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One-year Outcome of Different Unprotected Left Main Percutaneous Coronary Interventions Techniques in Acute Coronary Syndromes

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Abstract

BACKGROUND: Percutaneous coronary intervention (PCI) to unprotected left main coronary artery (ULMCA) showed recently great evolution with better outcomes. The long-term outcome of the different techniques needs to be evaluated.

AIM: We intended in this study to evaluate the impact of the different techniques of ULMCA stenting on the clinical outcomes.

METHODS: We included 65 patients with acute coronary syndrome and left main (LM) disease subjected to ULMCA intervention during the period from September 2018 to January 2020 in our multicenter observational prospective study. We excluded patients with age <18 and >75 years old, patients with conditions that interfere with LM coronary intervention, patients who refused to be included in study, and those with previous coronary artery bypass graft (CABG). Data were collected through reviewing patient's medical records and angiographic procedures. Angiographic assessment included evaluation of Syntax II score, EURO II score, and TIMI flow grading. The primary outcome was the major adverse cardiac and cerebral events (MACCE) at 1 year while the secondary outcomes included the development of acute kidney injury, 1 year mortality, and need for CABG post-PCI.

RESULTS: We included 46 males (70.8%) with median (Q1–Q3) age of 63 (53–70) years old. One-year MACCE was 46.2% when the angle between left anterior descending (LAD) and left circumflex (LCX) was >70° compared to 81.5% when it was <70° (p = 0.008). The wide angle was also associated with 0% 1-year mortality compared to 18.5% for narrow angle, a difference which is statistically significant (p = 0.03). The 1-year MACCE was 35.7% compared to 74.4% when it was not used (p = 0.013). When proximal optimization technique (POT) was used, the 1-year MACCE was 47.6% compared to 75% when it was not used (p = 0.041). None of the other studied parameters including those related to procedure technique was significantly affecting the outcome in our study.

CONCLUSIONS: We concluded that the non-use of final kissing inflation nor POT together with the lower angulation between LAD and LCX could predict worse clinical outcome at 1-year in unprotected LM PCI.

Introduction

About 5–10% of patients undergoing coronary angiography were shown to have left main coronary artery (LMCA) [1], [2]. Those represent the highest risk lesion subset and are associated with poor clinical outcomes coronary artery disease.

Early clinical trials showed that coronary artery bypass grafting (CABG) has better outcomes when compared to medical therapy in the treatment of LMCA disease, and accordingly, CABG was considered as the standard of care for the management of this subset of patients for a long time [3], [4].

In the later years, there were great advances in the medical device technology and percutaneous coronary intervention (PCI) techniques. PCIs became more popular with better outcomes due to these factors together with the advances in the adjunctive medical therapy and personal experiences [5], [6].

Despite that the short-term outcomes for LMCA stenting are well evaluated, its long-term trends in different patient subsets and with different techniques still need further elaboration. This may be important for helping clinical decision-making and is important for achieving better outcomes with LMCA disease management.

We intended in this study to evaluate the impact of the different techniques of unprotected LMCA (ULMCA) stenting on the clinical outcomes of acute coronary syndrome (ACS) patients.

Patients and Methods

The study protocol was approved by the Institutional Review Board at Cairo University and has been conducted in accordance with the principles set forth in the Helsinki Declaration. Informed consent was obtained from patients or first degree relative.

We included all adult patients admitted with ACS and left main (LM) arterial disease subjected to unprotected LM coronary intervention during the period from September 2018 to January 2020 in our multicenter observational prospective cohort study. We excluded from the study patients with age younger than 18 years and older than 75 years, patients with conditions that interfere with LM coronary intervention, patients who refused to be included in study, and those with previous CABG.

Following their admission, patients were subjected to detailed medical history, clinical examination, standard 12-lead ECG, routine laboratory investigations, and echocardiography. Cardiac catheterization and unprotected LM PCI were then done.

Angiographic assessment included evaluation of Syntax-II score, EURO-II score, and TIMI flow grading. The primary outcome of interest was the incidence of major adverse cardiac and cerebral events (MACCE) at 1 year follow-up. MACCE is defined as the composite of death, ACSs, target vessel revascularization (TVR), heart failure requiring hospitalization, and acute cerebrovascular event.

