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Original Research Article

Complex coronary intervention outcomes: real world left main coronary artery angioplasty experience from a tertiary care center in South India

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ABSTRACT

Background: Left Main Coronary Artery (LMCA) Disease is among the most complex forms of the coronary artery stenosis, the leading cause of mortality in the world.
Methods: In this analysis, 102 patients with elective angioplasty for LMCA stenosis with PCI from 6/2013 to 5/2016, 3 years (70 in GenxSync™ arm and 32 in other devices arm; 100 DES and 2 BMS) were included. RADHIKa Analysis compared post-hoc subgroups of GenxSync™ and control groups.
Results: Mean population age was 59.99±12.03 years; 60.27±10.49 years in GenxSync™ arm, and 58.31±14.32 years in control arm. A significant population (44, 43.14%) had diabetes, renal impairment (14, 13.73%) and hypertension (25, 24.51%). The MACCE in GenxSync™ arm was 17 13(18.58%) Versus 5(15.63%) [RR=0.93, RR'=-0.07, ψ=-14.01. p=0.3). Most patients presented with unstable Angina (41, 40.20%) in all, 31(44.29%) in GenxSync™ and 10 (31.25%) in Control arm. AWMI and IWMI were 18, 17.65% each, attributed to 12 (17.14%) in GenxSync™ 6 (18.75%) in Control. Effort angina was 15(21.43%) in GenxSync™ and 10 (31.25%) in Control and NSTEMI was 25,24.51% (18 (25.71%)- GenxSync™ 7(21.88%) Control). The MACE in GenxSync™ arm at 24, 12 and 6 months was 12(17.15%), 8(11.43%) and 4(5.71%) respectively versus corresponding MACE in the control arm as 5(15.63%), 2(2.86%) and 2(6.25%) respectively. The TVR was present only in GenxSync™ Arm, which was contributed by 2 CABGs and 12 months and 1 additional PCI at 24 months.
Conclusions: In real-world scenario of LMCA cases, performance and safety of various stents were similar. GenxSync™ Sirolimus Eluting Stent, in the post-hoc bifurcation had results similar to other real-world cases, based upon RADHIKa analysis.

Keywords: Complex angioplasty, Complex PCI, Drug eluting stent, GenxSync, left main angioplasty, Left main coronary artery stenosis, LMCA stenosis

INTRODUCTION

Left Main Coronary artery (LMCA) disease is among the most complex forms of the coronary artery stenosis, the

leading cause of mortality in the world. In the current scenario, there is still an ambiguity of choice between coronary-artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) for LMCA disease, earlier being more widely accepted treatment.[1] Coronary artery being the main artery supply to the myocardium, its stenosis leads to major myocardial damage.[2] Most recommended of strategy for LMCA stenosis treatment is coronary artery bypass graft (CABG) and PCI is recommended as an alternative to in patients with higher risk for surgical complication or low risk of PCI procedural complications or both.[3-5]

The basic guidelines are based upon a few studies randomized between these two strategy groups.[6,7] In the LMCA Stenosis treatment, has several complications post intervention, like any other stent implant procedure. In addition to Major Adverse Cardiac Events (MACE) which includes cardiovascular death, target vessel revascularization and myocardial infarction, additional consideration is required for cerebrovascular accidents (together called major adverse cardiac and cardiovascular events or MACCE).[8]

However, evidence level of both, PCI or CABG in LMCA treatment is yet limited that warrants addition of new evidence in favor of either of the treatment strategies. The enthusiastic cardiologists who opted treating left main artery with PCI including stent implant have further built further evidence on PCI and CABG as a treatment for LMCA stenosis.[9] This Evidence was comprised of LMCA Subsets of a few large randomized studies such as SYNTAX and some LMCA PCI specific studies.[10-13] In addition to the data from single studies, meta-analysis of multiple studies is a major contributor to the evidence of LMCA stenosis treatment.[11,14]

India being among the most populated geographies in the world, the cases of LMCA stenosis are also proportionately high in numbers. Based upon this aspect, we decided to evaluate the data of LMCA angioplasty that were performed in our hospital, a tertiary care center in South India.

