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Determination of Coronary Bifurcation Culprit Lesion in the field of Anterior ST Elevation Myocardial Infarction

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Introduction: Coronary bifurcation lesions are considered one of the challenging entities in the field of coronary intervention due to the risk of side branch loss and higher risk of stent thrombosis. However, there is limited data about the proper management of such lesions in the setting of myocardial infarction as most bifurcation lesion studies excluded patients with acute coronary syndromes (ACS). The aim of this study was to compare in-hospital and mid-term outcomes of single-stent and two-stents strategy in the management of bifurcation culprit lesions in patients presenting with anterior STEMI.
Methods: This retrospective multi-center study included all patients presented with anterior STEMI who underwent primary PCI between January 2017 and December 2019, coronary angiography showed true bifurcation lesion with sizable side branch that can be managed by stenting. Patients with left main bifurcation, those indicated for urgent CABG, and patients in cardiogenic shock were

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excluded. Included patients were divided into two groups according to the stenting strategy either single or two stents. Six months follow up data were collected by telephone calls and by examination of medical records.

Results: Out of 1355 anterior STEMI patients presented between January 2017 and December 2019, 158 patients (11.6%) were identified to have bifurcation culprit lesions with a sizable diagonal branch. 93 patients (59%) were treated by single stent while 65 patients (41%) were managed by two-stents strategy. The baseline characteristics and angiographic findings were similar in both groups except for higher side branch involvement in the two stents group (83.31%±11.20 vs 71.88%±15.05, t= -5.39, p <0.001). Mean fluoroscopy time (23.96±8.90 vs 17.81±5.72 mins) and contrast volume (259.23± 59.45 vs 232.58± 96.18 ml) were significantly higher in two stents group than single stent group (*p*=0.049). However, the angiographic success rates (residual stenosis ≤30% and restoration of TIMI flow grade II or III) were comparable (96.8% vs 99%, *MCp=0.151*). There is no significant difference in the overall incidence rate of MACE in both groups 6 months following the index procedure (13.9 % vs 16.9%, *FEp=0.698)*, with no difference between different bifurcation stenting techniques in patients managed with two stents.

Conclusion: Although two stents strategy in the setting of STEMI is much complex with more fluoroscopy time and contrast volume, the procedural success rate and the incidence of MACE were comparable to one stent strategy, on medium-term follow up.

Keywords: Coronary artery disease; ST segment elevation myocardial infarction; primary percutaneous coronary intervention; bifurcation lesions.

ABBREVIATIONS

ACE inhibitors : Angiotensin-Converting Enzyme inhibitors
ACS : Acute Coronary Syndrome
AMI : Acute Myocardial Infarction
ARBs : Angiotensin II Receptor Blockers
BFLs : Bifurcation Lesions
CABG : Coronary Artery Bypass Grafting
CAD : Coronary Artery Disease
CCU : Coronary Care Units
CIN : Contrast Induced Nephropathy
CKD : Chronic Kidney Disease
CVS : Cerebrovascular Stroke
DAPT : Dual Antiplatelet Therapy
DES : Drug Eluting Stents
EBC : European Bifurcation Club
ECG : Electrocardiography
KBI : Kissing Balloon Inflation
LAD : Left Anterior Descending artery
LDL-C : Low Density Lipoprotein Cholesterol
LV : Left Ventricular
LVEF : Left Ventricular Ejection Fraction
MACCE : Major Adverse Cardiovascular and Cerebrovascular Events
MB : Main Branch
MRA : Mineralocorticoid Receptor Antagonist
NSTEMI : Non ST –Segment Elevation Myocardial Infarction
PPCI : Primary Percutaneous Intervention
SB : Side Branch
ST : Stent Thrombosis
STEMI : ST-Segment Elevation Myocardial Infarction
TAP : T stenting with Minimal Protrusion
TIA : Transient Ischemic Attack
TLR : Target Lesion Revascularization
TTE : Transthoracic Echocardiography
TVR : Target Vessel Revascularization
VT : Ventricular Tachycardia

1. INTRODUCTION

The incidence of STEMI nowadays is decreasing, it is estimated in European countries to range from 43 to 144 per 100.000 per year [1]. In the USA, the incidence rate decreased from 133 per 100.000 in 1999 to 50 per 100.000 in 2008, whereas the incidence of NSTEMI remained constant or increased slightly [2].

Primary PCI is the strategy of choice for reperfusion in patients with symptoms onset less than 12 hrs if performed without delay (within 120 minutes from STEMI diagnosis) and by experienced team in high volume center [3], it was found that PPCI is superior to fibrinolysis in reducing major adverse events as: stroke, re-infarction and cardiovascular death [4].

Bifurcation lesions are one of the most challenging interventional cardiology subsets with 20% incidence of all coronary interventions, it usually associated with lower success rate and more adverse events on the long term [4,5].

Bifurcation lesion is defined by European bifurcation club as “a coronary artery narrowing occurring adjacent to and/or involving the origin of a significant SB. A significant SB is a branch, whose loss will have significant consequences regarding patient symptoms and ischemia of large myocardial territory [5].

Provisional stenting if feasible is the strategy of choice in treating the majority of bifurcation lesions based on European bifurcation club recommendation based on results from the Nordic IV and EBC TWO (European Bifurcation Club 2) trials, there was no difference noted between one and two stent strategies as regard the incidence of target lesion revascularization and cardiac death. The side branch (SB) should be treated if there is significant flow limitation, significant ostial stenosis or if SB is supplying large myocardial territory and its loss will cause significant myocardial ischemia [6].

Two stents strategy is usually considered when managing large side branch more than 2.5 mm in diameter with significant ostial involvement and when the lesion is extending 5 mm beyond the ostium and the loss of this branch will have drastic effects particularly significant myocardial ischemia [7].

1.1 Objectives of the Study

The aim of this study was to compare the in-hospital and mid-term outcomes of single-stent and two-stents strategy in the management of bifurcation culprit lesions in patients presenting with anterior ST segment elevation acute myocardial infarction (STEMI).

2. METHODS

The study included all patients admitted to two tertiary care hospitals (with 24/7 catheterization laboratories), from January 2017 to December 2019, who presented with anterior STEMI and underwent primary PCI, the study population were divided into two groups: single stent vs. two-stents strategy. We included patients with established diagnosis of anterior ST segment elevation acute myocardial infarction (STEMI) undergoing primary PCI, coronary angiography showed true bifurcation lesion with sizable side branch managed by stenting either single or two stents. We excluded patients having an indication for urgent coronary artery bypass grafting (CABG), and patients with cardiogenic shock.

