OUTCOME OF DOUBLE KISSING (DK) CRUSH VERSUS PROVISIONAL STENTING FOR LEFT MAIN DISTAL BIFURCATION LESIONS

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ABSTRACT

Objective: To determine whether a planned 2-stent double kissing crush technique is superior to provisional stenting patients presenting with true distal LM bifurcation lesions.

Study Design: Cross-sectional comparative study.

Place and Duration of Study: Armed Forces Institute of Cardiology/National Institute of Heart Diseases, Rawalpindi Pakistan, from Dec 2020 to May 2021.

Methodology: A total of 70 patients enrolled in the study presented with true distal LM bifurcation lesions (Medina 1, 1, 1 or 0, 1, 1). Patients were randomized to PS or DK crush technique. The primary end-point was peri hospital and 1 month composite rate target lesion failure (TLF): target vessel myocardial infarction (TVMI), cardiac death, stent thrombosis (ST), target vessel revascularization (TVR). Routine clinical follow up done at 2 weeks and 4 weeks followed by 3 and 6 months thereafter.

Results: A total of 70 patients fulfilling the inclusion criteria were enrolled in the study. The patient population was divided into two groups. Group A participants underwent DK crush technique while group B participants underwent provisional stenting. In group A [DK crush technique] 16 (45.7%) patients presented with Non-ST elevation MI followed by 14 (40%) who presented with chronic coronary syndrome (CCS) while in group B [Provisional stenting] 13 (37.1%) presented with chronic coronary syndrome followed by 9 (25.7%) who presented with non-ST elevation MI.

Conclusion: LM-PCI is an acceptable procedure in patients with true distal LM bifurcation lesions who are candidates for PCI. This study also showed that DK-Crush has good periprocedural and angiographic outcomes and superior to PS in complex LMCAD lesions. PS is an acceptable option in simple distal LMCAD.

Keywords: Double kissing, Left main bifuraction, provisional stenting.

INTRODUCTION

Turbulent flow patterns at the site of coronary bifurcations results in a predilection for endothelial injury and atherosclerotic plaque formation at these locations. While many different models have been used to classify coronary bifurcation lesions, the Medina classification has been adopted as the most widely used due to its simplicity. The Medina classification ascribes a binary score[1] (indicating >50% stenosis, or 0 indicating <50% stenosis) to three anatomic locations (proximal main vessel [MV], distal MV and side branch [SB][2]. Coronary bifurcation lesions account for 15-20% of all PCI[3]. Percutaneous revascularization of these lesions is technically challenging and results in lower success rates than non-bifurcation lesions[4].

Left main coronary artery (LMCA) disease was initially described in patients dying of cardiogenic shock after acute myocardial infarction (MI) because of large are of myocardium jeopardized[5]. Clinically significant LMCA disease has been found in 3-5% of all patients who undergo coronary angiography and in 10-30% of patients who undergo coronary artery bypass graft (CABG) surgery[6]. Owing to the large area of jeopardized myocardium, LMCA disease is associated with high morbidity and mortality, and thus CABG has been the standard revascularization strategy for ULMCAD[7].

Many factors contribute to the complexity of LM bifurcation lesions including coronary calcification, tortuosity, thrombus and specific risk factors: diabetes mellitus (DM), smoking, family history of ischemic heart diseases (IHD). DM is a recognized predictor of adverse clinical outcomes in patients with coronary artery disease (CAD). Patients with DM mostly have more extensive and complex CAD and worse outcomes after PCI[8]. LM-PCI poses challenges, which are amplified by the presence of DM. Approximately 80% of LM disease involves the distal bifurcation, which is associated with a higher risk of restenosis. DM is itself associated with an increased risk of in-stent restenosis (ISR) due to increased neo-intimal and smooth muscle cell proliferation[9]. Furthermore, patients with DM have increased thrombus burden, which is more resistant to standard antithrombotic therapy. The presence of DM is associated with stent thrombosis (ST) that in the setting of LMS, is likely to be fatal.