METHODS

In this analysis, 102 patients were included, who were treated with elective angioplasty for LMCA stenosis with PCI from 6/2013 to 5/2016, the period of 3 years. It included 100 cases of DES and 2 cases of BMS intervention. In the records, 70 (68.63%) patients were found to be treated with sirolimus eluting stent for all lesions. Zotarolimus and everolimus eluting stent was implanted 15 (14.71%) patients each and Bare Metal Stent (BMS) was inplanted in 2 patients (collectively called "Others" for this study). The longest follow-up was conducted at 2 years. All the subjects were older than 18 years. Both males and females were included in the study. All the subjects had minimum one lesion within LMCA or extended to one or both branches. All types of patients having single vessel disease, double vessel disease or triple vessel disease were included. The subjects who underwent PCI with stenting by any stent were included in the analysis. However, the patients who had LMCA lesion but did not undergo PCI for LMCA lesions were not included in this analysis.

Record of all subjects was fetched from the hospital records and was collected in an excel spreadsheet. The entered data was crosschecked with the patient files by the investigator. Data was cleaned for record inconsistency for common errors such as spellings and typo errors. No records were excluded for any reason.

The data was analyzed with Minitab Software for descriptive statistics and significance. A post hoc analysis of power with average age as the representative demographics was performed. All the analysis was performed by independent statistician.

As the groups were disparate, the comparisons were performed using innovative RADHIKa Analysis, which provides a bias-free comparative analysis even in retrospective and fetched data or historical data. In the Radhika analysis, the population, mean age, proportion of hypertension, proportion of renal impairment and baseline creatinine were used as the demographic predictors, proportions of anterior wall MI, inferior wall MI, effort angina, TMT positive, unstable angina and NSTEMI were used as disease characteristic based predictors and proportions of ostial-LMCA, complete LMCA, LMCA stenosis with triple vessel disease, LMCA stenosis with double vessel disease and isolated LMCA were taken as the angiographic predicators of the MACCE. Stent diameter and length with large diameter and long length proportions ware taken as device oriented predicators. As a method, the RADHIKa ratio was expected to be 1 or close to 1.

As a result, RADHIKa analysis returns a vertical box plot with dark and light boxes. The dark boxes signify uphill coordination and dark box signifies downhill coordination. The box plot dimensions indicate the tendency of the parameter along with the difference in two arms. The tails of the box indicate significance of the outcome in each direction. The white boxes above line of unity and dark boxes below line of unity signify denominator (control) performing better.[15]

RESULTS

The post-hoc power calculation of the study was performed with Minitab Software and was observed as 93% (Figure 1). In all 102 patients (70 in GenxSync™ Arm and 32 in Other arm) of left main coronary artery stenosis were included in the cohort. The population had a mean age of 59.99±12.03 years. In GenxSync™ arm, the mean age was 60.27±10.49 years and in control arm, it was 58.31±14.32 years. A Significant number of

patients (44, 43.14%) had diabetes, renal impairment (14, 13.73%) and hypertension (25, 24.51%). (Table 1).

Table 1: Baseline demographics.

	GenxSync™	Others
N	70	32
Age (Mean ±SD)	60.27±10.49	58.31±14.32
Hypertension (n, %)	22 (31.43%)	3 (9.38%)
Baseline creatinine (Mean ±SD)	1.04±0.38 %	1.23±0.95
Impaired renal function	5 (7.14%)	9 (28.13%)
Diabetes (n, %)	29 (41.43%)	15 (46.88%)

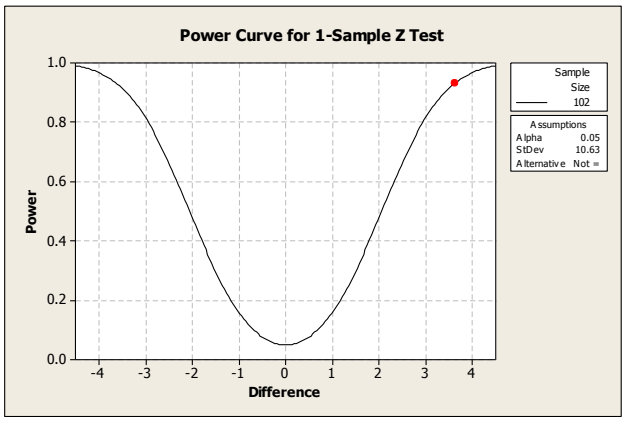

Figure 1: Post-hoc power calculation for sample size 102 using age as parameter.