The secondary outcomes studied included contrast-induced nephropathy represented by the development acute kidney injury (AKI), defined by the increase of serum creatinine by ≥0.3 mg/dl within 72 h or increase of serum creatinine by 1.5-fold of baseline within 1 week [7]. Other secondary outcomes included 1 year mortality and need for CABG post-PCI.

Statistical analysis

Data were initially evaluated for normality using Shapiro–Wilk test and z-value of skewness and kurtosis. Data with z-value of skewness and kurtosis between –1.96 and +1.96 [8] and Shapiro–Wilk test with p > 0.05 [9], [10] are considered as normally distributed. Our continuous variables were non-normally distributed and were accordingly, expressed as median (25^{th}–75^{th}) percentiles (Median [Q_1–Q_3]). Categorical variables were expressed as frequency and proportion. We used non-parametric test (Mann–Whitney U-test) to compare groups as regard quantitative variables and Chi-square test (χ^2) to compare groups regarding qualitative data. Exact test was used if the expected frequency is <5. Results were considered statistically significant if p ≤ 0.05. Data collection, coding, and analysis were done using the Statistical Package for the Social Sciences (SPSS version 22).

Results

We initially recruited 78 patients with ACS and LM disease in the study. Thirteen patients were subsequently excluded due to lesions considered not suitable for PCI according to the operator's opinion (10 patients) and withdrawal of consent (three patients). The remaining 65 patients represented our study population. The baseline demographic, clinical, and angiographic data are shown in Table 1.

Table 1: The baseline demographic, clinical, and angiographic data

Variable	Result
Age (median [Q_1–Q_3]) years old	63 (53–70)
Male gender (n [%])	46 (70.8)
Type of ACS (n [%])	
UA	39 (60)
NSTEMI	12 (18.5)
STEMI	14 21.5)
Diseased LM segments (n [%])	
Aorto-ostial	8 (12.3)
Mid-segment	3 (4.6)
Distal segment	37 (56.9)
Combined segments	17 (26.2)
Isolated LM (n [%])	11 (16.9)
Syntax score (median [Q_1–Q_3])	28 (20–35)
EUROSCORE (median [Q_1–Q_3])	4.80 (1.79–14.15)
Medina classification (n [%])	
1.1.1	24 (36.9)
1.1.0	24 (36.9)
1.0.1	4 (6.2)
Angulation between LAD and LCX (n [%])	
<70	31 (47.7)
>70	34 (52.3)
Used technique (n [%])	
1-stent technique	29 (54.7)
Planned 2-stent technique	
TAP	6 (11.3)
Culotte	4 (7.5)
Mini-crush	6 (11.3)
DK crush	8 (12.3)
DES used (n [%])	
Everolimus-eluting stent	28 (43.1)
Sirolimus-eluting stent	29 (44.6)
Biolimus-eluting stent	6 (9.2)
Paclitaxel-eluting stent	1 (1.5)
Zotarolimus-eluting stent	1 (1.5)
Adjunctive techniques (n [%])	
Side branch rewiring	39 (60)
Final kissing inflation	39 (60)
Proximal optimization technique	32 (49.2)
Stent deployment using IVUS	16 (24.6)
Procedural complication (n [%])	
Dissection	3 (4.6)
Acute stent thrombosis	9 (13.8)
Distal embolization	12 (18.5)
Side branch loss	2 (3.1)

n: Number, %: Percent, ACS: Acute coronary syndromes, UA: Unstable angina, NSTEMI: Non-ST elevation myocardial infarction, STEMI: ST-elevation myocardial infarction, LM: Left main.

The primary outcome of our study was the 1-year MACCE including the composite of death, ACSs, TVR, heart failure requiring hospitalization, and acute cerebrovascular event. The incidence of major adverse cardiovascular and cerebrovascular events within the 1st year after LM stenting in our study was 63.1% (Figure 1).