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Since the introduction of PCI in the late 1970s, the procedure underwent tremendous advancements with landmark innovations in every aspect of it, from stent design to adjuvant pharmaco therapy and radial access. These advancements have made PCI safer and more durable and thus, increasing the appeal of the procedure. With a widespread use of drug-eluting stents (DES), PCI for LMCA lesion has become technically more feasible and associated with favorable long-term clinical outcomes. Recently, several clinical trials using first- and second-generation DES found similar survival rates after PCI and CABG[10]. Recent data have reported that PCI with newer generation DES are effective for ostialand mid-shaft lesions of the LMCA, with clinical outcomes comparable to CABG. However, most patients with unprotected left main coronary artery disease (ULMCAD) have involvement of the distal LM bifurcation, which is associated with inferior outcomes after PCI compared with isolated ostial/shaft treatment. In recent data patients with low to intermediate SYNTAX (Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) scores were randomized to PCI with newer-generation stents versus CABG, 80% of patients had disease of the distal LM bifurcation, most commonly treated with a provisional stenting (PS) approach provided equal outcomes compared with CABG for the safety outcomes but with increased repeat revascularization with PCI[11].

Several recent trials favor PCI of ULMCAD with the need for repeat revascularization is higher with PCI than with CABG, out of which landmark trials included are: EXCEL (Evaluation of XIENCE Everolimus eluting stent versus coronary artery bypass surgery for effectiveness of left main revascularization) trial compared CABG with PCI using new-generation DES (everolimus eluting stents [EES]) among patients with significant LM disease[12], At 3 years of follow-up, the primary endpoint of death, stroke, or MI occurred with similar frequency in the CABG and PCI group. NOBLE (nordic-baltic-british left main revascularization Study) trial compared CABG with PCI using new-generation DES [biolimus-eluting stents (BES)] among patients with significant LM disease (mean SYNTAX score of 23)[13]. At follow up the primary endpoint of death, non-procedural MI, stroke, and repeat revascularization occurred more frequently in the PCI than in the CABG group.

Therefore current evidence indicates that PCI is an appropriate alternative to CABG in LM disease and low-to-intermediate anatomical complexity (SYNTAX Score <32). Among patients with LM disease and low anatomical complexity, there is evidence that the outcomes with respect to major clinical endpoints (MACE) are similar for PCI and CABG, resulting in a class I recommendation. However among patients with high anatomical complexity (SYNTAX Score >33), trials recommend CABG over PCI. Many stenting strategies have been explored for the treatment of bifurcation lesions, with ongoing debate regarding which technique is the most effective. DK Crush technique has been compared with other bifurcation strategies (eg, culotte technique) in DK-CRUSH-III trial but is never compared with provisional stenting. This study is objective to compare DK crush technique with provisional stenting.

METHODOLOGY

Data collected from the designed questionnaire/ proforma. It was cross-sectional comparative study conducted at Armed Forces Institute of Cardiology/ National Institute of Heart Diseases, Rawalpindi Pakistan, from December 2020 to May 2021. All participants satisfying inclusion criteria were enrolled in the study. Baseline demographics, risk factors and procedural details collected for all patients who underwent LM-PCI (DK crush or PS) during the study duration. For all patients clinical characteristics recorded were, age, gender, pre-procedure serum creatinine and risk factors including diabetes mellitus, hypertension and smoking. Post-pr-ocedure MACE calculated for all the enrolled patients.

A total 70 patients with LMCAD were enrolled in study. Patients were randomized in the study who fulfilled the inclusion criteria. Inclusion criteria included patients who presented with chronic coronary syndrome (CCS) silent ischemia, ACS, and PCI intended in a true distal LM bifurcation lesion (Medina 1,1,1 or 0,1,1)[14], with >50% angiographic stenosis of distal LMS or both the ostial left anterior descending (LAD) and left circumflex (LCx) coronary arteries. Other Non-LM lesions either critical lesions or chronic total occlusions (CTO) lesions in LAD or LCX were treated before LM-PCI. Patients excluded from study included those with cardiogenic shock, in-stent restenosis (ISR), LM lesions with heavy calcifications requiring atherectomy, need for oral anticoagulants (OACs), or any clinical condition with life expectancy <12 months or poor medication compliance. Operators criteria required for performing LM-PCI included those who have >300 PCIs/ year for 5 years with at least 20 LM PCIs per year including 3-5 DK crush cases.

Patients presented with LM disease were randomized to either DK Crush or PS based on medina score, angiographic anatomy and feasibility of either procedure. PS refers to treatment of compromised SB only if it is required after MV stenting. This strategy is considered preferred technique now for most bifurcation lesions[15]. In PS, both vessels are wired, then MV is predilated, followed by SB predilation if SB diameter stenosis is >70%. The MV stent is then deployed jailing the SB wire. If TIMI flow impaired in SB, re-crossing of SB is done. The jailed SB wire serve as a roadmap in cases of complete SB closure. Once rewired, jailed SB wire is withdrawn. If SB flow impaired, the SB ostium is dilated using either kissing balloon inflation (KBI) or a POT-SB-POT (proximal optimization technique) technique, where initial and final MV POT done with an isolated SB dilation in between. DK crush technique is a two stages of KBI. The first KBI is performed after deploying the SB stent and the second KBI is performed after deploying the MV stent[16] (figure).