A majority of patients had unstable angina (41, 40.20%) as the primary presenting diagnosis of which 31(44.29%) were in GenxSync™ arm and 10 (31.25%) were in control (others) arm. Anterior wall MI and Inferior wall MI was observed in equal numbers in both arms (18, 17.65%), of which 12 (17.14%) were in GenxSync™ and 6 (18.75%) in others arm. The effort angina contributed by 15 (21.43%) in GenxSync™ arm and 10(31.25%) in others arm and NSTEMI, (25,24.51% each) contributed by 18 (25.71%) in GenxSync™ arm and 7(21.88%) in others arm. P-value <0.001 (Table 2, Figure 2).

Table 2: Presentation of cardiac disease at baseline.

	GenxSync™	Others
Anterior wall MI (n, %)	12 (17.14%)	6 (18.75%)
Inferior wall MI (n, %)	12 (17.14%)	6 (18.75%)
Effort angina (n, %)	15 (21.43%)	10(31.25%)
TMT positive (n, %)	16 (22.86%)	8 (25.00%)
Unstable angina (n, %)	31(44.29%)	10 (31.25%)
NSTEMI (n, %)	18 (25.71%)	7(21.88%)

All the subjects had Left main coronary artery lesion, as the inclusion criterion. Disease characteristics were defined by lesion location and complexity was defined by the number of vessels involved in the lesion. The LMCA wasaffected in Ostial segment in 13 (18.57%) patients in GenxSync™ Arms and 12 (37.5%) patients in others arm. The Mid-LMCA lesions were in 5 (7.14%) patients in Genx Sync arm alone. The maximum lesions ere located in Distal LMCA contributed by 45 (64.29%) in GenxSync™ arm and 21 (65.63%) others arm. There were 1 (1.43%) lesion each in Mid and distal LMCA and the complete LMCA in GenxSyc arm, whereas, 2 lesions were present in Otial and Mid LMCA in GenxSync™ arm. The control arm had no lesion in these segments. (Table 3).

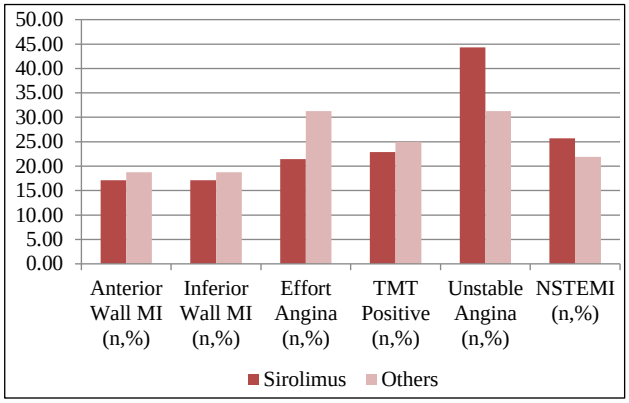

Figure 2: Presenting features of the disease.

Table 3: Comparative presentation of SES and others in disease characteristics.

	GenxSync™	Others
Ostial - LMCA (n, %)	13 (18.57%)	12 (37.5%)
Mid-LMCA (n, %)	5 (7.14%)	0 (0%)
Distal LMCA (n, %)	45 (64.29%)	21 (65.63%)
Ostial and mid LMCA (n, %)	2 (2.86%)	0 (0%)
Mid and distal LMCA (n, %)	1 (1.43%)	0 (0%)
Complete LMCA (n, %)	1 (1.43%)	0 (0%)
LMCA stenosis with tripple vessel disease (n, %)	10 (14.29%)	14.29 (7%)
LMCA stenosis with double vessel disease (n, %)	16 (22.86%)	22.86 (9%)
LMCA stenosis with single vessel disease (n, %)	16 (22.86%)	22.86 (5%)
Isolated LMCA disease	25 (35.71%)	35.71 (11%)

