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Original Article

COmplex Angioplasty ouTcome (COAT study) using CALD code: One Year follow up results of MV PCI

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Summary

Coronary Artery Disease (CAD) is the number one killer in the world, and therefore a major concern in both developed countries and developing nations alike[1]. CAD is characterized by reduced blood supply to the cardiac muscle, leading to ischaemia, and the characteristic angina or angina equivalent. Both Non-Invasive and Invasive strategies have been developed to tackle the issue of this infamous killer. Current Invasive strategies include- Balloon Angioplasty, Percutaneous Coronary Intervention (PCI) with coronary Stenting and Coronary Artery Bypass Grafting (CABG)[2]. However, there has been a gap in evidence as far as Invasive strategies go, particularly when it comes to PCI versus CABG. Most of the studies that compared PCI with CABG used 1st generation Drug Eluting Stents (DES) and may therefore have lead to a less favorable outcomes than the current 2nd Generation DES in case of Multi-Vessel CAD. This paper summarizes the outcomes of more than 200 patients who underwent three or more stents for CAD, with underlying risk factors along with a follow up over 1 year, with an aim to help cardiologists around the world shed inhibition for the use of minimally invasive PCI wherever applicable, against the favor of extensively invasive CABG for the treatment of CAD. This paper also aims to popularize use of the CALD-CODE system developed by the Indian Society of Cardiology, instead of the prevalent SYNTAX scoring system, that is cumbersome to use, with many limitations. (Indian J Cardiol 2022;25 (1-2):5-10)

Introduction

With the turn of the century, CAD has become the leading cause of death in India[3]. In comparison to the people of European ancestry, CAD affects Indians at least a decade earlier and in their most productive midlife years[4, 5].

Percutaneous Coronary Intervention (PCI) is the most effective treatment in patients presenting with Acute Coronary Syndromes (ACS), around half of these patients have hemodynamically significant lesions in multiple coronary artery locations that lead to increased morbidity and mortality[6-8]. Historically, CABG has been the treatment of choice in Multi Vessel Disease (MVD), however, DES-PCI is being increasingly used as an off-label indication in the same. There is a lot of inhibition that is seen in practitioners for the use of MV-PCI even in patients with suitable anatomy in the Indian context, and an early referral for CABG, when the prospect of MV-PCI, especially in patients requiring three DES

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or more, comes into play. This study aims to help shed those inhibitions, by sharing the outcomes of patients that underwent three or more DES implantations for CAD, over a follow up period of 1 year, with their demography, risk factors, complication rates , symptom relief according to New York Heart Association Functional Classification (NYHA), rate of readmissions, death, in the Indian Context.

Materials and Methods

This is a single center, retrospective, non-randomized, observational study. The study has been done at Post Graduate Department of Cardiology, JLN Medical, Ajmer. All procedures have been done using either radial access, or ulnar access where radial access was not achievable, after doing a modified Allen's test.

Sample size- 214 patients

All patients were admitted with a diagnosis of ACS in the department of cardiology, and Coronary Angiography (CAG) was done routinely as indicated in all patients, after ECG, 2D Echocardiography and cardiac biomarkers.

Inclusion Criteria

All patients with ACS that were more than or equal to eighteen years of age, and had anatomically suitable coronary artery for three or more stent implantations. Written informed consent was taken from all patient-participants of the trial.

Exclusion Criteria

1. Patient not giving written informed consent.
2. Patient less than 18 years of age.
3. Patients with ACS not undergoing CAG.
4. Patients with coronary artery suitable for less than 3 stent implantations.
5. Patients with renal dysfunction.
6. Patients with coronary anatomy not suitable for PCI.
7. Patients with clear indications for CABG.

Retrospective analysis of 240 patients admitted between January 1, 2019 to 31st December, 2019, were evaluated. Follow up was done telephonically enquired about regular drug compliance, current symptoms, and need for readmission, during the follow up period. Follow up was done till, 31st December, 2020. 26 patients were lost to follow up, through telephonic follow up and were not included in the statistical analysis.

