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Research Article

Safety and efficacy of hybrid platform design sirolimus eluting stent system in percutaneous coronary intervention in ST elevation myocardial infarction patients at 1 year after treatment

Louie Fisher[1]*, Anoop Mathew[1], Eapen Punnose[1], Ashish Indani[2], Poonam Bhutada[3]

[1]Department of Cardiology, MOSC Medical College Hospital, Kolenchery, India
[2]Tata Consultancy Services, Mumbai, India
[3]Krishnamugdha Institute of Advanced Learbing and Research, Mumbai, India

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***Correspondence:**
Dr. Louie Fisher,
E-mail: drlouiefischer@yahoo.com

ABSTRACT

Background: STEMI is among the most complex and dramatic clinical presentation of coronary artery disease. The highest risk of mortality and stent thrombosis is observed in the subjects undergoing primary PCI. Choice of stent is often critical in Primary Angioplasty in Myocardial Infarction. GenXsync (MIV Therapeutics India Ltd, Surat India) is a stent having hybrid stent platform biodegradable polymers with the confidence of Sirolimus. The primary objective of this study was to establish safety and efficacy of GenXsync Sirolimus Eluting hybrid design stent in STEMI.

Methods: A total of 73 patients of STEMI undergoing PCI were enrolled from June 2013 to January 2014. The average door to balloon time was 30±0.04 minutes with the minimumbeing15 minutes and maximum of 2 hours 44min. Most of the patients (69/ 73: 94.52%) underwent primary PCI. One patient (1.37%) was taken up for PCI after successful thrombolysis and two patients had to undergo rescue PCI after failed thrombolysis. All subjects underwent PCI with GenXsync Sirolimus Eluting hybrid design stent. Total 79 stents were used (average 1.08±0.38 stent per patient). The subjects were followed up for one year after discharge.

Results: There were 80.82% (59) males, 41.09% (30) diabetic, 27.39% (20) hypertensive, 52.05% (38) current smokers and 2 (2.74%), patients with chronic renal disease. The cardiac history was significantly complex, characterized by prior coronary artery disease in 4 (5.48%), prior MI in 5 (6.85%) including prior PCI in 2 (2.74%), congestive heart failure in 1 (1.37%), ST depression in 71 (97.26%), complete heart block in 4 (5.48%) and left bundle branchblock 1 (1.37%). At admission, 4 (5.4%) patients had cardiac arrest. Among the patients 32 (43.84%), 34 (46.58%), 7 (9.59%) had single, double and triple vessel disease respectively. Average Troponin I was 55.20± 59.34 and by Killip classification, the subjects with class I, class III and class IV were 65 (89.04%), 4 (5.48%), 4 (5.48%) respectively. At discharge there were 3 (3.34%) Major adverse cardiac events and at 1 year, there were 5 (5.48%) major adverse cardiac events. There were no acute stent thromboses. All subjects received dual antiplatelet therapy for one year (Aspirin and one among Clopidogrel, Prasugrel or Ticagrelor at the discretion of the operator). There were total of 2 (2.74%) stent thrombosis events between discharge and 1 year, including in 1 subject who discontinued Antiplatelet therapy within 1 year. None of 4 deaths including 2 cardiac were practically related with the device and procedure. These 4 deaths were due to cardiogenic shock (1), during MVR surgery (1), During surgery on leg, due to major bleeding (1) and Due to pre-existing CHF (1).

Conclusions: In contemporary practice of percutaneous coronary intervention in ST Elevation Myocardial Infarction, Genxsync stent was associated with low risks of stent thrombosis and MACE.

Keywords: GenXsync, STEMI, Drug eluting stent, MACE, Acute coronary syndrome, Stent thrombosis

INTRODUCTION

With the publication of the classical metaanalysis by Keeley et al, the superiority of primary percutaneous coronary interventionhas been well established even in patientstransported from a non-interventional hospital to anintervention centre for primary PCI.[1] Subsequently with the refinement of techniques and improvement in periprocedural pharmacotherapy the reduction in MACE became more evident.