All the patients who underwent PCI to the LMCA lesions were included in the analysis. In 36 (34.29%) patients stent were implanted in LMCA only of which 25 (34.72%) were in GenxSync™ arm and 11 (33.33%) were in Others arm. Extended segment stent implant was performed in 69 (67.64%) patients, of which 11 (10.48%) were in circumflex and majority (58-55.24%) were extension to LAD. In 10 patients (7.94%) 2 stents were used, 26 (20.63%) patients underwent PTCA to RCA or

Ramus and 90 (71.43%) PCIs were provisional stenting (Table 4). The post-operative period of all the patients was uneventful and all the patients were discharged in a stable condition. The mean stent diameter was 3.55±0.29 mm and men stent length was 20±19.61%. the diameter size ranged from 3.0mm to 4.00mm, with 65 (65.66%) patients receiving 3.5 mm diameter stents, 12 (12.12%) had 3.0mm diameters stents and 22 (22.22%) patients had 4.0mm stents. In all 20 (19.61%) patients had long stents (size > 30mm). The stent diameter in GenxSync™ was 3.58±0.29mm and in others was 3.48±0.296%mm. The 3.0mm stents in GenxSync™ arm were 9 (13.24%) and 3 (4.41%) in others arm. 3.5mm stents were 39 (57.35%) in GenxSync™ arm and 26 (38.24%) in others arm. The 4.0 mm stents were 20 (29.41%) in GenxSync™ arm and 2 (2.94%) others arm. Stent length in GenxSync™ arm was 23.69±7.89mm and in others arm it was 24.84±7.89mm. There were 13 stents (18.57%) in GenxSync™ arm above 30mm of length. (Table 5).

Table 4: Comparative presentation of SES and control arms.

	GenxSync ™	Others
Stenting location		
Stenting to LMCA	25(34.72%)	11(33.33%)
Stenting LMCA to LAD	39(54.17%)	19(57.58%)
Stenting LMCA to LCX	8 (11.11%)	3 (9.09%)
Strategy		
PTCA to RCA or ramus	18 (20.93%)	8 (20%)
2_stents stetegy used	8 (9.31%)	2 (5%)
Provisional stenting strategy used	60(69.76%)	30(75%)

Major adverse cardiac and cerebrovascular events (MACCE), the parameters of safety and performance in patients of LMCA PCI was observed at 2 years after PCI. The overall MACCE at 2 years was 18 (34.21%) and the MACE was 15 (26.53%) Table 7. The MACCE in GenxSync™ arm was 17 13(18.58%) versus 5(15.63%) [RR=0.93, absolute risk ratio RR'= -0.07, ψ=-14.01. p=0.3) (Table 09). The MACE in GenxSync™ arm at 24, 12 and 6 months was 12(17.15%), 8(11.43%) and 4(5.71%) respectively versus corresponding MACE in the control arm as 5(15.63%), 2(2.86%) and 2(6.25%) respectively. The TVR was present only in GenxSync™ Arm, which was contributed by 2 CABGs and 12 months and 1 additional PCI at 24 months (Table 6). Ratio-based conjugate analysis-RADHIKa The RADHIKa Analysis of precursors has the standardized ratio outcome (ψ) as 5.07, meaning that the control arm was more stringent in demographics and disease characteristics. The Radhika analysis of MACE at 24, 12 and 6 months respectively returned the RR' 0.20, 0.10 and 0.03 respectively, which meant that the GenxSync™ arm had safety and efficacy as various devices which are representative of the standard therapy in the control arm (Table 8, Figure 3).

Table 5: Device details-entire cohort.

Device details		
Stent type		
Sirolimus eluting stent (n, %)	70	68.63
Everolimus eluting stent (n, %)	15	14.71
Zotarolimus eluting stent (n, %)	15	14.71
BMS (n, %)	2	1.96
Stent Diameter (Mean ±SD)	3.55	0.29
3.0 mm (n, %)	12	12.12
3.5 mm (n, %)	65	65.66
≥4.0 mm (n, %)	22	22.22
Stent length (Mean ±SD)	24.051	7.89
Length >30	20	19.61

Table 6: Comparative presentation of device details SES and others.