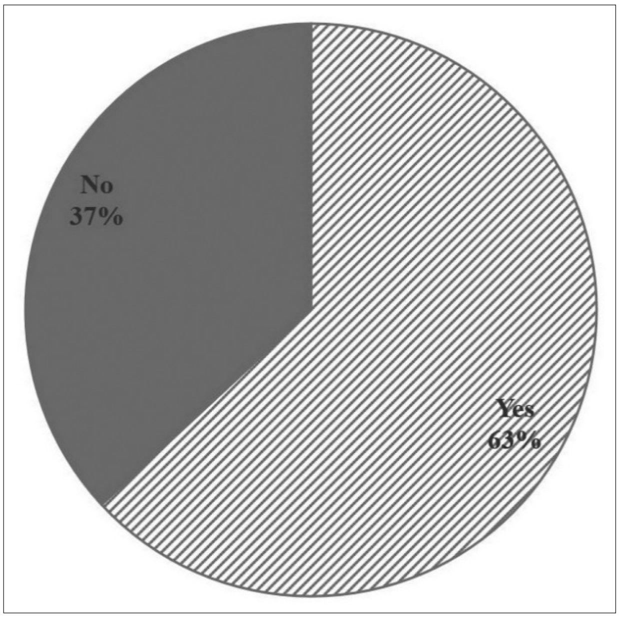

Figure 1: Incidence of 1-year major adverse cardiac and cerebral events

Seven patients died within 1 year of the procedure with 1-year mortality rate of 10.8%. CABG within 1 year of LM stenting was done in 4 patients (6.2%). AKI occurred in 20 patients (30.8%) (Figure 2).

The wide distal bifurcation angle between the left anterior descending (LAD) and left circumflex (LCX) (>70°) was associated with significantly lower 1-year MACCE rate. The incidence of 1-year MACCE was 46.2% when the angle was >70° compared to 81.5% when it was <70 ($p = 0.008$). The wide angle was also associated with 0% 1-year mortality compared to 18.5% for narrow angle, a difference which is statistically significant ($p = 0.03$) (Figure 3).

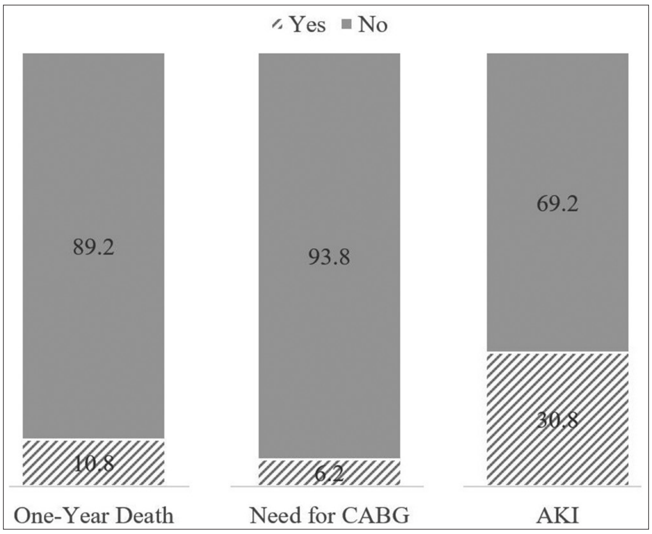

Figure 2: Incidence of 1-year death, need for coronary artery bypass graft, and acute kidney injury

The syntax score did not significantly affect the primary outcome of 1-year MACCE. It was 30 (21–36) in those who developed MACCE at 1 year compared to 25 (20–32) in those who did not develop MACCE ($p = 0.12$). It was even not significant predictor of any of the secondary outcomes (Figure 4).

