

IN-HOSPITAL AND LONG-TERM OUTCOMES OF CORONARY ARTERY BYPASS SURGERY – A SINGLE CENTER EXPERIENCE



Thesis submitted for the partial fulfillment of the requirement for the Degree of
M. Ch in CARDIO VASCULAR AND THORACIC SURGERY

By

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DECLARATION

I hereby declare that this dissertation entitled, “**In-hospital and long-term outcomes of coronary artery bypass surgery – A single center experience**” has been prepared by me under the capable supervision and guidance of **Prof. Dr. Jayakumar Karunakaran**, Professor senior grade, Department of Cardio Vascular and Thoracic Surgery, **Dr. Bineesh K Radhakrishnan**, Associate Professor, Department of Cardio Vascular and Thoracic Surgery, **Dr. Harikrishnan S**, Professor, Department of Cardiology, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram, Kerala.

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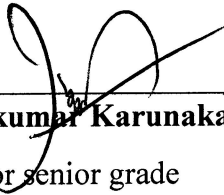
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This is to certify that the thesis entitled “**IN-HOSPITAL AND LONG-TERM OUTCOMES OF CORONARY ARTERY BYPASS SURGERY – A SINGLE CENTER EXPERIENCE**” is the bonafide work of **Dr. Sameer MD**, M. Ch CVTS senior resident, conducted at the Department of Cardiovascular and Thoracic surgery of Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram under our supervision and guidance. He has shown keen interest in preparing this project.

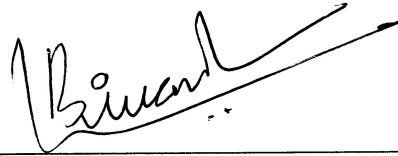


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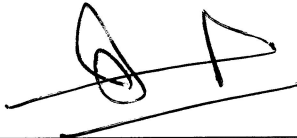


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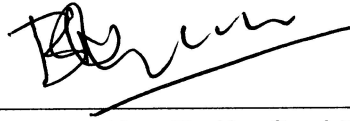
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SYNOPSIS

Introduction: Coronary artery bypass surgery is the most common adult cardiac operation performed across the world. Literature is replete with studies measuring outcomes following surgery. We looked into our experience and its follow-up over 10 years since operation in terms of survival and major adverse cardiac and cerebrovascular events (MACCE).

Materials and Methods: A retrospective analysis of patients who underwent CABG during 2003-2007 at our institution was performed. Significant factors for risk of in-hospital mortality and long-term MACCE were assessed. Kaplan-Meier curves were constructed for survival analysis, MACCE free survival, freedom from reintervention and freedom from symptom onset.

Results: A total of 1705 patients were analyzed. In-hospital mortality rate was 2.3% (N=40). Mean follow-up period was 7.7 ± 2.6 years. Long term cumulative MACCE event rate was 14.8%. Post-operative stroke and acute coronary syndromes were seen in 3.7% and 1.9% of patients on follow-up. Survival of freedom from re-intervention was 95.5% at 10-years and more than 50% of patients developed symptoms by 10 years. Overall cumulative actuarial survival at 10 years was 94.4%.

Conclusion: Pre-operative and operative characteristics are comparable to various studies across literature and represent true population at risk. Cardiogenic shock, congestive cardiac failure, moderate to severe mitral regurgitation at presentation and IABP support in the immediate post-operative period strongly predicted in-hospital mortality. MACCE free survival (84.2%) was better in this study. Actuarial survival was 94.4% and hence CABG with LIMA arterial graft and additional venous grafts can be safely done with good long-term survival and reduced MACCE events.

INTRODUCTION

During the late 90's and towards the early 21st century, there has been a steady rise in global burden of Non-Communicable Diseases (NCD) worldwide (1). Among the various non-communicable diseases, notable ones include cardiovascular disease (CVD), cancer, chronic respiratory disease, and diabetes mellitus. Among these, highest burden is contributed by cardiovascular disease.

