Research Article

Interventional Cardiology

Percutaneous coronary intervention in acute unprotected left main coronary artery disease: Provisional strategy or two-stent technique?

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Received date: January 13, 2021
Accepted date: January 27, 2021
Published date: February 03, 2021

Abstract:

Background: Primary percutaneous coronary intervention in acute unprotected left main coronary artery disease, however, tends to be a complex procedure as it lasts longer, requires more expertise, and frequently involves critical bifurcation and often results in more than one stent. Here we present a retrospective analysis of a specific group of patients treated with percutaneous coronary intervention in our center.

Methods: Retrospectively 55 patients with unprotected left main coronary artery lesions and acute coronary syndrome diagnosis treated with per cutaneous coronary intervention were identified: The two-stent technique was applied in 28 cases, and provisional stenting (PS) was applied in 27 cases.

Results: Current smoking (82.1% vs. 48.1%, p=0.007), prior myocardial infarction (35.7% vs. 7.4%, p=0.010) and prior coronary stent implantation history (28.6% vs. 3.7%, p=0.012) were more common in the two-stent technique group. While procedure duration was higher in the two-stent technique group compared to PS (58.21 vs. 33.15, p<0.001), door-balloon time was lower (29.7 vs. 42.1, p=0.006). However, creatinine levels 48-72 hours post-procedure (1.08 vs. 1.33, p=0.422) and in-hospital mortality rates were similar between the two groups (28.6% vs. 14.8%, p=0.229).

Conclusion: In the treatment of acute unprotected left main coronary artery with percutaneous coronary intervention, two-stent technique is a viable, effective and safe strategy as it has similar contrast-induced nephropathy and mortality rates compared to provisional strategy.

Keywords: Target Vessel Revascularization (TVR) • Nano-crush technique • Cardiovascular events (MACE) • Intravascular ultrasound (IVUS) • Acute coronary syndrome • Left main coronary artery disease • Percutaneous coronary intervention • Two stent technique • Provisional strategy

Introduction

Acute Coronary Syndrome (ACS) involving unprotected Left Main Coronary Artery (uLMCA) disease is associated with high morbidity and mortality as a large part of the left ventricular myocardium is jeopardized [1]. Additionally, Left Main Coronary Artery (LMCA) occlusion is frequently accompanied by multivessel coronary disease [2]. Incidence of uLMCA involvement among ACS presentations is 0.8%, with higher rates of cardiogenic shock, malignant arrhythmias and sudden cardiac death presenting as complications [3]. Although Percutaneous Coronary Intervention (PCI) is shown to be inferior or, at least, non-inferior to Coronary Artery Bypass Grafting (CABG) in the elective treatment of uLMCA lesions in certain circumstances, there are no evidence-based guidelines regarding the optimal management of acute uLMCA lesions [4,5]. High mortality rates with both emergency PCI and CABG have been reported [6]. PCI in uLMCA lesions is a challenging procedure which demands expertise, preprocedural planning and advanced technological back up, including intravascular ultrasound (IVUS).

While Provisional Stenting (PS) in distal uLMCA lesions is generally the easier path to choose given its simplicity and good clinical outcomes, a recent study found that the Two-Stent Technique (TST) yields similar outcomes in terms of four-year Myocardial Infarction (MI), Target Vessel Revascularization (TVR) and mortality rates [7]. However, there is still a lack of data in the literature comparing the two PCI approaches in acute settings without IVUS support. In this study, we retrospectively analyzed data from ACS patients with uLMCA culprit lesions treated with primary PCI or an early invasive strategy. We also documented in-hospital clinical and procedural outcomes, including a detailed comparison of the two percutaneous treatment techniques used in terms of procedural data, complication rates and mortality rates.