All patients were subjected to detailed history taking (personal history, past medical history, history of hypertension, DM, dyslipidemia, ACS or previous PCI, special habits (smoking, drug abuse), drug history, family history of CAD).All patients had full clinical evaluation on admission (consciousness level, vital signs, cardiac examinations and Killip class).

Standard well calibrated 12 leads ECG was obtained from every patient on admission, all ECGs were evaluated for the presence of ST segment elevation fulfilling 2017 ESC diagnostic criteria of STEMI [8]. Laboratory investigations, including hemoglobin level, high sensitivity cardiac troponin & serum creatinine, were also done.

Routine transthoracic echocardiography was done during hospital stay to all patients for assessment of Left ventricular (LV) dimensions, volumes, and ejection fraction, detection of LV resting regional wall motion abnormalities, assessment of mitral regurgitation grade if present, and detection of any mechanical complications.

2.1 PCI Procedure

All patients eligible to primary PCI received 300 mg aspirin PO plus one of P2Y12 inhibitors either clopidogrel 600 mg PO or ticagrelor 180 mg PO before the procedure [9].

2.1.1 Access site

Either trans-femoral or trans-radial approaches were used according to operator preference using 6fr or 7fr sheath. Once the arterial sheath is inserted, bolus dose of 70-100 IU/kg UFH was injected [9].

Coronary angiography was performed to assess the culprit lesion as regards site of the occlusion, severity of the occlusion, TIMI flow grade, presence of thrombus & assessment of thrombus burden, bifurcation lesion criteria (Medina classification [10], main branch diameter, side branch diameter, site of stenosis and degree of stenosis, and bifurcation angle. Medina classification of bifurcation lesion was determined after restoration of the flow in case of totally occluded culprit vessel (LAD).

2.1.2 Percutaneous coronary intervention

6 fr guiding catheter was used in most of the cases unless there was indication for the use of

7fr guiding catheter as simultaneous deflation of two stents. Several types of guidewires were used including floppy, intermediate and hydrophilic wires. The guiding catheter and guidewire selection was influenced by criteria related to the vessel anatomy, the lesion morphology, the devices used and the operator experience and preferences. In the presence of heavy thrombus burden: thrombus aspiration using suction device e.g., Diver C (Invatec) or Export aspiration catheter (Medtronic).

After successful guidewire crossing to distal bed and proper lesion preparation with balloon angioplasty, the lesion was assessed by the operator to choose the stenting strategy either provisional or upfront two stent technique from the start according to the SB diameter, degree of stenosis, extension of lesion into SB and bifurcation angle. The technique used in case two stents were used depends mainly on the operator experience and preference according to the lesion criteria as mentioned before. Drug eluting stents (DES) were used in all cases, post dilatation using NC balloons was performed guided by the degree of stent expansion and final kissing balloon inflation was used in provisional stenting in case of SB compromise following MB stent deployment [11,12].

2.2 Criteria Used for Assessing Success

- Angiographic success: defined as restoration of TIMI flow grade 3 with a residual stenosis of ≤ 30% assessed by quantitative coronary angiography performed at the angiographic core laboratory [11].
- Procedural success: defined as technical success without in-hospital major adverse cardiovascular and cerebrovascular events (MACCE) [11].
  - MACCE: defined as the composite of cardiovascular death, recurrent MI, stroke or repeat target vessel revascularization (TVR) [11].

Any complications that occurred during the procedure such as (dissection, re-occlusion, no-reflow, cardiac arrest) or access site complications (hematoma, bleeding, and pseudoaneurysm) were documented with the appropriate management.

2.3 Post-PPCI Management

A 12 lead ECG is obtained after PCI. The patients were monitored in a coronary care unit that has continuous ECG monitoring with routine post-PCI care.

2.4 Medications [8]

- Lifelong intake of low dose aspirin (75-100mg/d) in patients without allergy.
- At least 12 months intake of P2Y12 inhibitors in patients with low risk of bleeding, clopidogrel 75mg /day PO or ticagreolor 90 mg twice daily PO.
- Beta-blockers in all patients who tolerate these medications and without contraindications.
- ACE-I or ARBs and Spironolactone when indicated & no contraindications.
- Statins in all patients without contraindications irrespective of cholesterol levels to achieve LDL-C < 55 mg/dl.

2.5 Follow Up

Follow-up information was obtained by either clinical visits or telephone interviews. Hospital records of all patients were screened for the occurrence of clinical events to confirm the obtained information. Follow up data were classified into in-hospital, 1 month and after 6 months.

Clinical end points were the occurrence of:

1) Cardiac death (defined as death caused by acute myocardial infarction, ventricular arrhythmias, or refractory heart failure).
2) Nonfatal myocardial infarction (defined based on criteria of typical chest pain, elevated cardiac enzyme levels, and typical changes on the electrocardiogram).
3) Need for repeated percutaneous intervention for the target lesion or CABG.
4) Stroke
5) Major bleeding required hospital admission and blood transfusion

2.6 Statistical Analysis of the Data

Quantitative data were summarized by mean and median as measures of central tendency, and standard deviation, minimum and maximum as measures of dispersion. Categorical variables were summarized by frequency and percent. Chi-square test was performed to study significant association between two categorical variables. Fischer-Exact as well as MonteCarlo significance were used if more than 20% of total expected cell counts <5 at 0.05 level of significance. For 2

categories variables, independent sample t test or Mann-Whitney test were employed to test significant difference in mean and median quantitative variables respectively. For qualitative variables > 2 categories, we performed Kruskal-Wallis test. The choice of either test was based on variables' distribution by Kolmogorov-Smirnov test and sample size per group [13]. All statistical tests were two-sided and were performed using IBM SPSS statistics program version 21 [14]. P value less than 0.05 was considered statistically significant.

3. RESULTS

Between the period of January 2017 and December 2019, 1355 anterior STEMI patients presented to our hospital, 158 of patients (11.6%) were identified to have bifurcation culprit lesion following angiographic assessment by two independent operators. These patients were divided into two main groups according to the stenting strategy either single or two stents strategy. Patients who were lost during follow-up period were excluded.