Statistical Analysis was done using Pearson Correlation between groups, and deemed significant if 2 tailed p value was ≤ 0.01 in some cases and ≤ 0.05 in others, as indicated.

All patients received enoxaparin at the time of admission and heparin infusion during procedure. All patients were administered 180 mg Ticagrelor prior to stent implantation. Patients were already on Tablet Aspirin, Atorvastatin at recommended doses. Only patients with ACS were included, Clinical and demographic data including Age, Sex, Diabetes Mellitus, Hypertension, Smoking, Alcohol, Presenting Diagnosis, Presenting degree of symptoms and relief of symptoms according to NYHA was classified. Residual disease after stent implantation was assessed. Complications-intra-operative and post-procedural were assessed according to case notes. Death, if any, and probable cause of death was assessed according to the Death Certificate.

Angiographic Analysis

The computer-based ACOM PC 5.01 (Siemens Medical Systems, Inc., Erlangen, Germany) was used for off-line quantitative CAG analysis. Measurements were performed in end-diastole in the projection that best showed the diseased segment with as little foreshortening as possible. A quantitative analysis of the angiogram performed, image acquisition proceeds in the conventional manner, with the generation of a digital cineangiogram displayed on the image processor. Digital quantitation of selected image frames can be made with or without electronic magnification, easily accomplished with modern digital quantitative software and analysis systems. We have used Comprehensive Coronary Artery Lesion Description (CALD) code system and Coronary artery angiographic segmental (CAAS) classification for coronary artery lesion description[9].

Results

A total of 214 patients were included in the study, i.e. patients whose follow up could be successfully completed. In this study we observed that, young

patients i.e. <65 years of age constituted the bulk of the study population i.e. 152 patients (71%), out of which, 106 (49.5%) patients were male, and 46 patients were female (21.5%). 62 patients (29%) were ≥65 years old, out of which 42 (19.6%) patients were male and 20 (9.3%) patients were female. The total male population of the study (regardless of age) was 148 (69.2%) versus 66 (30.8%) female patients. (Table 1), (Figure 1)

Table 1 : Age-sex cross tabulation

		Sex		Total
		M	F	
Age Group	Count	106	46	152
<65 Years	% within Sex	71.6%	69.7%	71.0%
	Count	42	20	62
>=65 Years	% within Sex	28.4%	30.3%	29.0%
Total	Count	148	66	214
	% within Sex	100.0%	100.0%	100.0%