However the vexing issue of target vessel revascularisation and restenosis also became a matter of concern. Drug eluting stents heralded an era of marked reduction in TVR and restenosis. First-generation drug-eluting stents (DES), which impart the controlled release of sirolimus or paclitaxel from durable polymers to the vessel wall, have been consistently shown to reduce the risk of restenosis and target vessel revascularization compared with bare metal stents (BMS).[2]

But some of the metaanalysis have shown that first generation DES are associated with increased incidence stent thrombosis compared to BMS.[3] Late acquired stent malapposition, incomplete stent endothelialisation, fibrin deposition and persistent inflammation have all been suggested as the potential causative factors. To circumvent this Achilles heel of stent thrombosis, various strategies like newer antiproliferative drugs and better biocompatible polymers have been advocated.[4]

There is ongoing debate as to which stent platform among DES is superior in PPCI.In a study comparing various stents with identical structures, platforms and release kinetics but different anti proliferative agents—everolimus, sirolimus or zotarolimus —has shown similar outcomes, thus suggesting that platform rather than the drugs determine the outcomes, it is an impact of stent strut design in metallic stents and biodegradable scaffolds.[5]

At present, primarily two metal materials are used as stent struts: stainless steel and alloys. Stainless steel is a biologically inert metal and was the first material used in the design of coronary stents. In the era of BMSs, evidence suggested that a low stent strut thickness improved the safety of the stent.[6] Therefore, metallic alloys, such as cobalt–chromium (CoCr), were developed with increased levels of radio opacity and strength, allowing struts to be much thinner .(Drug eluting stents: developments and current status.[7]

However, some alloys are associated with higher elastic properties and greater stent recoil, which might be disadvantageous clinically LEADERS trial could establish the major difference of stent thrombosis between a first generation stent with durable polymer with a third generation stent with biodegradable polymer.[8] In this trial, the BioMatrix flex (TM) stent with biodegradable polymer had 1.5% Cardiac deaths as compared with 6.4% of the Cypher Select+ stent with Durable polymer. MI was 2.2% is BES vs. 5% in SES and TVR was 5.9% BES Vs. 12.1% in the SES arm. The Cardiac Death and MI composite endpoints, the indicators of DES safety and frequent manifestation of stent thrombosis (ST) was 3.7% in BES Vs 10% is SES.[9]

In the present study, we collected and processed the data of 73 consecutive patients with STEMI undergoing PCI at a tertiary care centre in south India. In addition, we studied the door to time balloon and its effect on the study outcome at 1 year from PPCI in STEMI. To keep the stent platform uniform, all subjects underwent PCI with implant of GenxSyncSirolimus eluting hybrid design stent (MIV therapeutics-India). Thereby, we could establish safety and efficacy of GenxSync Stent.

METHODS

This study was performed in a tertiary care in South India. In all, 73 consecutive patients of STEMI undergoing PCI were enrolled from June 2013 to January 2014. All the subjects underwent Standard PCI with implantation of GenxSync Stent. The intra-operative and post-operative treatment was similar in all the patients. We tried to monitor and minimize the door to balloon time.

The laboratory and clinical investigations included evaluation of ECG and cardiac enzymes, Blood sugar, glycosylated hemoglobin and serum creatinine for all subjects. A record of all vital parameters was maintained for all the patients. Each subject was assessed by physical examination and development of heart failure for Killip Classification, a significant predictor of mortality in MI. All patients underwent angioplasty with implantation of GenxSync Stent (MIV therapeutics, Surat, India).[10] All patients were followed up for one year after discharge.

The study was reviewed and approved by Ethics Committee at MOSC Medical College Hospital, Kolenchery, India.

The GenxSync Stent

GenxSync™ is a third generation Sirolimuseluting coronary stent system. Its Protea™platformis a hybrid design CoCr stent with close cells on the edges and uniform sinusoidal struts with alternate 'S' links (open cells) in the body. This hybrid design offers uniform drug delivery throughout stent length, higher flexibility, better deliverability and ultra-thin (85Micron) struts.

The coating on stent has Biodegradable poly-L-Lactic acid (PLLA) as a drug carrier and Sirolimus as an antiproliforative agent. The total coating thickness is 2 to 3 microns with median total drug content (on a 2.5 x 16 mm tent) 81 micrograms. Sirolimus is eluted from the stent over 40-50 days,with initial burst release followed by sustained delivery. The PLLA undergoes hydrolysis

into lactic acid and eventually metabolized as carbon dioxide and water. PLLA initially degrades by molecular weight reduction, followed by strength reduction and lastly mass. Hence, therapeutic dose of drug is already eluted before complete biodegradation of PLLA and the biomedical importance of polymer is over. After complete degradation of the polymer, thin strut low profile metallic stent remains behind in the arterial wall.

Statistical methods

All the data was compiled in an MS-Excel sheet and was validated from the case papers of the patients. The data was analysed in MS-Excel and Minitab Software. The Events and proportions including the demographics, medical history and events were reported as frequencies and expressed in percentages. The measurement data such as age, times etc. was reported by central tendency and spread and were reported as Mean±standard deviation. For calculation of significance, F test and z test was applied for proportions and means respectively.

