

Clinical Outcomes in Patients Undergoing Elective PCI of Cabg for Multivessel and Left Main Disease

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ABSTRACT

Introduction: Optimal revascularization strategy in patients with coronary artery disease remains a subject of debate between interventional cardiologists and surgeons. Numerous large scale randomized trials addressed this issue comparing coronary artery bypass grafting (CABG) with percutaneous coronary intervention (PCI) in patients with multivessel disease (MVD). The SYNTAX score has also established itself as an important prognostic tool in risk stratifying patients being considered for revascularization. The purpose of this study is to validate the appropriateness of SYNTAX score in management of multivessel disease in tertiary care center.

Material and methods: The study population included 30 patients subjected to coronary angiography that included male and female patients aged 45yrs-73yrs admitted in cardiology department. To qualify for participation in this study coronary angiography of multi-vessel disease and left main disease was compared based upon treatment plan of either PCI or CABG for 1 year. Out of the 30 patients 14 underwent CABG and 16 were subjected to PCI. Based on coronary angiography of patients SYNTAX score was calculated and analyzed retrospectively based on outcomes of immediate, early (<3m), late outcomes over a period of one year in both PCI and CABG groups.

Results: Out of 30 patients 24 were males and 6 were females. Of the 30 patients 16 patients underwent PCI with different drug eluting stents as mentioned in the chart and 14 patients underwent CABG. The descriptive statistics included variables like age with mean of 59.967, mean E.F. of 49.07, mean of number of lesions 3.700. The SYNTAX score had a mean of 18.233, mean Creatinine of 1.0167. In group statistics the p value is significant in cases of age (p=0.024), number of lesions (p=0.011), SYNTAX score (p=0.000), with non-significant values in variables like EF (P=0.865) and Creatinine (p=0.739). MACE occurred in 5 patients (16.66%): TVR in 3 (10%) with no MI, Stroke or death over a period of 1 year. The frequency of MACE was 40% in the high score group but was significantly higher than that in the low score group (60%). All these 5 patients presented with angina class III and all were subjected to coronary CT angiography and were found to have graft occlusion. Out of these five patients who developed angina after CABG 3 patients were managed medically one patient had to undergo redo surgery and one had to undergo graft stenting.

Conclusion: In the current observational, relatively small study, the SYNTAX score could be a useful tool to predict 1-year clinical outcomes in patients undergoing elective PCI of CABG for multivessel and left main disease.

Keywords: CABG, PCI, SYNTAX Score, MVD

gold standard for revascularization of LM-3VD.²⁻⁴ Recent randomized controlled trials have shown that overall major adverse cardiac and cerebrovascular events (MACCE) are lower with CABG than PCI in patients revascularized for unprotected LM-3VD. However, the outcomes of CABG and PCI were similar in patients who have focal disease with SYNTAX score ≤ 22 .⁵

Due to the more invasive nature and higher short term morbidity of CABG, PCI has been empirically considered a good alternative to CABG in patients who are deemed a high surgical risk. In clinical practice, surgical risk is defined by different criteria including age, general frailty and surgical risk scores.⁵ The latest guidelines for PCI recommend consideration of PCI over CABG in patients with LM-3VD who have favorable coronary anatomy for PCI when Society for Thoracic Surgeons (STS) score predicts operative mortality as $> 5\%$.⁶

The SYNTAX score (SXscore) has been recently developed as a combination of several previously validated angiographic classifications aiming to grade the coronary anatomy with respect to the number of lesions and their functional impact, location, and complexity.⁷ Higher SXscores, indicative of a more complex condition, are likely to represent a bigger therapeutic challenge and to have a potentially worse prognosis in patients undergoing contemporary revascularization with percutaneous coronary intervention (PCI).

So, for selection of patients for optimal revascularization quantification of the complexity of coronary artery disease (CAD), SYNTAX score takes into account not only the number of significant lesions and their location, but also the complexity of each lesion independently.

The predictive value of the SXscore was recently validated on a series of patients undergoing PCI for 3-vessel coronary artery disease in the Arterial Revascularization Therapies Study Part II.⁸

The SYNTAX score has also established itself as an important prognostic tool in risk stratifying patients being considered for revascularization. The SYNTAX score takes into account both the coronary anatomy and also the importance of the diseased coronary artery segment supplying the myocardium.