Patients and Methods

The data analyzed in this study include the demographic characteristics, procedural data and medical records of patients diagnosed with ACS with uLMCA lesion *via* coronary angiography (CAG) findings who were admitted to our hospital between 1 January 2016 and 30 June 2019. ST-Segment Elevation Myocardial Infarction (STEMI), Non-ST Segment Elevation Myocardial Infarction (NSTEMI) and unstable angina pectoris were accepted as ACS diagnosis. A uLMCA lesion was defined as more than 50% stenosis in the LMCA with no patent graft in the Left Anterior Descending (LAD) or circumflex (Cx) arteries. PS was defined as a single-stent implant to the proximal LMCA or directed from the LMCA distal to the LAD or Cx. TST was defined as complex PCI performed from LMCA distal to both LAD and Cx.

In our cases, XIENCE (Abbott, Everolimus eluting stent) and Ephesos (Alvimedica) stents were used. We could not use IVUS and optical coherence tomography imaging techniques during the interventions as these catheters were not routinely available in the catheterization laboratory. Intra-Aortic Balloon Pump (IABP) therapy was not used routinely on patients with cardiogenic shock, with the exception of four patients due to prolonged ischemia. The SYNTAX Score I grading system was used to determine the severity of Coronary Artery Disease (CAD).

Door-Balloon Time (DBT) was defined as the time interval (minute) between the patient's arrival to the Emergency Room (ER) and the passage of the guide wire from the culprit coronary artery lesion. Procedure Duration (PD) was defined as the time interval (minute) between the patient lying on the operating table in the catheterization laboratory and the final image recording. The first creatinine value was the value measured in the blood test at the time of the patient's arrival to the ER, and the control creatinine value was the value measured within 48-72 hours of hospitalization in the cardiology clinic. Ejection Fraction (EF) was taken as the result of the echocardiographic evaluation performed on the first day of hospitalization, and the control EF was taken as the result of echocardiographic evaluation performed before discharge. Cardiogenic shock, mechanical complications of acute MI, bleeding associated with antiplatelet therapy or on the puncture site and contrast-induced nephropathy were considered clinical complications. The study protocol was designed in accordance with the principles of the declaration of Helsinki, and the approval (no: 715224473/050.01.04/395) of the ethics committee was obtained.

Statistical analysis

The resulting power (post-hoc power analysis) for the available sample size was calculated through a power analysis software (Gpower 3.1.9.2, Brunsbuttel, Germany). According to the results of the post-hoc power analysis, it was observed that the power obtained for this sample (1-β) was 0.78, when 0.8 patients were selected for the effect size and 55 patients for the sample size. Statistical analysis was performed using SPSS 24.0. Categorical variables were expressed in the form of numbers or percentages, whereas continuous variables were represented by mean ± standard deviation. In the comparison of continuous variables, the compliance of parameters with the normal distribution was initially examined using the Kolmogorov-Smirnov test. The chi-square test and Fisher's exact test were used to assess differences in categorical variables. An independent samples t-test was used to compare data that complied with the normal distribution, while the nonparametric Mann-Whitney U test was used to detect differences in continuous variables with non-normal distribution. A binary logistic regression analysis was performed to identify the predictors of the presence of mortality on patients. Two-sided p-values<0.05 were considered statistically significant.

Results

The outcomes for a total of 55 uLMCA procedures treated with PCI were analyzed, including TST in 28 patients and PS in 27 patients. Primary clinical characteristics are shown in Table 1. Current smoking, prior MI and history of stent implantation were more common in the TST group; however, there were no other significant differences between the two groups in terms of baseline clinical characteristics.

Table 1: Baseline clinical characteristics.