Analysis and outcomes

Demographics and risk factors

We recruited 73 consecutive STEMI patients undergoing PCI in the study. The cohort was moderately young with a mean age was 58.74±11.67 years. Most (80.82%) patients were males. In the cohort 41.09% patients had Diabetes mellitus, 27.39% had hypertension and 52.05% were current smokers. Other risk factors included Chronic Renal Disease (2.74%) and pulmonary artery disease (13.70%) (Table 1).

Table 1: Demographics and risk factors.

Demographics	N (%)
Total (n)	73
Age (mean±sd)	58.74±11.67
Sex	
Male	59 (80.82%)
Female	14 (19.17%)
Diabetes	30 (41.10%)
HbA1C- all	6.5±1.56
Random blood sugar-all	185.60±86.52
Hypertension	20 (27.40%)
Current Smokers	38 (52.05%)
Chronic renal disease	2 (2.74%)
Serum cratinine	1.04±0.52
Pulmonary artery disease	10 (13.70%)
Heart rate	75.28±19.02
Height	160.63±8.83
Weight	58.91±10.33

In this study, as STEMI was an inclusion criterion. In addition, ECG revealed that 71 (97.26%) patients had ST depression, 4 (5.48%) patients had complete heart block and 1 (1.37%) had Left Bundle Brach Block. The mean Troponin-I was 55.20±59.34ng/ml. Killip classification of AMI, the precursor of mortality was classI - 89.04%, class III- 5.48%and class IV 5.48%. There were no subjects in Killip class II. This classification suggests that the mortality risk was higher in this cohort (Table 2).

Table 2: Cardiac history and disease characteristics.

Cardiac disease history	N (%)
Prior coronary artery disease	4 (5.48%)
Prior MI	5 (6.85%)
Prior PCI	2 (2.74%)
Congestive heart failure	1 (1.37%)
Cardiac arrest at admission	4 (5.4%)
ST depression	71 (97.26%)
Left Bundle Brach Block	1 (1.37%)
Complete heart Block	4 (5.48%)
Disease characteristics	
MI segment	
Anterior wall	22 (30.14%)
Inferior wall	49 (67.12%)
Posterior wall	2 (2.74%)
Diseased vessel Single, Double, tripple	32 (43.84%), 34 (46.58%), 7 (9.59%)
RCA, LM, LAD, Cx	40 (54.79%), 1 (1.37%), 21 (15.07%), 11(28.76%),
Troponin I	55.20± 59.34
AMI Killip class I/ II/ III/ IV	65 (89.04%), 4 (5.48%), 0, 4 (5.48%)
Lesion characteristics	
Lesion type A, B, C	7 (9.59%), 21 (28.76%), 45(61.64%)
Calcification: None, Mild, Moderate, Severe	0, 18 (24.65%), 4 (5.48%), 1 (1.37%)
Bifurcation lesions	8 (10.96%)
Ostial Lesions	21 (26.77%)

Table 3: Lesion and procedural characteristics.

Lesion and procedural characteristics	N (%)
Reference vessel Diameter	2.9±0.46
lesion length	12.20±5.85
Diameter stenosis (%) before stenting	73.48±11.05
Minimum lumen diameter before stenting	0.75 ±0.18
In stent residual diameter stenosis (%)	4.99 ± 4.35
In stent minimal lumen diameter (mm)	2.27 ± 0.42

Among other cardiac history, 5 (6.85%) patients had prior MI out of which 2 (2.74%) patients had history of PCI in the past. One patient (1.37%) had congestive heart failure and 4 (5.4%) patients were admitted with cardiac arrest. In 22 (30.14%) patients there was Anterior wall MI, 49

(67.12%) patients had Inferior wall MI and 2 (2.74%) patients had Posterior wall.

Out of 73patients, 32 (43.84%) had single vessel disease, 34 (46.58%) had double vessel disease and 7 (9.59%) patients had triple vessel disease. The right coronary artery, Left main, Circumflex artery and Left anterior Descending Artery were found to be culprit vessels in 54.79%, 1.37%, 15.07% and 28.76% cases respectively (Table 2). Baseline angiography revealed that the group had complex lesion morphology.

Table 4: PCI details.