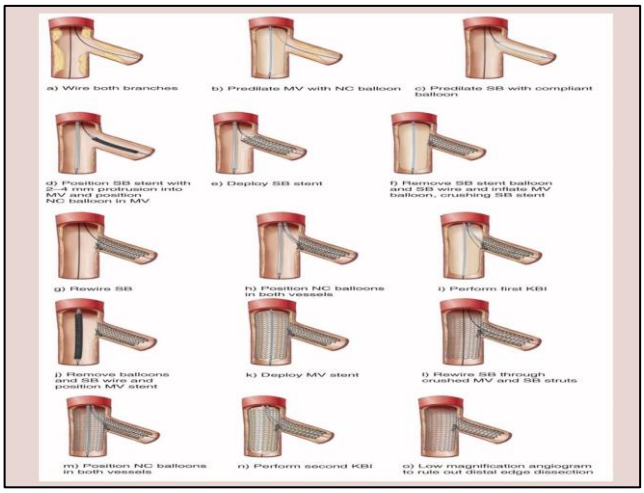

Figure: Steps DK crush technique (MV main vessel, SB side branch, NC non compliant).

The primary end point considered was target lesion failure (TLF): cardiac death, target vessel MI (TVMI) or target vessel revascularization (TVR). Cardiac death was defined as any death without a known clear non-cardiac cause. Periprocedural TVMI defined as >10 times URL (upper reference limit) rise of CK-MB (creatine kinase myocardial band) or >5 times URL rise of CK-MB plus any one of 1) angiographically documented new severe stenosis or total occlusion of target vessel 2) ECG evidence of new pathological Q-waves in >2 contiguous leads or new-onset LBBB or 3) imaging evidence of loss of viable myocardium or new regional wall motion abnormality (RWMA). TVR defined as ischemia or angina in the territory of target vessel requiring repeat PCI or CABG[17].

The LM bifurcation lesion categorized as being either simple or complex. Complex defined as the presence of both major criteria (SB-ostium lesion length >10 mm and Diameter stenosis >70%) plus any 2 minor criteria (distal bifurcation angle <450 or >700, main vessel diameter <2.5 mm, MV lesion length >25 mm, multiple bifurcations, thrombus-containing lesion, and severe calcification). Simple defined as the presence of >50% disease in distal left main stem or disease involving Ostia of both LAD and LCX branches with >70% stenosis.

Statistical analysis was performed using SPSS-23. Categorical data was expressed as percentages and continuous variables as mean ± SD or median as appropriate. For comparison of normally distributed variables, t-test applied. All values reported as mean ± SD and *p*-value of <0.05 considered statistically significant.

Patients clinical follow-up done at 2 and 4 weeks with office visit in most patients but telephonic follow-up in few patients. Follow-up angiography planned only in patients with TVMI based on ECG changes, RWMA on imaging or raised cardiac enzymes, or clinical symptoms compelling for coronary angiography. There after 3 and 6 months follow-up done for all patients.

RESULTS

A total of 70 patients fulfilling the inclusion criteria were enrolled in the study. The patient population was divided into two groups. Group A participants underwent DK crush technique while group B participants underwent provisional stenting. Both the groups had equal number of participants 35 in each group. The mean age of the study population was 63.63 ± 10.978. Among which 63 (90%) were males while 7 (10%) were females. Among which 38 (54.28%) patients were diabetic while 46 (65.7%) were hypertensive. Procedural aspect of the study participants shows 26 (37.14%) had elective PCI done previously, followed by 24 (34.28%) patients who had diagnostic coronary angiogram, while 10 (14.28%) patients had PPCI done previously. These demographic characteristics are presented in table-I.

In group A (DK crush technique) 16 (45.7%) patients presented with non-ST elevation MI followed by 14 (40%) who presented with chronic coronary syndrome (CCS) while in group B [Provisional stenting] 13 (37.1%) presented with chronic coronary syndrome

Table-I: Demographic characteristics of study population.