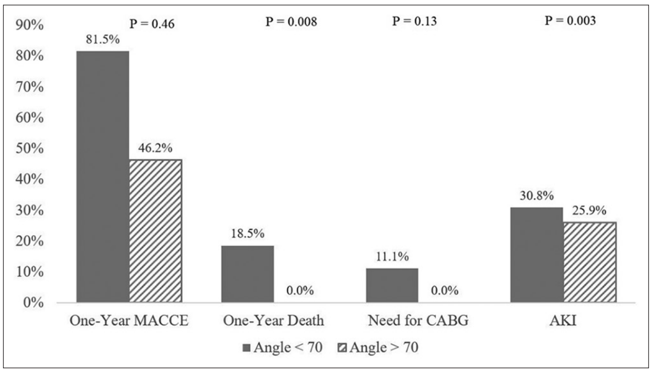

Figure 3: The relation between angulation and outcomes

Twenty-nine of our patients had 1-stent technique while 24 had planned 2-stent technique. Eighteen out of 29 patients who had 1-stent technique (62.1%) developed MACCE at 1-year follow-up and similarly, 16 out of 24 who had 2-stent technique (66.7%) had 1-year MACCE ($p = 0.48$). Similarly, the use of whether 1-stent or 2-stent techniques did not affect the secondary outcomes. The incidence of need for CABG, AKI, and 1-year death was 6.9%, 31%, and 13.8% in the 1-stent technique group compared to 4.2%, 25%, and 4.2% ($p = 0.57$, 0.43, and 0.24 respectively).

Within patients with planned 2-stent technique, none of the used technique had a significant effect of any of the outcome parameters. The use of TAP was associated with 66.7% 1-year MACCE compared to 75%, 83.3%, and 50% for culotte, mini-crush, and DK crush techniques, respectively ($p = 0.6$).

Within the patients with planned 2-stent technique, we compared the DK crush technique with the composite of other techniques together. The choice of either was not associated with a significant difference in outcomes. The DK crush group had and incidence of 1-year MACCE of 50% compared to 75% in the non-DK crush group ($p = 0.22$). The need for CABG, AKI, and 1-year death occurred in 12.5%, 25%, and 0% of DK crush group compared to 0%, 25%, and 6.3% in non-DK crush group ($p = 0.33$, 0.7, and 0.7, respectively).

The use of final kissing inflation (FKI) and proximal optimization technique (POT) was associated with significantly lower incidence of 1-year MACCE. When FKI was used, the 1-year MACCE was 35.7% compared to 74.4% when it was not used ($p = 0.013$). When POT was used, the 1-year MACCE was 47.6% compared to 75% when it was not used ($p = 0.041$).

We used intravascular ultrasound (IVUS) to guide stent deployment in 16 patients, 8 of them (50%) developed MACCE at 1 year while the other 50% did not while 33 of 49 patients who did not use IVUS (67.3%) developed MACCE ($p = 0.21$).

Discussion

CABG surgery continued to be the first-line therapy for ULMCA disease for several years. Subsequent advances achieved in medical technology including the revolution of developing the drug-eluting stents (DESs), together with the development in operator experiences and the advances in adjunctive pharmacotherapies rendered PCI a feasible alternative for ULMCA stenosis management. In 2008, Buszman *et al*. published one of the earliest studies that compared UPLMT PCI and CABG [11]. They showed a lower risk of 30-day MACCE events after PCI compared with CABG. The PCI group also showed a significant improvement in the left ventricular ejection fraction after 12 months. Both groups demonstrated similar improvement in angina and good long-term functional capacity on exercise stress testing [11]. This study, however, did not show the impact of different