	GenxSync ™	Others
Stent diameter (Mean±SD)	3.58(0.29%)	3.48 (0.296%)
3.0 mm (n, %)	9 (13.24%)	3 (4.41%)
3.5 mm (n, %)	39 (57.35%)	26 (38.24%)
≥4.0 mm (n, %)	20 (29.41%)	2 (2.94%)
Stent length (Mean±SD)	23.6(7.89%)	24.84 (7.89%)
Length >30	13 (18.57%)	0 (0%)

Table 7: Hierarchical cummulative MACCE at 6, 12 and 24 months-comparative presentation.

	GenxSync™			Others		
	24 months	12 months	6 months	24 months	12 months	6 months
MACE (n, %)	12(17.15%)	8(11.43%)	4(5.71%)	3(9.38%)	2(2.86%)	2(6.25%)
MACCE (n, %)	13(18.58%)	8(11.43%)	4(5.71%)	5(15.63%)	2(2.86%)	2(6.25%)
Death (n, %)	3(4.29%)	2(2.86%)	2(2.86%)	2(6.25%)	1(1.43%)	1(3.125%)
MI (n, %)	6(8.58%)	4(5.71%)	2(2.86%)	1(3.13%)	1(1.43%)	1(3.125%)
Target vessel revascularization (n, %)	3(4.29%)	2(2.86%)	0(0%)	0(0%)	0(0%)	0(0%)
CABG (n, %)	2(2.86%)	2(2.86%)	0(0%)	0(0%)	0(0%)	0(0%)
Repeat PCI (n, %)	1(1.43%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Cerebrovascular accident (n, %)	1(1.43%)	0(0%)	0(0%)	2(6.25%)	0(0%)	0(0%)