Variable	Mean ± SD / n(%)
Age	63.63 ± 10.978
Gender	
Male	63 (90)
Female	7 (10)
Diabetes	
Yes	38 (54.28)
No	32 (45.7)
Hypertension	
Yes	46 (65.7)
No	24 (34.2)
Smoking Status	
Yes	25 (35.7)
No	45 (64.2)
Previous Procedure	
Elective PCI	26 (37.14)
PPCI	10 (14.28)
CABG	3 (4.28)
Diagnostic Angiogram	24 (34.28)
None	7 (10)

followed by 9 (25.7%) who presented with non-ST elevation MI. In group A 22 (62.9%) patients had TVCAD with LMS disease while 13 (37.1%) had DVCAD with LMS disease whereas in group B 19 (54.3%) patients had DVCAD with LMS disease, 12 (34.3%) patients had TVCAD with LMS disease. Regarding the anatomical complexity assessed with SYNTAX score, 24 (68.6%) patients had SYNTAX score <32 in group A while 21 (60%) patients had SYNTAX score in range of 22-30 among group B. Left ventricular function assessment shows, In group A 15 (42.9%) patients had good LVEF function while in group B 16 (45.7%) good LVEF function. There was no mortality in group A while there was one mortality in provisional stenting group which was ACS presentation and died of irreversible ventricular fibrillation. These results are illustrated in table-II & III.

DISCUSSION

The debate of CABG vs PCI for ULMCAD and multivessel CAD is an old discussion. In current era PCI can be done safely in patients with LMCAD and low to intermediate SYNTAX score and acceptable risk factors[18]. One of the pioneer trial, EXCEL trial showed that at 3 years outcome of CABG and LM-PCI have equal outcomes[12]. Later on SYNTAX trial conducted among patients with LM and multivessel CAD, on account of anatomical complexity of lesion and based on scoring system into high (>33), intermediate (23-33) and low (0-22) SYNTAX score[19]. It showed that at 3 years the rate of death and MI were similar in CABG and PCI groups while stroke was significantly more likely to occur in CABG (2.2% vs 0.6%). SYNTAX trial also showed that at 10 years follow-up, no significant difference seen in all cause death between PCI and CABG. Pooled data from SYNTAX, PRECOMBAT (premier of randomized comparison of bypass surgery versus angioplasty using sirolimuseluting Stent in patients with left main coronary artery disease) and BEST (randomized comparison of coronary artery bypass surgery and everolimuseluting stent implantation in the treatment of patients with multivessel coronary artery disease) trials showed that for the treatment of LMCAD and multivessel CAD, PCI resulting in complete revascularization is associated with similar long-term survival rate comparable to CABG. The French LM registry also showed that LM-PCI is a safe option for patients with LMCAD. Unprotected LM-PCI with PES (paclitaxel eluting stents), with a strategy of PS for

Table-II: Clinical characteristics of DK group (n=35).

Variable	Mean ± SD / n (%)
Clinical Presentation	
ST elevation MI (STEMI)	2 (5.7%)
Non-ST elevation MI (NSTEMI)	16 (45.7%)
Unstable Angina	3 (8.61%)
Chronic coronary syndrome	14 (40%)
Multivessel Disease	
TVCAD with LMS disease	22 (62.9%)
DVCAD with LMS disease	13 (37.1%)
LMS Lesion Location	
Bifurcation	35 (100%)
Syntax Score	
<22	1 (2.9%)
22-30	10 (28.6%)
>32	24 (68.6%)
LVEF	
Good LVEF	15 (42.9%)
Fair LVEF	10 (28.6%)
Moderate LVEF	8 (22.9%)
Severe LV dysfunction	2 (5.7%)
Creatinine Level	1.097 ± 0.179
In-hospital mortality	
No	35 (100%)

Table-III: Table of association between syntax score and in-hospital mortality (group-A).

Syntax Score	In-Hospital Mortality	*p*-value
	No	
< 22		
22-30	35 (100%)	0.003
>32		

p-value 0.003 shows statistically significant relationship between syntax score and in hospital mortality

distal LMCAD provides excellent acute angiographic results and good mid-term clinical outcomes with a 15.8% rate of MACE at 2 years follow-up[20].

Table-IV: Clinical characteristics of provisional stenting group (n=35).

