CORONARY ANGIOGRAPHIC EVALUATION IN SYMPTOMATIC POST-CABG PATIENTS AND OUTCOME OF SAPHENOUS VENOUS GRAFT INTERVENTIONS

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A THESIS SUBMITTED BY

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TO

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM.

IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD

OF

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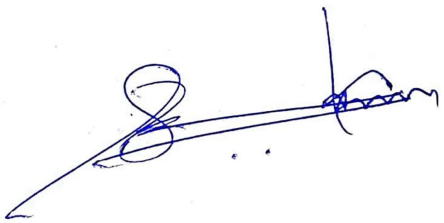
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DECLARATION BY THE STUDENT

I, Dr.Vishnu Kesavan, hereby certify that I had personally carried out the work depicted in the thesis titled **"CORONARY ANGIOGRAPHIC EVALUATION IN SYMPTOMATIC POST CABG PATIENTS AND OUTCOME OF SAPHENOUS VENOUS GRAFT GRAFT INTERVENTIONS"**

No part of this thesis has been submitted for the award of any other degree or diploma prior to this date.

27/12/23.



Dr.Vishnu Kesavan

CERTIFICATE BY THE RESEARCH GUIDE

Name of the Guide: Dr. Harikrishnan S

Division/Department: Cardiology

This is to certify that Dr. Vishnu Kesavan, department/division of Cardiology (Adult Cardiology & Intervention) of this institute has fulfilled the requirements prescribed for the Post-doctoral Fellowship degree of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, "CORONARY ANGIOGRAPHIC EVALUATION IN SYMPTOMATIC POST CABG PATIENTS AND OUTCOME OF SAPHENOUS VENOUS GRAFT INTERVENTIONS" was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date.

Clearance was obtained from the Institutional Ethics Committee for carrying out the study.



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27/12/2023 Dr.Bijulal S

APPROVAL OF THE THESIS

The thesis entitled

CORONARY ANGIOGRAPHIC EVALUATION IN SYMPTOMATIC POST CABG PATIENTS AND OUTCOME OF SAPHENOUS VENOUS GRAFT INTERVENTIONS

Submitted by

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TITLE

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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.

RIMA-Right Internal Mammary artery

SVG - Saphenous venous grafts

OM - Obtuse marginal

RPDA - Right posterior descending artery

PLVB/PLB - Posterior left ventricular branch

CTO - Chronic total occlusion

ISR - In stent restenosis

TLR - Target lesion revascularization

TVR - Target vessel revascularization

BMS - Bare metal stent

DES - Drug eluting stent

PN-Patent &Normal

PS-Patent & Stenosed

CO-Complete Occlusion

Introduction:

Many global studies like Veterans Affairs Cooperative Studies Program address the question of long-term patency of saphenous vein and IMA grafts.(1) But limited data exist which explains the Indian scenario. Secondary PCI in patients with prior CABG surgery is increasingly common. Follow up studies of Native vessel PCI compared to graft vessel interventions are also very few in numbers. In our study we are analyzing the long-term status of bypass grafts and the outcome of interventions in post CABG grafts

AIMS & OBJECTIVES

Aim:

1.To evaluate the long-term outcome of Saphenous venous grafts (SVG) & arterial grafts in patients undergoing CABG and present again with anginal symptoms.

2. Clinical and procedural outcome of PTCA (Percutaneous transluminal coronary angioplasty) in Grafts

Objectives:

1.Assess the condition of native vessel by Coronary angiogram (CAG) in cases of post CABG myocardial ischemia.

2.Assess the status of both arterial and venous grafts by CAG in post CABG symptomatic myocardial ischemia.

3.Asess the clinical and procedural outcome of graft vessel intervention (PTCA)

4.Asess the long-term Outcome of graft vessel interventions

REVIEW OF LITERATURE

Review of Literature:

Aortocoronary saphenous vein graft (SVG) implantation in humans was first performed by Garrett(2) and colleagues in May 1967, and later the technique was further refined by Favaloro (3).Coronary artery bypass grafting [CABG] remains the main strategy of coronary revascularization in patients with severe multivessel coronary artery disease [CAD], particularly when the proximal left anterior descending artery or left main coronary artery are involved.(4).

Grafts used for CABG are either arterial grafts that are typically harvested from the chest wall [internal thoracic arteries (ITA)], arms [radial artery (RA)], and abdomen [right gastroepiploic (RGEA)], or vein grafts harvested from the lower extremities (saphenous veins). Despite lower patency rates compared to arterial grafts, vein grafts remain the most frequently used graft in CABG, with a usage rate that approaches 90% globally.(5)(6)

Graft failure is defined as total graft occlusion, which stops blood flow to the area of the heart intended for revascularization. Technical aspects (such as harvesting technique, intraoperative graft storage and preservation, and

anastomotic technique), target vessel characteristics (including degree of stenosis, vessel diameter, and atherosclerotic burden of the distal vascular bed), and underlying patient-related atherosclerotic risk all play a role in the multifactorial process of graft failure. The primary cause of graft failure changes over time and with the type of graft used. After CABG, antithrombotic drugs are used to prevent early graft failure, or graft occlusion, which is characterized by acute thrombosis and occurs within the first month. Acute thrombosis can cause both artery and vein grafts to fail, but the latter is more likely to experience thrombotic graft occlusion.

SVG failure has a trimodal distribution.(7) Early failure occurs within the first 1–2 months, most likely from primary thrombosis caused by technical factors, poor runoff into small or severely diseased distal coronary arteries, or unrecognized intrinsic saphenous vein disease at the time of implantation.(8) The harvesting of venous conduits is associated with endothelial disruption. High-pressure distension to overcome veno-spasm may cause cell and medial damage.(9) Loss of endothelial cells may activate the extrinsic coagulation cascade via tissue factor, which is expressed in the exposed sub endothelium as a constitutive factor.

Furthermore, it should be noted that veins possess weaker inherent antithrombotic properties in comparison to arteries. This is due to the fact

that heparan sulfate, a proteoglycan molecule with anticoagulant properties that acts by enhancing the effectiveness of antithrombin III, is less abundant in the media and the poorly developed internal elastic lamina of veins as compared to arteries.(10) Veins produce lower levels of nitric oxide (NO) and prostacyclin, which are potent inhibitors of platelet activation, compared to arteries. Bypass grafting further reduces NO production.(11) The prothrombotic effects can result in early graft occlusion, and this risk is further increased by technical factors such as intact venous valves, anastomotic strictures, or graft implantation proximal to an atheromatous segment. It is important to take these factors into consideration to minimize the risk of complications during graft procedures.

Intermediate failure of saphenous vein grafts is usually caused by the development of neointimal hyperplasia, which is most prominent in the first year after bypass surgery but may occur up to 3 years after implantation. (12) Neointimal hyperplasia, defined as the accumulation of smooth muscle cells and extracellular matrix in the intimal compartment, is the major pathology responsible for graft failure between 1 month and 1 year after implantation.(13) The formation of intimal hyperplasia in the venous graft happens after the regeneration of endothelial cells, in contrast to the arterial injury model. This indicates that there are additional mechanisms involved in the grafted vein. (14) One such mechanism is related to the transient

ischemia that occurs during explantation, which results in reperfusion after grafting. This ischemia-reperfusion process reduces the production of antiproliferative mediators such as prostacyclin, NO, and adenosine by endothelial cells. Moreover, it significantly increases the formation of superoxide radicals that directly promote the proliferation of smooth muscle cells.(15)

Other hemodynamic factors like increase in wall stress incurred by saphenous veins on exposure to arterial pressures is a potential factor promoting intimal fibrosis. When the pressure in the arteries increases, it can cause the veins to expand, resulting in an increase in the diameter of the veins and a decrease in the average blood velocity. (16)These changes can lead to a decrease in shear stress, which is the force that blood flow exerts on the walls of blood vessels. This decrease in shear stress shifts the balance toward smooth muscle cell proliferation and intimal hyperplasia.

Late failure occurs after 3–5 years and results from accelerated atherosclerosis.(17) The natural history of SVG suggests significant failure rate with only 80% of SVGs remaining patent 5 years after surgery and about 60% remaining patent at 7–10 years(18)

Vein graft atheroma has more foam cells, multinucleate giant cells, and inflammatory cells than native coronary atheroma, similar to immune-

mediated atherosclerosis models.(19)Vein graft atherosclerosis and native vessel atheroma have distinct morphological differences. Vein graft atherosclerosis is usually diffuse, concentric, and friable, with a poorly developed or absent fibrous cap, and shows little evidence of calcification. On the other hand, native vessel atheroma is proximal, focal, eccentric, and non-friable, with a well-developed fibrous cap and frequent calcification.(13)

Modification of Graft disease:

Smoking cessation:

In the Coronary Artery Surgery Study (CASS), among smokers randomly assigned to bypass surgery, survival rate at 10 years was 68% for persistent smokers and 84% for those who stopped smoking within 6 months of surgery.(20) The benefit of smoking cessation in the surgically treated patients points to the specific impact of smoking in reducing survival in this group through its effects in promoting vein graft disease.