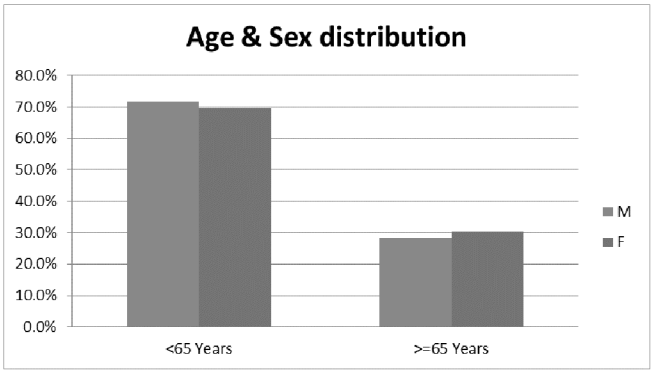

Fig. 1 : Age and Sex distribution of the study population

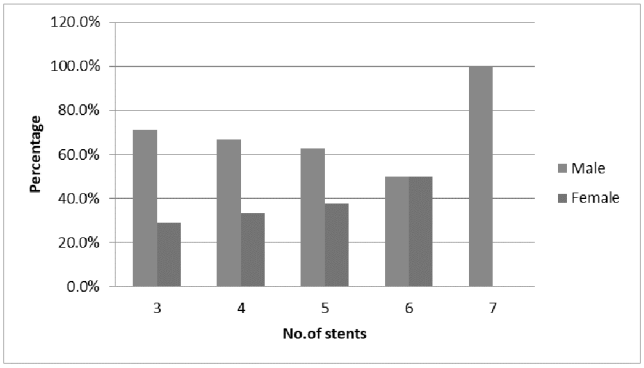

Fig. 2 : Number of stent distribution according to gender

The Major correlation tables from where data is derived can be found in Table 2

Unstable Angina was the most common diagnosis in patients that underwent CAG and had to get ≥3 stent implanted. It was present in 87 patients (40.7%). A diagnosis of Anterior Wall MI (AWMI), Inferior Wall MI(IWMI), Non-STEMI (NSTEMI), Infero-Lateral Wall MI (I+LWMI) was made in 56 (26.2%), 24 (11.2%), 22 (10.3%), 21 (9.8%) respectively. Inferior MI complicated with RVMI (I+RVMI) was present in only 4 (1.9%) patients requiring ≥3 stents.

Patients that were implanted with 3 stents were the maximum in number out of the 214 patients in the study group, i.e. 148 (69.2%), out of which 46 (21.5%) were in patients admitted with AWMI, 16 (7.5%) with IWMI, 15 (7%) with I+LWMI, 14 (6.5%) with NSTEMI and 4 (1.9%) with a diagnosis of I+RVMI.

4 stents were implanted in 45 patients (21%), while 5 stents were required by 16 patients (7.5%). 6 stents were required by 4 patients (1.9%), while 1 patients was even implanted with 7 stents (0.5%).

Residual Disease defined as angiographically defined coronary artery lesion, not undergoing PCI due to any reason, was present in 38 (17.8%) patients. The presence of residual disease was correlated with the present day NYHA (on follow up at 1 year) and was highly significant ($p<0.0001$). Residual Disease after PCI was also correlated by the number of readmissions made by the patient for any cardiac event over the follow up period of 1 year, which was also highly significantly correlative ($p<0.0001$).

Presenting symptoms were graded on the NYHA scale, and Symptom grading was again done using the same scale at 1 year follow up, over detailed telephonic interview. The average decrease in NYHA from presenting symptom grading to symptoms at 1 year follow up was a mean of 2.4159±597 in our study population.

Periprocedural complication developed in 1 patient (0.5%) in the form of proximal ostial dissection of the right coronary artery, however, patient was managed according to standard protocol, and at the end of 1 year of follow up, is now asymptomatic after PCI and guideline directed medical therapy.

Regular Follow up was defined as patient visiting the out-patient department every month for the follow up period to get assessed in person, about any symptom and/or for optimizing drug

