LONG TERM OUTCOMES OF PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS WITH PREVIOUS CORONARY ARTERY BYPASS GRAFT SURGERY

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D.M. TRAINEE

A THESIS SUBMITTED FOR THE DEGREE OF DM CARDIOLOGY

DEPARTMENT OF CARDIOLOGY

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, THIRUVANANTHAPURAM

JULY 2021

DECLARATION

I, **Dr. Anil Kumar B,** hereby declare that the project in this book titled **"LONG TERM OUTCOMES OF PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS WITH PREVIOUS CORONARY ARTERY BYPASS GRAFT SURGERY"** was undertaken by me under the supervision of the faculty, Department of Cardiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology.

Thiruvananthapuram

Date: 06/08/2021

Dr. Anil Kumar B

DM Trainee

CERTIFICATE

I, hereby certify that the work in this dissertation titled "**LONG TERM OUTCOMES OF PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS WITH PREVIOUS CORONARY ARTERY BYPASS GRAFT SURGERY**" is a certified record of original research work undertaken by Dr. Anil Kumar B done in the Department of Cardiology, in partial fulfilment of requirement for the purpose of award of D.M. cardiology degree.

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I, hereby certify that the work in this dissertation titled "**LONG TERM OUTCOMES OF PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS WITH PREVIOUS CORONARY ARTERY BYPASS GRAFT SURGERY**" is a certified record of original research work undertaken by Dr. Anil kumar B done in the Department of Cardiology, in partial fulfilment of requirement for the purpose of award of D.M. cardiology degree under my supervision and care.

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TITLE

"**LONG TERM OUTCOMES OF PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS WITH PREVIOUS CORONARY ARTERY BYPASS GRAFT SURGERY**"

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ACKNOWLEDGMENTS

It is with deep sense of gratitude, satisfaction and with the divine blessings of GOD that I submit this dissertation. I take this opportunity with much pleasure to thank all who contributed in many ways for the success of this study.

I would like to express my deep sense of thanks and gratitude to Dr. Ajit Kumar V.K., Professor Senior Grade, Dr. Krishnamoorthy K.M., Professor and Head, Department of Cardiology, SCTIMST for his contributions and suggestions during the entire work.

I am greatly indebted to my guide and supervisor Dr. Bijulal.S for the continued support and advice he has extended to me throughout my work towards this thesis.

I am grateful to Dr Deepanjan for providing valuable suggestions with regard to statistical analysis that helped me to make the study better.

I would also like to sincerely thank all the faculty members of Department of Cardiology, SCTIMST for all the support. I have no words to express my heartfelt gratitude and love to my family, who provided the most precious support.

I would like to thank my colleagues for their valuable suggestions.

I want to thank the technical staff and the nursing staff of SCTIMST for their friendly support and helping hands.

Finally, my sincere thanks to all my patients who consented to participate in this study.

Dr Anil Kumar B

ABBREVIATIONS

ACS	- Acute coronary syndrome
CABG	- Coronary artery bypass grafting
MACE	- Major adverse cardiac event
MI	- Myocardial infarction
NSTEMI	- Non–ST-segment–elevation myocardial infarction
PCI	- Percutaneous coronary intervention
STEMI	- ST-segment–elevation myocardial infarction
NV	- Native vessel
GV	- Graft vessel
TIA	- Transient ischemia attack
LMCA	- Left main coronary artery
LVEF	- Left ventricular ejection fraction
LAD	- Left anterior descending artery
LCX	- Left circumflex artery
RCA	- Right coronary artery
AWMI	- Anterior wall myocardial infarction
LWMI	- Lateral wall myocardial infarction
IWMI	- Inferior wall myocardial infarction
IPWMI	- Infero-posterior wall myocardial infarction
LIMA	- Left internal mammary artery
SVG	- Saphenous venous grafts
OM	- Obtuse marginal
RPDA	- Right posterior descending artery
PLVB	- Posterior left ventricular branch
CTO	- Chronic total occlusion
ISR	- In stent restenosis
ARB	- Angiotensin receptor blocker

ARNI	- Angiotensin receptor-neprilysin inhibitor
CCB	- Calcium channel blockers
MRA	- Mineralocorticoid receptor antagonist
TLR	- Target lesion revascularization
TVR	- Target vessel revascularization
BMS	- Bare metal stent
DES	- Drug eluting stent

INTRODUCTION:

Patients with a history of coronary artery bypass grafting (CABG) are often older, have more comorbidities, and require treatment of more complex target lesions. Gradual failure of a bypass graft, lesion recurrence, and disease progression in native coronary vessels are the main causes of repeat revascularization in patients with a history of CABG. 8% venous graft fails at 1 year, 38% at 5 years, and 75% at 10 years after surgery. IMA grafts patency: 88-95% for left IMA at 10 years and 65-90% for right IMA at 10 years. Incidence of MI is 2% to 3% per year over the first 5 years, with a 5-year cumulative incidence of non-fatal MI of 15%. Overall prevalence of ACS in patients with a history of CABG is 20%. PCI is the first choice for treating late (>1 month) graft failure, because of an increased mortality risk associated with redo CABG. Repeat target vessel revascularization is higher if PCI was performed in degenerated SVGs.

Liefke C. et.al found that the risk of cardiac death and target vessel revascularization was significantly higher in patients with previous CABG. The target vessel revascularization rate was highest in patients who underwent PCI of obstructed vein grafts. Rogerio Teixeira et.al found that a history of CABG was an independent predictor of hospital readmission for UA 1 year after the ACS, although it did not significantly influence survival or other ischemic endpoints in the short or medium term.

Ahmad shoaib et.al- compared clinical outcomes in NSTEMI undergoing PCI with or without prior CABG, concluded that Patients with prior CABG had more comorbid illness but CABG did not independently confer additional risk of mortality and MACE. Ho PC, et al. (2012) compared Drug eluting stenting of saphenous vein graft versus native coronary artery supplying same myocardial perfusion territory, found that improved outcomes with PCI of the native vessel, but a tendency of the operator to choose graft PCI. Hougard et.al. (2013) studied long term outcome following PCI with DES vs BMS in SVG graft Lesions and found showed no long-term benefit compared to BMS in Rates of all-cause mortality or stent failure.

From, India there is no appropriate data on outcomes of PCI in patients with previous CABG.

AIM AND HYPOTHESIS

HYPOTHESIS

PCI in patients with previous bypass surgery is more often associated with major adverse cardiac events (MACE)

AIM

To study the long-term outcomes of PCI in patients with previous coronary artery bypass graft surgery

RATIONALE

The data on PCI in patients with previous CABG is scarce in India

This study provides data on long term outcomes of Graft PCI and native vessel PCI in patients with previous CABG

REVIEW OF LITERATURE

Cardiovascular diseases plays the role of leading cause of death worldwide out of which more than 40% of the cardiovascular deaths are contributed by Coronary Artery Diseases (CAD) (1). Coronary artery bypass grafting (CABG) is the recommended revascularization procedure for complex coronary artery diseases, especially in patients with multivessel disease or left main vessel coronary artery disease (2).

Even though CABGs are reported to have a lower rate of repeat revascularization as opposed to percutaneous coronary intervention (PCI), saphenous venous grafts (SVGs) are prone to develop early atherosclerosis and degenerative changes, leading to early graft occlusion. Approximately around 20% of the SVGs develop obstructive lesions and would get occluded in the first 18 months of surgery due to accelerated vascular intimal hyperplasia (3),(4). More than 50% of the SVGs were known to get occluded at 10 years (5).

The revascularizations of saphenous grafts are challenging and it is an interesting matter of discussion for the last few years. A repeat coronary bypass graft is not recommended in the presence of a patent internal mammary graft to the left anterior descending artery because of the risk of high perioperative complications (6). The revascularization of SVGs percutaneously was reported to have a lower success rate with poor long-term outcomes as compared to percutaneous revascularization of native coronary artery (7).

SVG intervention is difficult in comparison to a native coronary artery intervention. There are many factors that make SVG intervention a real challenge. These factors are arterialization of the vein graft due to hohigh flow pressure, leading to hyperplasia of intima and further atherosclerosis. A thin cap of atherosclerotic plaque, makes it vulnerable for distal embolization event, and an obvious large thrombus burden especially in acute vascular occlusion (8). All these factors and additional neuro-humoral factors, leads to no-reflow that increases the risk for peri-procedure myocardial infarction (9). Coronary artery disease has got increased prevalence in low-middle-income countries and it is essential to analyse local evidence to assess and increase the effectiveness of CAD treatment strategies.

The remodeling process is the typical property of venous grafts. Venous grafts need to compensate the shear stress developed during the pulsatile blood flow which occurs in the arterial system and it consists of neointimal hyperplasia arising from vascular smooth muscle cells. The cytokines and local mediators that are involved in this process leads to development of highly atherogenic substrate on which atherosclerotic plaque develops (10).

Internal mammary artery (IMA) coronary grafting is the classical surgical approach which is being currently considered as the gold standard for this condition. The main reason for this approach is the high long-term patency rates reported for IMA grafts: 88-95% for left IMA at the end of 10 years and 65-90% for right IMA at the end of 10 years (11). Long-term follow-up studies on CABG have reported 67% of survival free of myocardial infarction (MI) 20 years after the surgery. More recent data indicated an incidence of 2% to 3% of MI a year over the first 5 years, with a 5-year cumulative incidence of non-fatal MI of about 15%, and a recurrent infarction in as many as 36% of patients at around 10 years. However, CABG has got a positive influence on long-term quality of life and functional capacity of patients (12) .

Arterial graft patency CABG surgery is superior at long term compared with venous grafts. Arterial grafts rarely undergo attrition from accelerated atherosclerosis. Arterial grafts usually require intervention as a consequence of the narrowing at sites of coronary anastomosis in response to surgical injury. Procedures on radial grafts are more challenging compared to that on IMA grafts or even SVGs because of development of coronary spasm during intervention (10).

Patients with prior coronary artery bypass grafting (CABG) at times require further revascularization procedures as a result of recurrent symptoms of angina or even acute coronary syndrome (ACS) (13). There are two potential explanations for a new major coronary event after CABG as like atherosclerotic disease progression in native coronary arteries or a new vascular disease development in the grafts. Previous authors of an angiography study on the post CABG grafts reported 8% venous graft failure at 1 year, 38% at 5 years, and 75% at 10 years after CABG. There are even studies that has reported progression of the atherosclerotic process in up to 51% around 15 years after CABG.

There are two therapeutic options that are available for patients who require a revascularization procedure after surgery: a repeat CABG or a Percutaneous Coronary Intervention (PCI). A repeat revascularization surgery is associated with a higher risk of major complications like increased mortality (> 12%), lesser improvement in angina, and even reduced patency of the venous grafts (14),(6). In these patients, disease progression in the native coronary vessel is approximately 5% per year during the first 10 years of surgery.

An increasing number of post-CABG patients are referred for PCI because of the increased procedural risk and reduced incidence of event-free survival associated with redo-surgery. PCI is the most common revascularization procedure after CABG as repeat CABG has got

poor clinical prognosis (15). PCI is recommended in patients with pre-existing co-morbidities, left ventricular dysfunction, lack of available saphenous vein grafts, and elderly patients (16). Repeat revascularization is indicated in presence of severe symptoms despite anti-angina medication, and also in less symptomatic or asymptomatic patients with suspected coronary disease at non-invasive testing (10).

In United States, approximately 300,000 coronary artery bypass graft (CABG) surgeries are done yearly (17). Since, graft may fail or even coronary artery disease progression occurs in other segments of the coronary tree, patients with previous CABG return with recurrent symptoms (18). The operative mortality of redo-operations is distinctly higher when compared to the first-time operation related mortality. Redo-operative mortality and morbidity can be even higher in elderly unstable patients with other additional risk factors (17).

Patients with repeat CABG operations are an increasing proportion of the patients with acute coronary syndromes and further episodes of stable angina who are being evaluated for revascularization (17). The Society for Thoracic Surgery database consists of 594,059 CABG operations performed a year that included 8.6% to 10.4% reoperations from 1987 to 1997 (19),(20),(21). Since early 1980's, PCI has been used to treat medically refractory myocardial ischemia in patients with previous history of CABG (22),(23). Even after the addition of stents, PCI of patients with previous CABG has been associated with poor outcomes than those patients without previous CABG (4),(24).

The Angina with Extremely Serious Operative Mortality Evaluation (AWESOME) trial started enrollment in the year February 1995 and enrollment completed on March 31, 2000. Patients those who met the three clinical eligibility criteria namely myocardial ischemia, medical refractoriness, high-risk adverse outcomes expected with CABG underwent Coronary angiography (CAG), which was reviewed by both a cardiothoracic surgeon and an interventional cardiologist. A total of 2,431 patients who met all three criteria were clinically eligible. After CAG had been reviewed by interventional cardiologist and the surgeon, a total of 781 (32%) were angiographically acceptable candidates for random allocation into revascularization method. Out of these patients, 454 (58%) consented for a randomized choice of revascularization method (25).The potential contribution from this trial helped in the comparison of CABG and PCI especially with focus on high-risk patients (26). This is an interesting trial that compares CABG and PCI in patients with myocardial ischemia who got

recruited because they were medically refractory as well as had risk factors for adverse outcomes following CABG. The mean age of patients in AWESOME randomized trial was 67 years which is at least 5 years older than the mean age of patients randomized in the Emory Angioplasty Surgery Trial (EAST) (62 years), Bypass Angioplasty Revascularization Investigation (BARI) (61 years) and the other PCI versus CABG trials (25). Similarly, the mean Left ventricular Ejection Fraction (LVEF) of AWESOME patients (0.45) is > 0.10 lower than the mean values for any of the previous randomized trial that compared CABG with PCI. 31% of AWESOME patients had history of prior CABG and 33 % had an MI within seven days. Both these group of patients were exclusion criterion in all previous trials (27) (28). The results of the AWESOME trial suggested PCI as an effective alternative to CABG for patients with medically refractory myocardial ischemia and who are at high risk of adverse outcomes with CABG. Patients with medically refractory myocardial ischemia and one or more of other risk factors have a comparable 3-year survival rate but there is a higher rate of repeat revascularization along with initial PCI.

The findings Stent Restenosis Study (STRESS) and the Belgium–Netherlands Stent (Benestent) trial, has clearly mentioned superior outcomes with stenting in native coronary arteries (29) . The STRESS Trial was designed to compare “Palmaz-Schatz” coronary stent to routine elective percutaneous transluminal coronary angioplasty (PTCA) in patients having new onset native coronary artery lesions, angina pectoris with good left ventricular function. The study found that patients treated with the “Palmaz-Schatz” coronary stent had a higher procedural success rate with fewer ischemic outcomes and a clear reduction in angiographic restenosis. They could also notice not only a reduction in target lesion revascularization but also better event-free survival at 6 months of clinical follow-up (30).

The results of one another randomized trial demonstrated that elective stent placement has got better angiographic and clinical outcomes than balloon angioplasty in the management of newer lesions in aorto-coronary venous grafts. Stent placement was associated with superior initial angiographic results with higher rates of procedural success, and fewer peri-procedural non–Q-wave myocardial infarctions. Even though the rates of restenosis were not significantly different between the two treatment modalities; at 6 months the luminal diameter was significantly larger among the stent group. There were a significantly large proportion of patients who were free from death, myocardial infarction, repeated coronary artery bypass surgery, and revascularization of the target lesion in the stent group (4).

The Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) trial was designed to evaluate the treatment strategies for diabetic patients with coronary artery disease. the In this trial,19% of patients who were diabetic had 81% five-year survival rates when treated with CABG but only 66% had five-year survival when treated with balloon angioplasty. Data from Coronary Angioplasty versus Bypass Revascularization Investigation (CABRI) study also showed higher mortality rate for diabetic patients, but not non-diabetic patients, when treated with PCI as compared to CABG (6).

Patients with history of CABG are often older with more comorbidities, and would require treatment of more complex target lesions (31). Gradual failure of bypass graft, lesion recurrence in graft, and disease progression into a native coronary vessel are the main causes of repeat revascularization in such patients (32). Current guidelines recommend Percutaneous Coronary Intervention (PCI) as the first choice to treat late (>1 month) graft failure, because of an increased risk of mortality associated with repeat CABG (18),(33). PCI in patients with prior CABG is also complex and more often associated with adverse outcomes (34).

Several studies have shown significantly higher repeat target vessel revascularization rates , if PCI was performed in degenerated saphenous vein grafts (34). This can bear an increased risk for friable debris and atherothrombotic material emobolisation. The introduction of Drug-Eluting Stents (DESs) improved clinical outcomes of PCI in bypass grafts, compared to bare metal stents. Newer-generation DESs showed even more promising short-term safety outcomes. But, there is a lack of long-term data to suggest outcomes after PCI with newer-generation DESs in patients with and without prior CABG (35).

Most CABG studies assessed patients treated with bare metal stents or first-generation DESs (36). The usage of first-generation DESs in graft vessel lesions were associated with improved long-term clinical outcomes in contrast to use of bare metal stent (35). There is only little evidence on use of second-generation DESs in patients with prior CABG (37). Long-term follow-up data are also limited but a previous study suggested the presence of a late “catch-up” in target vessel revascularization post PCI with first-generation DESs in Saphenous grafts (38).

A 5-year follow-up study after PCI with newer- generation DESs in patients with versus without previous CABG demonstrated a persistently lower risk of MI and stent thrombosis despite of the history of a prior CABG. PCI with newer- generation DESs in patients with prior CABG is a safer alternative. But, after treatment with newer-generation DESs, repeat

revascularizations risk remains high. In routine clinical practice, knowledge on the safety and increased risk of repeat target vessel revascularization following PCI in patients with previous CABG will be relevant especially in the presence of a diseased SVG (35).

PCI is usually the favorite strategy for onset early graft failure and clinical presentation with features of acute coronary syndromes. PCI is preferred for fragile patients, with comorbidities, especially those with renal and/or respiratory derangement. PCI is preferred over CABG especially when patent graft on LAD is present or if patent IMA graft was implanted, and if there is single graft lesion (39).

Redo-CABG is usually the preferred when the surgical risk is acceptable; there are adequately available venous or arterial conduits. CABG is preferred in instances like multiple graft lesions and total occlusions of native arteries and in case of larger amount of ischemic myocardium. Repeat-CABG is preferred in graft lesions supplying the LAD artery, when there is no patent IMA as well. The conduit of choice for revascularization during redo-CABG is in fact IMA (40).

PCI in patients who had prior CABG is associated with worse acute and long-term clinical outcomes compared to first time CABG. Similarly, patients with repeat CABG have 2-to-4-fold higher mortality risk than the first operation. A large series conducted by Cleveland Clinic Foundation demonstrated that the risk of reoperation was mainly due to comorbidities and less by the reoperation as such (41).

There are only limited data comparing the efficacy of PCI and redo-CABG in patients with previous who underwent CABG. In a long-term propensity analysis of survival of patients after repeat-CABG or PCI in patients with multiple vessel disease and high-risk features, either technique had nearly identical survival at 1 year and 5 years. In the AWESOME trial, overall, in-hospital mortality was higher among CABG (9.1%) patients than with PCI (0.5%) patients. Many aspects play important role in decision making principally regarding angiographic findings, graft characteristics, the amount of involved myocardium at risk, general conditions of the patient and comorbidities (10).

PCI on the native vessel supplied by the occluded graft is recommended whenever possible. In a large series of patients, graft PCI was associated with higher in-patient mortality and higher post- procedural complications compared with native vessel PCI. Patients undergoing bypass graft PCI in particular more frequently required intra- aortic balloon pump (IABP)

counter pulsations, longer fluoroscopy time and even larger amount of contrast. These patients less frequently achieved a flow of TIMI flow grade 3 after stenting and were requiring more frequent blood transfusions (10).

In case of chronic total occlusion (CTO) of a native coronary vessel, PCI should be performed by specialized personnel. PCI in CTO is indicated in case of cardiac ischemic symptoms, in presence of a moderate to large area of viable myocardium or non- transmural extent of MI in MRI. Surgical conduits can also be used to perform retrograde recanalization of CTOs. If PCI of the native vessel appears to be impossible, angioplasty in the occluded SVG is another option. PCI in surgical conduits is considered as a high- risk procedure because patients in many cases present with hemodynamic instability and even acute myocardial infarction. Thereby, the procedure can turn out to be a burden with high rate of poor procedural outcomes (42),(43) .

PCI in SVGs is associated with very high risk of atheroma embolization. This can result in no-reflow phenomenon, graft perforation or restenosis in native coronary vessels. In chronically occluded SVGs, the success rates are comparatively lower with higher complication rate and restenosis than in non- occluded SVGs. However, PCI on graft conduits is performed in up to 37% of patients with previous CABG surgery on SVGs. In general, chronically occluded SVGs are not considered a target for PCI as opposed to occluded SVGs which are culprit lesion of further acute coronary syndromes (10).

The usage of intracoronary embolic protection devices (EPD) should always be considered in SVG intervention because of the reduced embolization risk and reduced elevation of post-procedural myocardial enzymes. According to the anatomical feature of the lesion, the choice of best device should be made. For proximal type stenosis, distal EPD are recommended and vice versa. EPD are useful in severely diseased SVGs where application of it can have difficulties and that require experience (10).

Cautious strategies like direct stenting, minimal catheter maneuvers and avoidance of pre-stent and post-stent dilation are recommended to minimize distal embolization risk. In the scenario of significant under-deployment of the stent, high-pressure post-dilation has to be done with EPD in place (44). Additional devices might come into play in this special subset of PCI patients, since protection devices require landing zone and may not always fit all procedures.

Hybrid myocardial revascularization is a well-planned combination of CABG, with a catheter-based intervention into other coronary arteries during the same hospital stay or within 60 days of first procedure (45). Procedures can be performed in a hybrid operating room, or on separate occasions in conventional surgical and PCI suites sequentially. The major application of a hybrid revascularization strategy is in the use of an IMA-LAD graft using a minimal surgical technique, followed or preceded by PCI into other coronary vessels. It is reported that this strategy takes advantages of both the procedures (10).

The IMA-LAD bypass has got superior results compared to PCI, with higher rate of long-term vascular patency (46). It has shown to significantly reduce myocardial infarction, recurrent angina, the risk of death, and the need for further revascularization. There are again evidences to show that the routine use of DES provides good results at long-term and may even offer superior long-term patency (47). Ideally, hybrid revascularization strategy should be performed with minimally invasive surgical approaches to avoid sternotomy and extra-corporeal circulation. There can be a high potential for rapid recovery and lower complication rates compared to traditional surgery in such patients (45).

The uses of intraoperative angiography after CABG in hybrid suites are introduced with the goal of ensuring immediate quality control of graft. A high rate of bypass defects has also been identified by open-chest angiogram with the unique possibility of immediate revision of it. PCI is the preferred method for revision of angiographic defect of the surgical conduits, whereas anastomosis defects are corrected most often surgically (48).

Definitions:

- ***Cardiac death****:* Any death due to proximate cardiac cause eg: myocardial infarction (MI), low-output failure, fatal arrhythmia), unwitnessed death and death of unknown

cause, and all procedure-related deaths, including those related to concomitant treatment, were classified as cardiac death.

- ***Noncardiovascular death****:* Any death not covered by the above definitions, such as death caused by infection, malignancy, sepsis, pulmonary causes, accident, suicide, or trauma.

- ***lnstent Restenosis****:* Greater than 50% diameter stenosis at the stent site on follow-up angiography at any time after implantation

- ***Target lesion revascularization (TLR)****:* Any repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel performed for restenosis or other complication of the **target lesion**. The lesions in the segment from 5 mm proximal to the stent and to 5 mm distal to the stent were considered as involving the target lesion.

- ***Target Vessel Revascularisation****:* Any repeat percutaneous intervention or surgical bypass of **any segment of the target vessel**.

- The target vessel is defined as the entire major coronary vessel proximal and distal to the target lesion, which includes upstream and downstream branches and the target lesion itself.

MATERIALS &METHODS

STUDY DESIGN

This is a retrospective Observational study consisted of 219 patients with previous coronary artery bypass graft surgery, who underwent PCI at department of Cardiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, India, till December 2020.

The protocol was approved by the Institutional Ethics Committee

Inclusion criteria:

Post CABG Patients undergoing PCI at SCTIMST will be followed till Dec 2020

Exclusion criteria:

no specific exclusion criteria

Outcomes:

- Major adverse cardiovascular event
- Any death
- Cardiac death
- Myocardial infarction
- Target vessel revascularization
- Target lésion revascularisation
- Instent restenosis
- To assess the safety and efficacy of PCI strategy
- Functional status
- LV function

METHODOLOGY

The baseline characteristics and procedural details will be collected from the medical records.

The follow-up data will be collected from the medical records for those patients who continued to be under regular follow-up.

The follow-up data for the others will be collected by telephonic contact or in person or by a mailed questionnaire

Outcome will be assessed in terms of survival and complications and will then be correlated with various patient and procedural characteristics.

DATA ANALYSIS

The data will be analysed by the principal investigator. The data would be analyzed by the principal investigator with advice from statistician if required. All data will be handled with care to maintain patient confidentiality. Records will be maintained in both computer and paper formats. The closing point for any patient will be the time of their last visit to the follow-up clinic during study period. Categorical data will be analyzed as percent's, numerical data as mean SD, and comparisons by 2-sample Student t test or the 2-sample Wilcoxon rank sum (Mann-Whitney) test. Time-to-event data analysis would be done using the Cox proportional hazards model. Kaplan-Meier survival curves will be made to assess differences between groups for the time to an event data. The analysis will be performed using SPSS-28 statistical software

RESULTS

Baseline clinical characteristics:

A total of 219 patients who underwent PCI till Dec 31, 2020 with history of CABG at SCTIMST, were included. The mean age was 60.3±8, and 89.9% were male. The most common reason for the presentation was stable angina (54.5%). 18 (8.2%) patients presented with STEMI. IWMI was most common among patients who presented with STEMI (Fig.1). The median follow-up period of the study was 60(28-86) months. The most common comorbidity was hypertension (68.9%%), followed by diabetes (61.6%), dyslipidemia (57.5%), chronic kidney disease (CKD) (14.6%) and stroke (7.7%). Nearly half of patients were smokers and family history of coronary artery disease was seen in nearly one quarter of patients. 54% patients had history of myocardial infarction. Mean left ventricular ejection fraction at CABG and PCI were 64% and 56% respectively. Median duration between CABG and PCI was nearly 9 years (109±65 months). Left main disease was seen 21.9% of patients. LAD and RCA was seen in 99% and 95% of patients respectively. Triple vessel disease and double vessel disease was seen in 89% and 11% respectively. 18% patients had left main with triple vessel disease. Mean number of occluded vessels per patient was 2.89±0.31. The baseline characteristics of the patients were shown in table 1.

Table I. Baseline clinical characteristics of the study population.

Baseline clinical characteristics	**Overall (219)**
Age at CABG (years)	51±8
Age at PCI (years)	60.3±8
Sex (m)	197 (89.9%)
Diabetes mellitus	135 (61.6%)
Hypertension	151 (68.9%)
Dyslipidemia	126 (57.5%)
Family history of coronary artery disease	53 (24.2%)
Smoking	106 (48.4%)
Peripheral artery disease	18 (8.2%)
Chronic kidney disease	32 (14.6%)
TIA/stroke	17 (7.7%)
Prior myocardial infarction	119 (54.3%)

Previous percutaneous coronary intervention	15 (6.84%)
Clinical presentation	
STEMI	18 (8.2%)
NSTEMI	60 (27.3%)
UA	21 (9.58%)
Stable angina	120 (54.5%)
LVEF at CABG	64 ± 11.8
LVEF at PCI	56 ± 12
Mean duration b/w CABG and PCI (months)	109± 65
Native vessel disease	
Left main	48 (21.9%)
LAD	217 (99%)
LCX	200 (91.3%)
Ramus	35 (15.9%)
RCA	209 (95.4%)
Triple vessel disease	195 (89%)
Double vessel disease	24 (11%)
Left main +triple vessel disease	39 (17.8%)
Mean no of occluded vessels per patient	2.89 ± 0.31

TIA, Transient ischemia attack; LVEF, Left ventricular ejection fraction; STEMI, ST elevation myocardial infarction; NSTEMI, non-ST elevation myocardial infarction; LAD, Left anterior descending artery; LCX, Left circumflex artery, RCA, Right coronary artery

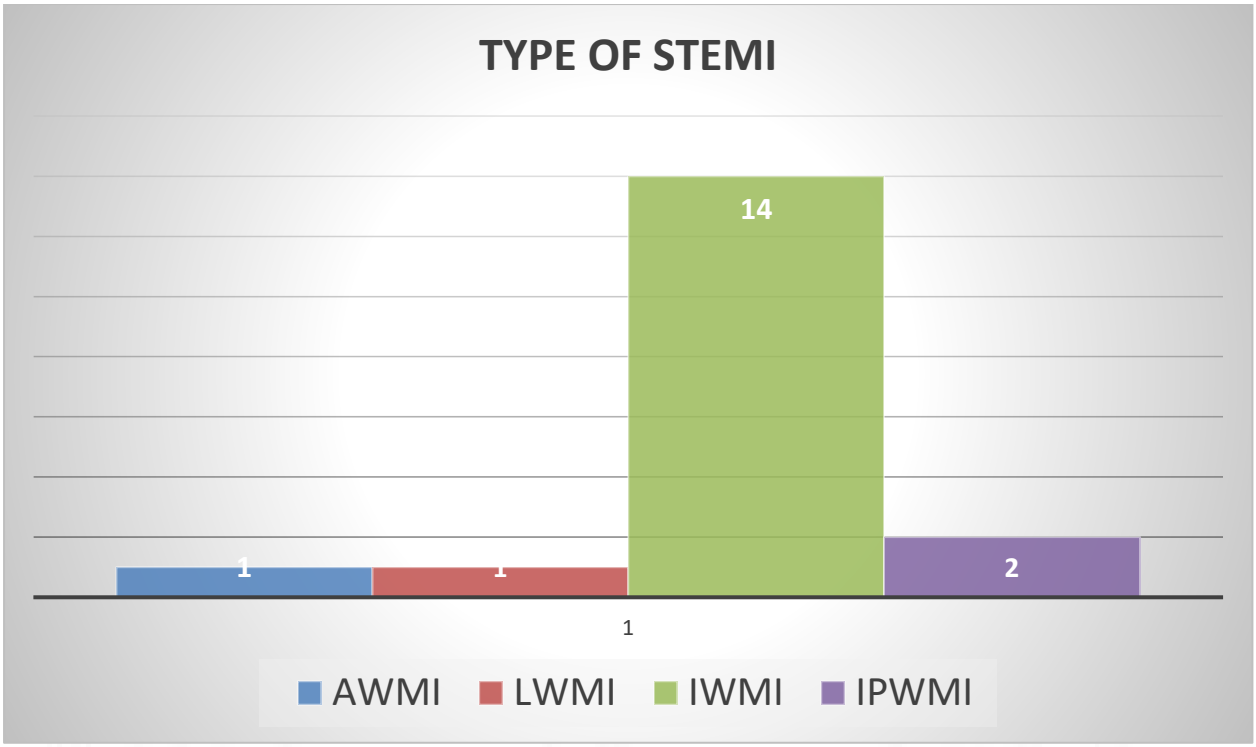


Figure:1: Types of STEMI at presentation. AWMI, Anterior wall myocardial infarction; LWMI, Lateral wall myocardial infarction; IWMI, Inferior wall myocardial infarction; IPWMI, Infer posterior wall myocardial infarction.