Lipid Lowering Therapy:

The Post-CABG trial included 1192 patients who underwent follow-up angiography about 4.3 years after recruitment. The results revealed that the

aggressive reduction of LDL cholesterol through lovastatin significantly decreased the progression of vein graft disease. Furthermore, the rate of vein graft occlusion and the occurrence of new vein graft lesions were also reduced.(21) The Cholesterol-Lowering Atherosclerosis Study (CLAS I and II) also underscore the need for an increasingly aggressive approach to cholesterol lowering in patients with established ischemic heart disease, including those with prior surgical revascularization.(22,23)

Anithrombotic regimen:

The Aspirin administered in the Veterans Administration (VA) Cooperative Studies has been found to enhance the patency of vein grafts 60 days and 1 year after coronary bypass surgery, as compared to the use of a placebo.(24) Based on the available data, there is strong evidence suggesting that aspirin has a positive impact on the patency of vein grafts.. However, it is recommended that it be initiated within 24 hours of surgery for optimal results.(24,25)

METHODS

Method:

Study Design: Cross sectional study

Study Place: Sree Chitra Tirunal Institute of Medical Sciences and Technology (SCTIMST) Sample Size: 246 patients

Study Period: 01/01/2013 to 31/12/2023

Inclusion Criteria:

Post CABG with new onset symptoms of Myocardial ischemia with ECG evidence of new ST T changes or New Regional wall motion abnormality/significant reduction in Ejection fraction or cardiac enzyme elevation (CK MB/TROP T) or Cardiac stress test positivity for inducible ischemia were subjected to undergo CAG.

Exclusion Criteria:

Post CABG patients with evidence of myocardial ischemia were excluded if there is a lack of therapeutic consequences (When no interventions are possible/When no coronary angiogram was performed).

Methods:

These EMR database is used to identify patients who underwent Coronary angiogram (CAG)/Percutaneous coronary intervention post CABG between 1st January 2013 to 31st December 2023.The data base was searched for specific symptoms of myocardial ischemia and the indication for CAG. Data were abstracted from the EMR as well as from review of patient charts and coronary angiograms.

Baseline evaluation

Baseline data include demographics, comorbidities, nature of coronary artery disease prior CABG, native vessel disease before CABG, total number of venous grafts, total number of arterial grafts, size of the grafts, size of anastomotic vessel. CAG evaluation includes condition of the native vessel disease, total number of intact grafts, graft pathologies like stenosis of arterial grafts, stenosis of venous grafts, stenosis of anastomotic site, kinking of bypass graft.

Angiographic analysis

Cine angiographic images of grafts has been assessed for patency, stenosis, TIMI grade flow & thrombotic occlusions. The angiographic graft patency was graded as fully patent with good antegrade flow (TIMI 3), patent with stenosis or compromised flow (TIMI 1-2) or occluded (TIMI 0 flow). However, smooth,

tubular stenoses within the graft that appeared to be in spasm and narrowed the lumen by 50% were also thought to be obstructive stenoses if they persisted after additional nitroglycerin administration. Details of the interventions for stenosed grafts are collected from the data base. We categorized graft CAG results into. 4 categories; patent and normal(PN),Patent but diseased with <50% stenosis(PS<50%),Patent vessel with >50% stenosis(PS>50%) and Complete occlusion(CO) based on previous similar study results.(26).These 4 categories has been labelled as Category A(PN),Category B(PS) and Category O(CO).Category B has been subdivided into B1& B2 where B1 is PS<50% and B2 is PS>50% stenosis. Category A and B1 is considered as Low profile lesions and Category B2 & O labeled as high profile lesions(Similar to categorization in a study by Fitzgibbon et al.(26))

Indications for PCI were defined as emergent Percutaneous coronary intervention (PCI), facilitated, or rescue PCI; urgent PCI referred to any procedure for non-ST-elevation (NSTEMI) and elective PCI for patients with chronic stable symptoms and positive functional or imaging noninvasive test for inducible ischemia.

Statistical analysis:

Data analysis done by primary investigator with assistance from a statistician. All statistical analysis were performed using SPSS version 25(SPSS, Inc,

Chicago, IL). Quantitative variables will be assessed by paired T- test. Correlations performed by with linear regression and Pearson's coefficient. $P<0.05$ will be taken as significant in all statistical comparisons.

RESULTS

Results:

Table 1: Baseline characteristics

Gender	Frequency	Percent
Female	24	9.8
Male	222	90.2
Comorbidity		
DM	149	60.8
HTN	171	69.5
SMOKING	111	45.1
DLP	149	60.6
FAMILY H/O CAD	56	22.8
TIA/STROKE	19	7.7
PVOD	19	7.7
CKD	33	13.4
PREV MI	135	54.9
PREV PCI	18	7.3

We had recruited 246 patients from our EMR dataset based on inclusion criteria above mentioned. Out of total 246 patients 24 were females(9.8%) and 222 were male patients(90.2%).149 out of 246 patients were diabetic(60.8%),171 hypertensive (69.5%),149 patients(60.6%) were dyslipidemia 111patients(45.1%) reported to have/had a habit of smoking cigarette/bidi at the time of CABG.56 patients reported family history of Coronary artery disease(22.8%).Other significant comorbidities include transient ischemia attack/Stroke in 19 (7.7%) of patients and peripheral vascular occlusive disease(PVOD) in 19 patients (7.7%),Chronic kidney disease in 33 patients (13.4%).

135 patients out of 246(54.9%) had history of myocardial infarction in the past (54.9%) and 18 patients (7.3%) already underwent Percutaneous intervention for the same.

Table 2: Spectrum of disease

Clinical presentation	Frequency	Percent
STEMI	18	7.3
NSTEMI	69	28
UA	25	10.2
SA	134	54.5
Disease type		
NATIVE LM DISEASE	50	20.3
LAD DISEASE	244	99.2
LCX DISEASE	221	89.8
RAMUS DISEASE	41	16.9
RCA DISEASE	232	94.3

Coronary evaluation by angiography prior CABG showed native Left main disease in 50 patients (20.3%), significant LAD disease in 244 patients (99.2%), Circumflex coronary artery disease in 221 (89.8%) patients.41

patients had ramus disease (16.9%),232 patients (94.3%) were having diseased right coronary arteries.

When looking at the spectrum of coronary artery disease 18 patients (7.3%) underwent initial coronary angiographic evaluation for ST elevation Myocardial infarction,69 patients (28%) were having non-ST elevation myocardial infarction,25 patients (10.2%) presented with unstable angina and 134 (54.5%) with stable anginal symptoms.

Table 3:Deatails of CABG and CAG

	Range	Mean	Median	IQR
Age at CABG	**33 - 75**	**51.17 ± 8.12**	**51**	45 - 57
Age at time of PCI/CAG	35 - 84	60.71 ± 8.357	62	54 - 67
LVEF at CABG	21 - 88	**63.29 ± 12.16**	**64**	**58-73**
LVEF at PCI/CAG	21 - 83	**56.54 ± 12.727**	**59**	**49-65**
Duration between CABG and CAG/PCI (in months)	2 - 276	114.17 ± 68.105	120	59.5-156.5
CPB time(minutes)	0 - 291	98.82 ± 41.444	94.5	79.25-113
Duration of follow up (months)	**1 - 312**	77.14 ± 58.418	67	39-108

Age at which CABG underwent ranges from 33 -75 years with a mean of 51.17 ± 8.12 and age at the time of percutaneous intervention of CAG after CABG ranges from 35-84 years with a mean of 60.71 ± 8.357.At the time of CABG the average

left ventricular ejection fraction was 60.71 ± 8.357 ranging from 21-88%.Ejection fraction recorded during percutaneous intervention was 21-84% with a mean EF of 56.54 ± 12.727.Duration of CAG /First percutaneous intervention after CABG ranges from 2 months to 276 months(Median 120 months and IQR-59.5-156.5).3 cases of CABG underwent procedure without cardiopulmonary bypass, rest 243 patients were under CPB. Average duration of bypass time ranges from a minimum of 32 minutes to maximum of 291 minutes. We had followed up all the intervention and post CABG graft patients and the follow up duration ranged from 1 months to 312 months(Median duration of 67 months and IQR-39-108).

763 grafts were studied in 246 patients with an average follow up duration of 8 years since CABG. Out of 763 grafts 227 were arterial grafts and 536 were venous(SVG) grafts.214 of 227 arterial grafts, were left internal mammary(LIMA) grafts to left anterior descending artery (LAD),10 left radial artery(LRA) to either diagonal or obtuse marginal(OM) branch and 3 patient received (right internal mammary artery) RIMA graft to Right coronary artery(RCA).We categorised graft CAG results into. 4 categories; patent and normal(PN)(A),Patent but diseased with <50% stenosis(PS<50%)(B1),Patent vessel with >50% stenosis(PS>50%)(B2) and Complete occlusion(CO)(C).B2 and C are considered as significant graft disease requiring intervention.

68.2% of LIMA grafts were patent on CAG following admission for myocardial ischemia.4 grafts(1.9%) noted to have mild disease(B1).29.9% of LIMA grafts

were significantly diseased on evaluation for myocardial ischemia. Out of these 19.6% were complete occlusion of LIMA with TIMI 0 flow. Majority of LIMA diseases were anastomotic site stenosis and atretic LIMA.

