Unprotected Left Main Coronary Artery Percutaneous Coronary Intervention-Our Experiences at a Tertiary Hospital

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Abstract:

Key Words:
Percutaneous
coronary
intervention,
coronary artery
bypass graft,
bare metal stent,
Drug eluting
stent.

Background: Aim of the study was to evaluate the primary procedural success of percutaneous coronary intervention of unprotected left main coronary artery stenosis using either Bare-metal stents or drug eluting stent.

Methods: Total 33 patients were enrolled in this very preliminary non-randomized prospective cohort study. Among them, Male: 25 and Female: 8. Total 35 stents were deployed. Mean age were for Male: 59 yrs, for Female: 62 yrs. Associated coronary artery diseases risk factors were dyslipidemia, High Blood pressure, Diabetes Mellitus, Positive family history for coronary artery diseases and smoking.

Results: Among the study group; 26 (78%) were Dyslipidemic, 24(70%) were hypertensive; 17 (51.5%) patients were Diabetic, 11(33%) were smoker and 7(21%) patients had family history of Ischaemic heart disease. Female patients were more obese (BMI M 26: F 27) and developed coronary artery diseases in advance age. Common stented territory were left main: 20 (60%), Left main to left anterior descending artery 7 (22%) and Left main to left circumflex artery 6 (18%). Average length and diameter of stent was 3.5 and 18 mm respectively. Stent used: Bare Metal Stent 5 (15%), Drug Eluting Stent: 28 (85%). Among the different Drug Eluting Stents, Everolimus eluting stents were 11 (39.3%), Sirolimus eluting 10(35.7%), Paclitaxel eluting 3 (10.7%), Biolimus eluting 3 (10.7%) and Zotarolimus eluting 1 (3.6%). In the present study, overall survival outcome was 94% (31 patient), mortality of cardiac cause 3% (1 patient) and 1 patient (3%) died of hepatocellular carcinoma.

Conclusion: Our study has shown that percutaneous coronary intervention of the unprotected left main is a safe and effective alternative to Coronary Artery Bypass Graft (CABG).

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Introduction:

Percutaneous Coronary revascularization (PCI) of Left Main Coronary artery (LMCA) has remained controversial, since LMCA balloon angioplasty first performed by Andreas Gruentzig in 1978. Summarizing his experiences, Gruentzig concluded, "we have not been too successful with dilatating left main stems although procedure is relatively simple, the potential complications are both sudden and serious".¹

Significant improvements in interventional techniques, adjunctive pharmacology and the introduction of drug eluting stent (DES) have fostered new interest for the Percutaneous treatment of unprotected left main stem (ULMCA) stenosis, challenging the current concept that holds Coronary artery bypass graft (CABG) surgery as the standard care for this

lesion subset. Many of the study has shown that no significant difference between PCI and CABG in terms of mortality and MI, whereas patients treated with PCI have an increased risk of target vessel revascularization. PCI of ULMCA stenosis has significantly increased in the last several years and upgraded from class III recommendation to a class IIa by ESC ⁶ or IIb recommendation by AHA/ACC.

In Bangladesh PCI of the unprotected left main coronary artery stenosis as an alternative to CABG is being done. But the superiority/noninferiority of PCI of ULMCA stenosis over CABG is yet to be addressed in our population. Therefore, we have carried out this very preliminary prospective cohort study of ULMCA stenosis stenting in our patient population and its clinical follow-up one year after the procedure.

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Methods:

Methods: Total 33 patients were enrolled in this very preliminary study. Among them, Male: 25 and Female: 8. Total 35 stents were deployed. PCI was done by using BMS and DES. Patient were followed up at our cardiac OPD and evaluated by clinically.

Procedure: CAG was performed as per standard protocol. Individual discretion was applied as per operator's choice, depending on patient's problem. Significant Left main coronary artery (LMCA) lesion was defined as stenosis as greater than 50% narrowing in angiogram with clinical symptoms. Quantitative angiographic measurements of the target lesion were obtained in order to deploy correct size stent. PCI was done with the Bare Metal stent (BMS) and DES. Among the stents used; BMS used was micro-Driver (Medtronic, USA), DES were Cypher (Cordis, USA), Promus Element (Boston Scientific, USA) and Endeavor Resolute (Medtronic, USA). Coronary angioplasty was performed according to standard rules. Predilatation was optional before stent implantation with a shorter balloon to avoid geographic miss. A successful procedures was defined as TIMI-3 antegrade flow, and <20% residual stenosis in two orthogonal views. Postdeployment dilation was performed at high inflation pressure in all patients. In the event of chest pain, post-procedural ECG and CPK were measured and compared with the baseline. Check angio were taken, whenever indicated.