The mean age of included patients was 56.14±9.96 years, and 133 patients (84%) were males. In the single stent group, mean age was 56.82 ± 9.59 years, and 81 patients were males (87%). In the two stents group, mean age was 55.16 ± 10.48 years, and 52 patients were males (80%) (Table 1).

Regarding risk factors (Table 1), 33 % of the study population had diabetes mellitus (52 patients). There was a higher incidence of diabetes among patients in the single stent group (36.6 % vs. 23.1%, MCp.021). 96 patients were hypertensive (60%), there was higher incidence of hypertension in the two stents group which was statistically significant (72.3 % vs. 52.7 %, p=0.013). 130 patients of the studied population (82 %) were dyslipidemic, there was no statistically significant difference regarding the incidence of dyslipidemia between the two studied groups (82.8% vs. 81.5 %, p=0.839). 70% of the study population were smokers (112 patients), there was a higher incidence of smoking in the single stent group with no statistically significant difference (74.2 % vs. 66.2 %, p=0.839).

In the single stent group, 88 patients (94.6%) underwent primary PCI, and 5 patients (5.4%) underwent rescue PCI after receiving thrombolytic therapy. In the two stents group, 60 patients (92.3%) underwent primary PCI, and 5 patients (7.7%) underwent rescue PCI after lytic administration, with no statistically significant difference (FEp=0.556) between different groups.

All our patients had anterior STEMI, whose culprit vessel was the left anterior descending artery at its bifurcation with the first diagonal in 137 patients (83 in the singe stent group and 54 in two-stents group), the second diagonal in 20 patients (9 in the single stent group and 11 in two-stents group) and the third diagonal in one patient in the single stent group. The LAD was occluded in its proximal segment in 80 patients (36 patients in the single stent group (38.7%) and 44 patients in the two-stents group (67.7%)), LAD was occluded at its mid segment in 76 patients (57 patients in the single stent group (62.3%) and 21 patients in the two-stents group (33.3%)) (Table 2).

The side branch involvement was assessed in all cases for planning the stenting strategy either provisional or elective two stents technique. The side branch degree of stenosis was significantly higher in the two stents group with mean degree of stenosis 83.31%± 11.20 in comparison to the single stent group where the mean degree of stenosis was 71.88%±15.05 (p<0.001) (Table 2).

The angle of bifurcation between LAD (MV) and the diagonal branch (SB) was assessed after restoration of the flow for planning the stenting strategy. The bifurcation angle was between (30-45) degrees in 23 patients (24.7%) in the single stent group versus 10 patients (15.3%) in the two stents group, the angle was between (45-60) degrees in 61 patients (65.5%) in the single stent group versus 51 patients (78.4%) in the two stents group while the angle was between (60-90) in 9 patients (9.6%) in the single stent group versus 4 patients in the two stents group (6%), with significantly higher number of patients with bifurcation angle between (45-60) degrees (p<0.001) (Table 2).

The culprit bifurcation lesion was categorized according to Medina classification (Table 3).

Procedural characteristics (Table 4): In the single stent group, femoral access was used in 52 patients (55.9 %) while radial access was used in 41 patients (44.1%). In the two stents group, radial access was used in 25 patients (38.5%) while femoral access was used in 40 patients (61.5%), with no statistically significant difference

(X2= 0.498, p=0.481). Balloon predilation of the main vessel was performed in 114 patients (62 patients in the single stent group (66.7%) and 52 patients (80%) in the two stents group) with no statistically significant difference between both groups.

The mean main branch (MB) stent diameter in the single stent group was 3.26±0.33 mm, while the mean MB stent diameter in the two-stent group was 3.44±0.32 mm. The mean MB stent length in the single stent group was 34.45±8.62 mm, while in the two stents group the mean MB stent length was 31.24 ± 9.34 mm, with statistically significant difference between both groups (t2.22, p=0.02) (t-3.29, p.001).The mean side branch stent diameter in patients managed with two stents strategy was 2.6±0.2 mm and the mean SB stent length was 18.7±7.19 mm (Table 4).

Table 1. Comparison between single stent and two stents treatment groups as regard the patient characteristics

Patients' characteristics	Strategy		p value
	Single Stent (n=93)	Two-Stent (n=65)	
Male gender, n (%)	81 (87.1%)	52 (80%)	X^2 1.44, p=0.229
Age (years), mean (SD)	56.82 (9.59)	55.16 (10.48)	t 1.03, p=0.313
DM, n (%)			
Type1	0	3 (4.6%)	
Type2	34 (36.6%)	15 (23.1%)	MCp=0.021*
HTN, n (%)	49 (52.7%)	47 (72.3%)	X^2 6.17, p=0.013*
Dyslipidemia, n (%)	77 (82.8%)	53 (81.5%)	X^2 041, p=0.839
Smoking, n (%)	69 (74.2%)	43 (66.2%)	X^2 1.19, p=0.274
CKD, n (%)	10 (10.5%)	4 (6.2%)	p=0.125
Previous PCI, n (%)	12 (12.9%)	7 (10.7%)	p=0.72

CKD=Chronic Kidney Disease, DM= Diabetes Mellitus, HTN= Hypertension, PCI= Percutaneous Coronary Intervention, SD= Standard Deviation

*X^2 Chi-square test, t Independent Sample t-test, MCp Monte Carlo significance, FEp Fischer Exact significance, *results≤.05 are significant*

Table 2. Angiographic data comparison between single and two stents groups

Angiographic data	Single stent (n=93)	Two stents (n=65)	p value
Dominance, n (%)			
Right	86 (92.5%)	60 (92.3%)	X^2 1.19,
Left	7 (7.5%)	5 (7.7%)	P=0.274
Site of LAD occlusion, n (%)			
Mid	57 (61.3%)	21 (32.3%)	X^2 12.85,
Proximal	36 (38.7%)	44 (67.7%)	P=0.001*
Initial TIMI flow, n (%)			
0	64 (68.8%)	50 (76.9%)	
I	16 (17.2%)	8 (12.3%)	MCp=0.687
II	10 (10.8%)	6 (9.2%)	
III	3 (3.2%)	1 (1.5%)	
SB stenosis degree, n (%)	71.88 (15.05%)	83.31 (11.20%)	t-5.39, p<.001*
SB stenosis site, n (%)			
No	3 (3.2%)	1 (1.5%)	
Mid	1 (1.1%)	1 (1.5%)	MCp=0.031*
Ostial	52 (55.9%)	50 (76.9%)	
Proximal	37 (39.8%)	13 (20.0%)	
Bifurcation angle, n (%)			
30-45°	23 (24.7%)	10 (15.3%)	
45-60°	61 (65.5%)	51 (78.4%)	p<.001*
60-90°	9 (9.6%)	4 (6%)	