Table 4:Arterial Graft Status

Graft disease -Arterial	PN (A)		PS<50%(B1)		PS>50%(B2)		CO(O)	
	n	%	n	%	n	%	n	%
LIMA	146	68.2	4	1.9	22	**10.3**	42	19.6
LRA-D/OM	4	40					6	60
RIMA to RCA	1	33.3					2	66.7

We hardly noticed any Ostial of mainstem disease in LIMA graft. Left radial artery to Diagonal/OM were 10 in number out of which 4 (40%) remain patent and normal during CAG and 6 were completely occluded(60%)on evaluation. Out

of 3 RIMA grafts 2 were completely occluded on follow up evaluation(66.7%),while 1 (33.3%) was patent and normal.

Table 5:Venous graft status

Graft disease -SVG	PN(A)		PS<50%(B1)		PS>50%(B2)		CO(O)	
	n	%	n	%	n	%	n	%
LAD	24	51.1	2	4.3	10	21.3	11	23.4
Diagonal	55	41	5	3.7	14	10.4	60	44.8
Ramus	10	34.5	1	3.4	1	3.4	17	58.6
OM1	34	26.2	5	3.8	26	20	65	50
OM2	6	17.1			8	22.9	21	60
RCA/PDA	48	29.8	6	3.7	29	18.0	78	48.4

Total venous grafts evaluated in our study(Table 5) was 536 and we found that 252 of them were completely occluded with TIMI 0 flow during evaluation which constitutes 47.01% of venous grafts. Out of these total venous grafts 85 grafts (15.8%) were significantly diseased which we categorised as patent and

stenosed(PS>50%).If we analyse individual SVG grafts to different vessels SVG to distal-most OM(OM2) showed maximum occlusion(88.9%) followed by SVG to

RCA(75%) and proximal OM(70).SVG to LAD were the grafts with least number of occlusion (44.7%).

Predictors of graft Occlusion:

We evaluated patient age category, comorbidities like DM,HTN, Dyslipidaemia, Chronic kidney disease and Previous MI, Previous percutaneous interventions for as predictors of graft occlusion. We took B2 &O category together to look for the hazard ratio of individual factors in predicting the graft outcome. Out of these age>50 years came to be a strong predictor for graft occlusion with a HR 1.84(95% CI 1.35-2.52) with a P value of <0.001.Dyslipidemia and previous myocardial infarction(MI) were also significant predictors of graft occlusion, with HR 0.70(P value of 0.025,0.019 respectively).Diabetes showed a HR of 1.23(95%CI-0.9-1.67) for graft occlusion with p value of 0.188 and previous PCI with HR-1.12 and p value of 0.691.Hypertension and CKD did not show any significant association with graft occlusion(Table 6).

Table 6:Predictors of Graft Occlusion

Predictors	HR	95.0% CI for HR	p
Age>50	1.84	1.35 - 2.52	**<0.001**
DM	1.23	0.9 - 1.67	0.188
HTN	0.78	0.56 - 1.08	0.139
DLP	0.70	0.52 - 0.96	**0.025**
CKD	0.80	0.51 - 1.24	0.32
PREV MI	0.70	0.52 - 0.94	**0.019**
PREV PCI	1.12	0.65 - 1.94	0.691