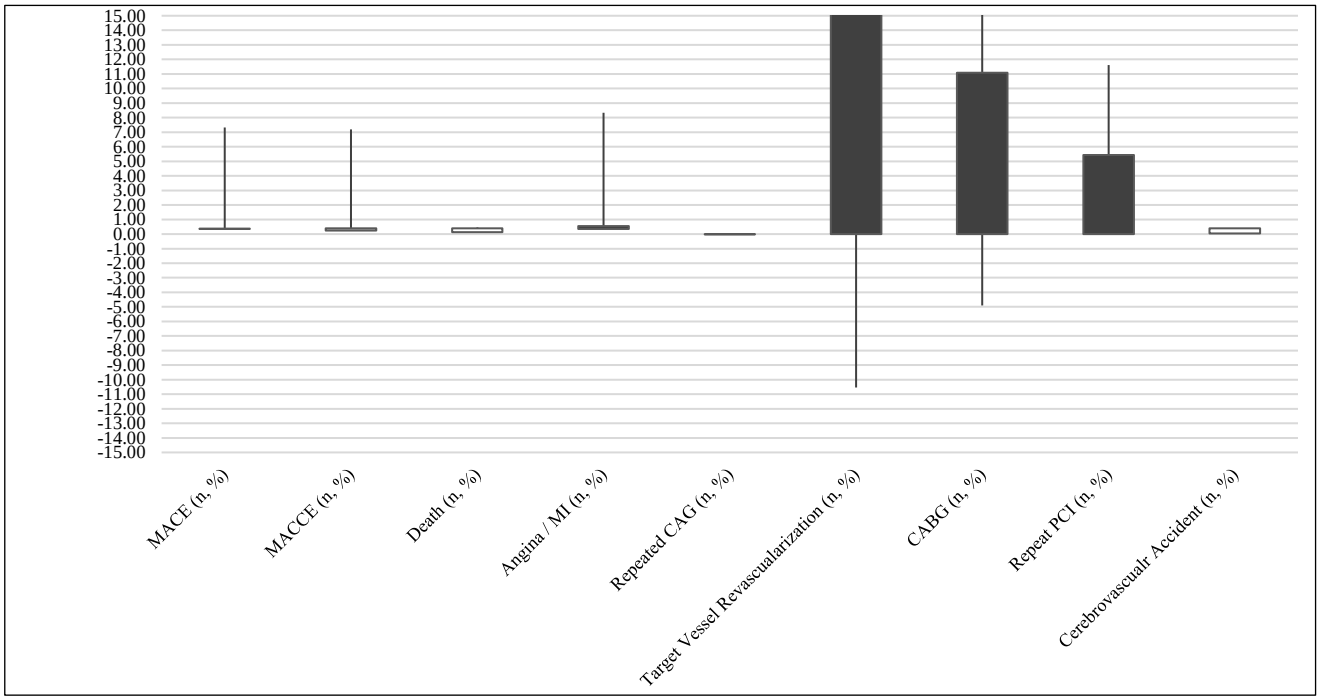

Figure 3: RADHIKa analysis of outcomes at 24 months.

The analysis can be better explained by graphical representation in Figure 3.

Table 8: Radhika score calculation-precursors.

Precursor	R
Number of participants	2.19
Age	1.01
Hypertension	3.37
Baseline creatinine	0.84
Impaired renal fucntion	0.26
Diabetes	0.89
Effort angina	0.69
Tmt positive	0.92
Unstable angina	1.42
NSTEMI	1.18
Ostial - LMCA	0.5
Ostial and mid LMCA (n, %)	56.15
Complete LMCA	27.58
Lmca stenosis with tripple vessel disease	0.66
Isolated lmca disease	1.04
Stenting LMCA to LAD	0.95
Stenting LMCA to LCX	1.23
2_stents stetegy used	1.87
Provisional stenting strategy used	0.94
Stent diameter	1.03
Diameter > / = 4.0 mm	10.16
Stent length	0.96
Length > 30	0.85
Radhika ratio (ψ)	5.073478

Table 9: RADHIKa analysis for MACE and MACCE along with components at 6, 12 and 24 months.

	Absolute Risk Ratio (RR')		
	24 months	12 months	6 months
MACE (n, %)	0.36	0.37	0.18
MACCE (n, %)	0.23	0.39	-0.03
Death (n, %)	0.13	0.40	-0.03
Angina / MI (n, %)	0.55	0.34	-0.03
Repeated CAG (n, %)	0.00	0.00	-0.03
Target vessel revascularization (n, %)	16.71	0.00	-0.03
CABG (n, %)	11.08	0.00	-0.03
Repeat PCI (n, %)	5.44	0.00	-0.03
Cerebrovascular accident (n, %)	0.04	0.40	-0.03

As per the analysis, at 24 months, the GenxSync™ was marginally better than the control arm devices in MACE, MACCE, and cerebrovascular accidents, while, it was clearly better in deaths. The control arm was relatively better in target vessel revascularization.

Considering various time-point analyses with RADHIKa, GenxSync™ was throughout better in safety in terms of MACE, MACCE, deaths, MI and cerebrovascular accidents. While, the performance in terms of target vessel revascularization is better in control arms at 12 and 14 months. At 6 months there was no TVR.