Drug Therapy

All the patients received Aspirin 300 mg/day and Clopidegrol as a loading dose 300 mg prior to PCI and continued for 9-12 months and received atorovastatin along with standard Medical management for CAD. During the procedure, an intravenous heparin bolus (100 IU/Kg) and GP IIb/IIIa receptor blocker was administered as required.

Results:

Table 1. shows the profile of studied population. Female patients were more obese (BMI; M 26: F 27) and developed CAD in advance age (M 59: F 62). CAD risk factors were more in male than female. Among the study group; 26 (78%) were

Dyslipidemic, 24(70%) were hypertensive; 17 (51.5%) patients were Diabetic, FH 7(21%) and 11(33%) were all male smoker. Fig 1. shows the percentage distribution of CAD risk factors. Table 2. shows the average size of stent used. Fig 2.Shows the percentage distribution of the stenotic territory of LM alone or associated with LAD/LCX ostium. Common stented territory were LM: 20 (60%), LM-LAD 7 (22%) and LM-LCX 6 (18%). Fig 3. shows the percentage distribution of common stent used were for BMS 5 (15%), DES: 28 (85%).

Table-IDemographic Profile of patient

| | Male | Female |
|----------------------|----------------|------------------|
| Number | N=25 | N=8 |
| Age (yrs) | 59.2±14.3 | 62.4±10.1 |
| $BMI(kg/m^2)$ | 26.0 ± 1.7 | 27.0 ± 3.1 |
| SBP(mmHg) | 126 ± 12.9 | 123.8 ± 16.8 |
| DBP(mmHg) | 75.4 ± 7.4 | 76.2 ± 7.4 |
| No. Risk Factor | 2.7 ± 0.7 | 2.6 ± 0.7 |
| RBS | 7.2 ± 1.5 | 6.7 ± 1.3 |
| Percentage of Lesion | 76.4±11.3 | 76.7±14.6 |

Data were presented as Mean \pm SD

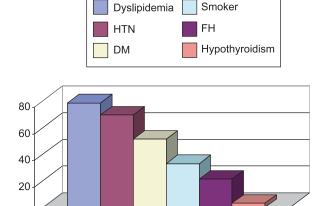


Fig.-1: Percentage Distribution of CAD risk Factors

Table-II

Average size of Stent used with inflation pressure

| | Length | Diameter | Inflation |
|--------|----------------|----------------|----------------|
| | (mm) | (mm) | Pressure (ATM) |
| Male | 18.4 ± 6.6 | 3.4 ± 0.27 | 14.9 ± 2.1 |
| Female | 17.1 ± 9.5 | 3.5 ± 0.47 | 14.5 ± 2.6 |

Data were presented as Mean \pm SD

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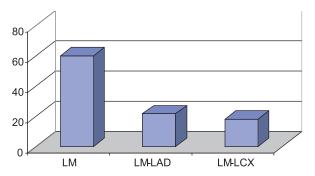


Fig.-2: Percentage distribution of Stenotic territory

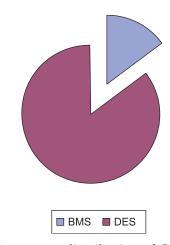
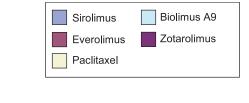


Fig.-3: Percentage distribution of Stent Used



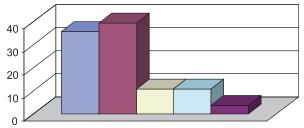


Fig.-4: Percentage distribuition of Different Drug Eluting Stent

Among the different DES, Everolimus elutining stents were 11 (39.3%), Sirolimus eluting 10(35.7%), Paclitaxel eluting 3 (10.7%), Biolimus eluting 3 (10.7%) and Zotarolimus eluting 1 (3.6%). At one year follow up, out of 33 patients, total 31(94%) patient survived and the overall

mortality was 2 (6%). Among them, one patient died 4 days after PCI and was on mechanical ventilatory support due to extensive anterior wall MI. Another gentleman died several months after the procedure due to non-cardiac cause (Hepatocelluler carcinoma). Thus, cardiac mortality at 12 months follow up was only 3% (1 patient).

Discussion:

In Bangladeshi patient perspective, CABG is the primary preferred option in managing ULMCA stenosis. With the advent in interventional procedures, now a day, many of the patients is being treated by PCI. But, it's superiority/ noninferiority over the CABG yet to be known in this setting. Therefore, we have carried out this non-randomized prospective cohort of this small number patient at our center, to see the one year post PCI clinical out come. Patient were followed up at our cardiac OPD and evaluated by clinically. No peri-procedural complication were noted in the studied patients and thereby the needs of urgent CABG. Check CAG was not done, because our study was to follow-up patient clinically for their sign and symptoms after the PCI.