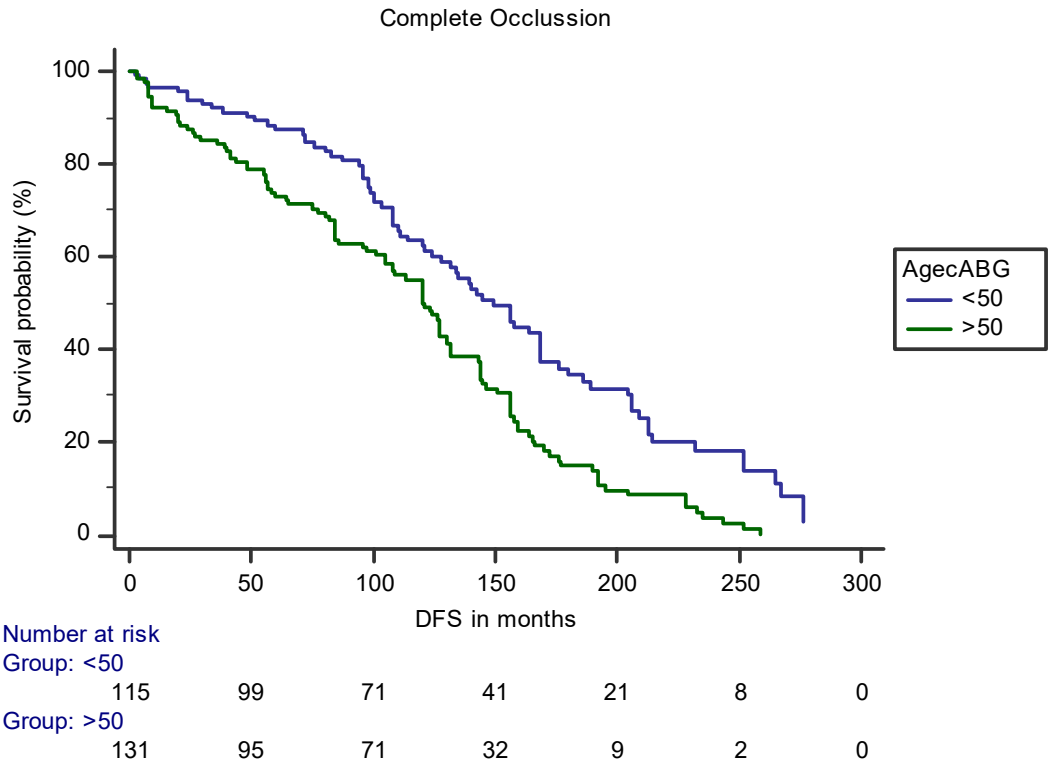


Figure1:Kaplan-Mier curve showing age as predictor of graft occlusion

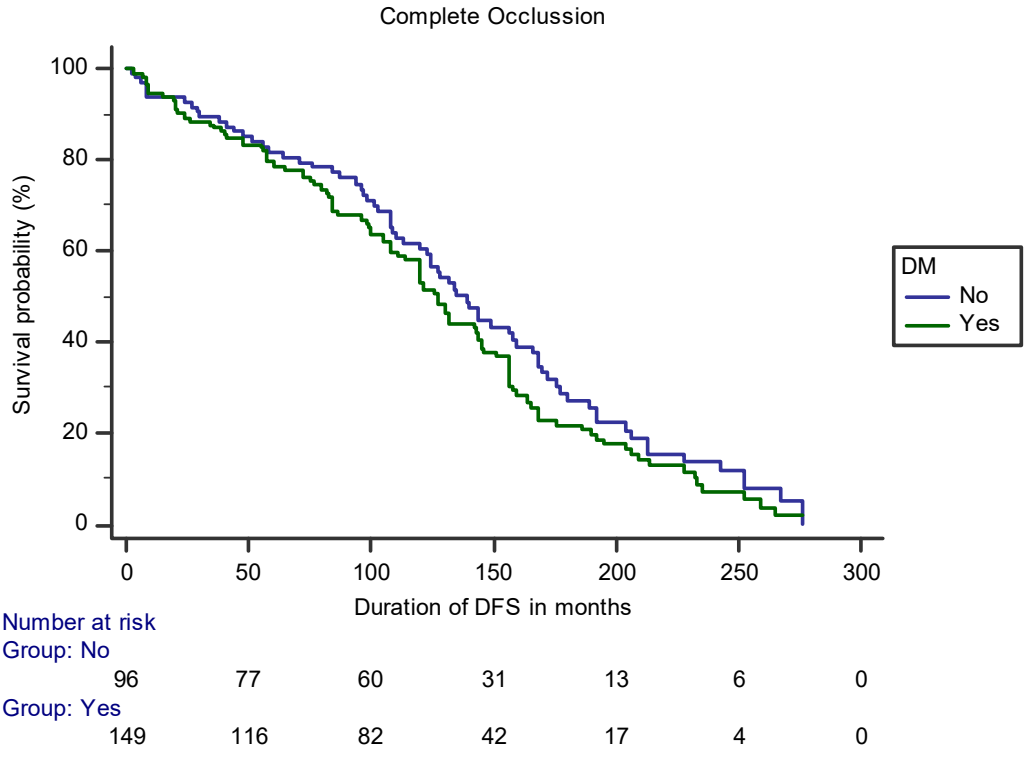


Figure 2:Kaplan-Mier curve showing DM as predictor of graft occlusion

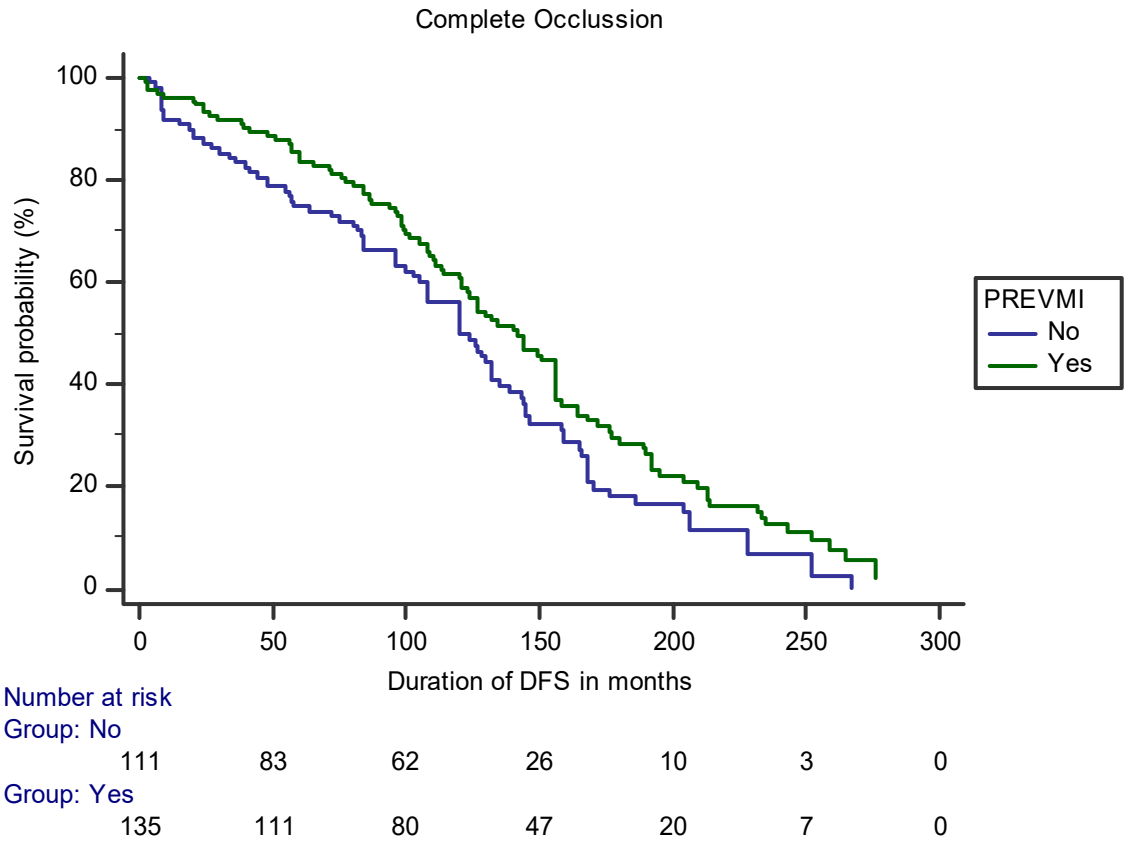


Figure 3:Kaplan Meir Curve showing Previous MI as predictor of graft occlusion

GRAFT INTERVENTIONS

Out of 246 patients 56 cases (22.8%)underwent intervention in grafts and 153 native vessel interventions(62.2%)and 24 cases underwent both graft and native vessel interventions(9.8%)(Figure 4, Table 7).5.3% cases were kept on medical follow Up.

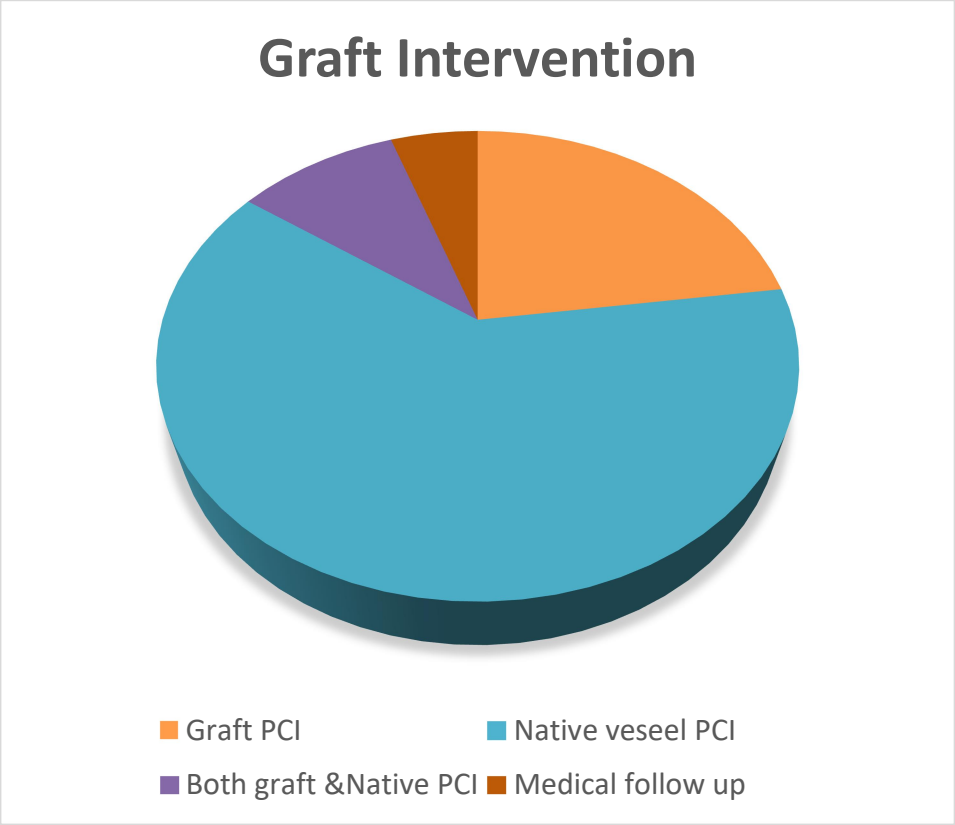


Figure 4:Frequency of Graft Intervention

Table 7: Frequency of graft Interventions

Type	Number	Percent
GRAFT PCI	56	22.8
NATIVE VESSE	153	62.2
BOTH	24	9.8
MEDICAL MANAGEMENT	13	5.3

TYPE OF GARFT VESSEL PCI

Majority of graft interventions were venous graft interventions (92.4%).Out of these majority of interventions were done on SVG grafts to early obtuse marginal branch(OM) or Ramus intermedius(41.3%) followed by SVG to RCA(31.2%)(Table 8).

Table 8:Type of Graft vessel PCI

PCI VESSEL	Frequency	Percent
SVG to LAD	6	7.5
SVG to diagonal	10	12.5
SVG to RCA/PDA	25	31.2
SVG to Ramus/OM	33	41.3
LIMA to LAD	5	6.3
LRA / RIMA	1	1.3
Total	80	100.0

PROCEDURAL CHARACTERISTICS:

62 cases(76.3%) Underwent PCI by using DES (Drug eluting stent) and 13.8% cases used Bare metal stent(Table 9).Average stent diameter used was 3.05+/-0.67 and average length of stent was 20.4+/-7.46mm(Table 10).Distal embolic protection used in 14 cases(17.5%) and routine pre-dilatation performed in 64.5% cases and post dilated only in 42.1% cases.

Table 9:Type of stent Used

Type of stent	Number	Percent
POBA	2	2.5
BMS	12	13.8
DES	62	76.3

Table 10:Stent Diameter(in millimetres)

Graft stent	Mean(mm)	Range(mm)
Graft stent dm	3.05 ± 0.657	2.5 - 3.5
Graft stent length	20.4 ± 7.466	15 - 24

Table 11:Procedural Characteristics

Procedure	Number	Percent
Use of Distal protection device	**14**	**17.5**
Predilation	**49**	**64.5**
Post dilatation	**32**	**42.1**
Any POBA	**5**	**6.3**

PROCEDURAL OUTCOME:

Procedural outcomes were assessed by means of TIMI Flow. TIMI flow grade is used to determine procedural success. No flow/slow flow recorded separately and classified under Failure TIMI1/TIMI 0.TIMI III Flow obtained in 91.3% cases and No flow/Slow flow noticed in 8.7% cases. Time to MACE ranges between 0.3 months to 300 months.

Table 12:Procedural Outcome

Procedural outcome	NO.	PERCENT
TIMI 3 flow	**73**	**91.3**
Noflow/Slow flow	**7**	**8.7**

LONG TERM OUTCOME

Primary outcome variables includes Cardiac death,MI,Repeat revascuarisation either in the form of Target vessel revascularisation(TVR),Target lesion revascularisation(TLR) or redo CABG.Time to mace is calculated in months and represented in mean and Interquartile range. All cause death occurred in 2 patients and cardiac death happened in another 2 cases(2.9%). MI as primary outcome noted in 27.9% cases. TLR represent 18.8% cases and TVR occurred in 15.9% cases. One patient underwent redo CABG (Table 13)

Table 13:Longterm Outcome

MACE	NO.	PERCENT
ALL CAUSE DEATH	2	3
CARDIAC DEATH	2	2.9
MI	19	27.9
NSTEMI/UA	21	30.9
HF HOSPITALIZATION	5	7.4
F/U CAG	30	44.1
ISR	15	21.7
TLR	13	18.8
TVR	11	15.9
ANY OTHER REVASCULARISATION	11	15.9
REDO CABG	1	1.4

DISCUSSION

Discussion:

The data we present here represent an average 8-year follow-up after CABG surgery. Our study was conducted retrospectively in symptomatic post-CABG patients. Over eight years, the SVG patency rate was 36.54%, while the arterial graft patency rate was 70.1%, with most arterial grafts being LIMA. Of the evaluated LIMA grafts, 29.9% were significantly diseased and 19.6% of these cases showed complete occlusion of LIMA with TIMI 0 flow. In short only 2/3rd of venous grafts and 1/3rd arterial grafts are occluded after 8 years.