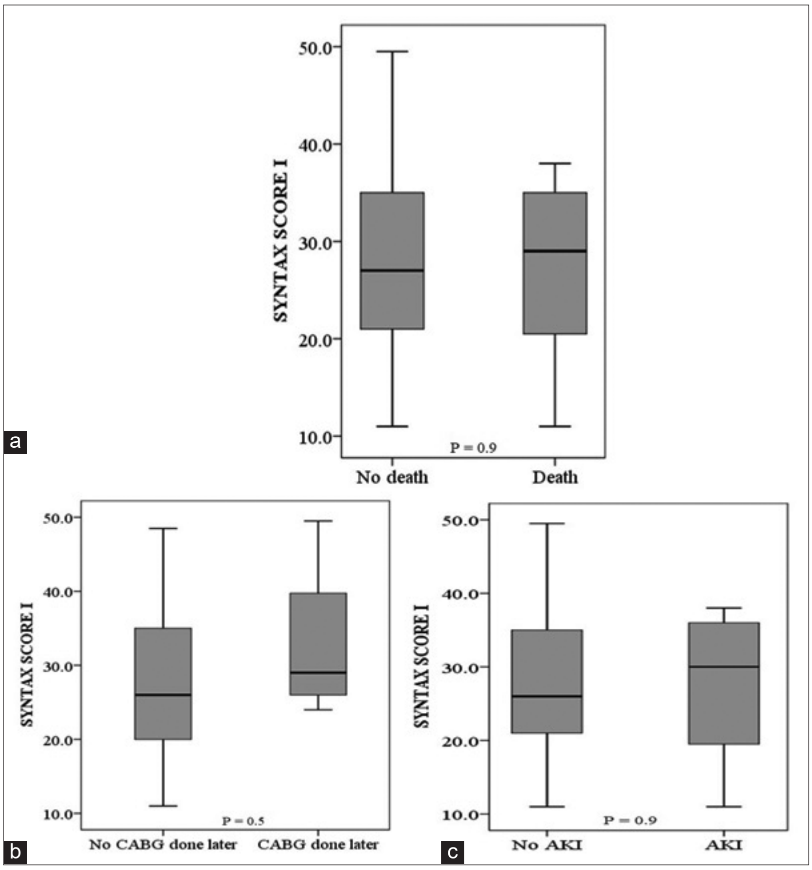

Figure 4: The effect of the Syntax score on the clinical outcomes, (a) 1 year death, (b) coronary artery bypass graft done later, and (c) acute kidney injury

techniques of PCI as they standardized the technique using provisional stenting and FKIs.

Even with the consideration of the great advances in PCI techniques and operator experience, UPLMCA bifurcation PCI is still challenging. Our study was a multicenter observational prospective study conducted on patients presented with ACS due to LMCA disease to assess different techniques of PCI in ULMCA and their impact on different outcomes including MACCE after 1 year as a primary outcome. The secondary outcomes of our study were AKI, need for CABG, and 1-year mortality within 1 year after the procedure.

We found that the distal bifurcation angle between LAD and LCX <0°, non-use of FKI, and non-use of POTs is significantly associated with higher incidence of 1-year MACCE. None of the other studied variables were seen to be predictors for the occurrence of 1-year MACCE.

Amemiya *et al*. found also that the target lesion revascularization (TLR) is higher with lower bifurcation angle [12]. At 1-year, free survival rate from MACE was 66.7% in low bifurcation angle group compared to 85.7% and 91.1% in middle and high bifurcation angles, respectively [12]. It should be emphasized that they considered the proximal bifurcation angle between LM and LAD rather than the distal bifurcation angle that we used. They also did not elucidate relationship between angulation and MI or hospital death. The SYNTAX trial showed that the angle between the LAD and LCX is not a significant predictor for clinical results [13]. A wide angle between LM and LAD was also seen to be associated with a reduced event rate after stenting because of a less frequent TLR [12]. In the subset of patients with culotte and crush techniques, a wide angle between the LAD and the LCX was seen to significantly predict worse outcome [14], [15], [16]. However, there was an evidence of lower MACCE rate after DK crush technique when the bifurcation angle was >70° compared with the culotte stenting technique [17]. Stent implantation in the main vessel may affect the bifurcation angle. Some authors showed that stent implantation increased the angle between main vessel and the main branch which was explained by the straightening of the main vessel caused by the stent scaffold [18]. These findings support the notion that the main vessel angle might affect the clinical outcome after single-stent strategy from LM to LAD in LM bifurcation lesions.

Several mechanisms could explain the effect of angulation on the clinical outcomes. The bifurcation angle is considered as one of the contributing factors of stent fracture [19]. The mechanical stress applied by extrinsic compression may cause stent fracture which may play a role in stent restenosis [20]. The maximal angulation in the target lesion might have a role in this stent fracture [21]. The mechanical constraints might cause stent fractures which may be microfracture which is not visible by angiography. The angulation of the bifurcation causes some form of stent bending which also plays a role in the impact of the angulation on the clinical outcome [22].

Many of the studies that evaluated the different bifurcation techniques on the clinical outcomes compared the 1-stent versus planned 2-stent techniques. We did not elucidate any significant impact from using one-stent versus two-stent techniques on either 1-year MACCE or other secondary outcomes. Despite that Kandzari *et al*. found a more favorable clinical outcomes at 3 years with the use of provisional stent technique, these favorable results were not present at 1 month follow-up [23]. This 3-year favorable outcome was also ameliorated if both distal LM major side branches had an ostial diameter stenosis ≥50% [23].