Graft characteristics:

Among arterial grafts 185 (84.4%) patients underwent LIMA to LAD and 10 (4.5%) patients underwent LRA to OM/LCX. Among venous grafts 75% patients underwent SVG to OM and SVG to RCA, nearly half of patients underwent SVG to diagonal. Overall, 28.8% arterial grafts and 65% venous grafts were occluded at baseline. LIMA to LAD is occluded in 51 (27.5%) patients. Among venous grafts SVG to OM and SVG to RCA were more commonly occluded. The baseline graft characteristics of the patients were shown in table 2.

Table 2. Baseline graft characteristics of the study population.

Graft characteristics		
Arterial grafts		Number of grafts Occluded
LIMA to LAD	185 (84.4%)	51/185 (27.5%)
LRA to OM/LCX	10 (4.5%)	6/10 (60%)
LRA to Diagonal	1 (0.45%)	0/1
LRA TO RPDA	3 (1.3%)	1/3 (33%)
RIMA TO PLVB	1 (0.45%)	0/1
RIMA TO Diagonal	1 (0.45%)	0/1
Venous grafts		
SVG to LAD	34 (15.5%)	19/34 (55.8%)
SVG to Diagonal	121 (55.2%)	65/121 (53.7%)
SVG to Ramus	24 (10.9%)	16/24 (66.6%)
SVG to LCX	9 (4.1%)	2/9 (22.2%)
SVG to OM	166 (75.7%)	122/166 (73.4%)
SVG to RCA	165 (75.3%)	114/165 (69%)

LIMA, Left internal mammary artery; SVG, Saphenous venous grafts; OM, Obtuse marginal; RPDA, Right posterior descending artery; PLVB, Posterior left ventricular branch

Procedural and angiographic characteristics:

Most (89%) of the patients had triple-vessel disease and remaining (11%) patients double vessel disease. Mean number of lesions treated per patient 1.69 ±0.89, with 360 stents (83.3% DES). Additionally, 10% of the lesions were chronic total occlusion (CTO). The mean left ventricular ejection fraction (LVEF) at PCI was 56% ± 12%. In total, two-third of the patients were treated on the native coronary arteries, 24.2% on grafts, and 9% on both types of vessels (Fig.2). Multi-vessel intervention was performed in 26% of the patients. A majority (83.3%) of the patients underwent implantation with the DES. Average stent diameter and average stent length were 2.88 ± 0.43 and 21.96 ± 6 respectively. Distal protection devices were employed in 5.9% of the study population. Left main intervention was done in 10.9% cases. Majority of patients (35.6%) underwent native vessel PCI to LCX/OM followed by PCI to RCA (27.3%). Nearly one fourth patients underwent graft vessel PCI, graft PCI to OM/LCX (13.6%) is more commonly performed followed by graft PCI to RCA/PDA (11%). Among DES, XIENCE stent (18.3%) was more commonly used followed by ORSIRO (14%) (Fig.3).

Among Bare metal stents (BMS), DRIVER stent is more commonly used followed by PROKINETIC stent. Most of the patients received dual antiplatelet therapy (DAPT), statins and beta blockers. One patient received ARNI. Nearly 72% cases were treated with ACEI/ARB. 61% cases received antianginal therapy. Detailed procedural characteristics were shown in table 3.

Table 3. Procedural characteristics of study population:

Procedural characteristics	**N=219 (%)**
Type of PCI	
Native vessel	146 (66.6%)
Graft PCI	53 (24.2%)
Both	20 (9.1%)
Distal protection device used	13 (5.9%)
Mean no of lesions treated/patient	1.69 ± 0.89
Multivessel PCI	57 (26%)
At least 1 CTO treated	22 (10%)
At least 1 ISR treated	5 (2.2%)
Mean no of stents/patient	1.64 ± 0.95
Type of stent	
BMS	34 (15.5%)
DES	179 (81.7%)
POBA	6 (2.7%)
Total no of stents	N = 360
BMS	60 (16.6%)
DES	300 (83.3%)
Average stent diameter(mm)	2.88 ± 0.43
Average stent length (mm)	21.96 ± 6
Type of vessel treated	N=219
Native vessel	
LM Intervention	24 (10.9%)

PCI to LAD	43 (19.6%)
PCI to Diagonal	4 (1.8%)
PCI to LCX/OM	78 (35.6%)
PCI to Ramus	9 (4.1%)
PCI to RCA	60 (27.3%)
Graft vessel	
SVG to LAD	8 (3.6%)
SVG to Diagonal	8 (3.6%)
SVG to RCA/PDA	24 (10.9%)
SVG to LCX/OM	30 (13.65%)
SVG to Ramus	2 (0.9%)
LIMA to LAD	5 (2.2%)

Medical treatment	**N=215**
Aspirin	215 (100%)
Clopidogrel	210 (97.6%)
Ticagrelor	4 (1.8%)
Prasugrel	1 (0.45%)
Statins	215 (100%)
Betablockers	205 (95.3%)
ACEI	110 (50.2%)
ARB	47 (21.4%)
ARNI	1 (0.45%)
Antianginal	131 (60.9%)
CCB	71 (33%)
Diuretics	73 (33.9%)
MRA	45 (20.9%)

CTO, Chronic total occlusion; ISR, In stent restenosis; ARB, Angiotensin receptor blocker; ARNI, Angiotensin receptor-neprilysin inhibitor; CCB, Calcium channel blockers; MRA, Mineralocorticoid receptor antagonist.

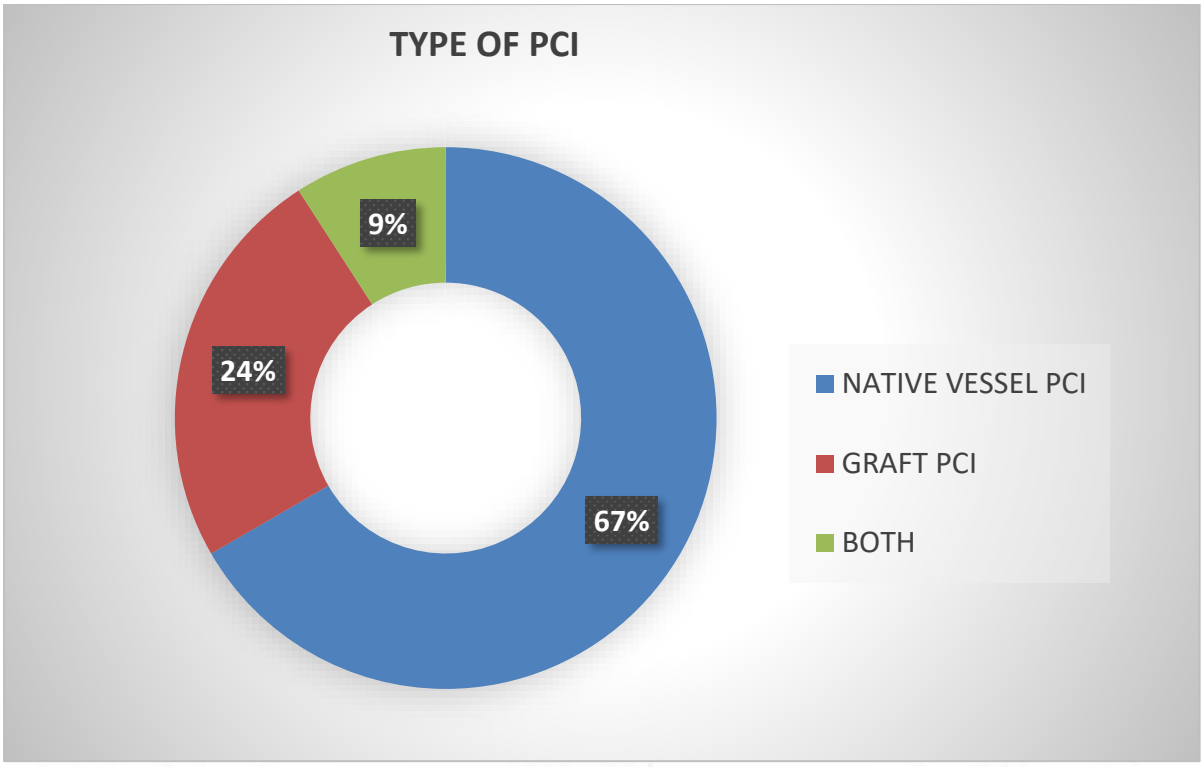
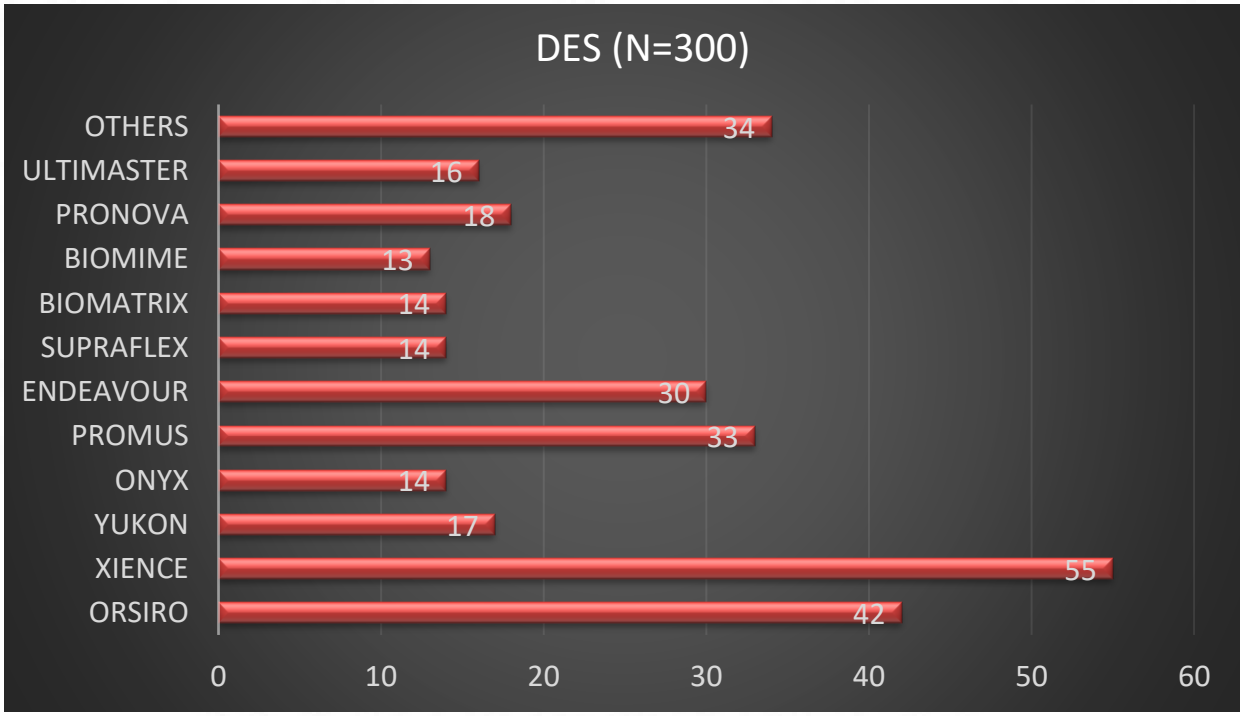


Figure 2. Types of Percutaneous coronary intervention (PCI)



- Figure 3. Different types of Drug eluding stents (DES). NOTE: Others include, CYPHER-3, TAXUS-3, RAPSTORM-7, GENX-7, FLEXYRAP-1, TAXCOR-2, STAINFLEX-1, SUPRALIMUS-1, EXCEL-4, TETRIIMUS-5

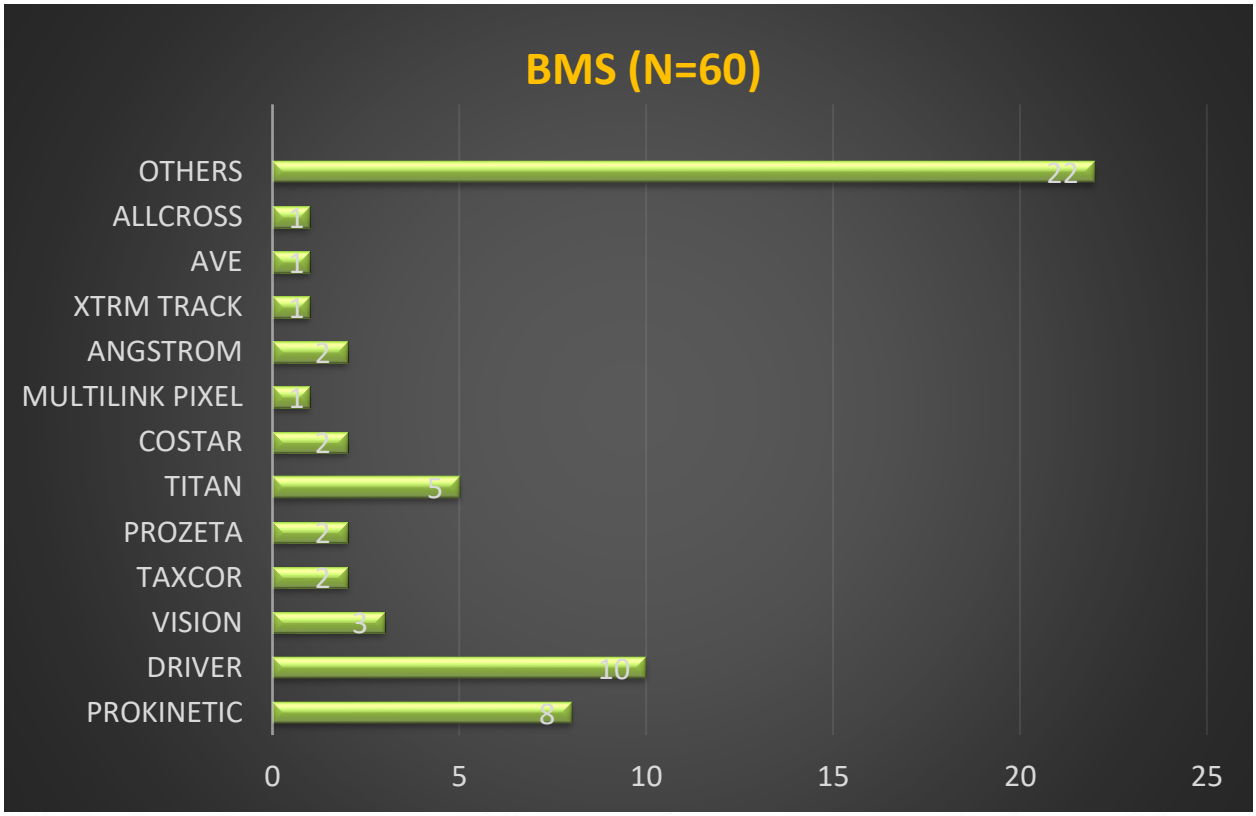


Figure 4. Different types of Bare metal stents (BMS)