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INTRODUCTION

Optimal revascularization strategy remains a subject of debate. Numerous large scale randomized trials addressed this issue comparing CABG with PCI in patients with MVD.¹ Coronary artery bypass graft surgery (CABG) is the traditional

The purpose of this study was to validate the appropriateness of SYNTAX score in management of multivessel disease in tertiary care center.

MATERIAL AND METHODS

This study was done in Batra Hospital and Medical Research Centre (BHMRC), which is one of the premiere institutes of Delhi and a referral Centre of south Delhi, based on procedural volume and expertise in cardiovascular sciences.

The study population included 30 patients who were admitted with coronary artery disease who had NYHA class II-III angina and patients with acute myocardial infarction and cardiogenic shock were excluded. All the 30 patients were subjected to coronary angiography that included male and female patients aged 45yrs-73yrs admitted in cardiology department.

To qualify for participation in this study coronary angiography of multi-vessel disease and left main disease was compared based upon treatment plan of either PCI or CABG during year March 2012 - March 2013 and procedural data collected in BHMRC. Out of the 30 patients 14 underwent CABG and 16 were subjected to PCI.

Based on coronary angiography of patients SYNTAX score was calculated and analyzed retrospectively based on outcomes of immediate, early (<3m), late outcomes over a period of one year in both PCI and CABG groups. Information was also gathered on left main CAD, left main with DM, double or TVD and protected or unprotected left main CAD based on coronary angiography report.

History of diabetes, hypertension was based upon history taking and evaluation. Left ventricular systolic dysfunction was assessed based on echocardiography report. Additional data collected on whether CABG procedures utilised arterial, venous or both the grafts.

SYNTAX score forms the basis of this observational study. The score is calculated on the basis of various coronary angiographies of multivessel or left main disease which were taken up for either PCI or CABG and points were allotted on the basis of SYNTAX score algorithm mentioned later. Website www.SYNTAXscore.com was also used for this purpose of calculation. SYNTAX score was used to stratify early and late outcomes after PCI/CABG.

Analysis: Outcomes in terms of major adverse cardiac and cerebral events (MACCE) including death, stroke, documented nonfatal MI were analyzed in immediate, early (<3m) or late (<1yr) duration.

All patients when clinically indicated were subjected to either coronary angiography/CT coronary angiography to confirm status of the grafts. The subsequent findings will be discussed later.

STATISTICAL ANALYSIS

Data were expressed based on Mean, standard deviation with percentages for normally distributed parameters or median (interquartile ranges) for non-parametric parameters. Variables were compared with unpaired t-Tests, Fisher’s exact test, Chi-square test. Categorical data were analyzed using a chi-squared statistic (χ^2) or Fisher’s exact test for 2x2 comparisons.

RESULTS

A total of 30 patients included in this study according to inclusion and exclusion criteria during March 2012-March 2013. Out of 30 patients 24 were males and 6 were females. Of the 30 patients 16 patients underwent PCI with different drug eluting stents as mentioned in the chart and 14 patients underwent CABG. The descriptive statistics included variables like age with mean of 59.967 and standard deviation (S.D.) of 8.0107, mean E.F. of 49.07, S. D=10.319, mean of number of lesions 3.700 and S.D. of 1.6640. The SYNTAX score had a mean of 18.233 and S.D. of 9.9045, mean Creatinine of 1.0167 and S.D. of 0.17827. (table 1)

It shows 14.3% of females underwent CABG and 25.0% underwent PCI and 85.7% of males underwent CABG and 75.0% underwent PCI. 57.1% of CABG group and 43.8% of PCI group had Diabetes. shows 71.4% hypertensive

The Pearson Chi-square value of 0.741 with a degree of freedom 1. The continuity correction value of 0.231 and likelihood value of 0.748 with asymptomatic significance value of 0.631 and 0.387 respectively. The Fisher’s test value is 0.466 which is not significant.

Shows 71.4% of patients with total occlusion greater than 3m underwent CABG and 37.5% underwent PCI i.e. 10 out of total 14 in CABG group and 6 out of 16 in PCI group.

Pearson Chi-square value of 3.453 with asymptomatic significance (2-sided) value of 0.063 with degree of freedom of 1. the continuity correction and likelihood values are 2.225 and 3.534 with asymptomatic significance (2-sided) values of 0.136 and 0.060 respectively with degree of freedom of 1 each. The Fisher’s exact test value came out to be 0.081 which is not significant.