In studies on SVG graft patency, Bourassa MG et al. found that between 10 and 12 years following surgery, 60% of grafts maintain their patency. Out of all patent grafts, 45% have atherosclerotic lesions on angiography 10–12 years post-surgery, and 70% of these lesions cause the graft lumen diameter to decrease by 50% or more.(27)Furthermore, they discovered that anomalies in cholesterol lipoprotein fractions are linked to atherosclerosis of saphenous vein grafts rather than age, sex, or cigarette smoking. In our study we found previous myocardial infarction, dyslipidaemia and advanced age(age>50years) have significant association with graft occlusion rate.(27) Other factors like Diabetes ,hypertension, chronic kidney diseases did not appear as a significant predictor in graft occlusion rate.

The substantial correlation between atherosclerosis and graft occlusion in SVG grafts during a 10-year follow-up is highlighted by L Campeau et al.(27)Their analysis revealed a ten-year graft patency percentage of approximately 63.3 percent, which is far higher than ours. (27)

It is generally established that SVG grafts have a greater attrition rate when compared to arterial grafts, particularly 8–10 years after CABG. Research by B. W. Lytle,(1) in their 5–12 year follow-up studies on post–CABG grafts, clearly show it. It is evident from the comparison of <5 year and >5 year grafts that SVG grafts attrition occurs more quickly and that arterial graft patency is comparatively steady.(1).Even so, we did not perform a comparative analysis using a 5-year threshold, as the average period of graft expiration in our patients varies from 5 to 12 years (Mean-8 years). In our circumstances, where there is an extremely large variance in graft patency, the pattern is still the same. During this period, almost two thirds of venous grafts occluded, although only one third of arterial grafts did, indicating a high venous graft attrition rate.

When comparing SVG grafts to the natural vessels to which they are attached, there is a noticeable difference in the rate of occlusion. We observed nearly 90% of venous grafts attached to distal OM s are occluded on follow up while the rate of occlusion is least among the SVGs supplying LAD territory(45%).Numerous studies have demonstrated that the recipient vessel's diameter affects the patency of SVG grafts. Then patency rate increases with the recipient vessel's

diameter.(28).The graft is maintained open because flow grows in tandem with the recipient vessel's diameter. It has been attributed as the main cause of the greater patency of SVG grafts to LAD compared to OM. Research by Goldman et al.(1) also reveals a comparable pattern in graft vascular patency that is explained by the same theory. During the surgical procedure, the distal OM can be difficult to access. However, the accuracy of the surgeon may be improved due to the easily accessible placement of the LAD. This can be a contributing factor towards better survival rates in LAD grafts.

It is clear from our study that when comparing the conduits used for LAD, arterial conduits performed better than venous conduits. Approximately 55% of SVG grafts to LAD were patent when compared to IMA grafts, which showed a 70% survival rate. Numerous studies have shown that in the past, surgeons considered LIMA for patients with superior clinical profiles, and that patients undergoing SVGs typically had more advanced disease at the beginning of their treatment than patients receiving IMA grafts.(5).Therefore, to solve this puzzle, prospectively designed randomised controlled trials are needed.

The reports available in the literature suggest that after 10 years, saphenous vein grafts (SVGs) exhibit a patency rate of approximately 40% to 50%, whereas internal mammary artery (IMA) grafts exhibit a patency rate of 90% to 95% (2,13). Our study reports patency rates of 36.54% and 70.1% for SVGs and IMA

grafts, respectively. It is plausible that the high rate of occlusion that we have observed in our study is a consequence of the selective inclusion of only symptomatic patients in our cohort. Consequently, asymptomatic post-coronary artery bypass grafting (CABG) patients, as well as those who did not survive or receive hospital care, were indirectly excluded. This could potentially lead to a biased estimate of the prevalence of occlusion after CABG. Therefore, caution is warranted when interpreting these findings.

Limitations:

Due to the prolonged duration of the study and the progressive nature of coronary artery disease, we collected data solely from patients who underwent angiograms for clinical reasons. It should be noted that the data only includes individuals who survived, which may indicate better graft patency compared to those who did not survive. Additionally, the data only includes symptomatic cases who attended a hospital facility, which could potentially lead to a significant dropout of post-CABG patients. Therefore, we cannot accurately predict the exact lifespan of grafts. We were unable to determine if graft patency influenced survival, which is a potential weakness of our study.

CONCLUSION

Conclusion:

To summarize, we have conducted a comprehensive study on the patency of arterial and venous grafts for a duration of 8 years post-operation. Our findings reveal that arterial grafts have better patency compared to saphenous vein grafts. Furthermore, the patency rate for saphenous venous grafts and arterial grafts after 5 years is poorer than previously estimated. Previous Myocardial infarction, advanced age and dyslipidaemia can significantly affect long term graft survival.

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APPENDIX

SREECHITRA TIRUNAL INSTITUTE OF TECHNOLOGY & MEDICAL SCIENCES TRIVANDRUM

INFORMED CONSENT FORM

Title of Study:
Coronary Angiographic evaluation in symptomatic post CABG patients and outcome of SVG interventions

Principal Investigator: Dr.Vishnu Kesavan.PDF,Adult Cardiology & Interventions
Guides: Dr.Harikrishnan S.Professor, Department of Cardiology.
Dr. Bijulal S.Professor, Department of Cardiology.

Please tick the following points:

(i) I agree to participate as a participant in the study described in the Participant Information Sheet attached to this form. [ ]

(ii) I acknowledge that I have read the Participant Information Sheet, which explains why Ihave been selected, the aims of the study and the nature and the possible risks of the investigation, and the information sheet has been explained to me to my satisfaction. [ ]

(iii)Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer because of myparticipation, and I have received satisfactory answers. [ ]

(iv)I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ](v)I agree that research data gathered from the results of the study may be published if I cannot be identified. [ ]

(vi) I understand that if I have any questions relating to my participation in this research, Imay contact my doctor, who will be happy to answer them. [ ]

(vii) I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet attached to this form [].

Name of Participant

_____

Signature of Participant

Date Time _____

Name of Witness _____

Signature of Witness

Date Time _____

Name of Person conducting Informed Consent discussion

_____

Signature of Person conducting Informed
Consent discussionDate Time

ശ്രീ ചിത്ര തിരുനാൽ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആൻഡ് ടെക്നോളജി, തിരുവനന്തപുരം, കേരളം - 695011

അറിയിച്ച സമ്മത ഫോം

പഠനത്തിന്റെ ശീർഷകം:
രോഗലക്ഷണങ്ങൾക്ക് ശേഷമുള്ള കൊറോണറി ആർട്ടറി ബൈപാസ് രോഗികളിൽ കൊറോണറി ആൻജിയോഗ്രാഫിക് വിലയിരുത്തലും സഫീനസ് വെനസ് ഗ്രാഫ്റ്റ് ഇടപെടലുകളുടെ ഫലവും.

പ്രിൻസിപ്പൽ ഇൻവെസ്റ്റിഗേറ്റർ: ഡോ. വിഷ്ണു കേശവൻ.പിഡിഎഫ്, മുതിർന്നവർക്കുള്ള കാർഡിയോളജിയും ഇടപെടലുകളും
ഗൈഡുകൾ: കാർഡിയോളജി വകുപ്പ് ഡോ .ഹരികൃഷ്ണൻ എസ്.
കാർഡിയോളജി വകുപ്പ് ഡോ. ബിജു ലാൽ എസ്.
കാർഡിയോളജി വകുപ്പ് ഡോ. സഞ്ജയ് ജി.

ഇനിപ്പറയുന്ന പോയിന്റുകളിൽ ടിക്ക് ചെയ്യുക:
(i) ഈ രൂപത്തിൽ ഘടിപ്പിച്ചിരിക്കുന്ന പങ്കാളി വിവര ഷീറ്റിൽ വിവരിച്ചിരിക്കുന്ന പഠനത്തിലെ പങ്കാളിയായി പങ്കെടുക്കാൻ ഞാൻ സമ്മതിക്കുന്നു. []
. . []
(iii) ഈ സമ്മത ഫോമിൽ ഒപ്പിടുന്നതിന് മുമ്പ്, എന്റെ പങ്കാളിത്തത്തിന്റെ ഫലമായി സാധ്യമായ ഏതെങ്കിലും ശാരീരികവും മാനസികവുമായ ഒരു ദ്രോഹവുമായി ബന്ധപ്പെട്ട ഏതെങ്കിലും ചോദ്യങ്ങളൊന്നും എനിക്ക് ലഭിച്ച അവസരം ലഭിച്ചു, എനിക്ക് തൃപ്തികരമായ ഉത്തരങ്ങൾ ലഭിച്ചു. []
.
(v) പഠന ഫലങ്ങളിൽ നിന്ന് ശേഖരിച്ച ഗവേഷണ ഡാറ്റ എന്നെ തിരിച്ചറിയാൻ കഴിയാത്തതിനാൽ പ്രസിദ്ധീകരിക്കുമെന്ന് ഞാൻ സമ്മതിക്കുന്നു. []
(vi) ഈ ഗവേഷണത്തിൽ എന്റെ പങ്കാളിത്തവുമായി ബന്ധപ്പെട്ട് എന്തെങ്കിലും ചോദ്യങ്ങളുണ്ടെങ്കിൽ, ഞാൻ എന്റെ ഡോക്ടറുമായി ബന്ധപ്പെടാം, അവർക്ക് ഉത്തരം നൽകുന്നതിൽ സന്തോഷമായിരിക്കും. []
(vii) ഈ സമ്മത ഫോമിന്റെ ഒരു പകർപ്പ് ലഭിച്ചതും ഈ ഫോമിലേക്ക് ഘടിപ്പിച്ചിരിക്കുന്ന പങ്കാളികളുടെ വിവര ഷീറ്റും ഞാൻ അംഗീകരിക്കുന്നു [] 27

പങ്കെടുക്കുന്നയാളുടെ പേര്
_____

പങ്കെടുക്കുന്നയാളുടെ ഒപ്പ്

തീയതി സമയം _____

PARTICIPANT INFORMATION SHEET

Title of the study:

Coronary Angiographic evaluation in symptomatic post CABG patients and outcome of SVG intervention.