The use of 1-stent technique was not associated with favorable outcome compared to 2-stent technique in our study. However, Cho *et al*. reported a better 3-year MACCE, TLR, and myocardial infarction (MI) with 1-stent strategy [24]. In sub-analysis of the study data, they showed that these clinical benefits were confined to the early generation DES with similar clinical outcomes including 3-year MACE, MI, and TLR for both 1-stent and 2-stent strategy groups for patients who had the new generation DES used [24]. The improved outcome with the new generations of DES represents not only an improved stent profile but also development of PCI technique (e.g. POT and final kissing balloon inflation) and operator experience that may have contributed to improvement in clinical outcomes after using the 2-stent strategy. The results of Song *et al*. [16] suggested that the use of new-generation DES, non-compliant balloon, or final kissing balloon was associated with better long-term outcomes in patients with bifurcation lesions who were treated by a 2-stent strategy. POT can optimize the stent diameter to LMCA diameter, in addition to correcting stent mal-apposition and reducing ellipticity of the stented segment [25]. The use of FKI was seen by many previous studies to improve the clinical outcome in 2-stent techniques [26], [27]. Despite that the FKI could cause a change in the stent shape, other studies [28], [29] showed that it could prevent stent distortion caused by balloon dilation through the side branch. In our study, FKI was associated by 35.7% 1-year MACCE compared to 74.4% if FKI was not used and POT was associated by 47.6% 1-year MACCE compared to 75% when it was not used; these differences were seen to be statistically significant. Finet *et al*. [25] compared six different optimization sequences for bifurcation provisional stenting. The MACE rate did not improve with the use of KBI in this study. They considered that the proximal stent deformation might increase stent restenosis rate and subsequently, TLR. They concluded that the re-POT improved the final angiographic results by maintaining circular vessel shape and avoiding side branch obstruction. These experimental findings confirm the beneficial effect of using re-POT as a final step of bifurcation PCI.

Planned 2-stent technique might be mandatory if both side branches are significantly diseased. Many studies, like ours, included different techniques within the 2-stent groups as the DK crush and culotte stenting [30], [31], [32], [33]. In patients with true distal LM bifurcation disease, comparing the DK crush technique with either culotte 2-stent technique [30] or a provisional 1-stent strategy [31] revealed better outcomes in favor of DK crush technique. During a 5-year evaluation of the different bifurcation techniques, the 2-stent technique, apart from DK crush, was a significant predictor of 5-year MACCE while the DK crush was associated with better clinical outcome [32]. Among patients treated with the 2-stent technique, Palmerini *et al*. showed contradictory results showing that the different treatment approaches (T stenting, V stenting, and crush stenting) provided similar clinical outcomes [33]. Similarly, the use of the different techniques in our study was not associated by any significant advantages in terms of clinical outcomes.

The use of IVUS guidance during LM PCI did not affect any of the study outcomes in our study. Despite that many studies revealed a favorable outcome with lower incidence of MACE and death with the use of IVUS guided in comparison to angiography-guided stent implantation [34], [35], some of these studies [35] revealed more complex lesions and more comorbidities in the angiography-guided stent implantation group. These differences may affect the study results. We used IVUS to guide the stent deployment only in 16 patients. This small sample size made the conclusion regarding its efficacy to be questioned.

The degree of lesion complexity guided by syntax score did not affect any of the study outcomes. Many other studies showed that higher syntax scores are independent predictor for incidence of MACCE [36]. This discrepancy may be explained by different centers, different operators, small sample size, and relatively short period of follow-up.

Our study is limited by the small sample size. The choice of the procedure technique was left to the operator discretion with no randomization of the different techniques. This may represent a source of bias. The use of adjunctive devices as the IVUS included very limited number of patients.

Conclusions

We concluded in this study that the non-use of FKI nor POT together with the lower angulation between LM and LAD could predict worse clinical outcome at 1-year in unprotected LM PCI which is a reliable therapeutic strategy for LM diseases treatment in ACSs patients.

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