64.3% patients undergoing CABG (9 out of 14) had blunt stump

Variable	Studygroup	Number	Mean	Std. Deviation	T value	P value
Age	CABG	14	63.429	8.3732	2.387	0.024
	PCI	16	56.938	6.5061		
EF	CABG	14	48.71	10.709	-0.172	0.865
	PCI	16	49.38	10.308		
Number of Lesions	CABG	14	4.500	1.9904	2.722	0.011
	PCI	16	3.000	.8944		
Score	CABG	14	25.036	9.2351	4.568	0.000
	PCI	16	12.281	5.8962		
Creatinine	CABG	14	1.0286	.18576	0.337	0.739
	PCI	16	1.0063	.17689		

CABG group and PCI group variables are not significant with each other.

Table-1: Demographic details

Variable	CABG		PCI		Total	
	Number	%	Number	%	Number	%
Sex						
Female	2	14.3%	4	25%	6	20%
Male	12	85.7%	12	75%	24	80%
Total	14	100%	16	100%	30	100%
Diabetes						
Absent	6	42.9%	9	56.3%	15	50%
Present	8	57.1%	7	43.8%	15	50%
Total	14	100%	16	100%	30	100%
Hypertension						
Absent	4	28.6%	7	43.8%	11	36.7%
Present	10	71.4%	9	56.3%	19	63.3%
Total	14	100%	16	100%	30	100%

Table-2: Comparison of Gender, Diabetic and HTN in both groups.

Variable	CABG		PCI		Total	
	Number	%	Number	%	Number	%
Age of total occlusion greater than 3 months						
Absent	4	28.6%	10	62.5%	14	46.7%
Present	10	71.4%	6	37.5%	16	53.3%
Total	14	100%	16	100%	30	100%
Blunt stump						
Absent	5	35.7%	10	62.5%	15	50%
Present	9	64.3%	6	37.5%	15	50%
Total	14	100%	16	100%	30	100%
Bridging collaterals						
Absent	9	64.3%	15	93.8%	24	80%
Present	5	35.7%	1	6.3%	6	20%
Total	14	100%	16	100%	30	100%

Table-3: Comparison of age of occlusion greater than 3 months and surgeries in groups.

and 37.5% patients underwent PCI (6 out of 16). Pearson Chi square value of 2.143 with asymptomatic significance value of 0.143 with 1 degree of freedom. The continuity correction and likelihood ratio values of 1.205 and 20170 with asymptomatic significance value of 0.272 and 0.142 respectively with 1 degree of freedom which is not significant.

35.7% of patients with bridging collaterals underwent CABG (5 out of 14) and 6.3% underwent PCI (1 out of 16). Pearson Chi square value of 4.051 with asymptomatic significance (2-sided) value of 0.44. the continuity correction and likelihood ratio of 2.419 and 4.294 with an asymptomatic significance (2-sided) values of 0.120 and 0.038. The Fisher's exact test value is 0.072 which is not significant.

Patients were followed up on telephonic basis as well as subsequent visits to OPD or after being admitted about their wellbeing as well as regarding symptoms of angina, MI, stroke or need for revascularization process. Another patient with SYNTAX score of 11 was followed up with CT angiography for angina symptoms which showed occluded SVG to PDA graft, patent LIMA to LAD and SVG to OM grafts with significant stenosis in native mid RCA involving a long segment. Another patient with a SYNTAX score of 37 had to undergo redo surgery for graft occlusion.

Another patient with a SYNTAX score of 15 also had graft occlusion post CABG for which the culprit graft had to be stented. Another patient with a SYNTAX score of 21 also suffered graft occlusion diagnosed with CT angiography after the patient complained of angina class III and was admitted for

angina symptoms and was managed medically.

Another patient with a SYNTAX score of 43.5 with CAD-TVD post CABG, patent LIMA to LAD graft, occluded SVG to OM2, SVG-OM2 graft as was observed after CT angiography which was done after the patient complained of angina 4m after CABG. This patient was managed medically.

MACE occurred in 5 patients (16.66%): TVR in 3 (10%) with no MI, Stroke or death over a period of 1 year. The frequency of MACE was 40% in the high score group but was significantly higher than that in the low score group (60%). All these 5 patients presented with angina class III and all were subjected to coronary CT angiography and were found to have graft occlusion. Out of these five patients who developed angina after CABG 3 patients were managed medically one patient had to undergo redo surgery and one had to undergo graft stenting. Rest all the patients were doing fine and did not suffer from complications like restenosis, MI, CVA or death during the 12month follow-up.