Principal Investigator:

Dr. Vishnu kesavan, PDF, Department of Cardiology, SCTIMST

Co-Principal Investigator:

DR Harikrishnan S , Professor, Department of Cardiology,
SCTIMST, TrivandrumDR Bijulal S Professor, Department
of Cardiology, SCTIMST, Trivandrum

Sir/ Madam,

We invite you to take part in our study titled “Coronary Angiographic evaluation in symptomatic post CABGpatients and outcome of SVG intervention”.
Before you agree to participate in this research study, it is important that you read and understand this information sheet which will provide you with all the information needed for participation in this study so thatyou can make a well informed and considered decision about participation. In addition, should you have any questions, the investigator and his team members will be happy to answer them and explain to you more about this research study, the procedure involved and the related issues. You may ask them any questions youmay have regarding the study or ask them to explain any word or information that you don’t clearly understand.

Study Overview

You are invited to take part in this study as you underwent coronary Angiographic evaluation after bypass graftsurgery due to your symptomatic status. As part of follow-up, you would be clinically evaluated in this study. Patients with CABG who underwent Coronary angiogram between 2013 to 2023 at, SCTIMST will be includedin the study.

Purpose of this study

The purpose of this study is to evaluate the status of bypass graft after CABG.

Study Procedures

If you are willing to participate, your data will be analyzed from Our computer registry, and you will be interviewed and examined by investigator and the clinical findings will be noted. This shall be planned when you are followed up in OPD. Coronary artery (blood vessel supplying heart) status prior to bypass graft surgery will be collected and the number and nature of grafts attached during surgery will be noted. Data will be charted based on the type of grafts used (arterial Vs venous grafts). Angiographic data will be collected from Coronary angiography performed after bypass graft surgery to know status of the grafts.If you had undergone any angioplasty during that time that will be separately mentioned in the study.

Risks and Discomfort

This study involves only history, clinical examination along with previous data evaluation, which will becompleted in 30 to 40 minutes time. There is no specific risks associated with the study.

Benefits

Taking part in this research study may benefit you in early detection of worsening of symptoms. We also do hope that this study will shed light on whether bypass patients are at risk of developing graft failure and outcome of graft interventions on follow-up and in future for decision making based on the same.

Confidentiality

Your privacy is very important to us and the results of the tests performed on you will be treated as highly confidential, and nobody other than the investigators listed above will be knowing the test results. Your name or any other identifiable details will not be published in any research paper or scientific presentation arising out of the study.

Rights

Your participation in the trial is voluntary. You do not have to take part in this study if you are unwilling and you will not be losing any of your rights as a patient if you choose not to participate. You will also be at the liberty to withdraw from the study at any stage (even after signing this consent form) of the study in case youwant to withdraw.

Contact Information

When you read this information, your treating doctor will be available to discuss and answer any questionsyou may have. If you have any queries, please contact:

Dr Vishnu Kesavan

Post-doctoral Fellow, Department of Cardiology,
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If you have any questions, concerns or complaints about the research please contact:

Dr.Srinivas G

Member Secretary, Institutional Ethics Committee,
Sree Chitra Tirunal Institute for Medical Sciences and Technology
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ശ്രീചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി, തിരുവനന്തപുരം, കേരളം 695011

പങ്കെടുക്കുന്നവർക്കുള്ള കാര്യവിവരണപത്രം

പഠനശീർഷകം: സിഎബിജി ശസ്ത്രക്രിയാനന്തരം രോഗലക്ഷണങ്ങളുള്ള രോഗികളിലെ കൊറോണറി ആൻജിയോഗ്രാഫി ഉപയോഗിച്ചുള്ള വിലയിരുത്തലും എസ്വിജി ഇടപെടലിലെ നേട്ടങ്ങളും.

പ്രധാന ഗവേഷകൻ

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ഡോ. ഹരികൃഷ്ണൻ എസ്, പ്രൊഫസർ, കാർഡിയോളജി ഡിപ്പാർട്ട്മെന്റ്, SCTIMST

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ശ്രീ/ശ്രീമതി,

സിഎബിജി ശസ്ത്രക്രിയാനന്തരം രോഗലക്ഷണങ്ങളുള്ള രോഗികളിലെ കൊറോണറി ആൻജിയോഗ്രാഫി ഉപയോഗിച്ചുള്ള വിലയിരുത്തലും എസ്വിജി ഇടപെടലിലെ നേട്ടങ്ങളും, എന്ന പഠനത്തിൽ പങ്കെടുക്കുന്നതിനായി താങ്കളെ ഞങ്ങൾ ക്ഷണിക്കുന്നു. ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നതിന് മുമ്പ് പഠനത്തെപ്പറ്റി വേണ്ടുന്ന എല്ലാ വിവരങ്ങളും നൽകിയിട്ടുള്ള ഈ കാര്യവിവരണപത്രം വായിക്കുകയും മനസ്സിലാക്കുകയും ചെയ്യേത് കാര്യബോധത്തോടെയും വേണ്ടുന്ന പരിഗണനകളോടെയും തീരുമാനമെടുക്കുന്നതിന് പ്രധാനമാണ്. കൂടാതെ, താങ്കൾക്കെന്തെങ്കിലും ചോദ്യങ്ങൾ ഉണ്ടെങ്കിൽ ഗവേഷകനും ആദ്ദേഹത്തിന്റെ സംഘാംഗങ്ങളും മറുപടിനൽകുന്നതിലും ഈ ഗവേഷണത്തെപ്പറ്റിയും നടപടികളും ബന്ധപ്പെട്ട പ്രശ്നങ്ങളും കൂടുതലായി വിശദീകരിക്കുന്നതിലും സന്തോഷമുള്ളവരായിരിക്കും.. ഈ പഠനത്തെപ്പറ്റി താങ്കൾക്കേതു ചോദ്യവും ചോദിക്കാം, അല്ലെങ്കിൽ, വ്യക്തമായി മനസ്സിലാവാത്ത ഏത് വാക്കിനെപ്പറ്റിയും വിവരത്തെപ്പറ്റിയും വിശദീകരിക്കാനാവശ്യപ്പെടാം.

പഠനാവലോകനം

ബൈപാസ് ഗ്രാഫറ്റ് ശസ്ത്രക്രിയാനന്തരം താങ്കളുടെ രോഗലക്ഷണങ്ങൾ കാരണം കോറോണറി ആൻജിയോഗ്രഫി വിലയിരുത്തലിന് വിധേയമായി എന്നതിനാലാണ് ഈ പഠനത്ിൽ പങ്കെടുക്കാകൻ താങ്കളെ ക്ഷണിക്കുന്നത്. തുടർചികിത്സയുടെ ഭാഗമായി ഈ പഠനത്തിൽ ക്ലിനിക്കലായി താങ്കളെ വിലയിരുത്തും. സിഎബിജി നടത്തിയ കൊറോണറി ആൻജിയോഗ്രാമിന്, SCTIMST യിൽ വിധേയരായ 2013 മുതൽ 2023 വരെ യുള്ള രോഗികളെ ഈ പഠനത്തിലുൾപ്പെടുത്തും.

ഈ പഠനത്തിന്റെ ഉദ്ദേശം

സിഎബിജിക്കുശഷം ബൈപാസ് ഗ്രാഫ്റ്റിന്റെ നില വിലയിരുത്തുക എന്നതാണ് ഈ പഠനത്തിന്റെ ഉദ്ദേശം.

പഠനനടപടിക്രമങ്ങൾ

താങ്കൾക്ക് പങ്കെടുക്കാൻ താത്പര്യമുണ്ടെങ്കിൽ നമ്മുടെ കമ്പ്യൂട്ടർ രജിസ്ട്രിയിൽനിന്നുമുള്ള താങ്കളുടെ വിവരങ്ങൾ വിയിരുത്തുകയും ഗവേഷകൻ താങ്കളുമായി അഭിമുഖവും പരിശഓധനയും നടത്തുകയും ക്ലിനിക്കൽ കണ്ടെത്തലുകൾ രേഖപ്പെടുത്തുകയും ചെയ്യും. താങ്കൾ ഒപിഡിയിൽ വരുമ്പോൾ ഇത് ചെയ്യാൻ ആസൂത്രണം ചെയ്യും. ഗവേഷകർ വിശദാംശങ്ങൾ താങ്കളുമായി പങ്കുവെയ്ക്കും.