LAD= Left Anterior Descending, SB= Side Branch, TIMI= Thrombolysis in Myocardial Infarction

*X^2 Chi-square test, t Independent Sample t-test, MCp Monte Carlo significance, *results≤.05 are significant*

Table 3. Distribution of Medina classification in both treatment groups

Medina classification	Strategy		p value
	Single Stent (n=93)	Two-Stents n=65)	
0-1-0, n (%)	1 (1.1%)	0	MCp=0.001*
0-1-1, n (%)	28 (30.1%)	12 (18.5%)	
1-0-1, n (%)	14 (15.1%)	1 (1.5%)	
1-1-0, n (%)	4 (4.3%)	1 (1.5%)	
1-1-1, n (%)	46 (49.5%)	51 (78.5%)	

*MCp Monte Carlo significance, *results≤.05 are significant*

Table 4. Comparison between single stent and two stents groups as regards procedural characteristics

Procedural characteristics	Single stent (n=93)	Two stents (n=65)	P value
Pre-dilatation, n (%)	62 (66.7%)	52 (80.0%)	p<.001*, X^2 33.41
Thrombus aspiration, n (%)	14 (15.1%)	6 (9.2%)	X^2 1.17, p=0.279
GPIIb/IIIa inhibitors use, n (%)	15 (16.1%)	8 (12.3%)	X^2.449, p=0.503
Type of DES, n (%)			
Biolimus A9	17 (18.3%)	41 (63.1%)	p<.001*
Everolimus	35 (37.6%)	14 (21.5%)	X^2 35.83
Sirolimus	33 (35.5%)	10 (15.4%)	
Final kissing, n (%)	43 (46.2%)	63 (97%)	X^2 38.54, P<.001
MB Stent diameter (mm), m(SD)	3.26(0.33)	3.44(0.32)	t-3.29, p=0.001*
MB Stent length (mm), m(SD)	34.45(8.62)	31.24(9.34)	t2.22, p=0.028*
SB stent diameter (mm), m(SD)		2.6 (0.2)	
SB stent length (mm), m(SD)		18.7 (7.19)	
Volume of contrast (ml), m(SD)	232.58(96.18)	259.23(59.45)	t1.833, p=0.049*
Fluoroscopy time (min), m(SD)	17.81(5.72)	23.96(8.90)	t.167, p<.001*

DES= Drug Eluting Stent, MB= Main Branch, SB= Side Branch
*X^2 Chi-square test, t Independent Sample t-test, MCpMonteCarlo significance, FEpFischerExact significance, *results≤.05 are significant*

Kissing balloon inflation (KBI) was done in 104 patients of the whole study population (43 patients(46.2%) in the single stent group while it was performed in 63 patients(97%) in the two stents group), while it was not performed in 54 patients (50 patients (53.8%) in the single stent group and it was not accessible only in 2 patients in the two stents group (3%)), with significant difference between the two groups (P<0.001, X^2 38.54) (Table 4).

Regarding the stenting strategy in the two stents group (65 patients), T stenting or TAP (T and small protrusion) technique was performed in 20 patients (30.7%), Culotte technique was done only in 4 patients (6.1%), Mini-crush technique was performed in 27 patients (41.5%) and DK-crush technique was done in 14 patients (21.5%) (Table 4).

The mean fluoroscopy time was significantly longer in two stents group 23.96 ±8.90 minutes while it was 17.81±5.72 minutes in single stent group (t=0.167, p<0.001). The mean contrast volume in single stent group was 232.58± 96.18 ml, and 259.23± 59.45 ml in the two stents group, with statistically significant difference between both groups (t=1.833, p=0.049) (Table 4).

3.1 Intra-Procedural Complications (Table 5)

Complications that occurred during the procedure were the following: Dissection in the side branch (diagonal branch) after balloon predilation occurred only in 3 patients and was managed by two stents strategy (4.6%) with no patients in single stent group, but non statistically significant difference (MCp=0.080). Distal thrombotic embolization occurred in 4 patients of the who). Lossdy population (2 patients in the single stent group (2.2%), and 2 patients in the two stents group (3.1%)), with no statistically significant difference (MCp= 0.151).Coronary no-reflow occurred in 11 patients of the whole study population (6 patients in the single stent group (6.5%) and 5 patients in the two stents group

(7.7%)) with no statistically significant difference (FEp= 0.761). Loss of side branch (bifurcating diagonal branch) occurred in 5 patients in the single stent group (5.4%) and it was successfully managed in 3 patients (3.2%) by side branch wire recrossing and kissing balloon inflation, while no patients in the two stents group experienced such complication.

Acute stent thrombosis occurred in 8 patients in the whole study population (5%); 5 patients in the two stents group (7.6%) and 3 patients in the single stent group (3.2%), but no statistically significant difference between both groups. In the single stent group, it occurred in 3 patients, one patient developed acute stent thrombosis intraprocedurally and died on table despite trial of manual thrombus aspiration, balloon inflations and IC injection of tirofiban. The other two patients experienced re-infarction in hospital due to stent thrombosis, one patient in day 2 after the index procedure and was successfully managed by ticagrelor reloading, manual thrombus aspiration and IC tirofiban injection, the other patient experienced stent thrombosis on day 3 and unfortunately died due to refractory pulmonary edema. In the two stents group, ST occurred in 5 patients, 3 patients experienced ST intraprocedurally and was successfully managed using IC injection of tirofiban and manual thrombus aspiration , 2 patients experienced reinfarction in hospital (one patient on day 1, and one patient on day 2), the first patient was successfully managed by ticagrelor reloading , IC tirofiban and manual thrombus aspiration with good final results while the other patient died in hospital due to pulmonary edema and subsequent ventilator acquired pneumonia.