Outcomes:

Among the 219 cases, only 14 were lost to follow-up (6.3%), leaving a total of 205 patients who were followed. The median follow-up time was 60 months (range, 28-86 months). Seventy-eight cases of MACEs occurred (38.2%), including 25 cardiac mortalities (12.2%), 55 MIs (26.9%), 31 ISR (15%), 23 TLR (11%), 26 TVR (12.7%). 2 patients underwent redo CABG (Fig. 5, Table 4). On follow-up functional class assessment was done in 176 patients. Majority of patients were in FC-II (52%). 9% cases were having FC-III symptoms (Fig. 6). Kaplan-Meier survival analysis showed freedom from all cause death at 1, 3, 5 years was 94.3%, 90% and 86.7% respectively (fig. 7), and freedom from MACE at 1, 3, 5 years was 89%, 79.8% and 67.7% respectively (Fig. 8)

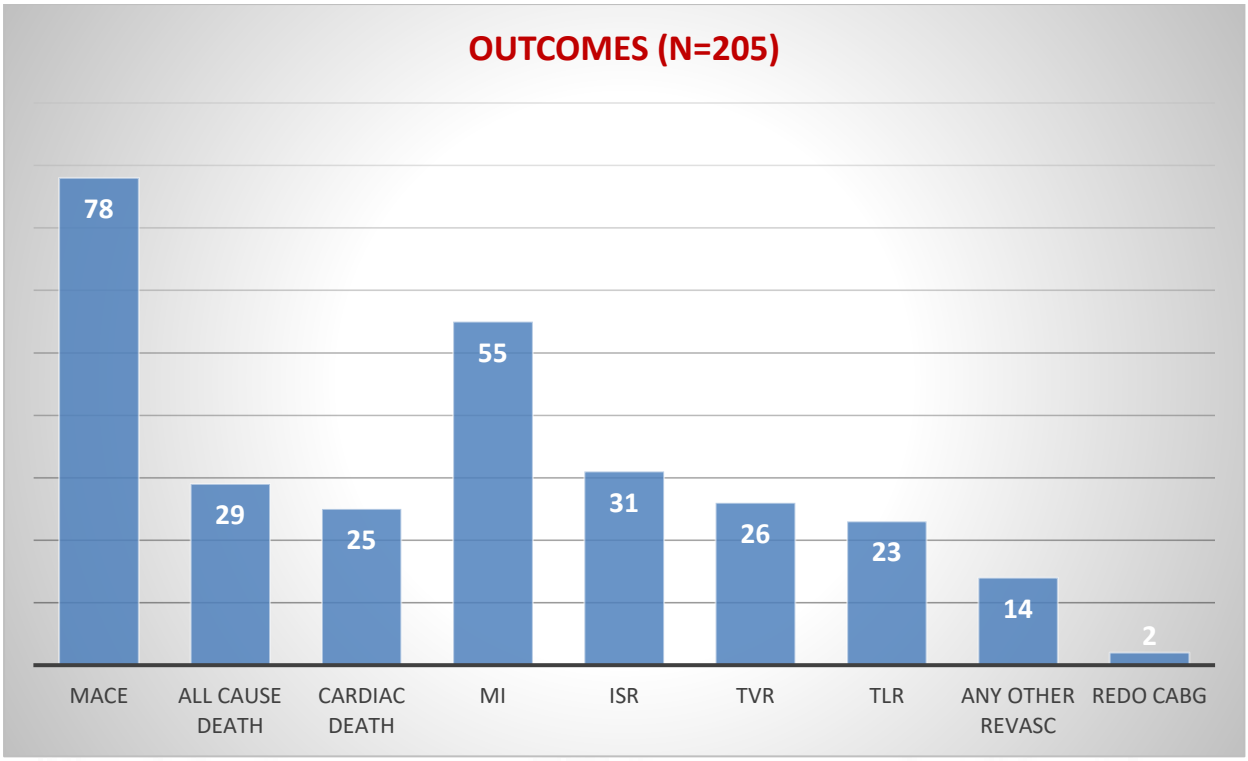


Figure 5, Overall outcomes of study population. TLR, Target lesion revascularization; MI, Myocardial infarction; ISR, Instent restenosis; TVR, Target vessel revascularization; CABG, Coronary artery bypass grafting; MACE, major adverse cardiac event.

Table 4, Overall outcomes of study population

Outcomes	**Overall (205)**
Median duration of f/u (months)	60 (28-86)
Mace	78 (38.2%)
All cause death	29 (14.2%)
Cardiac death	25 (12.2%)
MI	55 (26.9%)
ISR	31 (15.1%)
TLR	23 (11.2%)
TVR	26 (12.7%)
Any other vessel revascularization	14 (6.8%)
Redo CABG	2 (0.98%)

TLR, Target lesion revascularization; MI, Myocardial infarction; ISR, Instent restenosis; TVR, Target vessel revascularization; CABG, Coronary artery bypass grafting; MACE, major adverse cardiac event

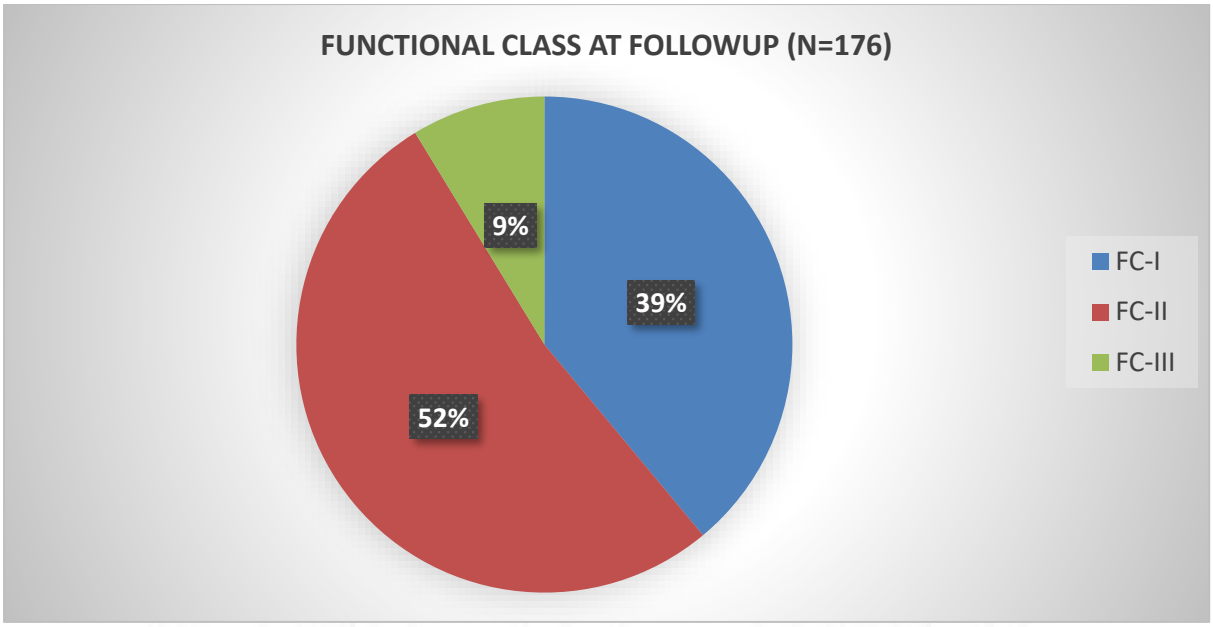


Figure 6. Functional status of study population at follow-up (n=176)

Predictors of Mortality and MACE:

Multivariate analysis (Table 5) showed Diabetes Mellitus, HR (95% CI) 2.67(1.04-6.86), p =0.03, LVEF<55% at PCI, HR (95% CI) 2.31(1.72-3.51), p=0.04, stent type (BMS) HR (95% CI) 6.50(2.75-15.38), p=<0.01 and chronic kidney disease HR (95% CI)3.25(1.32-7.98), p=<0.01 were independent predictors of mortality. (Table 7.)

Multivariate analysis (Table 6) showed Age at CABG>50 years, HR (95% CI) 2.44(1.79-3.81), p =0.04, stent type (BMS) HR (95% CI) 1.90(1.36-2.67), p=0.03 and chronic kidney disease HR (95% CI) 2.45(1.10-2.40) p=<0.01 were independent predictors of MACE. (Table 8.)

Table 5. Analysis of risk factors for mortality.

	Died (N=29)	Survived (176)	P value
Male sex	29 (100)	156(89.1)	0.06
Mean age at CABG	48.3+6.4	51.5+8.3	**0.04**
Mean age at PCI	58.7+8.9	60.4+8.4	0.32
Comorbidities			
DM	23(79.3)	104 (59.4)	**0.04**
Hypertension	20(68.9)	120 (68.6)	0.97
CKD	9(31.0)	21 (11.9)	**<0.01**

Dyslipidemia	20(68.9)	98(55.9)	0.18
Stroke	4(13.8)	12(6.8)	0.19
PVOD	1(3.4)	15(8.6)	0.34
Previous MI	19(65.5)	90(51.4)	0.20
LVEF at CABG	58.5+12.8	65.2+11.6	**<0.01**
LVEF at PCI	50.5+12.6	57.3+12.3	**<0.01**
Presentation			
STEMI	4(13.7)	13 (7.5)	0.24
NSTEMI	7(24.2)	51 (29.2)	
UA	5(17.3)	14 (7.9)	
SA	13(44.8)	98 (55.4)	
ACS	16 (55.2)	78 (44.3)	0.28
Non-ACS	13 (44.8)	98 (55.7)	
No. of diseased vessel	87	544	0.93
LM	5 (5.7)	41 (7.3)	
LAD	29 (33.3)	174 (32.0)	
LCX	26 (29.9)	161 (29.6)	
RCA	27 (31.0)	168 (31.0)	
LM+3VD	9	33	0.13
Arterial grafts	24 (25.5)	167 (27.7)	0.65
Venous grafts	70 (74.5)	437 (72.3)	
No. of occluded grafts	45 (47.9)	318 (52.6)	0.39
Arterial	4(16.7)	51 (16.0)	
Venous	41(58.6)	267 (84.0)	
No of stents used	1.41+0.62	1.69+1.00	0.14
BMS	13 (44.8)	17(9.8)	**<0.01**

DES	16 (55.2)	154 (89.0)	
Both	0	2(1.2)	
Embolic protection device	1(3.4)	12(6.8)	0.54
ISR	6(20.6)	25(14.3)	0.37
TVR	4(13.8)	22(12.6)	0.84
TLR	4(13.8)	19(10.9)	0.59

UA, Unstable angina; SA, Stable angina; CKD, Chronic kidney disease; PVOD, Peripheral vascular occlusive disease

Table 6. Analysis of risk factors for major adverse cardiac events.

	MACE(N=78)	No MACE (127)	P value
Male sex	73 (93.6)	124 (97.6)	0.23
Mean age at CABG	49.5+7.9	51.9+8.2	**0.04**
Mean age at PCI	58.8+9.1	61.0+7.9	0.07
Comorbidities			
DM	54(69.2)	73 (57.4)	0.09
Hypertension	58(74.4)	82 (64.6)	0.22
CKD	17(21.8)	13 (10.1)	**0.03**
Dyslipidemia	53(67.9)	73(10.2)	0.17
Stroke	8(10.2)	8(6.2)	0.31
PVOD	10(12.8)	6(4.7)	0.06
Previous MI	44(56.4)	65(51.2)	0.69
LVEF at CABG	63.1+14.3	65.1+10.6	0.25
LVEF at PCI	53.8+13.4	57.7+11.8	0.38
Presentation			
STEMI	10 (12.8)	7 (5.5)	0.051
NSTEMI	21 (26.9)	37 (29.1)	
UA	11 (14.1)	8 (6.3)	
SA	36 (46.1)	75 (59.1)	

ACS	42 (53.9)	52(40.9)	0.07
NON-ACS	36 (46.1)	75(59.1)	
No. of diseased vessel	242	389	
LM	19 (5.7)	27 (6.9)	0.90
LAD	77 (33.3)	126 (32.3)	
LCX	71 (29.9)	116 (29.8)	
RCA	75 (31.0)	120 (30.8)	
LM+3VD	15	23	0.70
Arterial grafts	67 (26.0)	124 (28.1)	0.656
Venous grafts	190 (74.0)	317 (71.9)	
No. of occluded grafts	126 (50.2)	239(54.2)	0.16
Arterial	11(16.7)	44 (18.4)	**0.01**
Venous	115(58.6)	195 (81.6)	
No of stents used	1.45+0.85	1.78+1.01	**0.03**
BMS	21 (26.6)	9(9.4)	**<0.01**
DES	55 (69.6)	115(89.8)	
Both	3 (3.8)	1 (0.8)	
EPD	4	9	0.71

ACS, Acute coronary syndrome; EPD, Embolic protection device

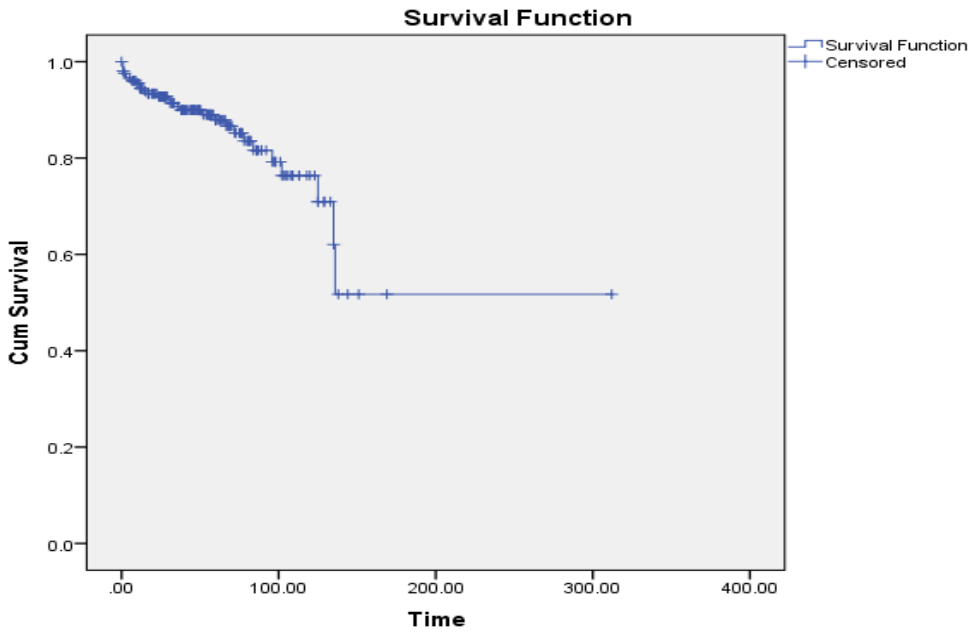
Table 7. Predictors of mortality

Parameters	HR (95% CI)	P value
Diabetes Mellitus	2.67(1.04-6.86)	0.03
LVEF<55% at PCI	2.31(1.72-3.51)	0.04
CKD	3.25(1.32-7.98)	<0.01
BMS	6.50(2.75-15.38)	<0.01
DES	0.21(0.12-0.38)	<0.01