	TST(n=28)	PS (n=27)	p-value
Age, years	64.3 ± 12	66.9 ± 12.5	0.432
Male, %	89.3	74.1	0.147
Current smoker, n (%)	23(82.1)	13(48.1)	0.007
Hypertension, n (%)	17(60.7)	19(70.3)	0.46
Diabetes mellitus, n (%)	6(21.4)	7(25.9)	0.701
Hyperlipidemia, n (%)	5(17.8)	1(3.7)	0.092
Prior MI, n (%)	10(35.7)	2(7.4)	0.01
Prior PCI, n (%)	8(28.6)	1(3.7)	0.012
Prior CABG, n (%)	1(3.6)	1(3.7)	0.981
Atrial fibrillation, n (%)	0(0.0)	2(7.4)	0.146
Prior stroke, n (%)	3(10.7)	0(0.0)	0.089
STEMI, n (%)	16(57.1)	12(44.4)	0.401
Creatinine(mg/dL)	1.12	1.21	0.71
EF, %	43	43.2	0.963

Abbreviations: MI: Myocardial Infarction; PCI: Percutaneous Coronary Intervention; CABG: Coronary Artery By-pass Graft; STEMI: ST Elevation Myocardial Infarction; EF: Ejection Fraction.

In six patients with coronary stent history, we found that stents had also been implanted to other coronary arteries. During CAG, three patients with prior LMCA stent thrombosis were treated with kissing balloon angioplasty. Both groups had one patient with a history of CABG occlusion as well as non-functional LAD and Cx grafts. In the TST group, there were 16 STEMI (eight anterior MI and eight LMCA/3 vessel disease, based on electrocardiography) and 12 NSTEMI cases. In the PS group, there were 12 STEMI (nine anterior MI and three LMCA/3 vessel disease based on electrocardiography), 14 NSTEMI and one USAP cases. Possible reasons for PCI of the uLMCA in patients diagnosed with NSTEMI include patient rejection of cardiovascular surgery, the patient being at higher risk of surgery complications, recurrent angina pectoris while waiting for surgical treatment, dynamic ST segment change and new onset cardiogenic shock.

All patients in the TST group had distal LMCA lesions, while two patients in the PS group had ostial LMCA lesions. One of these was a congenital coronary anomaly, with the LMCA originating from the right sinus Valsalva. To treat bifurcation in TST patients, the following techniques were applied: seven culotte, four Double-Kissing (DK) crush, two mini-crush and 11 T-stenting with small protrusion (TAP). Kissing balloon angioplasty and a mini-crush plus TAP were also applied in three stent thrombosis cases and one trifurcation case, respectively. The procedure began with a one-stent technique in seven patients, but terminated with TST after complications developed in the side branch ostium. Of these, the TAP technique was applied in six cases and the culotte technique in one.

PCI procedure and complication results are shown in Table 2. SYNTAX scores were similar in both groups: 16 patients had moderate scores (22-32) and 39 patients had low scores (<22), with no significant differences found. Drug eluting stent (DES) usage rates were similar between the two groups, and no cases presented with in-hospital stent thrombosis. Femoral access rates during PCI were similar in both groups. CAG was initiated with radial puncture in a total of eight patients, with crossover from radial to femoral access performed for catheter support when an LMCA lesion was detected.

Table 2: Procedural characteristics and in-hospital outcomes.

	TST (n=28)	PS (n=27)	p-value	TST(n=28)
Femoral access, n (%)	27(96.3)	26(96.4)	0.16	16(57.1)
Syntax score I, n	19.4	18	0.211	16(57.1)
DBT (min.)	29.7	42.1	0.006	16(57.1)
Procedure duration(min.)	58.2	33.1	<0.001	16(57.1)
Medina classification, n (%)				
1,1,1	13(46.4)	5(18.5)	0.027	16(57.1)
1,1,0	4(14.3)	5(18.5)	0.671	16(57.1)
1,0,1	3(10.7)	1(3.7)	0.317	16(57.1)