3.2 In Hospital Complications (Table 6)

Cardiac arrest during hospital stay occurred in 3 patients (1 patient in the single stent group (1%) and 2 patients in the two stents group (3%)). Cardiogenic shock following intervention occurred in 2 patients in the single stent group (2.1%) who experienced shock and died during CCU stay. Pulmonary edema developed in 6 patients (3.7%) in the CCU following percutaneous intervention (4 patients in single stent group (4.3%) and 2 patients in two stents group (3%)). In the single stent group, one patient developed refractory pulmonary edema due to acute stent thrombosis on day 3 and unfortunately died while the other 3 patients were successfully managed with IV diuretics, vasodilators, and non- invasive ventilation. In the two stents group, one patient developed pulmonary edema and died due to severe ventilator acquired pneumonia while the other patient was successfully managed.

Cardiac arrhythmia occurred in 3 patients (1.8%) following the procedure (2 patients in the single stent group (2.1%) and 1 patient in the two stents group (1.5%)), the two patients in the single stent group were managed using IV amiodarone and DC cardioversion but the patient in the two stents group died as result of incessant VT.

Contrast induced nephropathy occurred in 10 patients (6.3%) of the whole study population (7 patients in the single stent group (7.5%) and 3 patients in the two stents group (4.6%)), with no statistically significant difference (FEp=0.527), all patients were managed conservatively. Contrast induced nephropathy occurrence was significantly correlated with baseline serum creatinine (p=0.005). Patients who experienced CIN received larger amounts of contrast than patients who did not experience CIN but without significant correlation.

Local vascular complications mainly access site hematoma occurred in 14 patients of the whole study (8 patients in the single stent group (8.6%) and 6 patients in the two stents group (9.2%)), with significantly higher percentage of local vascular complications in patients with femoral access. All patients were managed through ultrasound guided compression without need for surgical intervention.
There was no significant difference between different two stents techniques regarding in hospital complications.

3.3 Follow up after 1 month (Table 7, Fig. 1)

The MACCE rate 1 month following the procedure in the single stent group is 8.6 % vs. 9.2 % in the two stents group with no statistically significant difference (FEp=0.082). Cardiac death occurred in 6 patients (3.7%) of the whole study population after 1 month following index procedure (4 patients in single stent group (4.3%) and 2 patients in two stents group (3%)) with no significant difference between both groups. Advanced killip class on admission (killip class II/III) was associated significantly with higher incidence of cardiac death, 6 patients suffered cardiac death (2 patients (1.4%) from killip class I subgroup and 2 patients (16.7%) from killip class II subgroup and 2 patients

(28.5%) from killip class III subgroup) (MCp=0.024).Re-infarction secondary to acute stent thrombosis occurred in 4 patients (2.5%) of the whole study population (2 patients (2.1%) in the single stent group and 2 patients (3%) in the two stents group), with no statistically significant difference (FEp =0.135), but this mandated target lesion revascularization (TLR). Heart failure requiring office visit or hospitalization occurred in 8 patients (5%) of the whole study population (3 patients in the single stent group (3.2%) and 5 patients in the two stents group (7.7%)), with no statistically significant difference (FEp =0.455).

Table 5. Comparison of procedural complications between the two management techniques

Procedural complications	Technique		p value
	Single Stent(n=93)	Two-Stent(n=65)	
Coronary artery dissection, n (%)	0	3 (4.6%)	MCp=0.080
Distal embolization, n (%)	2 (2.2%)	2 (3.1%)	MCp=0.151
Slow Flow, n (%)	6 (6.5%)	5 (7.7%)	FEp=0.761
Loss of side branch, n (%)	5 (5.4%)	0	FEp=0.078
Acute stent thrombosis, n (%)	3 (3.2%)	5 (7.6%)	FEp=0.411

*MCp Monte Carlo significance, FEp Fischer Exact significance, *results≤.05 are significant*

Table 6. Comparison of in-hospital complications between patients undergoing one stent and two-stent techniques

In-hospital complications	Technique		p value
	Single stent(n=93)	Two-stent(n=65)	
Cardiac arrest, n (%)	1 (1.1%)	2 (3.1%)	FEp=0.569
Arrhythmia, n (%)	2 (2.2%)	1 (1.5%)	FEp=0.160
Cardiogenic shock, n (%)	2 (2.2%)	0	FEp=0.425
Pulmonary edema, n (%)	4 (4.3%)	2 (3.1%)	FEp=0.569
CIN, n (%)	7 (7.5%)	3 (4.6%)	FEp=0.527
Access site hematoma, n (%)	8 (8.6%)	6 (9.2%)	FEp=0.8

CIN= Contrast Induced Nephropathy
*FEp Fischer Exact significance, *results≤.05 are significant*

Table 7. Comparison between both stenting groups according to 1-month MACCE

One-month MACCE	Strategy		Significance
	Single stent (n=93)	Two stents (n=65)	
Overall MACCE rate, n (%)	8 (8.6 %)	6 (9.2%)	FEp=0.082
CV death, n (%)	4 (4.3%)	2 (3%)	FEp=0.637
Myocardial infarction, n (%)	2 (2.1 %)	2 (3%)	FEp=0.905
TLR, n (%)	2 (2.1%)	2 (3%)	FEp=0.741
Heart failure, n (%)	3 (3.2 %)	5 (7.7%)	FEp=0.698

CV= Cardiovascular, MACCE= Major Adverse Cardiovascular and Cerebrovascular Events, TLR= Target Lesion revascularization.
*FEp Fischer Exact significance, *results≤.05 are significant*

Table 8. Comparison between both stenting groups according to 6 months MACCE

Six months MACCE	Strategy		Significance
	Single stent (n=93)	Two stents (n=65)	
Overall MACCE rate, n (%)	9 (9.6%)	6 (9.2%)	FEp=0.327
CV death, n (%)	2 (2.2%)	1 (1.5%)	FEp=0.637
Myocardial infarction, n (%)	3 (3.2%)	3 (4.6%)	FEp=0.905
TVR, n (%)	1 (1.1%)	2 (3.1%)	FEp=0.741
Stroke or TIA, n (%)	3 (3.2%)	0	FEp=0.425
Heart failure, n (%)	4 (4.3%)	5 (7.7%)	FEp=0.698
Major bleeding, n (%)	2 (2.2%)	1 (1.5%)	FEp=1