LVEF, Left ventricular ejection fraction; CKD, Chronic kidney disease

Table 8. Predictors of MACE

Parameters	HR (95% CI)	P value
Age at CABG>50 yrs	2.44(1.79-3.81)	0.04
CKD	2.45(1.10-2.40)	<0.01
BMS	1.90(1.36-2.67)	0.03
DES	0.12(0.08-0.17)	<0.01



Survival at

1month = 98%

6 months = 96.5%

12 months = 94.3%

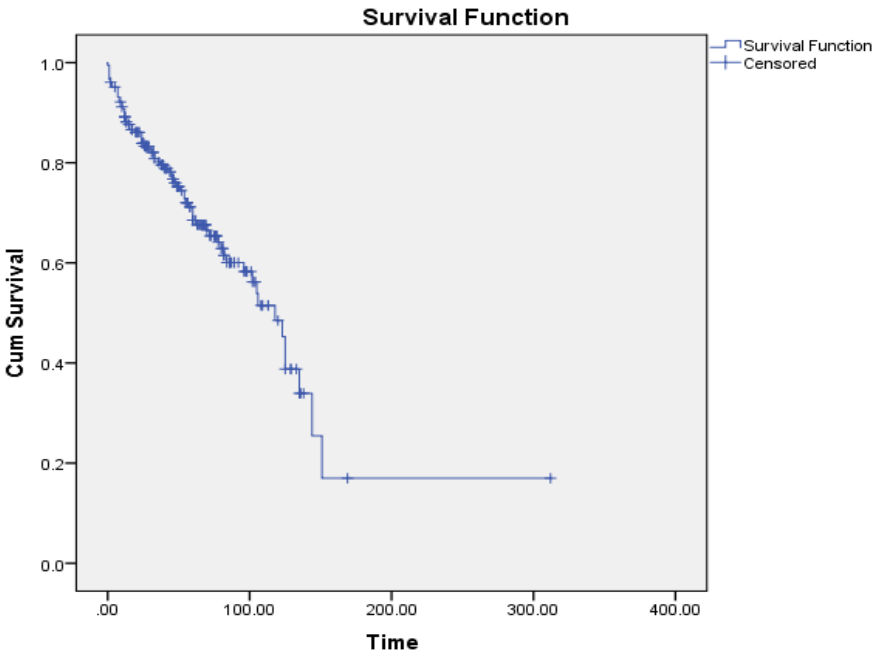
2 years = 92.4%

3 years = 90%

4 years = 89%

5 years = 86.7%

Figure 7. Kaplan-Meier survival curves at clinical follow-up (Mortality free)



Freedom from MACE at

1month = 96.6%

6months = 95%

12 months = 89%

2 years = 83.5%

3 years = 79.8%

4 years = 75.3%

5 years = 67.7%

Figure 8. Kaplan-Meier survival curves at clinical follow-up (MACE free)

Comparison of different PCI strategies. NV-PCI was performed in 146 patients (66.6%), graft-PCI in 53 patients (24.2%) and both graft and native vessel PCI was performed in 20 patients (9.1%). Compared with the NV-PCI group, the graft-PCI group had more completely occluded NVs and completely occluded venous grafts. Clinical baseline, angiographic and procedural data of the two groups are shown in Table 9. 187 patients were followed up for a mean time of 5.5years, including 138 patients in the NV-PCI group and 49 patients in the graft-PCI group. MACEs occurred in 44 patients in the NV-PCI group (31.9%) and 28 patients in the graft-PCI group (57.1%) (p=<0.01). Mortality occurred in 10 patients (20.8%) in graft PCI group and 15 patients (10.9%) in NV-PCI group (P=0.04). MI occurred in 18 patients (36.7%) in graft PCI group and 31 patients (22.5%) in NV-PCI group which is statistically significant (P=0.05). There was significant occurrence of TLR (18.4% vs 7.2%, p=0.01) and ISR (28.5% vs 10.1%, P=<0.01) is noted in graft PCI group compared to NV-PCI group.

Table 9. Clinical baseline, procedural data and outcomes of the two groups (GV PCI vs NV PCI)

	Graft PCI(N=53)	NV-PCI (N=146)	P value
Male sex	49 (92.4)	128(87.6)	0.11
Mean age at CABG	50.1+7.9	51.9+8.2	**0.02**
Mean age at PCI	61.3+6.9	60.3+8.7	0.87
Comorbidities			
DM	31(58.5)	88 (60.3)	0.99
HTN	41(77.4)	94 (64.3)	0.15
CKD	11(20.8)	18 (12.3)	0.18
Dyslipidemia	34(64.1)	78(53.4)	0.38
Stroke	7(13.2)	10(6.8)	0.31
PVOD	3(5.7)	13(8.9)	0.60
Previous MI	23(43.4)	82(56.2)	0.29
LVEF at CABG	64.5+10.2	64.1+12.7	0.81
LVEF at PCI	57.4+12.5	55.7+12.7	0.41

No. of diseased vessel	181	435	**<0.01**
LM	13 (7.2)	30 (6.9)	
LAD	52 (28.7)	140 (32.1)	
LCX	45 (24.9)	131 (30.1)	
RCA	71 (39.2)	134 (30.8)	
LM+3VD	13	26	0.70
Arterial grafts	46 (24.0)	138 (30.2)	**0.03**
Venous grafts	145 (76.0)	320 (69.8)	
No. of occluded grafts	124 (64.9)	220 (48.0)	**0.02**
Arterial	12(26.0)	42 (30.4)	**<0.01**
Venous	112(77.2)	178 (55.6)	
No of stents used	1.66±0.79	1.64±0.90	0.88
BMS	7 (13.2)	21(14.4)	0.08
DES	45 (84.9)	124(85.5)	
Both	1(1.9)	1 (0.1)	
Outcomes:	Graft PCI (N=49)	NV-PCI (N=138)	**P=Value**
Mean follow-up (Months)	67.9+41.2	62.5+46.4	0.83
ISR	14(28.5)	14(10.1)	**<0.01**
TVR	9(18.4)	13(9.4)	0.07
TLR	9(18.4)	10(7.2)	**0.01**
Any other revascularization	3(6.1)	7(5.0)	0.42
Redo CABG	1(2.0)	1(0.7)	0.61
Mortality	10(20.8)	15(10.9)	**0.04**
MACE	28(57.1)	44(31.9)	**<0.01**
MI	18(36.7)	31(22.5)	0.05

Comparison of outcomes of graft PCI with or without EPD usage:

Embolic protection device (EPD) was used in 13 patients (24.5%) during graft PCI. Use of embolic protection device was associated with trend towards improving outcomes. Cumulative incidence of MACE occurred in 4 patients (33.3%) in EPD group and 22 patients (61.1%) in without EPD group (P=0.07). MI occurred in 2 patients (16.7%) in EPD group and 15 patients (41.7%) in without EPD group (P=0.09). Comparison of outcomes between patients who underwent graft PCI with and without EPD are shown in table 10.

Table10. Comparison of outcomes between patients who underwent graft PCI with and without EPD

Outcomes	GRAFT PCI WITH EPD(N=12)	GRAFT PCI WITHOUT EPD (36)	P= Value
Mean duration of follow-up (months)	77.9+46.9	64.2+44.4	0.55
ISR	4(33.3)	6(16.7)	0.83
TVR	2(16.7)	6(16.7)	0.84
TLR	3(25.0)	3(8.3)	0.79
Any other revascularization	1(8.3)	1(2.7)	0.56
Mortality	1(8.3)	7(19.4)	0.37
MACE	4(33.3)	22(61.1)	0.07
MI	2(16.7)	15(41.7)	0.09

Comparison of the stent types for PCI. DESs were used in 179 patients (81.7%) and BMSs in 34 patients (15.5%). The groups did not differ significantly in baseline clinical characteristics and the number of occluded NVs or grafts (P>0.05). The BMS group had fewer stents (P=0.03). Baseline clinical, procedural data and outcomes of the two groups are listed in Table 11. Of the 200 patients who completed the long-term follow-up, 170 were in the DES group and 30 in the BMS group. There were 55 (30%) occurrences of MACEs in the DES group and 21 (61.8%) in the BMS group (p=0.01). The DES group had a higher overall survival, MACE-free and MI-free survival compared with the BMS group (both P=<0.01). No significant difference was found with respect to TLR, TVR and ISR (P=>0.05).

Table 11. Clinical baseline, procedural data and outcomes of the two groups (DES vs BMS)

	DES (179)	BMS (34)	P value
Male sex	161 (89.9)	31 (91.2)	0.86
Mean age at CABG	51.3+7.9	49.8+9.3	0.32
Mean age at PCI	60.5+8.1	58.1+9.6	0.13
Comorbidities			
DM	111(62.0)	21(61.8)	0.97
HTN	123(68.7)	23(67.6)	0.90
CKD	25(14.0)	7(20.6)	0.32
Dyslipidemia	100(55.8)	22(64.7)	0.34
Stroke	14(7.8)	3(8.8)	0.84
PVOD	18(10.0)	0(0.0)	0.05
Previous MI	98(54.7)	19(55.9)	0.90
LVEF at CABG	64.9+11.4	60.3+14.6	**0.04**
LVEF at PCI	56.3+12.7	57.1+12.7	0.74
Presentation			
STEMI	11(6.1)	6(17.6)	**0.02**
NSTEMI	55(30.7)	4(11.8)	
USA	16(8.9)	5(14.7)	
CSA	97(54.2)	19(55.9)	
Arterial grafts	170 (34.3)	27(27.6)	0.45
Venous grafts	436 (65.7)	83 (72.4)	
No. of occluded grafts	341 (64.6)	40 (35.9)	0.42
Arterial	53(46.0)	3(17.6)	0.17
Venous	288(51.6)	37(82.3)	
No of stents used	1.70+0.97	1.32+0.63	0.03
EPD	8 (4.5)	4 (11.7)	0.09
OUTCOMES:	**DES (N=170)**	**BMS (N=30)**	**P Value**
ISR	22(12.9)	8(26.7)	0.08

TVR	20(11.7)	4(13.3)	0.92
TLR	19(11.1)	3(9.9)	0.75
Redo CABG	1(5.9)	1(3.3)	0.40
Any other revascularisation	8(4.7)	5(16.7)	0.19
Mortality	16 (9.4)	13 (43.3)	<**0.01**
MACE	55(32.3)	21(69.9)	<**0.01**
MI	39(22.9)	15(49.9)	<**0.01**

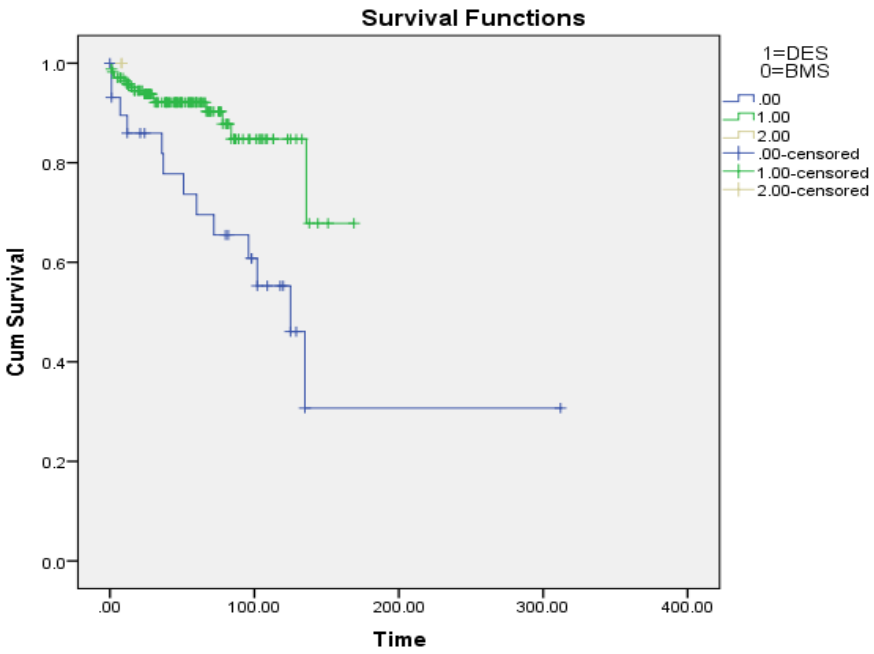


Figure 9. Kaplan-Meier survival curves at clinical follow-up based on stent type (Death vs stent type p<0.01)

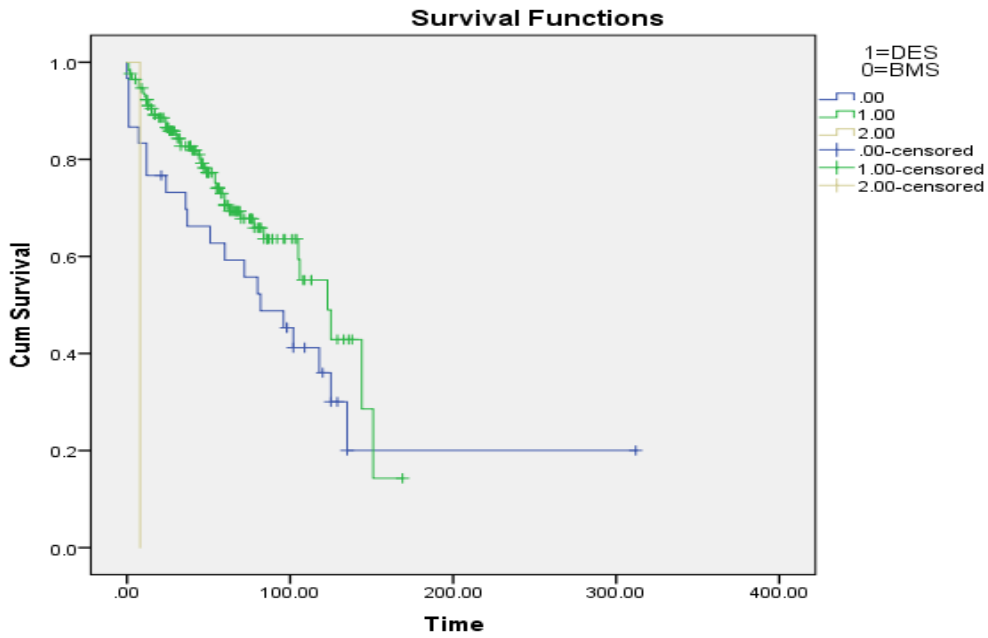


Figure 10. Kaplan-Meier survival curves at clinical follow-up based on stent type (MACE vs stent type p=<0.01)

DISCUSSION

The 10-year patency rate of the internal mammary artery graft (IMA) has been previously reported to be 85-95% (49) compared with only 40% saphenous venous grafts. Majority of patients with diseased graft vessels are older and usually had a severe coronary artery disease prior to CABG (50). In our study majority of patients noted to have multiple comorbidities (Hypertension (69%), Diabetes mellitus (61.6%) dyslipidemia (57.5%)). Nearly half of the patients were smokers. 32 patients (14.6%) were noted to have chronic kidney disease. Similar to study by Liefke C et.al stable angina is the most common clinical presentation prior to PCI(37). Comparison of baseline comorbidities of our study with other similar studies are shown in table12.