Variable	Mean ± SD/ n (%)
Clinical Presentation	
ST elevation MI	5 (14.3%)
Non-ST elevation MI	9 (25.7%)
Unstable Angina	8 (22.1%)
Chronic coronary syndrome	13 (37.1%)
Multivessel Disease	
TVCAD with LMS disease	12(34.3%)
DVCAD with LMS disease	19(54.3%)
SVCAD with LMS disease	4(11.4%)
LMS Lesion Location	
Bifurcation	35 (100%)
Syntax Score	
Less than 22	5 (14.3%)
22-30	21 (60%)
Greater than 32	9 (25.7%)
LVEF	
Good LVEF	16 (45.7%)
Fair LVEF	7 (20%)
Moderate LVEF	11 (31.4%)
Severe LV dysfunction	1 (2.9%)
Creatinine level	1.04 ± 0.26
In-Hospital Mortality	
Yes	1 (2.85%)
No	34 (97.14%)

Table-V: Table of association between syntax score and in-hospital mortality (group-B).

Syntax Score	In-Hospital Mortality		*p*-value
	Yes	No	
<22 22-30 >32	1 (2.85%)	34 (97.14%)	0.004

p-value 0.004 shows statistically significant relationship between syntax score and in hospital mortality

In this study we shared our experience of LM-PCI with DK-CRUSH or PS. We studied 72 patients with distal LM disease and evaluated angiographic and clinical outcomes of distal LM disease treated either with DK-Crush or PS strategy. Patients were randomized to either planned 2-stent strategy DK-Crush or PS based on distal LM lesion morphology, simple or complex lesion. So we planned DK-Crush for complex LM lesions and PS for simple lesions. Radial access used as default access site (MATRIX and RIVAL trials) unless there were limitations with it, and then femoral access used in such cases. We used 7F (French) size guiding catheters for all procedures and 7F heath-less technique used in case of radial access. Unfractionated heparin (UFH) used according to body weight as anticoagulant of choice in all patients with activated clotting time (ACT) goal between 250-350 seconds. Guide wire selection was according to lesion morphology but work-horse wires used in default. All patients were preloaded with aspirin 300mg and clopidogrel[21], 600mg but potent P2Y12 inhibitor ticagrelor also used based on ischemic and bleeding risks of patients. Newer generation drug-eluting stents (DES) used in all cases as a default stent choice. With advancements in stents technology, newer generation DES have higher efficacy and safety in comparison with both early-generation DES and BMS (bare metallic stents) and also having thin struts (50–100 mm). Moreover, the risk of very late stent thrombosis is at least comparable to that of BMS and lower than that of early-generation DES[22]. We treated all other critical lesions in the target vessels before LM-PCI.

In conclusion of this study, comparing angiographic results of the two techniques used, DK-Crush is far superior to PS in true distal LM bifurcation lesions. Contrary to previous studies on 2-stent strategies which favored PS because of increased long-term TVF, TVMI, TVR in planned 2-stenr strategy. In recent study of DK-CRUSH-V[23] trial concluded thatcompared to PS, DK crush resulted in better outcome in ST, TVMI, and TLF. Planned 2-stent technique with DK-Crush is superior to PS because in prior technique SB is well-prepared with good angiographic results, while in bail-out SB stenting there was difficulty in stenting through MB stent struts and poor lesion preparation. There was no clinical or angiographic TVMI seen in patients with DK-Crush technique. However in this study there was no significant difference in the rate of clinically and angiographically significant periprocedural TVMI between the two groups, with mortality of 1 (2.85%) in PS group in a patient presented with ACS and occluded LM, who died of irreversible VF. Also early and mid-term follow-up of patients in the two groups showed no significant difference in TLR, with increased rates of ISR at the SB ostium in patients undergone PS technique.

LIMITATION OF STUDY

Although recent advances favor use of intracoronary imaging in all complex cases especially LM-PCI to improve procedure outcomes, guide stent and balloon sizing, identify procedure related complications like; stent edge dissection, stent under-expansionand measuring exact vessel diameter. But due to limited resources IVUS (intravascular ultrasonography) or OCT

(optical coherence tomography) not used in routine in all cases with exception of few cases where it was used. Some of the recent landmark trials also favor use of FFR (fractional flow reserve) especially in SB stenting if required. FAME (fractional flow reserve versus angiography for Multivessel Evaluation) trial concluded that at 12 months FFR guided PCI is superior to angio-graphic guided PCI and used a cut-off value of <80 as significant. But due to limitations in financial resources, FFR not used in our study.

CONCLUSION

LM-PCI is an accept-able procedure in feasible patients with true distal LM bifurcation lesions. We also found that DK-Crush has good periprocedural and angiographic outcomes with good outcomes and superior to PS in complex LMCAD lesions. PS is an acceptable option in simple distal LMCAD.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

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