Current guideline recommend PCI of the LMCA with stents as a class IIa or IIb alternative to CABG in patients with condition that associated with a low risk of PCI and or increased risk of adverse surgical outcomes.⁷

The introduction of DES has fostered new interest for the PCI of ULMCA stenosis, raising the question on the relative efficacy of DES compared with BMS. Uses of DES either Sirolimus or Paclitaxel eluting stents shows significant reduction of repeat revascularization and mortality over the uses of BMS. 8-10 In particular, ISAR left Main Trial randomized to Sirolimus eluting stent (SES) or Paclitaxel eluting stent (PES). At one year, the cumulative incidence of death, MI or Target vessel revascularization (TVR) was 13.6% in PES treated patient and 15.8% in SES treated patients (p=0.44). 11

Percutaneous revascularization of unprotected LMCA stenosis with DES probably should be limited to proximal and or midshaft stenosis that can be treated with a single stented more simple distal bifurcation stenosis with V, T or kissing techniques using current DES platforms. These procedures are best performed electively by skilled interventionist of high volume center with on-site surgical back up and the IVUS to ensure optimal stent expansion, symmetry and apposition. Periprocedural support of IABP may be used prophylactically in patient with compromised LV function with LVEF<35%. Stent implantation, pre and post dilatation balloon inflation should be performed rapidly with short total inflation duration. The presence of distal LMCA stenosis was an independent predictor of major adverse cardiovascular events after DES implantation. 12 Inadequate coverage at the ostium of side branch, ¹³ multiple layers of metal or polymer are associated with increased incidence of stent thrombosis. 14 In addition, delayed or incomplete endothelialization is more likely to occur after DES implantation particularly in stent overlap¹⁵ and may need dual antiplatelet (DAPT) for indefinite period. Because of the delayed endothelization, concern have been raised on long term DES safety with respect to the risk of late stent thrombosis. 16 Provide consistent reassuring evidence of a low risk of stent thrombosis after DES implantation for ULMCA stenosis.¹⁷ In the ISAR LEFT MAIN trial the cumulative rate of two year definite stent thrombosis in the whole cohort of patients was 0.5% with no significant difference between the two stent type. 11

Accurate assessment of the degree of ULMCA stenosis may have prognostic importance. ¹⁸ Angiographically significant ULMCA stenosis defined as a lesion causing a greater than 50% reduction in luminal diameter visual assessment or QCA. Intra and inter observer variability, the variable anatomy of the LMCA can make the evaluation of lesion severity problematic due to ostial angulations, vessel overlap and foreshortening. With the uses of Intravascular Ultrasound (IBUS) or Fraction Flow reserve (FFR) may overcome this problem. ¹⁹⁻²²

The anatomical location of the disease has been reported to carry prognostic implication in patients undergoing DES implantation for the treatment of ULMCA stenosis. The distal bifurcation is more prone to the development of

atherosclerotic lesion because of flow disturbances. ²³ The presence of distal ULMCA stenosis still represents a technical challenge. In the GISE study, a significant reduction of death/ MI and TVR in patients treated with the one stent technique compared to double stent. Whereas, those treated with double stent for the distal ULMCA stenosis, has significantly higher risk of major adverse cardiovascular events. ²⁴

In our present prospective non-randomized cohort, we have successfully performed PCI to ULMCA stenosis. In the present study, survival outcome were 94% (31patient) and mortality was 6% (2 patient). Among the survived patient all are doing well at one year clinical follow-up. No periprocedural complication, acute or late stent thrombosis developed. IABP used in one patient of resuscitated cardiac arrest following extensive anterior wall MI. It was very difficult to address whether PCI is superior over CABG in context to our population based on clinical evaluation. We need more patient inclusion, randomization into PCI and CABG group to compare the superiority of PCI over CABG in treating ULMCA stenosis. We need to evaluate the patient by check CAG at our follow-up at 9 and 12 months, if required earlier, to see the stent patency or the development of stent re-stenosis. In addition, we need to address the superiority of drug eluting stents over bare metal stents in ULMCA stenosis stenting. In this regard, we need multicenter study in perspective of Bangladeshi patient population.

Study Limitations:

We didn't use Intravascular ultrasound (IVUS) and Fractional Flow Reserve (FFR) to evaluate the lesions before and after PCI.

Conclusion:

Although, CABG remains the standard of care for the treatment of ULMCA stenosis, significant improvements have recently occurred in the field of percutaneous revascularization. The introduction of DES represented a major breakthrough in this field with significant reduction in the development of TVR and probably mortality. IVUS and FFR could have provide more accurate lesion type with the uses of more appropriate stent size and optimizing the final results.

Conflict of Interest - None.

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