1,0,0	2(7.1)	3(11.1)	0.609	16(57.1)
0,1,1	2(7.1)	3(11.1)	0.609	16(57.1)
0,1,0	3(10.7)	10(37.0)	0.022	16(57.1)
0,0,1	1(3.6)	0(0.0)	0.322	16(57.1)
Balloon pre-dilatation, n (%)	22(78.6)	23(85.2)	0.525	16(57.1)
DES implantation, n (%)	21(75.0)	19(70.4)	0.396	16(57.1)
Stent size, mm				
3	18 (64.3)	14 (51.9)	0.35	16(57.1)
3.5	4 (14.3)	7 (25.9)	0.281	16(57.1)
4	2 (7.1)	5 (18.5)	0.201	16(57.1)
4.5	1 (3.6)	1 (3.7)	0.979	16(57.1)
Final kissing balloon, n (%)	26(92.9)	5(18.5)	<0.001	16(57.1)
Proximal optimization technique, n(%)	17(67.8)	13(48.1)	0.141	16(57.1)
Critical lesion in RCA, n (%)	11(39.3)	7(25.9)	0.291	16(57.1)
IABP implantation, n (%)	3(10.7)	1(3.7)	0.317	16(57.1)
Preferred second antiplatelet agent				
Ticagrelor, n (%)	6(21.4)	4(14.8)	0.604	16(57.1)
Prasugrel, n (%)	8(28.5)	11(40.7)	0.605	16(57.1)
Clopidogrel, n (%)	14(50.0)	12(44.4)	0.958	16(57.1)
In-hospital complications, n (%)	14(50.0)	6(22.2)	0.03	16(57.1)
Bleeding, n (%)	3(10.7)	0(0.0)	0.08	16(57.1)
Cardiogenic shock, n (%)	9(32.1)	5(18.5)	0.251	16(57.1)
Contrast-induced nephropathy, n (%)	2(7.1)	1(3.7)	0.521	16(57.1)
Creatinine level, 48-72 hours after the intervention, mg/dL	1.08	1.33	0.422	16(57.1)
Control EF, %	52.8	51.9	0.771	16(57.1)
Mortality, n (%)	8(28.6)	4(14.8)	0.229	16(57.1)

Abbreviations: DBT: Door-to-Balloon Time; DES: Drug Eluting Stent; RCA: Right Coronary Artery; IABP: Intra-Aortic Balloon Pump; EF: Ejection Fraction.

The rates of observed thrombus formation during CAG were similar in both groups (78.6% vs. 70.4%, p=0.490). Major bleeding was not present in either group, and puncture-related minor bleeding rates were not statistically different (p=0.080). Cardiogenic shock rates (32.1% vs. 18.5%, p=0.251) were not statistically significant, but were numerically more common in the TST group. In-hospital mortality rates were similar in both groups (28.6% vs. 14.8%, p=0.229).

Age, Syntax score, narrow LAD-CX angle (<70 degrees), PS or TST and STEMI were the associated predictors of mortality in the univariate analysis. In the multivariate regression analysis, Syntax score (Odds Ratio [OR]: 0.840, 95% Confidence Interval [CI]: 0.723-0.974, and p=0.022), STEMI (OR: 1.050, 95%CI: 0.921-1.372, and p=0.023) were found to be independently associated with the mortality (Table 3).

Discussion

While there are numerous evidence-based recommendations regarding the treatment of uLMCA lesions in the 2018 European Society of Cardiology (ESC) Guidelines on myocardial revascularization, there are no definitive guidelines for the optimal treatment of acute uLMCA disease. Furthermore, there are no prospective studies on choice of treatment modality for acute uLMCA lesions in the current literature [8]. PCI has the advantage of restoring coronary flow and improving hemodynamic stability faster than CABG in acute uLMCA; PCI may therefore be the treatment of choice. Although it is difficult to conduct a randomized study comparing two treatment strategies for acute uLMCA disease, we wanted to evaluate the results of acute percutaneous treatment retrospectively. In NOBLE (The Nordic-Baltic British left main revascularization study) and EXCEL (Evaluation of Xience Everolimus Eluting stent Versus coronary arterial Bypass

Table 3: Univariate analysis and multivariate model for mortality in patients.