PCI Details	N (%)
Thrombolysis followed by PCI	1 (1.37%)
Rescue PCI	2 (2.24%)
Primary PCI	69 (94.52%)
Door to balloon time (Minutes)	0.30±0.40 (Min 15 - Max 164)
Primary PCI after late presentation	1 (1.37%)
Thrombus aspiration	64 (87.67%)
Aspirin loading dose given	71 (97.26%)
Aspirin Loading dose	308.80±39.16
Clopidogrel loading dose given	32 (43.84%)
Clopidogrel loading dose	199.32±240.79
Highest activated clotting time	328.72±134.26

Eight (10.96%) lesions were bifurcation lesions and 26.77% lesions were at ostial lesions. Majority of the lesions were complex C type (61.64%) and B type (28.76%) and only a few (9.59%) lesions were simple A type lesions. In 24.65% lesions there was mild calcification, in 5.48% calcification was moderate and in 1.37% there was severe calcification. Rest of the lesions had no calcification (Table 2).

Table 5: Stent details.

Stent Details	N (%)
Stent - GenxSync	80 (100%)
Stent per patient	1.09±0.38
3 stent / patient	2 (2.74%)
2 stent / patient	3 (4.11%)
1 stent / patient	68 (93.15%)
Mean Stent Diameter	2.87±0.42 mm
Mean stent Length	22.06±7.72 mm

Primary PCI was performed in 69 (94.52%) patients. In 1 (1.37%) successful thrombolysis was followed by PCI, whereas in 2 (2.24%) patients, rescue PCI was performed following failed thrombolysis. In 64 (87.67%) patients thrombus aspiration was performed before stent implantation (Table 4). All the subjects underwent PCI with implantation of GenxSync SES. Total 79 stents were implanted in 73 patients (average 1.09±0.38 stent per patient). In most patients (93.15%), one stent was used. In 2(2.74%) Patients 3 stents were implanted and in 3 (4.11%) patients 2 stents were implanted (Table 5). The mean lesion length 12.20±5.85mm mean reference vessel diameter was 2.9±0.46 mm with a mean minimum lumen diameter before procedure of 0.75±0.18mm. Hence, the mean pre-procedural Diameter stenosis was 73.48±11.05 mm.

Table 6: Door to balloon time.

Door to balloon time	N (%)
Mean	2:55
Maximum	8:17
Minimum	0:15
Median	1:10

After angioplasty, in-stent minimum lumen diameter was 2.27±0.42 mm. Hence, residual post procedure diameter stenosis in-stent was 4.99±4.35%. Average stent length was 22.06±7.72 mm and average diameter of the stent used was 2.87±0.42 mm (Table 4, 5) Loading dose of aspirin was given to almost all subjects (97.26%). GPIIB / IIIA inhibitors were given to 84.93% patients (Table7).

Table 7: Details of drugs prescribed during and after procedure.

Drugs	N (%)
Aspirin	73 (100%)
Clopidogrel	32 (43.84%)
Ticagrelor	3 (4.11%)
Prasugrel	53 (72.60%)
Statin	72 (98.63%)
GPllB/lllA	62 (84.93%)
Intracoronary Dilzem	39 (53.43%)
Intracoronary Adenosine	34 (46.57%)
Intracoronary Nikoram	44 (60.27%)
Intracoronary SNP	33 (44.20%)

RESULTS

Median door to balloon time was 70 minutes with a minimum of 15 minutes and maximum of 8 hours 17 min (Table 6). In all subjects procedure was successful in establishing TIMI flow grade II or more. The post procedural period was uneventful in majority 83.56% population.

In 2 (2.74%) patients there was residual thrombosis of grade 5. Distal thrombus was observed in 6 (8.22%) patients. An intimal flap was formed in 2 (2.74%) patients and in 2 (2.74%) the side branch was lost (Table 8).

At discharge, total MACE was 3 (4.11%) which comprised of 1 (1.37%) Death, 2 (2.74%) events of Target Vessel Revascularization (TVR) by re-PCI. There was no evidence of major bleeding or acute stent thrombosis (Table 9). All subjects received dual antiplatelet therapy (Aspirin and one among Clopidogrel,

Prasugrel or Ticagrelor at the discretion of the operator). At 1 year, there were 6 (9.52%) major adverse cardiac events. MACE comprised of 4 deaths and 2 re-PCI. Between discharge and 1 year, there were 3 deaths and no event of MI or revascularization.

Table 8: Procedural success and complications.

Procedural success and Complications	
Procedural success	73 (100%)
TIMI flow baseline 0, I, II, III	59 (80.82%), 7(9.59%), 5 (6.85%), 2 (2.74%)
TIMI flow post stenting 0, I, II, III	0, 1(1.37%), 6 (8.22%), 66 (90.41%)
TIMI flow final 0, I, II, III	0, 0, 2(2.73%), 71 (97.26%)
Procedural complications	
Residual thrombosis Grade 5	2 (2.74%)
Distal thrombus	6 (8.22%)
Intimal flap	2 (2.74%)
Side branch Loss	2 (2.74%)
Edge dissection	0
None	61 (83.56%)

Table 9: Clinical outcomes - at discharge.