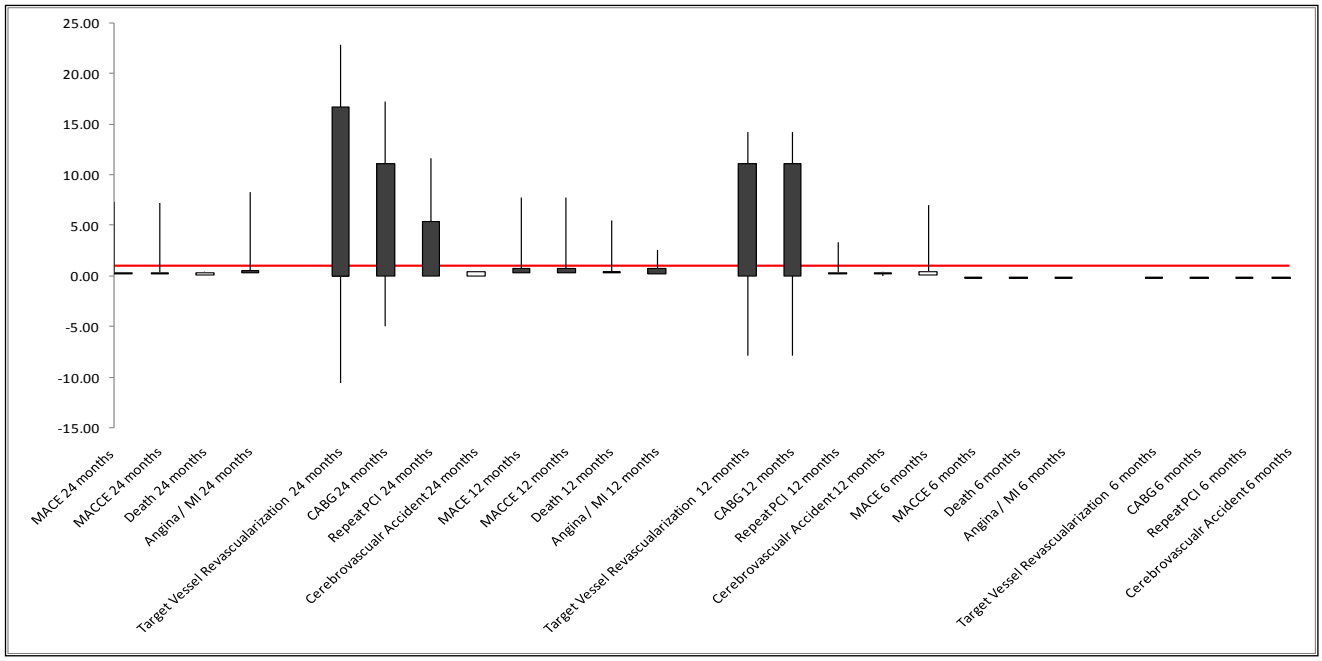

Figure 4: RADHIKa analysis representation up to 24 months.

DISCUSSION

The left main coronary artery (LMCA) has been a challenge in revascularization pertaining to its immediate and late outcomes. Tirchoh K et al, have demonstrated the anatomy of LMCA, especially true bifurcation lesions among the major contributor of the complexity in the coronary artery intervention and its outcomes.

In the study of 607 patients undergoing unprotected LMCA PCI, the rate of cardiac deaths was reported as 5.8% at 3 years, while TLR rate was 27%.[16] Tan Q et al, conducted a study in 123 patients of LMCA stenosis with age more than 70 years. The intervention procedure was randomized between IVUS guided versus non-IVUS guided intervention. Two year MACE in this study was 42.4% while the IVUS guided arm remained much better than the other. In TLR also, IVUS arm performed better as compared with other arm, with a total MACE of 15.6%. However, both arms have similar safety profile as Indicated by the incidence of death and MI in the 2 groups.[17] Chen SL et al, examined various Intervention methods in DKCRUSH-III study, in which at 3 years, MACE rate was 31.9%. In the current group, the relative complexity was similar with significant number of Bifurcations and different 2 stent techniques. Hence, the 26.43% MACE in this group was justified in the similar lines.

As this study did not have comparative design, to establish correct and unbiased relative inferences, ratio-based standardization methodology called RADHIKa. The original Article of RADHIKa was published by Indani A et al justifying its utility and robustness. correctness of the method was proven by using comparison between two arms of randomized SPIRIT III study. The analysis was also conducted in various device studies and its validity was observed.[15] The RADHIKa comparison of the outcomes at various time points was performed. The outcomes of the RADHIKa analysis demonstrated that in comparative analysis, the control devices were almost equivalent in demographics, or rather the GenxSync™ arm was little more stringent. Whereas the comparative standardized analysis demonstrated the results of performance same as control with a little better safety profile.

CONCLUSION

Group had complex and a real-world scenario of LMCA cases. The outcomes of various stents were similar pertaining to performance and safety. GenxSync™ sirolimus eluting stent as a device under evaluation, in the post-hoc bifurcation has results similar to other real-world cases.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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