DISCUSSION

The main finding of this study was that the SYNTAX score could be a useful as a predictor of 1-year clinical outcomes in patients undergoing elective PCI/CABG for multivessel or LMCA disease.

This score does not account for the type of graft anastomosed and the characteristics of the graft disease (if present). In the present study complications of graft occlusion was seen with SVG grafts only.

In our study 5 patients who underwent CABG had graft occlusions within a follow up of 3 months which can be attributed to various technical reasons as well as graft thrombosis like usage of saphenous venous grafts. All the complications noted above were observed within 3 months of CABG. One year after coronary surgery, 10% to 20% of saphenous vein grafts fail. Saphenous vein graft failure during the first year of surgery is due to technical errors, thrombosis, and intimal hyperplasia. All saphenous vein grafts experience endothelial damage during harvesting and initial exposure to arterial pressure. This intimal injury leads to platelet adherence that may result in graft thrombosis and acute occlusion. Platelet adherence to the intimal surface is also the initial event in the development of intimal hyperplasia. After adhering to the intima, platelets release mitogenic proteins, stimulating smooth muscle cell migration, resulting in intimal proliferation and hyperplasia. No major complications were observed in patients undergoing PCI. In our short term limited study the patients undergoing PCI with stenting to left main which is 80% stenosed in distal part with a syntax score of 26 fared better without any complications. This study, however, short term with limited power does emphasize that patients undergoing PCI to multivessel or even left main stenting is feasible and is a good option over CABG. This could be attributed to optimal medical management and with the advent of second and third generation drug eluting stents.

The potential clinical applications of the score include long term risk stratification of patients who have previously undergone CABG to aid in the identification of a group at high risk for future clinical events and repeat revascularisation.

Other potential applications of the SYNTAX score is in research setting to include allowance of incorporation of CABG patients into stent trials measuring the score.

In the SYNTAX trial, CABG was associated with a lower rate of major adverse cardiac and cerebrovascular events at 1 year in patients with 3-vessel disease or LMCA disease as compared with PCI.⁹ Furthermore, in the SYNTAX trial, subgroup analysis of patients with LMCA disease showed that PCI had safety and efficacy outcomes comparable to those attained with CABG at 1 year.¹⁰ However, in another previous study that examined the usefulness of SYNTAX score in patients undergoing PCI for LMCA disease, high SYNTAX score was significantly associated with cardiac mortality and MACE.¹¹ Consistent with previous reports, our findings showed that high SYNTAX score was associated with the development of MACE.

Capodanno et al. reported that score 37 was the optimal cutoff value to distinguish between patients at low and high risk of MACE.¹¹ Nevertheless, a SYNTAX score 26 was associated with the development of MACE in this study. This difference between the previous study by Capodanno et al. and the present study was due to a difference in the number of patients with LMCA plus multivessel disease. Patients with LMCA plus 2-vessel or 3-vessel disease accounted for 31% (79/255) and 22% (55/255) of the study population in Capodanno's study and for 12% (6/49) and 4% (2/49) in our study. The present results are in agreement with a recent study showing a SYNTAX score 28 as the optimal cutoff value for predicting MACE in patients undergoing PCI for unprotected LMCA disease.¹²

The most recent guidelines on myocardial revascularization

have recommended the SYNTAX score as a risk stratification score to be used in candidates for PCI (class IIa, level of evidence B) but not in those for CABG (class III, level of evidence B).² This ability to identify patients at a high risk for the occurrence of adverse events has important clinical implications. It enables physicians to adequately inform their patients regarding the potential risk of adverse events and the selection of a revascularization procedure (PCI vs. CABG).

CONCLUSION

The result of our trial shows that multivessel PCI may be a suitable alternative to CABG in select group of patient, especially with introduction of second and third generation drug eluting stents. Nevertheless, drug eluting stents may also be associated with complications, particularly stent thrombosis, and it has yet to be proven in a randomized trial that the hard end points of death, repeat revascularization, cerebrovascular accidents and myocardial infarction are the same with both revascularization techniques.

The SYNTAX score will provide a solid dataset to assess the various issues in left main and multivessel disease and will set new guidelines for patients in the future.

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