In hospital clinical outcomes	N (%)
N	71 (97.26%)
MACE	3 (4.11%)
Cardiac death	1 (1.37%)
Myocardial Infarction	0
Target vessel revascularization	2 (2.74%)
CABG	0
PCI	2 (2.74%)
Non-MACE	
cerebrovascular episode / intra cranial haemorrhage	0
Stent thrombosis (acute)	0

Table 10: Clinical outcome 1 year.

1 year follow-up	N (%)
N	63 (94.52%)
MACE	6(9.52%)
Cardiac death	2 (3.18%)
Myocardial infarction	2 (3.18%)
Target vessel revascularization	2 (3.18%)
CABG	0
PCI	2 (3.18%)
Non-MACE	
Non Cardiac Death	2 (3.18%)
Cerebrovascular episode / intra cranial haemorrhage	0
Congestive cardiac failure	2 (3.18%)
Stent thrombosis (Sub-acute and late)	2 (3.18%)

There were 2 non-fatal MI, pertaining to 2 stent thrombosis events. In addition there was a non-cardiac death. There were total 2 (2.74%) stent thrombosis events between discharge and 1 year, including in 1 subject who discontinued Antiplatelet therapy within 1 year (Table 10).

Table 11: Cause of death.

Causes of Death	N
Cause	N
Cardiogenic shock	1
During MVR surgery	1
During surgery on leg, due to TIMI major bleed type V	1
Due to CHF	1

None of 4 deaths including 2 cardiac were practically related to the device or procedure. These 4 deaths were due to Cardiogenic shock (1), during MVR surgery (1), During surgery on leg, due to major bleeding (1) and Due to pre-existing CHF (1) (Table 11).

DISCUSSION

STEMI being the most critical subset of CAD, several trials have been performed to establish not only efficacy but also safety of the treatment for STEMI. Initially, the polymer on first generation stents imposed higher risk of stent thrombosis in DES implants. Hence, outcomes of studies performed favoured use of Bare Metal Stent (BMS) over DES.[11,12]

However, meta-analysis presented a different view of various drug eluting stents.[13] The Horizon AMI and Horizon - III studies have demonstrated that rates of MACE and stent thrombosis are similar in DES and BMS. Rather, the DES is more effective in controlling hyperplastic neo-intimal growth.[14] Various small and large studies and meta-analysis have established that second generation stents are better in the clinical outcomes, while being as safe as a BMS in thrombotic events. Sabate et al discussed data of second generation DES on the same lines.[15]

For second generation stents, several clinical trials were performed and have demonstrated that DES performed better than BMS in STEMI, unlike the first generation DES as in study performed by Palmerini et al.[16] This study demonstrated that use of new generation devices helped in reduction of cardiac deaths, myocardial infarction and stent thrombosis events at 1 year.

The results from Horizon AMI and this study had similar demographics. At 1 year, 1696 patients in the bivalirudin group and 1702 patients in the control group were followed up. The rate of MACE was 11·9% and 11·9% bivalirudin group and control group respectively. The 1-year cardiac death rates were 2·1% and 3·8% in

bivalirudin group and control group respectively. Compared to this, in the present study the MACE rate at 1 year was 9.52% and cardiac mortality was 4.76%.

Comfortable - AMI and Examination trials established the 2 year safety in terms of reduced Death and Myocardial infarction and undelying stent thrombosis events.[17,18] These studies as stand-alone and a part of pooled meta-analysis have also demonstrated efficacy in terms of reduction of MACE.[19] GenxSync is a Third generation stent with biodegradable polymer and advanced design of platform. The platform is specially engineered for low vessel injury by increasing metal on the ends (close cell design on ends and open cells in the body).

This helps in improvement of clinical results post PCI and in long term. Due to biodegradable polymer, we can ensure the long-term safety of Bare metal stent with the biodegradable polymers. In this study, the evidence cardiac death, MI and TVR for GenxSync in STEMI was 2.74% each. This result is comparable with the existing data from similar population of various DES. However, this will require further validation for complete comparability analysis.

CONCLUSION

In a complex cohort of "all-comers" registry, 1 year clinical outcomes analysis demonstrates that in contemporary practice of percutaneous coronary intervention in ST Elevation Myocardial Infarction, GenxSync stent was associated with low risks of stent thrombosis and MACE.

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