CV= Cardiovascular, MACCE= Major Adverse Cardiovascular and Cerebrovascular Events, TIA= Transient Ischemic Attack, TVR= Target Vessel Revascularization
*FEp Fischer Exact significance, *results≤.05 are significant*

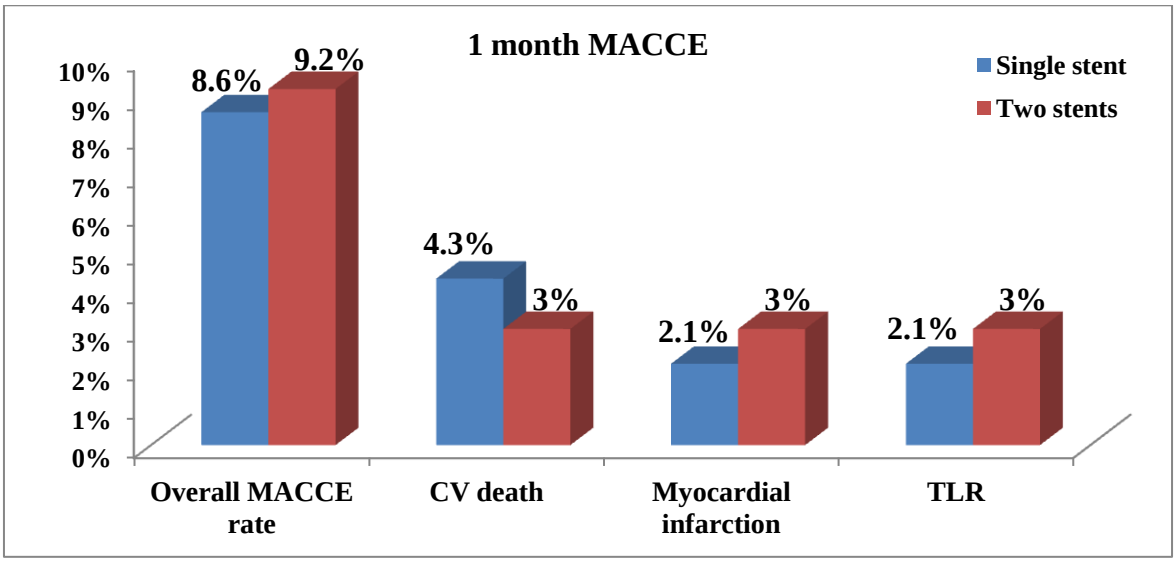

Fig. 1. Comparison between both groups regarding1-month MACCE

There was no significant difference between different two stents techniques regarding the incidence of complications 1 month following the index procedure (Table 9).

3.4 Follow up after 6 months (Table 8, Fig. 2)

The MACCE rate in the single stent group is 9.6 % vs. 9.2% in the two stents group with no statistically significant difference (FEp=0.327). Cardiac death occurred in 3 patients (1.89%) after 6 months following the index procedure (2 patients in the single stent group (2.2%) and 1 patient in the two stents group (1.5%)) with no statistically significant difference (FEp=0.637). Myocardial infarction occurred in 6 patients (3.7%) (3 patients in the single stent group (3.2%) and 3 patients in the two stents group (4.6%)), with no statistically significant difference (FEp=0.905); one patient in the single stent group developed MI due to late stent thrombosis and was managed by stenting with newer DES generation (TLR) with very good final results and no in hospital complications, the other two patients developed NSTEMI and were managed by stenting. In the two stents group, two patients developed MI due to late stent thrombosis and were adequately managed by stenting with newer DES generation (TLR). The third patient developed NSTEMI and was managed conservatively upon patient request.

Cerebrovascular stroke or transient ischemic attacks occurred in 3 patients in the single stent group while no patients in two stents group experienced such complications, with no statistically significant difference (FEp =0.425). Heart failure requiring office visit or hospitalization occurred in 9 patients (5.6%) of the whole study population (4 patients in the single stent group (4.3%) and 5 patients in the two stents group (7.7%)), non-statistically significant difference (FEp=0.698). Major bleeding (upper gastrointestinal bleeding secondary to DAPT intake) required hospitalization and blood transfusion occurred in 3 patients (2 patients (2.1%) in the single stent group and 1 patient (1.5%) in the two stents group) with no significant difference.

There were no significant differences between different two stents techniques regarding the incidence of complications 6 months following the index procedure (Table 9).

4. DISCUSSION

A coronary bifurcation lesion is a stenosis at or near a side branch, this is found in 15-20% of all percutaneous interventions and impose higher thrombosis and restenosis risk even with the use of advanced techniques. Managing bifurcation lesions harbors fear of plaque redistribution across the carina and side branch occlusion as historically demonstrated by Meier et al back in 1984 when 54% of their 557 patients had endangered side branches by the main branch balloon inflation and further 5% of those were actually occluded [15].

Although a provisional SB stenting strategy for bifurcation lesions has been proposed, this technique may be associated with residual

ischemia, especially in the true bifurcation culprit lesion types with a large and diseased SB. Although bifurcation lesions represent up to 15-20% of all coronary lesions treated by PCI, there are few data regarding the incidence, angiographic characteristics, and outcome of BFLs in the setting of ST-segment elevation myocardial infarction (STEMI) as most bifurcation lesion studies excluded patients in the setting of acute coronary syndrome.

Bifurcating lesions are the culprit lesions in approximately 10% of STEMI patients in an observational study by Salinas et al. [16] carried on 2746 patients, of which 274 patients had bifurcation culprit lesion, of which 84% underwent provisional stenting. Frangos et al. [11] investigated the impact of bifurcation lesions on angiographic characteristics and procedural success in primary percutaneous coronary interventions (PCIs), bifurcation culprit lesions in STEMI were detected in 114 (10.7%) out of 1070 patients. In our study, out of 1355 anterior STEMI patients managed with percutaneous angioplasty, 158 of patients (11.6%) were identified to have bifurcation culprit lesion, those included patients were managed by stenting either single or two stents strategy.