Table 2 : Correlations of various factors

		Sex	No.of stents	Alive/ Dead1	Regular Followup	Need for Readmission	Drug Compliance	HTN	DM	Smoking +Tobacco	Alcohol	Decrease in NYHA
Sex	Pearson Correlation	1	.058	-.048	.046	-.041	.104	.087	.014	-.469**	-.148*	-.143*
	Sig. (2-tailed)		.397	.486	.506	.555	.129	.204	.839	.000	.031	.036
	N	214	214	214	214	214	214	214	214	214	214	214
No.of stents	Pearson Correlation	.058	1	.106	.040	-.079	.110	.012	.275**	-.036	.049	-.101
	Sig. (2-tailed)	.397		.120	.564	.250	.108	.862	.000	.605	.478	.140
	N	214	214	214	214	214	214	214	214	214	214	214
Alive/Dead	Pearson Correlation	-.048	.106	1	.373**	-.482**	.464**	-.042	.133	-.115	.041	.040
	Sig. (2-tailed)	.486	.120		.000	.000	.000	.542	.052	.094	.554	.559
	N	214	214	214	214	214	214	214	214	214	214	214
Regular Followup	Pearson Correlation	.046	.040	.373**	1	-.213**	.250**	.084	.069	-.062	.015	-.067
	Sig. (2-tailed)	.506	.564	.000		.002	.000	.219	.314	.364	.825	.328
	N	214	214	214	214	214	214	214	214	214	214	214
Need for Readmission	Pearson Correlation	-.041	-.079	-.482**	-.213**	1	-.666**	.129	-.099	.067	.157*	-.197**
	Sig. (2-tailed)	.555	.250	.000	.002		.000	.059	.148	.332	.021	.004
	N	214	214	214	214	214	214	214	214	214	214	214
Drug Compliance	Pearson Correlation	.104	.110	.464**	.250**	-.666**	1	-.073	.057	-.103	-.113	.192**
	Sig. (2-tailed)	.129	.108	.000	.000	.000		.286	.403	.133	.100	.005
	N	214	214	214	214	214	214	214	214	214	214	214
HTN	Pearson Correlation	.087	.012	-.042	.084	.129	-.073	1	-.155*	-.087	-.047	-.123
	Sig. (2-tailed)	.204	.862	.542	.219	.059	.286		.024	.206	.498	.074
	N	214	214	214	214	214	214	214	214	214	214	214
DM	Pearson Correlation	.014	.275**	.133	.069	-.099	.057	-.155*	1	-.339**	-.002	-.108
	Sig. (2-tailed)	.839	.000	.052	.314	.148	.403	.024		.000	.976	.114
	N	214	214	214	214	214	214	214	214	214	214	214
Smoking + Tobacco	Pearson Correlation	-.469**	-.036	-.115	-.062	.067	-.103	-.087	-.339**	1	.157*	.179**
	Sig. (2-tailed)	.000	.605	.094	.364	.332	.133	.206	.000		.021	.009
	N	214	214	214	214	214	214	214	214	214	214	214
Alcohol	Pearson Correlation	-.148*	.049	.041	.015	.157*	-.113	-.047	-.002	.157*	1	.068
	Sig. (2-tailed)	.031	.478	.554	.825	.021	.100	.498	.976	.021		.319
	N	214	214	214	214	214	214	214	214	214	214	214
Decrease in NYHA	Pearson Correlation	-.143*	-.101	.040	-.067	-.197**	.192**	-.123	-.108	.179**	.068	1
	Sig. (2-tailed)	.036	.140	.559	.328	.004	.005	.074	.114	.009	.319	
	N	214	214	214	214	214	214	214	214	214	214	214

**. Correlation is significant at the 0.01 level (2-tailed). *. Correlation is significant at the 0.05 level (2-tailed).

dosages. It was seen that patients that were not regular with the follow up had a significant need for readmission (p=0.02) and were also more likely to have mortality (p<0.001). 7(3.27%) of the 214 patients died, during the period of follow up, out of which 4 (1.9%) died due to myocardial infarction due to possible late stent thrombosis, 1 (0.5%) patient died due to pneumonia and the cause of death was unrelated to implicated cardiovascular condition in 2 (0.9%) patients i.e. road traffic accident and Intestinal Perforation.

The study also had a subgroup analysis depicted in Table 3, to come to conclusion on the nature of underlying disease and the need for multiple revascularizations.

As we can see, the combination of Hypertension (HTN) and Diabetes Mellitus (DM) and the combination of DM and smoking, both significantly affected the number of stents, i.e. these combinations led to a higher number of stents implanted. However, the

Table 3: Table depicting the correlation between various underlying mechanisms and need for revascularization

		HTN + DM	DM + Smoking	HTN +Smoking	No. of stents
HTN + DM	Pearson Correlation	1	1.000**	.147*	.214**
	Sig. (2-tailed)		0.000	.032	.002
	N	214	214	214	214
DM + Smoking	Pearson Correlation	1.000**	1	.147*	.214**
	Sig. (2-tailed)	0.000		.032	.002
	N	214	214	214	214
HTN + Smoking	Pearson Correlation	.147*	.147*	1	-.023
	Sig. (2-tailed)	.032	.032		.742
	N	214	214	214	214
No. of stents	Pearson Correlation	.214**	.214**	-.023	1
	Sig. (2-tailed)	.002	.002	.742	
	N	214	214	214	214

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

combination of HTN and smoking did not significantly impact the number of stents.