Table 12. comparison of baseline comorbidities of our study with other similar studies

Baseline characteristics	**Our study (N=205)**	**Liu et.al (N=289)**	**Liefke C et.al (N-202)**
AGE (years)	60.3±8	63.2±8	68.5±9.4
Sex (males)	197 (89.9%)	211 (73%)	161 (79.8%)
Diabetes mellitus	135 (61.6%)	154(53.3%)	58 (28.7%)
Hypertension	151 (68.9%)	186 (64.3%)	113 (55.9%)
Dyslipidemia	126 (57.5%)	193 (66.7%)	143/199(71.9%)
Family history of CAD	53 (24.2%)		108/181 (59.7%)
Smoking	106 (48.4%)	154(53.29%)	22(10.9%)
Peripheral artery disease	18 (8.2%)		26(14%)
Chronic kidney disease	32 (14.6%)		13(6.4%)
Prior myocardial infarction	119 (54.3%)	115 (39.8%)	82 (40.6%)
Previous PCI	15 (6.84%)	61 (21.1%)	81(40%)
PRESENTATION			
STEMI	18 (8.2%)	34(11.7%)	-
NSTEMI	60 (27.3%)	29 (10%)	40(19.8%)
Unstable angina	21(9.6%)	185(64%)	51(25.2%)
Stable angina	120 (54.7%)	41(14.1%)	111(55%)

Median duration of follow-up in our study is 60 months. Cumulative incidence of MACE occurred in 78 (38.2%), cardiac death in 25 (12.2%) and MI in 55 (26.9%) patients. In our study incidence of MI is higher in comparison to other similar studies. Comparison of long-term outcomes of our study with other similar studies are shown in table13.

Table13. showing comparison of long-term outcomes of our study with other similar studies

Outcomes	**Our study (N=205)**	**Liu et.al (N=289)**	**Lief et.al (N-202)**
MEDIAN DURATION OF F/U (MONTHS)	60 (28-86)	37 (6-78)	60
MACE	78 (38.2%)	88 (33.2%)	
All cause death	29 (14.2%)		**35 (17.4%)**
CVS death	25 (12.2%)	17 (6.4%)	20 (10.4%)
MI	55 (26.9%)	**18 (6.8%)**	**22 (11.5%)**
TLR	23 (11.2%)		
TVR	26 (12.7%)	53(20.2%)	47 (25%)

MI, Myocardial infarction; MACE, Major adverse cardiovascular event; TLR, Target lesion revascularization; TVR, target vessel revascularization

Major findings of our study are

1. Multivariate analysis showed Diabetes Mellitus, Chronic Kidney disease (CKD), Left ventricular dysfunction, Stent type (BMS) are independent risk factors for Mortality and Old age, CKD, Stent type (BMS) are independent risk factors for occurrence of MACEs in post-CABG patients who are undergoing revascularization.
2. DESs are associated with better outcomes compared to BMSs with significant reduced mortality and MACE and MI rate.
3. NV- PCI is associated with significantly better outcomes with regard to MACE, Mortality, MI, ISR and TVR rate compared to GV-PCI. Hence NV -PCI to be preferred whenever feasible.

4. Use of distal embolic protection device shows a trend towards lower rate MI and MACE

Ghulfran adanan et.al studied graft PCI outcomes in 110 patients, study conducted between January 2011 to March 2020. Results showed No significant difference in MACE (P=0.48), TVR) (p=0.69), and TLR (p=0.54) with DES as compared to either BMS or POBA. Multivariate Cox regression analysis showed that ACS event, stroke, and female sex were independently associated with MACE(51).

In a study by Liu et al. found that Diabetes, older age and graft-PCI are independent risk factors for MACEs in patients post-CABG who are undergoing revascularization. NV-PCI has superior long-term outcomes compared with graft-PCI. DESs are the first choice for graft-PCI due to their safety and efficacy and their association with reduced mortality and MACE rate (52)

Liefke C et.al (Netherlands) studied long term outcomes of consecutive patients with previous CABG treated with newer generation DES, found that the risk of cardiac death and TVR was significantly higher in patients with previous CABG. TVR rate was highest in patients who underwent PCI of obstructed vein grafts(37).

In a study by Fatemeh Behboudi et.al, 60% of cases underwent PCI on the native coronary arteries, 32% on graft arteries, and 8% on both types of vessels. At 6 months, the cumulative incidence of major cardiovascular event was 5.6% (no death or myocardial infarction, but 4 target lesion revascularizations) and 4 (5.6 %) in-stent restenosis. There was no statistically significant difference in the comparison of MACE between the patients treated in either native arteries or in the grafts (15% vs.12%, p value = 0.8). Multivariate analysis showed that hypertension and the use of the bare metal stent were the independent predictors of MACE and that chronic total occlusion was the independent predictor of the procedural failure rate(31).

Saphenous venous grafts usually deteriorate within 3 years resulting in myocardial ischemia and recurrent and refractory heart failure with poor prognosis (26). Management of myocardial ischemia due to Graft lesions following CABG have remained an important clinical challenge.

There are two options of Graft revascularization one is Redo CABG and second option being PCI; however, Redo CABG is often difficult, with high incidence of complications and

reduced survival, and relatively poor results with regard to symptomatic improvement, graft patency and MACE-free survival (53). Older age, systemic atherosclerosis, other system disease and disseminated malignancy are also contraindications for a redo CABG. In addition, door sites for new grafts are less following ≥2 attempts at CABG. Percutaneous coronary intervention (PCI) has therefore become the preferred treatment modality for graft lesions, the majority of which are saphenous vein grafts (SVG) (50). PCI has also become the preferred first-line treatment for myocardial ischemia in patients with previous CABG, due to its excellent safety and efficacy (54).

There are two options for graft revascularization following CABG, one is native vessel (NV)PCI and other option being graft PCI. Graft PCI is a complex procedure among the two, because of anatomy of saphenous vein leading to low success rate, but when compared to repeat CABG graft PCI showed superior outcomes (55). Complications related to graft PCI include distal embolization during procedure, restenosis and doubtful long-term efficacy; therefore, current guidelines do not recommend graft PCI for the treatment of completely occluded grafts (56)

Graft PCI may be considered when the native vessel is diffusely diseased, completely occluded, failed opening or unlikely to open as decided by the operator. NV PCI has higher procedural success when compared to graft PCI in complex coronary disease. NV PCI is relatively easier procedure and does not require specialized instrumentation. Long term patency rates are higher for reopened native coronary artery compared to degenerated venous grafts, however complexity of native vessel lesions effects the PCI success rate (32).

Comparison studies of different PCI strategies for post-CABG graft lesions show conflicting findings. In a study by de Feyter PJ et.al with thousand patients with a mean follow-up time of 29 months, SVG-PCI was shown to have a two-fold mortality risk and 1.6-fold MACE occurrence compared with NV-PCI (57).

In a prospective study including 190 patients NV-PCI and 88 patients with graft-PCI, the graft-PCI group had significantly higher incidence rates of MACEs, mortality and TVR than the NV-PCI group (43.2 vs. 19.6%, log-rank P<0.001; 19.3 vs. 6.9%, log-rank P=0.008; 23.9 vs. 12.7%, log-rank P=0.02, respectively), and graft-PCI was shown to be an independent risk factor for MACEs [hazard ratio (HR), 2.84; 95% CI, 1.45-5.57; P=0.002] (58).

Liu et al.compared the prognosis of graft-percutaneous coronary intervention (PCI) and native vessel (NV)-PCI in 265 patients (190 NV-PCI and 75 graft-PCI). The mean follow-up time was 37 months. Cumulative incidence of MACEs occurred in 54 patients in the NV-PCI group (28.4%) and 34 patients in the graft-PCI group (45.3%). The NV-PCI group had a higher MACE-free and revascularization-free survival compared with the graft-PCI group (71.6 vs. 54.7%, log-rank P=0.008; 82.6 vs. 73.3%, log-rank P=0.048, respectively). No significant difference was found in the MI-free survival and overall survival between the groups (94.2 vs. 90.7%, log-rank P=0.124; 94.7 vs. 90.7%, log-rank P=0.099, respectively). Thus, they recommended that NV-PCI to be preferred for post-CABG graft disease. In the case of failed NV-PCI, graft-PCI can be considered(52).

Guering Eid-Lidt et al**.** compared the in-hospital and long-term outcomes of Graft PCI and NV PCI in patients with previous coronary artery bypass grafting. (78 NV-PCI and 49 graft-PCI). The incidence of no reflow phenomenon was higher in Graft PCI group (10.2% vs. 1.2%, p = 0.0001). The cumulative incidence of major adverse cardiac events was higher in graft PCI group (10.2% vs. 2.5%, p = 0.041). There was a lower MACE (major adverse cardiovascular events) free survival at 3years in the graft PCI group (65.0% vs. 89.1%, p = 0.024)(16).

By contrast, in a retrospective study of 618 patients subjected to PCI post-CABG with a mean follow-up time of 27 months, the NV-PCI and SVG-PCI groups did not show significant differences in the incidence rates of mortality (10.0 vs. 8.0%, P=0.22), MI (9.0 vs. 6.0%, P=0.20) or TVR (26.0 vs. 25.0%, P=0.80) (59).

Dong liu et al compared long term outcomes of 157 patients with diabetes and previous CABG, who underwent PCI of either a graft vessel (GV) (n=44) or a native vessel (NV) (n=113), between January 1st 2009 and June 1st 2015. Results showed no difference in in-hospital mortality and long-term incidence of MACE, cardiac death, MI, or revascularization. PCI success [hazard ratio (HR), 11.488; 95% confidence interval (CI), 1.135–116.303; P<0.05] was independent predictor of MACE. Thus, the vessel (graft vessel or native vessel) with higher estimated PCI success rate should be prioritized by operators.

In the present study MACEs occurred in 48 (32.9%) patients in the NV-PCI group and 30 patients (56.6%) in the graft-PCI group (p=<0.01). Mortality occurred in 10 patients (20.8%) in graft PCI group and 15 patients (10.9%) in NV-PCI group (P=0.04). MI occurred in 20 patients (37.8%) in graft PCI group and 35 patients (24%) in NV-PCI group which is statistically significant (P=0.05). There was significant occurrence of TLR (20% vs 8.2%, p=0.01) and

ISR (28.3% vs 10.9%, P=<0.01) noted in graft PCI group compared to NV-PCI group. Hence NV-PCI to be preferred to GV-PCI for revascularization in post CABG patients

Bare metal stents (BMS) and drug-eluting stents (DES) are two types of stents available for PCI in post CABG patients. Efficacy of SVG-PCI can be affected by restenosis (59). In a meta- analysis by Hakeem et al revealed BMSs are inferior to DESs. 29 studies with a total of 7,994 patients (4,187 with DESs and 3,807 with BMSs) are analyzed. Mean follow-up duration is 6-48months. In their meta-analysis, BMSs were found to be inferior to BMSs with regard to the incidence of mortality (12 vs. 17%, P=0.0002), MACEs (19 vs. 28%, P<0.001), demonstrating a higher safety and efficacy of DESs. In addition, compared with DESs, BMSs had significantly higher incidences of mortality (OR, 0.68; 95% CI, 0.53-0.88; P=0.004), Major cardiovascular (OR, 0.64; 95% CI, 0.51-0.82; P<0.001), TLR (OR, 0.6; 95% CI, 0.43-0.83; P=0.002) and target vessel failure (OR, 0.57; 95% CI, 0.41-0.80; P=0.001) (60).

A systematic review and meta-analysis of Comparison of DES with BMS for PCI of Saphenous Vein Graft Lesions by Mosleh et al. found that Patients who underwent PCI with DES had lower MACE rate (P<.001), lower all-cause mortality rate (P<.001), lower TVR rate P<.001), and TLR rate (P<.01). There was no significant reduction in myocardial infarction (MI) in the DES group compared with the BMS group(61).

By contrast, other studies did not find significant difference between DESs and BMSs in the long-term follow-up subsequent to SVG-PCI (17,32,33). In Stenting of Saphenous Vein Grafts (SOS) study) by Brilakis ES et.al.found that, at the end of 36 months follow-up, there is no significant difference in overall mortality between the DES and BMS groups (5 vs. 12%; HR, 1.56; 95% CI, 0.72-4.11; P=0.27)(55). In a study by Goswami NJ et.al, 284 patients with DESs and 95 patients with BMSs, found that, despite a significantly lower inpatient mortality rate in the DES group, there is no significant difference between the groups with respect to the incidence of MACEs at 3 years, suggesting better long-term safety profile (but non superiority) of DESs(62).

In a study by Liu et al. DESs are used in 239 patients (82.7%) and BMSs in 50 patients (17.3%). Mean follow-up period is 37 months. Results showed a trend towards better outcomes in DESs group compared to BMSs group. In patients with NV-PCI, DESs were superior to BMSs with respect to occurrence of MACE and TVR. No significant differences

observed with regard to MI and mortality. In graft PCI patients DESs were used in 56 cases and BMSs in 19 cases. Use of DESs showed a trend towards better outcomes(52). Similarly in our study use of DESs associated with better outcomes compared with BMSs.

Limitations in the present study.

1. the design of the study was retrospective and non-randomized, and the course of treatment was determined by the individual operator.
2. Antiplatelet treatment was administered for a variable duration and the length of the time-frame for inclusion in this study (5 years) may have introduced confounding effects as a result of developments in techniques and equipment.
3. Clinical outcomes and postprocedural complication are self-reported, such outcomes are vulnerable to reporting biases, and complications may be under-reported,
4. the use of BMSs in the graft-PCI procedures was relatively low. A prospective, randomized study with angiographic follow-up is therefore warranted to control for confounding factors.
5. The study was done in a single-center, and the sample size is relatively small, which may not represent the whole general population in our region.
6. In patients with SVG disease outcomes are affected by many factors like graft plaque volume, degree of graft degeneration, treatment techniques, etc. that could not be accounted for in this retrospective analysis

CONCLUSION:

1. Diabetes Mellitus, Chronic kidney disease, LV dysfunction, Stent type (BMS) are independent risk factors for Mortality in post-Coronary artery bypass graft surgery patients who are undergoing revascularization
2. Old age, Chronic kidney disease, Stent type (BMS) are independent risk factors for MACEs in post-Coronary artery bypass graft surgery patients who are undergoing revascularization
3. NV- PCI is associated with significantly better outcomes. Hence, it should be preferred. GV-PCI maybe considered when NV-PCI is not feasible or failed.
4. Drug eluting stents are the first choice for Percutaneous coronary intervention in post-Coronary artery bypass graft surgery patients due to their safety and efficacy and their association with reduced mortality and MACE and MI rate.
5. Use of distal embolic protection device shows a trend towards lower rate of MI and MACE

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APPENDIX

PROFORMA:

PATIENT VARIABLES

Patient initials

AGE- GENDER-

HOSPITAL NO.

Address- MOBILE NO.

