planned double stenting technique. All these factors

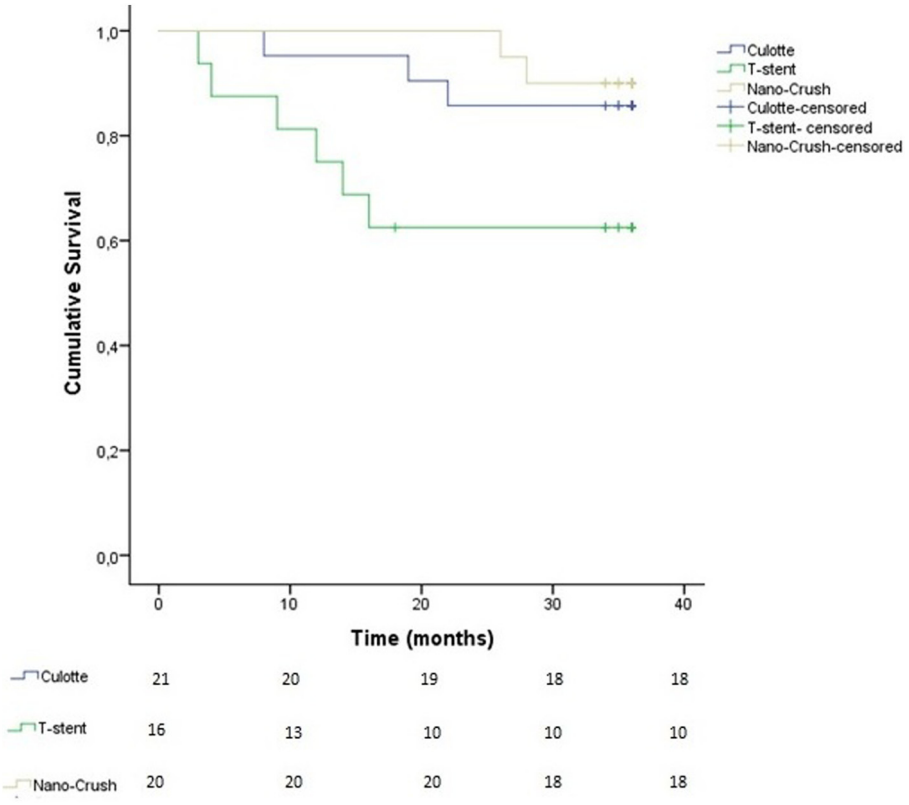

Fig. 2. Comparison of mid-term cardiovascular mortality of the three groups of patients.

might be responsible for the slightly worse outcome of T/TAP stenting group of patients and for the slower recovery of the EF observed in the follow-up echocardiographic controls in T/TAP and Culotte group of patients.

4.1. Study limitations

Our brief study suffers a number of limitations which include the retrospective non-randomized fashion nature, which enables hard recommendations, the small patients sample which came from both the single center nature and the particular patients setting (STEMI complicated by CS with really complex LM bifurcation disease requiring double stenting) and finally the use of different stent platforms which might induce differences in the outcomes independent from the stenting technique used. Moreover the very strict inclusion criteria identified a sample of relatively young patients with a relatively low Syntax score which usually do not reflect the CS standard population but on the contrary offered a relatively clear scenario in order to analyze different stenting techniques without the influence of age, multiple comorbidities and extended ischemic heart disease.

5. Conclusion

In this retrospective study, revascularization of patients with CS with complex distal/bifurcation LM disease as culprit lesion was accomplished with acceptable rate of complication and mortality using double stenting techniques. In such setting, techniques that minimize rewiring and kissing steps and shorten ischemic time should probably be preferred.

Conflict of interest

None of the authors have conflict of interest to declare.

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