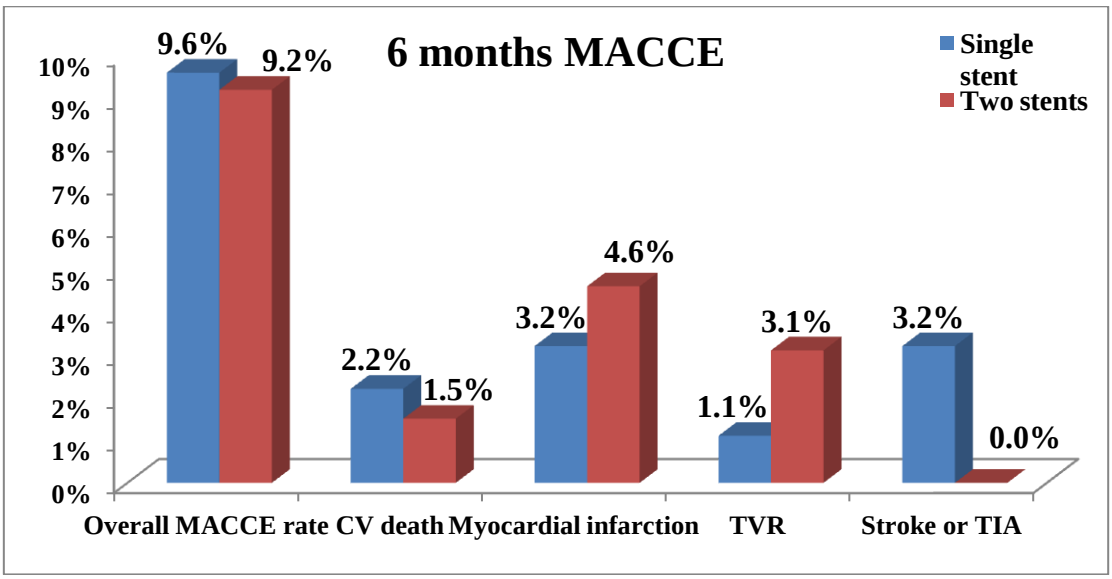

Fig. 2. Comparison between both groups regarding 6 months MACCE

Table 9. Comparison between different two stents bifurcation techniques regarding MACCE incidence

Complications	Two stents technique				Significance
MACCE at 1 month	**DK-crush (n=14)**	**Mini-crush (n=27)**	**Culotte (n=4)**	**T-stent/TAP (n=20)**	
CV death, n (%)	1 (7%)	1(3.7%)	0	0	MCp=1
Heart failure, n (%)	1(7.1%)	1(7.4%)	0	3 (15%)	MCp=0.716
Re-infarction, n (%)	1 (7%)	0	0	1 (5%)	MCp=0.950
TLR, n (%)	1 (7%)	0	0	1 (5%)	MCp=0.950
MACCE at 6 months					
CV death, n (%)	0	1(3.7%)	0	0	MCp=1
Heart failure, n (%)	2 (14.3%)	1(7.4%)	0	2 (10%)	MCp=0.860
Myocardial infarction, n (%)	0	2(7.4%)	0	1 (5%)	MCp=0.921
TLR, n (%)	0	2(7.4%)	0	0	MCp=0.688
Major bleeding, n (%)	0	0	0	1 (5%)	MCp=0.810

CV= Cardiovascular, MACCE= Major Adverse Cardiovascular and Cerebrovascular Events, TLR= Target Lesion Revascularization

*MCp Monte Carlo significance, *results≤.05 are significant*

In our study, the mean age of total sample was 56.14±9.96 years, 84% of patients were males (87% in single stent group vs. 80% in two stents group), 33% of patients were diabetics with higher incidence in single stent group (36.6 % vs. 23.1%, MCp.021), 60% of patients were hypertensive with higher incidence of hypertension in the two stents group (72.3 % vs. 52.7 %, p=0.013), 82 % of patients had dyslipidemia with no significant difference between the two groups (82.8% vs. 81.5%,p=0.839).

In the current study, we can appreciate that, primary PCI was done in 93.6% of the included patients (94.6% in single stent group vs. 92.3% in two stents group while 6.4% of study population underwent rescue PCI after receiving thrombolytic therapy (5.4 in single stent group % vs. 7.7% in two stents group), FEp=0.556.

The side branch degree of stenosis was significantly higher in two stents group with mean degree of stenosis 83.31%±11.20 in comparison to single stent group where the mean degree of stenosis was 71.88%±15.05 (p<0.001). Most of the patients had bifurcation angle between (45-60) degrees (65.5% in single stent group versus 78.4% in two stents group) (p<0.001). Most patients had true bifurcation lesions; medina classification (1.1.1) was found in 49.5% of patients in single stent group versus 78.5% of patients in two stents group.

Abdel-Hakim et al. [17] reported that LAD/diagonal arteries were found to be the culprit lesion in 65% of the patients with bifurcation lesions. The distribution of bifurcation lesions according to Medina classification was as follows: type (1,1,1) 58%, type (1,0,1) 10%, type (1,1,0) 16.7%, type (1,0,0) 8%, type (0,1,1) 2%, type (0,1,0) 3% and type (0,0,1) 2.3%. Dudek et al. [18] reported that LAD was found to be the culprit in 55 % of patients with BFL. Dudek et al didn't classify bifurcation culprit lesion according to Medina classification [18].

We can notice that in our study, all of our patients were managed with drug eluting stents with significantly higher percentage of new generation of drug eluting stents in comparison to Dudek et al. [18] and Choi et al. [19] and this can be attributed to that most of these studies were conducted in earlier time before the advent of newer DES generations.

We can appreciate that in comparison to the previously mentioned studies, all patients have double guidewire protection with significantly higher percentage of patients managed with two stents strategy (41.1%) of the whole study population in comparison to Frangos et al. [11], Salina et al. [16] and Abdel-Hakim et al. [17].

We have higher percentage of kissing balloon inflation, more fluoroscopy time and contrast volumes in patients managed with two stents and this is consistent with the results of Salina et al. [16], Dudek et al. [18], Choi et al. [19], Kwan et al. [20] and Yurtdas et al. [21]. In the present study, crush techniques and T stenting were the most utilized stenting techniques in patients managed with two stents and these findings are in line with Choi et al. [19], Kwan et al. [20] and Yurtdas et al. [21].

In our study, the angiographic success rate (defined as restoration of TIMI flow grade 3 with a residual stenosis of ≤ 30% assessed by quantitative coronary angiography) was 94.6% in the single stent group versus 93.3% in the two stents group with no statistically significant difference. The procedural success rate was defined as technical success without in-hospital major adverse cardiovascular and cerebrovascular events (MACCE) and it was 91.3% in single stent group versus 90.7% in two stents group with no statistically significant difference.