അപായങ്ങളും അസ്വസ്ഥതകളും

ഈ പഠനത്തിൽ ചരിത്രം, ക്ലിനിക്കൽ പരിശോധനയോടൊപ്പം മുൻകാല വിവരങ്ങളുടെ വിലയിരുത്തൽ എന്നിവമാത്രമാണടങ്ങുന്നത്, ആയത് 30 മുതൽ 40 മിനിട്ടുകൾക്കകം പൂർത്തിയാകും.

നേട്ടങ്ങൾ

ഈ ഗവോഷണ പഠനത്തിൽ പങ്കെടുക്കുന്നതിലൂടെ രോഗലക്ഷണങ്ങൾ മോശമാകുന്നത് നേരത്തെ കണ്ടെത്താൻ കഴിഞ്ഞേക്കാമെന്ന നേട്ടം താങ്കൾക്കുണ്ടായേക്കാം. ബൈപാസ് രോഗികൾക്ക് ഗ്രാഫ്റ്റ് പരാജയം ഉണ്ടാകാൻ സാദ്ധ്യതയുണ്ടോ എന്നതിനെക്കുറിച്ചും, തുടർചികിത്സയിലെ ഗ്രാഫ്റ്റ് സംബന്ധമായ ഇടപെടലുകളുടെ അനന്തര ഫലങ്ങളെക്കുറിച്ചും ഈ പഠനം വെളിച്ചം വീശുമെന്നും അതിനെ അടിസ്ഥാനമാക്കി ഭാവിയിൽ തീരുമാനങ്ങളെടുക്കുവാൻ സഹായകരമാകുമെന്നും ഞങ്ങൾ കരുതുന്നു.

രഹസ്യാത്മകത?

താങ്കളുടെ സ്വകാര്യത ഞങ്ങൾക്ക് വളരെ പ്രധാനമാണ്, താങ്കളിൽ നടത്തിയ പരിശോധനകൾ വളരെ രഹസ്യമായിരിക്കുകയും പരിശോധനാഫലങ്ങൾ പഠനവുമായിബന്ധപ്പെട്ട ഗവേഷകർക്കുമാത്രം അറിയുന്നതുമായിരിക്കും. ഈ പഠനത്തിൽ നിന്നുണ്ടാകുന്ന പ്രസിദ്ധീകരിക്കുന്ന ഏത് ഗവേഷണപ്രബന്ധത്തിലോ ശാസ്ത്രീയ പ്രദർശനങ്ങളിലോ താങ്കളെ തിരിച്ചറിയാനിടയാക്കുന്ന വിശദാംശങ്ങളൊന്നും ഉണ്ടാകില്ല.

അവകാശങ്ങൾ

ഈ പഠനത്തിലെ താങ്കളുടെ പങ്കാളിത്തം സ്വമേധയായുള്ളതാണ്. ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നത് താങ്കളുടെ തീരുമാനപ്രകാരമാണ്. താങ്കൾക്ക് സമ്മതമല്ലെങ്കിൽ ഈ പഠനത്തിൽ പങ്കെടുക്കാതിരിക്കാം, പങ്കടുക്കാതിരിക്കുന്തുകൊണ്ട് താങ്കളുടെ അവകാശങ്ങളൊന്നും നഷ്ടപ്പെടില്ല. പഠനത്തിന്റെ ഏത് ഘട്ടത്തിലും (സമ്മതപത്രം ഒപ്പിട്ടശേഷവും) താങ്കൾക്ക് വേണമെങ്കിൽ പഠനത്തിൽനിന്നും പിൻമാറാൻ സ്വാതന്ത്ര്യമുണ്ട്.

ബന്ധപ്പെടാനുള്ള വിവരങ്ങൾ

താങ്കൾ ഈ വിവരങ്ങൾ വായിക്കുമ്പോൾ താങ്കളെ ചികിത്സിക്കുന്ന ഡോക്ടർ താങ്കളോട് ചർച്ചചെയ്യാനും താങ്കൾക്കുണ്ടായേക്കാവുന്ന ഏത് ചോദ്യത്തിനും ഉത്തരം നൽകാനും ഉണ്ടാകും. താങ്കൾക്ക് കൂടുതൽ ചോദ്യങ്ങളുണ്ടെങ്കിൽ ദയവായി ബന്ധപ്പെടുക.

ഡോ. വിഷ്ണു കേശവൻ പോസ്റ്റ് ഡോക്ടറൽ ഫെല്ലോ, കാർഡിയോളജി ഡിപ്പാർട്ടമെന്റ്, ശ്രീചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി, ഫോൺ 8928792287, ഇമെയിൽ vishnukesavan2k7@gmail.com

താങ്കൾക്ക് ഗവേഷണത്തെപ്പറ്റി ചോദ്യങ്ങളോ പരാതികളോ ഉണ്ടെങ്കിൽ ബന്ധപ്പെടുക

ഡോ. ശ്രീനിവാസ് ജി, മെമ്പർ സെക്രട്ടറി, ഇൻസ്റ്റിറ്റ്യൂഷണൽ എത്തിക്സ് കമ്മിറ്റി,

ശ്രീചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി. ഫോൺ 0471-2524-689 ഇമെയിൽ: iec.mem.sec@sctimst.ac.in

CAG EVALUATION OF GRAFTS Final

CAG evaluation of grafts

1. Study ID

2. Date-1st CAG

Example: January 7, 2019

3. Date(Grft CAG)

Example: January 7, 2019

4. Age

5. SEX

Check all that apply.

- [ ] MALE
- [ ] FEMALE
- [ ] OTHERS

6. Height(cm)

7. Weight(kg)

8. Risk factors

Check all that apply.

- [ ] 1.DM
- [ ] 2.HTN
- [ ] 3.DLP
- [ ] 4.FAMILY HISTORY OF CAD
- [ ] 5.Aortoarteritis

9. Smoker(At the time of CAD)

Mark only one oval.

- ◯ current
- ◯ Former
- ◯ Never

17. Nature of CABG

Check all that apply.

- [ ] ELECTIVE
- [ ] URGENT/EARLY
- [ ] EMERGENCY

18. CABG Dt

Example: January 7, 2019

19. SX METHOD

Check all that apply.

- [ ] OFF PUMP
- [ ] ON PUMP

20. GFT NO.

Check all that apply.

	1	2	3	4	5
LIMA	☐	☐	☐	☐	☐
RIMA	☐	☐	☐	☐	☐
RADIAL	☐	☐	☐	☐	☐
SVG	☐	☐	☐	☐	☐
Total arterial	☐	☐	☐	☐	☐
Total venous	☐	☐	☐	☐	☐

21. CAD 2

Check all that apply.

- [ ] CCS
- [ ] UA
- [ ] STEMI
- [ ] NSTEMI
- [ ] HF/WORSENING DYSPNEA/DECREASED EF

22. EF2

23. CREAT 2

24. CPB time

GRFT by CINE

10. COMORBIDITY

Mark only one oval.

- ◯ CKD
- ◯ CVA
- ◯ CLD
- ◯ COPD
- ◯ Option 5

11. CREAT 1(PRIOR CABG)

12. EF1

Untitled Section

13. CAD1

Check all that apply.

- [ ] UA
- [ ] NSTEMI
- [ ] STEMI
- [ ] CCS

14. HF STAt.

Mark only one oval.

- ◯ No HF
- ◯ HFrEF
- ◯ HFpEF
- ◯ HFmrEF
- ◯ HFimprovedEF

15. LM d/s

Mark only one oval.

0	1	2
◯	◯	◯

16. SVD/DVD/TVD

Mark only one oval.

1	2	3	4	5
◯	◯	◯	◯	◯

25. GRFT PATNCY(CAG)

Check all that apply.

	A:PN	B1:PS(<50%)	B2:PS(>50%)	O:CO
LIMA	☐	☐	☐	☐
SVG D1	☐	☐	☐	☐
SVG D2	☐	☐	☐	☐
SVG R	☐	☐	☐	☐
SVG O1	☐	☐	☐	☐
SVG O2	☐	☐	☐	☐
SVG P	☐	☐	☐	☐
RADIAL	☐	☐	☐	☐
RIMA	☐	☐	☐	☐

Untitled Section

26. GRFT PTNCY(CT CAG)

Check all that apply.

	A:PN	B1:PS(<50%)	B2:PS(>50%)	O:CO
LIMA	☐	☐	☐	☐
SVG D1	☐	☐	☐	☐
SVG D2	☐	☐	☐	☐
SVG R	☐	☐	☐	☐
SVG O1	☐	☐	☐	☐
SVG O2	☐	☐	☐	☐
SVG P	☐	☐	☐	☐
RADIAL	☐	☐	☐	☐
RIMA	☐	☐	☐	☐

Untitled Section

33. HbA1c 2

34. *Mark only one oval.*

- Option 1

Graft by CINE

35. GRAFT PATENCY(CAG)

Check all that apply.