Univariate analysis	p-value	OR (95% CI)	Multivariate analysis	p-value	OR (95% CI)
Age	0.224	0.95(0.89-1.02)			
Syntax score I, n	0.023	0.81 (0.68-0.97)	Syntax score I, n	0.022	0.84 (0.72-0.97)
LAD-CX angle	0.736	0.99 (0.95-1.03)			
PS or TST	0.326	1.42 (0.81-5.01)			
STEMI	0.019	0.98 (0.81-1.17)	STEMI	0.023	1.05(0.92-1.37)

Abbreviations: OR: Odds Ratio; CI: Confidence Interval; PS: Provisional Stenting; TST: Two Stent Technique.

Surgery for Effectiveness of Left Main Revascularization) trials evaluating PCI vs. CABG in the treatment of uLMCA disease, acute treatment (within 24 h) was excluded [9,10]. Consideration increases mortality associated with cardiogenic shock as well as the risk of complications. It also delays exit from the pump and extubation after surgery. PCI can thus be performed in appropriate acute LMCA lesions more efficaciously than CABG.

In our results, in-hospital mortality was 85.7% in all patients with cardiogenic shock, whether treated with TST or PS. According to data from the Assessing Optimal Percutaneous Coronary Intervention for the LMCA (AOI-LMCA) Registry, 180-day mortality in ACS patients with cardiogenic shock who underwent PCI to the uLMCA was significantly higher than in patients without cardiogenic shock [11]. In our results, the cardiogenic shock rate was 25.4% and the mortality rate was 21.8% in all 55 patients. Luca et al. determined in-hospital mortality was 58% in 24 MI patients with PCI-treated uLMCA lesions [12]. When examining the results of 62 uLMCA cases with MI treated *via* PCI, including 23 STEMI and 39 NSTEMI, diabetes mellitus, endotracheal intubation and lower EF were found to be associated with increased mortality [13]. In our study, we could not analyze clinical conditions or risk factors predicting mortality in acute uLMCA disease due to the low patient mortality rate.

While PD was significantly higher in the TST group when compared with PS group, DBT was significantly lower. This may be because current smoking, prior CAD, prior PCI and cardiogenic shock (numerically) were more common in the TST group; therefore, the ER team could act faster at diagnosis and upon transfer to the catheter lab. Andell et al. emphasize that IVUS guidance in the treatment of uLMCA was associated with decreased risk of stent thrombosis, restenosis and all-cause mortality compared to cases treated without IVUS guidance. The most probable explanation for this benefit is larger and more appropriately sized stenting [14]. However, IVUS catheters were not routinely used in our laboratory, particularly in acute PCI cases. For this reason, stenting was performed to the uLMCA without IVUS assessment. According to the ESC 2018 myocardial revascularization guidelines, routine use of IABPs in patients with cardiogenic shock due to ACS is not recommended [8]. Thus, IABPs were not routinely used in acute MI patients with cardiogenic shock in our study.

In a trial comparing stenting to the LMCA lesions with PS and DK crush techniques excluding recent MI (<24 h), cardiac mortality and Target Vessel Revascularization (TVR) were not different at the primary efficacy endpoint; however, target lesion failure and stent thrombosis were found to be more common in the PS group [15]. In the three-year outcomes for the same study, PS for uLMCA was associated with significantly increased rates of target vessel failure, stent thrombosis and TVR compared with DK crush stenting [16]. In a meta-analysis of seven studies involving 2,328 patients, PS and TST results for uLMCA bifurcation lesions were compared. During follow-up (32 months on average), PS decreased the risk of Major Adverse Cardiovascular Events (MACE) and TVR compared to TST [17].