Discussion

This is a unique study, of it's kind, that has correlated the risk of having more stent implanted with various commonly diagnosed clinical cardiac risk factors like diabetes mellitus, hypertension, smoking and alcohol. This study also allays the apprehension behind the general notion in the cardiac interventionists' mind that more number of stents lead to more adverse prognosis and should be avoided even if suitable anatomy of coronaries is present, in favor of CABG.

Complete Revascularization (CR) defined anatomically as, all diseased arterial systems with vessel size ≥1.5 mm (2-2.25mm for PCI) with at least one significant stenosis >50% receive a graft or stent[10].

In the SYNTAX trial, a CR was obtained in 57% of the patients treated with PCI and in 64% patients with CABG and multivessel disease[11]. In our study, Complete revascularization was achieved in 82.2% (175 patients), while 17.8% patients had residual disease post-PCI. The greater degree of CR seen in our study may have been attributed to the greater level of competence and high case load at this center, and an easier, descriptive lesion and it's complexity description from our institute's grown classification system, the CALD-CODE system, that allows for greater number of vessels to be amenable to PCI[9].

Gender based differences in CAD, have attributed a greater percentage load of CAD in the male population, this was resonated in another study that was dedicated to the north Indian population with 3660 patients[12], our study focusing on the western population, in Ajmer, Rajasthan, India involving 214 patients resonated similar findings. In our study, also, male presentation was predominant accounting for 69.2% of the total study population. However, an important point to note is the distribution of the age groups, wherein, maximum patients were less than 70 years of age in the male population (86.48%), this can be hypothesis generating that patients with relatively younger age are more prone to undergo multiple stenting i.e. they may have diffuse disease/ multiple significant coronary lesions.

To the best of our knowledge, there has been no other study in the medical literature, that has evaluated the average decrease in symptoms based on NYHA classification., post PCI. In this regard, hence it is a novel study, as far as the English literature on such topics go. The average NYHA at presentation was 3.52 and the mean NYHA post PCI 1.103±0.3044 rounded off to NYHA class 1. It is of particular importance to note that none of the patients had to be continued or started with a metabolic modulator

for symptom-limiting angina. However all patients received anti-platelet agents and atorvastatin according to guidelines. These results are encouraging, to say the least, in favour of catheter based complete revascularization.

There have been no study till date, that have specifically evaluated multi-stent PCI peri-procedural complication rates, in this also, our study is a novel study. There have been research in the form of the ISCHEMIA trial[12] and the JCD-KiCS[13], both landmark trials that evaluated periprocedural complication rates. A total of 96 patients (5.8%) patients in ISCHEMIA-eligible group developed peri-procedural complications. In our study, peri-procedural complications occurred in only 1 patient (0.5%) in the form of Ostial RCA dissection. The low rate of periprocedural complication in our study can be attributed to the meticulous attention to detail to reduce complications along with the experience gained over several years of interventions, and with the use of the in-house CALD-CODE system that have lead to the right patient selection

Conclusions

Given the encouraging results of the study, with minimal complications, on one year follow up, we encourage the use of the CALD-CODE system in place of the SYNTAX score with many limitations, including not taking into account any clinical variable, normal anatomic anomalies, and assessment is based on pure visual interpretation and other semi-quantitative and subjective variables, which for even simple measures may be inaccurate. The CALD-CODE system uses fixed values and is easily interpretable and reproducible, thereby making it more relevant and convenient in present day interventional cardiology. This study also proves that using the CALD-CODE system, a greater number of patients are able to defer more complex and invasive CABG, and interventional cardiologists are able to achieve complete revascularization with appropriate lesion selection, with minimal complications even with multi-stenting strategy.

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