Risk factors:

Diabetes:

Hypertension:

Dyslipidemia:

Smoking:

Family history of CAD:

Previous PCI:

Clinical syndrome at presentation

- NSTEMI /STEMI
- Unstable angina
- Stable angina

LVEF:

Total number of lesions treated per patient

- 1
- 2
- ≥3

Type of stent:

Graft PCI/ Native vessel:

Distal protection/ no protection:

Complete revascularization/ incomplete revascularization:

OUTCOME MEASURES:

- Any death
- Cardiac death
- Myocardial infarction
- Target vessel revascularization
- Target lésion revascularisation
- Definite stent thrombosis
- To assess the safety and efficacy of PCI strategy
- Functional status
- Angina severity
- LV function

SREE CHITRA THIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

PATIENT INFORMATION SHEET

TITLE: LONG TERM OUTCOMES OF PERCUTANEOUS CORONARY INTERVENTION (PCI) IN PATIENTS WITH PREVIOUS CORONARY ARTERY BYPASS GRAFTING (CABG)

Name of Investigators: DR ANIL KUMAR.B, DR SIVASANKARAN S, DR BIJULAL S.

Dear Patient/Parent We welcome you and thank you for your interest in this research project titled "LONG TERM OUTCOMES OF PERCUTANEOUS CORONARY INTERVENTION (PCI) IN PATIENTS WITH PREVIOUS CORONARY ARTERY BYPASS GRAFTING (CABG)". Before you participate in this study, it is important for you to understand why this research is being carried out. This form will provide you all the relevant details of this research. It will explain the nature, the purpose, the benefits, the risks, the discomforts, the precautions and the information about how this project will be carried out. It is important that you read and understand the contents of the form carefully. This form may contain certain scientific terms and hence, if you have any doubts or if you want more information, you are free to ask the study personnel or the contact person mentioned below before you give your consent and also at any time during the entire course of the project.

This is a study on wellbeing of patients, who have undergone percutaneous coronary intervention (PCI), who have already undergone CABG prior to this. Patients with a history of CABG, may require PCI due to progression of native disease or graft occlusion. In this study am looking at long outcomes of patients who have undergone both these procedures. As a part of this study, I will document all the routine investigations and treatments you have undergone and exact time lag between various events during this.

What does the present study involve? The records of the previous operation that you have undergone will be collected from the hospital database. You will be contacted by phone/ by mail to visit the hospital on a particular day. You will usually come in to hospital on the day of appointment. A specialist doctor will explain the proposed study design to you and ask you to sign the consent form to confirm that you understand the procedure and agree to go ahead with it. Please ask any questions you want. Kindly, give permission to look into your old records from hospital database. Your personal details will be hidden. All records of your study will be kept confidential. Your identity will not be revealed in any publication or release of results. Study records will be kept indefinitely for analysis and follow-up. Similar information will be collected from all the patients who are included in this study and that data will be analyzed.

Following enrolment into the study, you will undergo the following tests- usually done as part of routine follow up evaluation:

- Functional status- History
- Electrocardiogram
- Echocardiogram
- Any other test deemed necessary as part of evaluation

How long does it take?

The hospital visit will be a routine consultation, and the tests done will be part of routine follow up. This may take up to 2-3 hours. Please be prepared to be in the hospital OPD during that time.

WHAT ARE THE RESPONSIBILITIES OF PARTICIPANTS?

Your decision to participate in this study is voluntary, your own personal choice. You may choose not to continue at any time, for any reason, without notice.

WHAT ARE THE EXPECTED RISKS FOR THE PARTICIPANTS?

The study involves collection of previous data from case records, and a follow up evaluation to assess the functional status and outcome of prior surgery. There will be no risks for the participants because of participation in the study. They will be managed according to the hospital protocol. No specific intervention will be done.

WHAT ARE THE EXPECTED BENEFITS OF THE RESEARCH TO THE PARTICIPANTS?

The participants are evaluated in detail for any cardiac cause for functional impairment. A follow up examination and evaluation may be helpful in identification of any risk factors for poor outcomes or functional deterioration. It may be helpful in detecting patients who require early intervention or addition of medical therapy. The data derived from the study may be helpful in planning appropriate timing and surgical strategies for patients with similar conditions in the future.

WILL PARTICIPANTS BE COMPENSATED FOR PARTICIPATION IN THIS TRIAL?

You will not be paid for participation in the study.

WILL MY PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?

All records of your study will be kept confidential. Your identity will not be revealed in any publication or release of results. Study records will be kept indefinitely for analysis and follow-up.

CAN I WITHDRAW FROM THE STUDY AT ANY TIME DURING THE STUDY PERIOD?

Yes, you can. Your decision will not affect your regular medical care.

IF THERE ARE ANY NEW FINDINGS / INFORMATION, WOULD I BE INFORMED?

Yes.

WHAT HAPPENS IN CASE OF A STUDY RELATED INJURY?

There will be no study related injury.

IS THERE ANY ALTERNATIVE TO THE TREATMENT MENTIONED?

Not applicable.

If you have any further questions, please ask: Dr. Anil Kumar B (Principal investigator), Senior Resident, Department of Cardiology (Email: anilkm27@sctimst.ac.in Ph No: 9293141241) For any technical clarifications, please contact Dr. Mala Ramanathan, Member Secretary, IEC, SCTIMST and Additional Professor, AMCHSS, SCTIMST (Email: iec.mem.sec@sctimst.ac.in, Phone no. 0471-2524234)

STUDY CONSENT FORM

TITLE OF THE STUDY: Long term outcomes of percutaneous coronary intervention (PCI) in patients with previous coronary artery bypass grafting (CABG)

Study number: All post CABG patients undergoing PCI at SCTIMST will be included in study

Participant's name:

Date of Birth / Age (in years):

I_____ _____,
son/daughter of _____

(Please tick boxes).

[ ] Declare that I have read the above information provided to me regarding the study: "Early and 1 year outcomes after transcatheter aortic valve implantation." and have clarified any doubts that I had.

[ ] I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights.

[ ] I understand that the study staff and institutional ethics committee members may not need my permission to look at my health records even if I withdraw from the trial. I agree to this access.

[ ] I understand that my identity may not be revealed in any information released to third parties or published.

[ ] I voluntarily agree to take part in this study.

[ ] I received a copy of this signed consent form.

Name: Name of witness:

Signature: Relation to participant:

Date: Date:

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered. _____ _____

Name and Signature of Person Obtaining Consent

Dr. Anil Kumar Boddu

Senior resident

Dept. of Cardiology SCTIMST

For any technical clarifications, please contact Dr. Mala Ramanathan, Member Secretary, IEC, SCTIMST and Additional Professor, AMCHSS, SCTIMST (Email: iec.mem.sec@sctimst.ac.in, Phone no. 0471-2524234)

പഠന സമ്മതപത്രം

പഠനശീർഷകം

കൊറോണറി ആർട്ടറി ബൈപ്പാസ് ഗ്രാഫ്റ്റിംഗിന് (സിഎബിജി) വിധേയരായിട്ടുള്ള രോഗികളിലെ പെർക്യൂട്ടേനിയസ് കൊറോണറി ഇടപെടലുകളുടെ (പിസിഐ) ദീർഘകാല നേട്ടങ്ങൾ

പഠന നമ്പർ

പിസിഐയ്ക്ക് വിധേയരാകുന്ന SCTIMST സിഎബിജി കഴിഞ്ഞ എല്ലാവരെയും പഠനത്തിൽ ഉൾപ്പെടുത്തും.

പങ്കാളിയുടെ പേര് _____ ജനനതീയതി/ വയസ്സ് (വർഷത്തിൽ) :____

ഞാൻ..... പുത്രൻ/പുത്രി.....
(ദയവായി കോളങ്ങൾ അടയാളപ്പെടുത്തുക)

- മുകളിൽ, കൊറോണറി ആർട്ടറി ബൈപ്പാസ് ഗ്രാഫ്റ്റിംഗിന് (സിഎബിജി) വിധേയരായിട്ടുള്ള രോഗികളിലെ പെർക്യൂട്ടേനിയസ് കൊറോണറി ഇടപെടലുകളുടെ (പിസിഐ) ദീർഘകാല നേട്ടങ്ങൾ എന്ന പഠന സംബന്ധിയായി എനിക്കു നൽകിയ വിവരങ്ങൾ വായിച്ചു എന്നു പ്രസ്താവിക്കുന്നു. എന്റെ എല്ലാ സംശയങ്ങളും പരിഹരിച്ചു.[ ]
- എന്റെ ഈ പഠനത്തിലുള്ള പങ്കാളിത്തം പൂർണ്ണമായും സ്വമേധയാ ആണെന്നും അനുവാദം എനിക്ക് ഏതുസമയത്തും എന്റെ ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളെയോ ബാധിക്കാതെ പിൻവലിക്കാൻ അവകാശമുണ്ടെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
- ഞാൻ ഈ പഠനത്തിൽ നിന്നും പിൻമാറിയാലും പഠനം നടത്തുന്നവർക്കും സ്ഥാപനത്തിലെ നൈതിക കമ്മിറ്റി അംഗങ്ങൾക്കും എന്റെ ആരോഗ്യരേഖകൾ പരിശോധിക്കുന്നതിന് എന്റെ അനുവാദം ആവശ്യമില്ലെന്ന്ഞാൻ മനസ്സിലാക്കുന്നു. അതിനോട് ഞാൻ യോജിക്കുന്നു. [ ]
- എന്നെ തിരിച്ചറിയാനുതകുന്ന വിവരങ്ങൾ ഒന്നും മൂന്നാം കക്ഷികൾക്കു നൽകുകയോ പ്രസിദ്ധീകരിക്കുകയോ ചെയ്യില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
- ഞാൻ സ്വമേധയാ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു. [ ]
- ഒപ്പിട്ട സമ്മതപത്രത്തിന്റെ ഒരു പ്രതി എനിക്ക് ലഭിച്ചു [ ]

പങ്കെടുക്കുന്നയാളുടെ പേര്

ഒപ്പ്

തീയതി

സാക്ഷിയുടെ പേര്

ഒപ്പ്

തീയതി

(സമ്മതം വാങ്ങുന്നയാൾ)

മെഡിക്കൽ റിസർച്ച് പ്രോജക്ടിനാവശ്യമായ സമ്മതപത്രത്തിനു വേണ്ടുന്ന എല്ലാ ഘടകങ്ങളും തൃപ്തികരമായി നിർവഹിച്ചിരിക്കുന്നുവെന്ന് ഞാൻ ബോധ്യപ്പെടുത്തുന്നു. പഠനപങ്കാളിയുമായി ഗവേഷണപദ്ധതിയെപ്പറ്റി സാങ്കേതികേതര പദങ്ങളുപയോഗിച്ച് എല്ലാ വിവരങ്ങളെപ്പറ്റിയും ചർച്ച നടത്തുകയും പ്രതീക്ഷിക്കാവുന്ന അപകടസാധ്യതകളും പാർശ്വഫലങ്ങളും വിശദീകരിക്കുകയും ചെയ്തു. പങ്കാളിയെ ചോദ്യങ്ങൾ ചോദിക്കാൻ പ്രേരിപ്പിക്കുകയും എല്ലാ ചോദ്യങ്ങൾക്കും ഉത്തരം നൽകുകയും ചെയ്തു എന്നും ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു.

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേര്

ഒപ്പ്

പ്രധാന ഗവേഷകൻ

ഡോ. അനിൽകുമാർ ബി

സീനിയർ റെസിഡന്റ്

കാർഡിയോളജി ഡിപ്പാർട്ട്മെന്റ്

സാങ്കേതീക വിശദീകരണത്തിന് ബന്ധപ്പെടുക. ഡോ. മാല രാമനാഥൻ, മെമ്പർസെക്രട്ടറി, SCTIMST-IEC, അഡീഷണൽ പ്രൊഫസർ AMCHSS, SCTIMST (ഫോൺ. 0471 2524234) ഇമെയിൽ

ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി,

തിരുവനന്തപുരം

രോഗികൾക്കുള്ള കാര്യവിവരണപത്രം

പഠനശീർഷകം

കൊറോണറി ആർട്ടറി ബൈപ്പാസ് ഗ്രാഫ്റ്റിംഗിന് (സിഎബിജി) വിധേയരായിട്ടുള്ള രോഗികളിലെ പെർക്യൂട്ടേനിയസ് കൊറോണറി ഇടപെടലുകളുടെ (പിസിഐ) ദീർഘകാല നേട്ടങ്ങൾ

ഗവേഷകരുടെ പേര്

ഡോ. അനിൽ കുമാർ,

ഡോ. ശിവശങ്കരൻ എസ്,

ഡോ. ബിജുലാൽ

പ്രിയ സുഹൃത്ത്/രക്ഷകർത്താവ്,

കൊറോണറി ആർട്ടറി ബൈപ്പാസ് ഗ്രാഫ്റ്റിംഗിന് (സിഎബിജി) വിധേയരായിട്ടുള്ള രോഗികളിലെ പെർക്യൂട്ടേനിയസ് കൊറോണറി ഇടപെടലുകളുടെ (പിസിഐ) ദീർഘകാല നേട്ടങ്ങൾ എന്ന ഗവേഷണ പദ്ധതിയിൽ താത്പര്യം കാണിച്ചതിന് താങ്കളെ സ്വാഗതം ചെയ്യുകയും നന്ദി പ്രകാശിപ്പിക്കുകയും ചെയ്യുന്നു.

ഗവേഷണ പഠനത്തിൽ പങ്കെടുക്കുന്നതിനുമുൻപ്, ഈ ഗവേഷണം എന്തിനാണ് നടത്തുന്നതെന്ന് താങ്കളറിയേണ്ടത് പ്രധാനമാണ്. ഗവേഷണത്തെപ്പറ്റി വ്യക്തമായി അറിയുന്നതിന് പ്രസക്തമായ എല്ലാ വിവരങ്ങളും ഈ പത്രികയിൽ നൽകിയിട്ടുണ്ട്. ഈ പദ്ധതി എങ്ങനെ നടപ്പാക്കുമെന്നതിന്റെ -സ്വഭാവം, ഉദ്ദേശം, നേട്ടങ്ങൾ, അപായങ്ങൾ, അസ്വസ്ഥതകൾ, മുൻകരുതലുകൾ എന്നിവയുടെ വിവരങ്ങൾ ഈ പത്രിക വിശദീകരിക്കുന്നു. താങ്കൾ ശ്രദ്ധാപൂർവ്വം ഉള്ളടക്കം വയിച്ച് മനസ്സിലാക്കുന്നത് പ്രധാനമാണ്. ഈ പത്രികയിൽ ചില ശാസ്ത്ര പദങ്ങൾ ഉണ്ടായേക്കാം, ആകയാൽ സമ്മതപത്രം ഒപ്പിടുന്നതിന് മുമ്പോ പദ്ധതിസമയത്ത് ആകെയോ, താങ്കൾക്കെന്തെങ്കിലും സംശയങ്ങളുണ്ടെങ്കിൽ, അഥവാ താങ്കൾക്ക് കൂടുതൽ വിവരങ്ങൾ ആവശ്യമെങ്കിൽ ഗവേഷകരോടോ അല്ലെങ്കിൽ ബന്ധപ്പെടുവാനായി താഴെപ്പറഞ്ഞിരിക്കുന്നവരോടോ ചോദിക്കാൻ താങ്കൾക്ക് സ്വാതന്ത്ര്യമുണ്ട്.