In light of the results of these studies and our own, we would like to emphasize that the primary aim in acute revascularization of LMCA is to improve hemodynamics by providing distal coronary artery flow. While PS can be applied more quickly, TST may be necessary in some cases depending on the Medina classification of the bifurcation lesion or side branch complications which arise during surgery. According to our results, TST was preferred in cases with a Medina classification of 1,1,1 and PS was preferred in cases with a Medina classification of 0,1,0. The character of the lesion should thus influence the physician's technique preference in acute uLMCA lesions treated with PCI.

There is consensus that PS is the preferred strategy for non-LMCA bifurcation lesions. However, the situation is slightly different in uLMCA bifurcations because of the larger arterial lumen and plaque burden, greater angle between the two distal branches, blood supply to a greater area of the myocardium *via* the side branch and mismatch between the LMCA and side branch diameters [18,19]. Zhang et al. determined that PS resulted in lower ostial residual stenosis of the LAD, whereas TST resulted in lower ostial residual stenosis of the Cx [19]. Analysis of the long-term results (median

3.1 years, up to 10 years) of 867 patients with single or double stenting applied to the uLMCA found that death, MI and ST rates were similar for both strategies [20].

In a DKCRUSH-III (Clinical Outcome After DK Crush Versus Culotte Stenting of Distal Left Main Bifurcation Lesions: The 3-Year Follow-Up Results) trial, MACE and stent thrombosis (8.2% vs. 23.7%, p<0.001; 0% vs. 3.4%, p=0.007) were found to be significantly lower in the DK crush group [21]. Rigatelli et al. compared the nano-crush and culotte techniques in uLMCA bifurcation stenting, excluding STEMI patients. The nano-crush technique was shown to be superior to the culotte technique in terms of procedural time, contrast volume and X-ray dose [22]. In our study, the most commonly used bifurcation strategy in the TST group was the TAP technique. This may be due to the angle of bifurcation or the need to employ the TAP technique due to the development of side branch ostium complications. The results of a three-year long-term follow-up of uLMCA bifurcation double stenting in STEMI patients with cardiogenic shock indicated that the nano-crush technique used less contrast medium volume and resulted in shorter fluoroscopy time than the cullote and T-stenting techniques [23]. The benefits of TST are linked to the experience of the interventional cardiologist who chooses it as the optimal technique for bifurcation lesions. All bifurcation techniques create a new T-shaped or Y-shaped neo-carina, thereby changing the natural anatomy. This is also the main advantage of PS [18].

Conclusion

In-hospital mortality is high in both emergent PCI and CABG treatments in acute MI due to the severity of uLMCA disease. There is no consensus or definitive recommendation regarding the ideal acute treatment modality for these cases yet. PCI is increasingly being used as the preferred treatment thanks to new antiplatelet agents, new generation DES, IVUS guidance and increased interventional cardiologist experience. PCI is particularly applicable in cases of hemodynamic instability and emergency revascularization due to its shorter procedural time and low contrast volume. However, there may be cases in which TST should be applied based on the anatomy of the lesion, Medina classification, thrombus embolization, or plaque or carina shift to the side branch ostium. While our results found that in-hospital clinical complications were more common in acute PCI with TST to the uLMCA, contrast-induced nephropathy and death rates were similar with PS when complication subcomponents were considered individually. TST can thus be applied without hesitation when the interventional cardiologist has the experience to determine the most suitable strategy based on the anatomy of the uLMCA lesion and the Medina classification.

Study Limitations

Our study is single-centered and retrospective. Acute uLMCA occlusion is extremely life-threatening clinical condition, so we could not randomize the patients. The number of patients was low as there were not many uLMCA patients treated with ad hoc PCI, and only this number of patients could be identified in the 4-year retrospective study. Further, IVUS catheters are not routinely used in our laboratory. Given that our study is retrospective, we could not obtain contrast agent volume data for each patient and thus did not include contrast volume in our results.

Conflicts of Interest

There are no conflicts of interest for authors in terms that are not clear and may affect their decisions on the content of their work (such as financial or personal interests).

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