	A:PATENT,NORMAL	B1:PATENT ,STENOSED(<50% OCCLUSION)	B2:PATENT STENOSED(>50% OCCLUSION)	O:COMPLETE OCCLUSION
LIMA	☐	☐	☐	☐
SVG1	☐	☐	☐	☐
SVG2	☐	☐	☐	☐
SVG3	☐	☐	☐	☐
SVG4	☐	☐	☐	☐
RIMA	☐	☐	☐	☐
RADIAL	☐	☐	☐	☐

Untitled Section

36. GRAFT PATENCY(CT CORONARY)

Check all that apply.

	A:PATENT,NORMAL	B1:PATENT ,STENOSED(<50% OCCLUSION)	B2:PATENT STENOSED(>50% OCCLUSION)	O:COMPLETE OCCLUSION
LIMA	☐	☐	☐	☐
SVG1	☐	☐	☐	☐
SVG2	☐	☐	☐	☐
SVG3	☐	☐	☐	☐
SVG4	☐	☐	☐	☐
RIMA	☐	☐	☐	☐
RADIAL	☐	☐	☐	☐

Untitled Section

37. GRAFT DISEASE(CAG)

Check all that apply.

	I:No intimal irregularity	II:Irregularity<50% of intimal surface	III:Irregularity >50% of intimal surface	Thrombus	Severe anastomotic site stenosis
LIMA	☐	☐	☐	☐	☐
SVG1	☐	☐	☐	☐	☐
SVG2	☐	☐	☐	☐	☐
SVG3	☐	☐	☐	☐	☐
SVG4	☐	☐	☐	☐	☐
RIMA	☐	☐	☐	☐	☐
RADIAL	☐	☐	☐	☐	☐

38. GRAFT DISEASE(CT coronary)

Check all that apply.

	I:No intimal irregularity	II:Irregularity<50% of intimal surface	III:Irregularity >50% of intimal surface	Thrombus	Severe anastomotic site stenosis
LIMA	☐	☐	☐	☐	☐
SVG1	☐	☐	☐	☐	☐
SVG2	☐	☐	☐	☐	☐
SVG3	☐	☐	☐	☐	☐
SVG4	☐	☐	☐	☐	☐
RIMA	☐	☐	☐	☐	☐
RADIAL	☐	☐	☐	☐	☐

39. TIMI Flow in graft

Check all that apply.

	TIMI 0	TIMI 1	TIMI 2	TIMI 3
LIMA	☐	☐	☐	☐
SVG1	☐	☐	☐	☐
SVG2	☐	☐	☐	☐
SVG3	☐	☐	☐	☐
SVG4	☐	☐	☐	☐
RIMA	☐	☐	☐	☐
RADIAL	☐	☐	☐	☐

40. Any graft intervention

Mark only one oval.

- Yes
- No

41. ACCESS

Mark only one oval.

- RADIAL
- FEMORAL
- BRACHIAL

42. Number of post CABG interventions

Mark only one oval.

- 0
- 1
- 2
- 3
- 4
- 5

43. Nature of graft intervention

Check all that apply.

- ☐ Balloon only
- ☐ Balloon+ stent
- ☐ Thrombosuction

44. Timing of Intervention

Mark only one oval.

- Elective
- Emergency
- Urgent/Early

https://docs.google.com/forms/d/1Gpl1vdSe-IxYEVIuZgxiSxpHEbSe7ndFKgHNvFgR-o4/1/edit
14/08/2023, 16:12 CAG EVALUATION OF GRAFTS

45. No.of graft lesions addressed

Mark only one oval.

- 0
- 1
- 2
- 3
- 4
- 5

46. Number of stents

Check all that apply.

	1	2	3	4
DES	☐	☐	☐	☐
BMS	☐	☐	☐	☐

47. Graft interevned and lesions addressed

Check all that apply.

	0	1	2	3	4
Arterial graft	☐	☐	☐	☐	☐
Venous graft	☐	☐	☐	☐	☐

Untitled Section

48. Native vessel Intervened & lesions addressed

Check all that apply.

	0	1	2	3	4
Grafted native vessel with patent graft	☐	☐	☐	☐	☐
Grafted native vessel with graft failure	☐	☐	☐	☐	☐
Non grafted vessel	☐	☐	☐	☐	☐
LM	☐	☐	☐	☐	☐

Procedural outcome

49. Outcome of graft intervention(TIMI flow)

Mark only one oval.

- 0
- 1
- 2
- 3

50. Pocedural Outcome

Check all that apply.

- ☐ In hospital MACE
- ☐ MI
- ☐ CVA
- ☐ A/C RF
- ☐ Major bleeding

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)
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Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013/RR-21)

SCT/IEC/2062/MAY/2023 30.09.2023

Dr. Vishnu Kesavan
Post Doctoral Fellow
Department of Cardiology
SCTIMST, Thiruvananthapuram

Dear Dr. Vishnu Kesavan,

The Institutional Ethics Committee held on 20th May, 2023, reviewed and discussed your application to conduct the study titled "**CORONARY ANGIOGRAPHIC EVALUATION IN SYMPTOMATIC POST- CABG PATIENTS AND OUTCOME OF SAPHENOUS VENOUS GRAFT INTERVENTIONS**" (IEC/2062).

Principal Investigator	Dr. Vishnu Kesavan, Post Doctoral Fellow, Department of Cardiology, SCTIMST
Co-Principal Investigator(s)	Dr. Harikrishnan S, Professor, Department of Cardiology, SCTIMST Dr. Bijulal S, Professor, Department of Cardiology, SCTIMST
Duration of the study	120 Months (Retrospective & Prospective)

The following members of the Ethics Sub-committee were present at the meeting held on 20th May, 2023

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
2.	Dr. Pradeep S	MBBS, MD	Male	Basic Medical Scientist	No
3.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
4.	Adv. Priya Kaimal	LLM, MBL	Female	Legal Expert	No
5.	Dr. P. Manickam	BSMS, MSc (Epid), PhD	Male	Health Science Expert/ Social Scientist	No
6.	Dr. Manikandan.S	MBBS,MD,PDCC	Male	Clinician	Yes
7.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

The following documents were reviewed:

First submission

1. *Responses/Amendments made based on the Reviewer's comments*
2. *Covering letter addressed to the Chairperson, IEC, SCTIMST*
3. *IEC Application Form*
4. *Project Proposal*
5. *CV of PI and Co-PIs*
6. *Informed Consent Form in English and Malayalam*
7. *Participant Information Sheet in English and Malayalam*
8. *Case Record Form*
9. *Declaration form*
10. *Checklist Form*
11. *SRC Recommendation Letter*

Second submission

1. *Covering letter addressed to the Chairperson, IEC, SCTIMST with responses made based on the Reviewer's comments*
2. *IEC Application Form*
3. *Project Proposal*
4. *CV of PI and Co-PIs*
5. *Informed Consent Form in English and Malayalam*
6. *Participant Information Sheet in English and Malayalam*
7. *Case Record Form*
8. *Declaration form*
9. *Checklist Form*
10. *SRC Recommendation Letter dated 11.09.2023*

Third submission

1. *Covering letter addressed to the Member Secretary, IEC, SCTIMST with responses made based on the Reviewer's comments*
2. *Covering letter addressed to the Chairperson, IEC, SCTIMST*
3. *IEC Application Form*
4. *Project Proposal*
5. *CV of PI and Co-PIs*
6. *Informed Consent Form in English and Malayalam*
7. *Participant Information Sheet in English and Malayalam*
8. *Case Record Form*
9. *Declaration form*
10. *Checklist Form*

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.

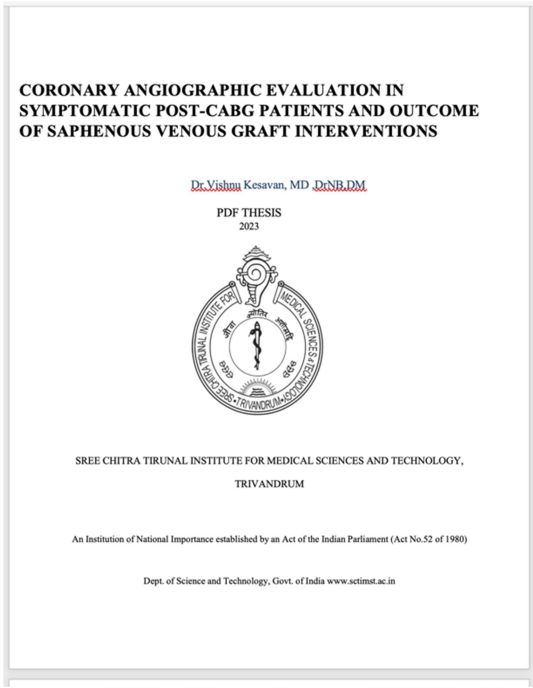
There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Dr. G. Srinivas
Member Secretary, IEC

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST
THIRUVANANTHAPURAM

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST, THIRUVANANTHAPURAM



CORONARY ANGIOGRAPHIC EVALUATION IN SYMPTOMATIC POST-CABG PATIENTS AND OUTCOME OF SAPHENOUS VENOUS GRAFT INTERVENTIONS

Dr.Vishnu Kesavan, MD ,DrNB,DM

PDF THESIS
2023

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY,
TRIVANDRUM

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Dept. of Science and Technology, Govt. of India www.sctimst.ac.in