പിസിഐയ്ക്ക് കാർഡിയാക് കതീറ്ററൈസേഷൻ ആവശ്യമുണ്ട്, താങ്കളുടെ കൊറോണറി മഹാധമനിയിലേക്ക് ഒരു കതീറ്റർ കടത്തി സാധാരണയായി അയഡിൻ അടിസ്ഥാനമായ മരുന്ന് കുത്തിവയ്ക്കുന്നു. അതിറോസ്ക്ലിറോസിസ് ആവരണം വളർന്ന് അടയപ്പെടുകയോ സങ്കോചിക്കുകയോ ചെയ്ത കൊറോണറി ധമനികൾ തുറക്കാൻ ഡോക്ടർമാർ പിസിഐ ഉപയോഗിക്കുന്നു. കൊറോണറി ഹൃദ്രോഗത്തിന്റെ ലക്ഷണങ്ങളിൽ നിന്നു മോചിപ്പിക്കാനോ ഹൃദയസ്തംഭനത്തിനു ശേഷം ഹൃദയത്തിനുണ്ടാകുന്ന തകരാർ കുറയ്ക്കാനോ പിസിഐ ഉപയോഗിച്ചേക്കാം. തടസ്സമുണ്ടായ മഹാധമനി തുറക്കാൻ ഡോക്ടർ ഗൈഡ്വയറിനു മുകളിലൂടെ

മറ്റൊരു കത്തിറ്റർ കടത്തി കത്തിറ്ററിന്റെ അറ്റത്തുള്ള ഒരു ബലൂൺ വിർപ്പിക്കും. സ്റ്റെന്റ് എന്നുപേരുള്ള ഒരു ചെറിയ വലയുടെ കുഴൽ മഹാധമനി തുറന്നിരിക്കാൻ നിക്ഷേപിച്ചേക്കാം.

പിസിഐയിൽ ഗുരുതരമായ സങ്കീർണ്ണതകൾ മിക്കപ്പോഴും ഉണ്ടാവാറില്ല, പക്ഷേ അതുണ്ടാവാനും സാദ്ധ്യതയുണ്ട്. രക്തസ്രാവം, രക്തക്കുഴൽ തകരാർ, കുത്തിവയ്ക്കുന്ന മരുന്നിന്റെ ചികിത്സിക്കാൻ കഴിയുന്ന അലർജി, ഇതു ചെയ്യുന്നതിനിടെ ആവശ്യമായേക്കാവുന്ന അടിയന്തിര കൊറോണറി ബൈപ്പാസ് ഗ്രാഫ്റ്റിംഗ്, ഹൃദയതാളത്തിന്റെ ക്രമരാഹിത്യം, മഹാധമനികളുടെ തകരാർ, വൃക്കകളുടെ തകരാർ, ഹൃദയസ്തംഭനം, മസ്തിഷ്കാഘാതം, അല്ലെങ്കിൽ രക്തം കട്ടപിടിക്കുക തുടങ്ങിയവയാണ് ഈ സങ്കീർണ്ണതകൾ. ബലൂൺ താത്കാലികമായി ഹൃദയത്തിലേയ്ക്കുള്ള രക്തപ്രവാഹം തടഞ്ഞേക്കാമെന്നതിനാൽ, ചിലപ്പോൾ പിസിഐയ്ക്കിടയിൽ നെഞ്ചുവേദന അനുഭവപ്പെട്ടേക്കാം. ചികിത്സിച്ച മഹാധമനിയുടെ ഭാഗത്ത് റെസ്റ്റിനോസിസ് അല്ലെങ്കിൽ കലകളുടെ വീണ്ടുമുള്ള വളർച്ചമൂലം തുടർന്നുള്ള മാസങ്ങളിൽ മഹാധമനി വീണ്ടും ഇടുങ്ങുകയോ തടസ്സപ്പെടുകയോ ചെയ്തേക്കാം. താങ്കൾക്ക് കൂടുതൽ പ്രായമുണ്ടെങ്കിൽ, ദീർഘകാലമായുള്ള വൃക്കരോഗമുണ്ടെങ്കിൽ, ചികിത്സാനടപടിക്കിടെ ഹൃദയ തകരാർ ഉണ്ടായാൽ, അല്ലെങ്കിൽ വ്യപകമായ ഹൃദ്രോഗമോ കൊറോണറി മഹാധമനിയിൽ ഒന്നിലേറെ തടസ്സങ്ങളോ ഉണ്ടെങ്കിൽ സങ്കീർണ്ണതകളുടെ അപായം വർദ്ധിച്ചതായിരിക്കും, താങ്കൾക്ക് തുടർച്ചയായ മരുന്നും കാർഡിയോളജിസ്റ്റിന്റെ തുടർചികിത്സയും ആവശ്യമായി വന്നേക്കാം.

ഇപ്പോഴത്തെ പഠനത്തിലുൾക്കൊള്ളുന്നതെന്താണ്?

താങ്കൾ വിധേയമായ മുമ്പത്തെ ശസ്ത്രക്രിയയുടെ വിവരങ്ങൾ ആശുപത്രി രേഖകളിൽ നിന്നും ശേഖരിക്കും. താങ്കളെ ഫോൺവഴിയോ തപാൽവഴിയോ ബന്ധപ്പെട്ട് ഒരു പ്രത്യേക ദിവസം ആശുപത്രി സന്ദർശിക്കാനാവശ്യപ്പെടും. താങ്കൾ സാധാരണയായി നിശ്ചിത ദിവസമാണ് ആശുപത്രിയിൽ വരുന്നത്. ഒരു വിദഗ്ദ്ധഡോക്ടർ താങ്കളോട് ഉദ്ദേശിക്കുന്ന പഠനത്തിന്റെ രൂപരേഖ വിശദീകരിക്കുകയും നടപടികൾ താങ്കൾക്ക് മനസ്സിലായി എന്നുറപ്പാക്കാനും അത് തുടരാൻ സമ്മതിക്കുന്നതിനും ഒരു സമ്മതപത്രം ഒപ്പിടാനാവശ്യപ്പെടും. താങ്കൾക്കാവശ്യമുള്ള ഏതുചോദ്യവും ദയവായി ചോദിക്കുക.

പഠനത്തിൽ ഉൾപ്പെടുത്തിയ ശേഷം, സാധാരണയായി തുടർചികിത്സയുടെയും വിലയിരുത്തലിന്റെയും ഭാഗമായി ചെയ്യപ്പെടുന്ന താഴെപ്പറയുന്ന പരിശോധനകൾക്ക് താങ്കൾ വിധേയമാകും.

- പ്രവർത്തന നിലവാരം - ചരിത്രം
- ഇലക്ട്രോ കാർഡിയോഗ്രാം
- എക്കോകാർഡിയോഗ്രാം
- വിലയിരുത്തലിന് ആവശ്യമായ മറ്റ് പരിശോധനകൾ

ഇതിനെത്ര സമയമെടുക്കും?

ആശുപത്രി സന്ദർശനം പതിവ് ചികിത്സയ്ക്കാണ്, പതിവ് തുടർചികിത്സയുടെ ഭാഗമാണ് പരിശോധനകൾ. ഇത് 2 മുതൽ 3 മണിക്കൂർ എടുത്തേക്കാം. ആശുപത്രിയുടെ ഒപിഡിയിൽ ആ സമയത്തുണ്ടാവാൻ തയാറാകുക.

പങ്കാളികളുടെ ഉത്തരവാദിത്വങ്ങളെന്തെല്ലാം?

പഠനത്തിൽ പങ്കെടുക്കാനുള്ള താങ്കളുടെ തീരുമാനം സ്വമേധയാ ആണ്. താങ്കളുടെ വ്യക്തിപരമായ തീരുമാനം. താങ്കൾക്ക് ഏതുസമയത്തും എന്തുകാരണത്താലും മുന്നറിയിപ്പില്ലാതെ പഠനത്തിൽ നിന്നും പിൻമാറാം

പങ്കാളികൾക്ക് പ്രതീക്ഷിക്കുന്ന അപായമെന്തെല്ലാം?

ചികിത്സാരേഖകളിൽനിന്നുള്ള വിവരശേഖരണവും ശസ്ത്രക്രിയയ്ക്കുശേഷമുള്ള പ്രവർത്തന നിലവാരം വിലയിരുത്തുന്ന തുടർചികിത്സയിലെ വിവരങ്ങളും ശേഖരിക്കുകയാണ് പഠനത്തിൽ ഉൾക്കൊള്ളുന്നത്. പഠനത്തിൽ പങ്കെടുക്കുന്നതുകൊണ്ട് പങ്കാളിക്ക് അപായമൊന്നുമുണ്ടാകില്ല. അവ ആശുപത്രി പ്രവർത്തനചട്ടപ്രകാരം കൈകാര്യം ചെയ്യപ്പെടും. ഒരു പ്രത്യേക ഇടപെടലും നടത്തുന്നില്ല.

ഗവേഷണത്തിൽനിന്നും പങ്കാളികൾക്ക് പ്രതീക്ഷിക്കപ്പെടുന്ന നേട്ടങ്ങളെന്തെല്ലാം?

പങ്കാളികളിൽ പ്രവർത്തനപരമായ തകരാറുകൾക്ക് കാരണമായി ഹൃദയത്തിന്റെ എന്തെങ്കിലും തകരാറുണ്ടോയെന്ന് വിശദമായി വിലയിരുത്തപ്പെടും. തുടർപരിശോധനയും വിലയിരുത്തലും മോശം ഫലത്തിന്റെ അപായസാദ്ധതകളൾ അല്ലെങ്കിൽ പ്രവർത്തനപരമായ ശേഷികുറഞ്ഞുവരുന്നത് കണ്ടെത്താൻ സഹായകമാണ്. നേരത്തെയുള്ള ഇടപെടലുകളോ അധികമായ മരുന്നുചികിത്സയോ ആവശ്യമുള്ള രോഗികളെ കണ്ടെത്താനിത് സഹായകമാണ്. സമാനമായ അവസ്ഥയിലുള്ള രോഗികൾക്ക് വേണ്ടും വിധമുള്ള ചികിത്സ ആസൂത്രണം ചെയ്യാനും, ശസ്ത്രക്രിയാതന്ത്രവും വേണ്ടുന്ന സമയവും നിശ്ചയിക്കാനും പഠനഫലങ്ങൾ ഭാവിയിൽ സഹായകമായേക്കാം.

പങ്കാളികൾക്ക് പ്രതിഫലം നൽകുമോ?

ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതിന് താങ്കൾക്ക് പ്രതിഫലമൊന്നും നൽകില്ല

പഠനത്തിലുള്ള എന്റെ പങ്കാളിത്തം രഹസ്യമായി സൂക്ഷിക്കുമോ?

താങ്കലുടെ പഠനത്തിലെ രേഖകളെല്ലാം രഹസ്യമായി സൂക്ഷിക്കും. പ്രസിദ്ധീകരണങ്ങളിലോ, പഠനഫലം പപൂറത്തുവിടുമ്പോഴോ താങ്കളുടെ വ്യക്തിവിവരങ്ങൾ വെളിവാക്കില്ല. പഠനരേഖകൾ അനന്തമായി വിലയിരുത്തലിനും തുടർചികിത്സയ്ക്കുമായി സൂക്ഷിക്കും.

പഠനകാലയളവിലെപ്പോഴും എനിക്ക് പഠനത്തിൽനിന്നും പിൻവാങ്ങാമോ?

താങ്കൾക്ക് കഴിയും. താങ്കളുടെ തീരുമാനം താങ്കളുടെ വൈദ്യ പരിചരണത്തെ ബാധിക്കില്ല.

പുതുതായി എന്തെങ്കിലും കണ്ടെത്തിയാലോ പുതിയവിവരങ്ങളുണ്ടെങ്കിലോ എന്നെ അറിയിക്കുമോ?

അറിയിക്കും

പഠനസംബന്ധിയായി പരുക്കുണ്ടായാലെന്ത് സംഭവിക്കും. ?

പഠന സംബന്ധിയായി ഒരു പരുക്കുമുണ്ടാകില്ല.

നിർദ്ദേശിതമായ ചികിത്സയ്ക്ക് പകരമെന്തെങ്കിലുമുണ്ടോ?

ബാധകമല്ല

താങ്കൾക്ക് കൂടുതലെന്തെങ്കിലും ചോദ്യങ്ങളുണ്ടെങ്കിൽ ദയവായി ചോദിക്കുക. ഡോ. അനിൽ കുമാർ ബി (പ്രധാന ഗവേഷകൻ), സീനിയർ റെസിഡന്റ്, കാർഡിയോളജി ഡിപ്പാർട്ട്മെന്റ്, ഫോൺ. 9293141241) ഇമെയിൽ. anilkm27@gmail.com

വിശദീകരണത്തിന് ബന്ധപ്പെടുക. ഡോ. മാല രാമനാഥൻ, മെമ്പർസെക്രട്ടറി, SCTIMST-IEC, അഡീഷണൽ പ്രൊഫസർ AMCHSS, SCTIMST (ഫോൺ. 0471 2524234) ഇമെയിൽ iec.mem.sec@sctimst.ac.in

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by harsh pandey

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श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
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DUPLICATE

Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/1492 /NOVEMBER-2019 26.12.2019

Dr. Anil Kumar Boddu
Senior Resident
Department of Cardiology
SCTIMST, Thiruvananthapuram

Dear Dr. Anil Kumar Boddu,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "LONG TERM OUTCOMES OF PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS WITH PREVIOUS CORONARY ARTERY BYPASS GRAFTING (IEC/1492)" on 5th November, 2019.

The following documents were reviewed:

Original submission

1. *Covering Letter addressed to the Chairperson, IEC, SCTIMST with checklist*
2. *TAC Approval Letter*
3. *IEC Application Form*
4. *Forwarding Letter from the HOD*
5. *Project Proposal*
6. *Patient Information Sheet and Consent Form in English and Malayalam*
7. *Proforma*
8. *CV of Principal Investigator and Co-Principal Investigators*

Revised submission

1. *Covering Letter addressed to the Chairperson, IEC, SCTIMST dated 21.12.2019 with checklist*
2. *TAC Approval Letter*
3. *IEC Application Form*
4. *Project Proposal*
5. *Patient Information Sheet and Consent Form in English and Malayalam*
6. *Proforma*
7. *Forwarding Letter from the HOD*
8. *Telephone Recruitment and Interview Script in English and Malayalam*
9. *CV of Principal Investigator and Co-Principal Investigators*

The following members of the Ethics Committee were present at the meeting held on 5th November, 2019 at G. Parthasarathi Board Room, AMCHSS, SCTIMST

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. R V G Menon	M Tech, PhD	Male	Lay Person (Chairman)	No
2.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
3.	Dr. K R S Krishnan	M.E., Ph.D.	Male	Medical Technology	Yes
4.	Dr. Harikrishna Varma PR	Ph.D(Materials Science)	Male	Medical Technology	Yes
5.	Dr. S S Giri Sankar	LL.M. Ph.D.	Male	Legal Expert	No
6.	Dr. V. Raman Kutty	M D, M Phil, M P H	Male	Health Sciences Expert/Clinician	Yes
7.	Dr. Aneesh V Pillai	BA. LLB (Hons.), LLM, Ph. D, SET (Law)	Male	Legal Expert	No
8.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
9.	Dr. P. Manickam	BSMS, MSc (Epid).,PhD	Male	Health Science Expert/ Social Scientist	No
10.	Dr. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
11.	Mr. Satheesh Chandran	MSW, PGDPM	Male	Lay person/ NGO/ Social Scientist	No
12.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
13.	Dr. Mala Ramanathan	PhD	Female	Social Scientist (Member Secretary)	Yes

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:
The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Mala Ramanathan
Member Secretary, IEC