The MACCE rate 1 month following the procedure in the single stent group was 8.6 % vs. 9.2 % in the two stents group with no significant difference between different two stents techniques. Heart failure occurred in 8 patients (5%) of the whole study population (3 patients in the single stent group (3.2%) and 5 patients in the two stents group (7.7%)), with no statistically significant difference. Cardiac mortality occurred in 6 patients (3.7%) of the whole study population after 1 month following index procedure (4 patients in the single stent group (4.3%) and 2 patients in the two stents group (3%)) with no significant difference between both groups. Re-infarction secondary to acute stent thrombosis occurred in 4 patients (2.5%) of the whole study population (2 patients (2.1%) in the single stent group and 2 patients (3%) in the two stents group), with no statistically significant difference and this was managed by target lesion revascularization (TLR).

Frangos et al. [11] reported that the angiographic success rate (residual stenosis ≤30% and TIMI flow grade 3) was 96.5% in the BFL group and 99.1% in the non-BFL group (p = 0.18). SB

angiographic success (residual stenosis ≤50% and TIMI flow grade 3) rate was 90.4%. There was a statistically significant difference between the angiographic success of true BFLs (83%) and false BFLs (96.7%, p = 0.014), with similar procedural success with no procedural death or need for urgent CABG.

Abdel-Hakim et al. [17] reported that the procedural success rate was 92% in the bifurcation group and 93% in the non-bifurcation group (P=0.65), in-hospital MACE rate was 13.3% in the bifurcation group and 11.4% in the non-bifurcation group (P=0.72). Corresponding rates were 3.3% vs. 2% for in hospital mortality (P=0.35), 4% vs. 4.4% for recurrent myocardial infarction (P=0.81), and 6% vs. 5% for target lesion revascularization (TLR), respectively (P=0.94).

We can notice that in comparison to the previously mentioned studies we have similar angiographic, procedural success rate and incidence of adverse events 30 days after the index procedure with no significant difference between patients managed by single or two stents strategy.

In our study, we can appreciate that after 6 months follow up, the MACCE rate in the single stent group is 9.6 % vs. 9.2% in the two stents group but no statistically significant difference can be found. Cardiac mortality occurred in 3 patients (1.89%) after 6 months following the index procedure (2 patients in the single stent group (2.2%) and 1 patient in the two stents group (1.5%)). Myocardial infarction occurred in 6 patients (3.7%) of the whole study population (3 patients in the single stent group (3.2%) and 3 patients in the two stents group (4.6%)), with no statistically significant difference. Target lesion revascularization occurred in 3 patients (1.8%) (1 patient in the single stent group (1.1%) and 2 patients in the two stents group (3.1%)). Cerebrovascular stroke or TIA occurred in 3 patients in the single stent group while no patients in the two stents group experienced such complications, which was not statistically significant. Major bleeding requiring hospitalization and blood transfusion occurred in 3 patients (2 patients (2.1%) in the single stent group and 1 patient (1.5%) in the two stents group) with no significant difference. There were no significant differences between different two stents techniques regarding the incidence of complications 6 months following the index procedure.

Salina et al. [16] reported that at long-term 5 years follow-up, there were no differences in all-cause death or the composite endpoint with slightly higher numbers for target vessel revascularization and coronary artery bypass grafting in the BIF group. Target lesion revascularization occurred in 17 (6%) patients in the BIF group compared with 12 (4%) in the MC group (crude HR, 1.44; 95%CI, 0.69-3.02; P = 0.33 and adjusted HR, 1.47; 95%CI, 0.70-3.09; P = 0.31). Abdel-Hakim et al. [17] reported that 1 year MACCE follow up was as following, mortality was 4.6% in the bifurcation group versus 3% in the non-bifurcation group (P=0.15), corresponding rates were 6.6% vs. 6% for recurrent myocardial infarction (P=0.91), 11.3% vs. 10.5% for TLR (P=0.74), and 22.6% vs. 19.5% for MACE (P=0.56) after one year, respectively. Dudek et al. [18] reported that at three years there were still no significant differences in the rates of all-cause death in BFL patients with 1 vs. >1 stent implanted (5.3% vs. 6.3%, p=0.69), definite/ probable stent thrombosis (3.8% vs. 4.9%, p=0.64), or ischemic target vessel revascularization (11% vs. 18%, p=0.10).

We can notice in our study that we had no significant difference between the both stenting groups regarding incidence of MACCE after 6 months follow up and this is consistent with most of the results of the previously mentioned studies while these studies had longer follow up duration except for Choi et al. [19] who reported the two-stent strategy was associated with higher rates of MACE despite successful treatment of the side branch which was mainly driven by higher incidence of stent thrombosis and target lesion revascularization with no significant difference between the two groups regarding the incidence of cardiac death and MI.

5. CONCLUSIONS

The incidence of bifurcation lesions in STEMI patients is under-estimated and the best treatment strategy is still under investigation. Although two stents strategy in the setting of STEMI is much complex with more fluoroscopy time and contrast volume than one stent technique, the procedural success rate, and the incidence of complications between two groups were comparable on the short and medium-term follow up. So, we can conclude that two stents strategy can be safely performed for management of bifurcation culprit lesions during primary PCI.

6. STUDY LIMITATIONS

The sample size was relatively small, and larger studies are needed to validate these results.This was an observational retrospective non-randomized study; therefore, uncontrolled variables may have had an impact on the outcomes of comparison between the groups. The intravascular imaging modalities were not available for dedicated assessment of bifurcation lesion characteristics such as side branch ostium and the extent of the lesion into the side branch and for the optimization of bifurcation stenting results. Also, the selection of treatment strategy, medication, stent type, and stenting technique was based on the operator's discretion.

CONSENT AND ETHICAL APPROVAL

An informed consent was obtained from every patient. The study was approved by the responsible ethics committee.

CONFERENCE DISCLAIMER

Some part of this manuscript was previously presented and published in the conference: ESC CONGRESS 2021: SAVE THE DATE dated Friday 27 August to Monday 30 August 2021 in Amsterdam, Netherlands Web Link of the proceeding: https://www.escardio.org/The-ESC/Press-Office/Press-releases/ESC-CONGRESS-2021-SAVE-THE-DATE.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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