The United Nations and World Health Organization (WHO) collaboratively anticipated this global burden of NCD being responsible for high disease severity and case-fatality especially in low-income and middle-income countries as compared to high-income countries (2,3). This was recognized as major threat for sustainable development in the 21st century.

Cardiovascular diseases (CVD) are a group of conditions which affect Heart and blood vessels resulting in end-organ dysfunction, which can culminate in end-organ failure and even death. These diseases consisting of ischemic heart disease, stroke, heart failure, peripheral arterial disease, number of other cardiac and vascular conditions constitute the leading cause of disease burden and global mortality (4). Furthermore, these contribute to reduced quality of life significantly. As per WHO estimates, 17.9 million deaths globally are due to cardiovascular diseases. This corresponds to 330 million years of life lost and another 35.6 million disability adjusted life years (5).

The burden of cardiovascular disease and its risk factors are on the rise in low- and middle-income countries due to ongoing epidemiological transition, and this has resulted in nearly 80% of cardiovascular related deaths globally (6). Prospective Urban Rural Epidemiologic (PURE) cohort study performed comparative study among high, medium and low-income countries of

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cardiovascular risk factors. This group used a validated scoring system, INTERHEART risk score to quantify risk factor burden among these countries and concluded high risk in low- and middle-income group countries (2).

In view of this significant global burden and its impact on development, WHO developed targets for prevention and control of NCDs in 2013. These sustainable developmental goals include 25% relative reduction in overall mortality due to cardiovascular diseases, 25% relative reduction in prevalence of high blood pressure, controlling the rise in diabetes and obesity, and to ensure at least 50% of patients with cardiovascular diseases to have access to relevant drugs and medical counselling by 2025 (7). Although, these goals were set up in 2013, only few developed countries are closer to achieve these targets, making this a far-fetched dream for a large group of patients by 2020 globally.

Parallel to the global trend, cardiovascular diseases are the leading cause of mortality in India (8). Our country of 1.3 billion people with cultural and lifestyle diversities pose great challenge to compile cardiovascular disease burden in the country. In 2017, India state-level disease burden initiative CVD collaborators group estimated the prevalence and disability adjusted life years due to cardiovascular diseases and its risk factors. Their analysis revealed estimated prevalence of CVD in 2016 to be 54.5 million. Cardiovascular deaths amounted to 28% of the total deaths in India with 14% of the total DALY's. Also, the leading risk factors for cardiovascular diseases in India were identified as dietary risks, high total cholesterol, high systolic blood pressure, tobacco use, air pollution, high fasting plasma glucose, high body mass index (1).

Hence, National Health Policy 2017 aimed to reduce 25% of premature deaths from cardiovascular diseases along with screening and treatment of 80% of hypertensive patients by

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2025 (9). Initiatives to promote health care delivery like formation of National List of Essential Medicines and devices from WHO's Essential Medicine List has been adopted. Recently, even National List of Essential Diagnostics has been launched to promote effective diagnostic services(8).

Still today, CVD remains a major cause of morbidity and mortality worldwide irrespective of income group countries. American Heart Association in its recent 2020 statistics update suggested seven approaches to stay 'Heart Healthy' with "AHAs My Life Check – LIFE's SIMPLE 7". A simple pictogram describes these essential 7 steps (10).



Keep healthy weight – Be physically active – Tobacco free – keep healthy blood pressure – Learn about cholesterol – Control Diabetes Mellitus – Eat a heart-healthy diet. (Adapted from AHA 2020 statistics update by Salim et.al).

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Ischemic heart disease or coronary artery disease is the major cause of cardiovascular disease and significantly contributes to mortality. Atherosclerosis is the main cause of coronary heart disease as well as peripheral artery disease and large artery stroke. Various causal and modifiable risk factors have been identified over years which account for mortality in both males and females (11).

Coronary artery disease can present as a clinical spectrum of asymptomatic state, where diagnosis was made incidentally during routine health checkups in susceptible population and symptomatic for the disease. Symptoms range from chronic stable angina with development of pain on exertion to Acute coronary Syndromes which can be Unstable angina or Myocardial Infarction. Whatever may be the presentation, if significant stenosis of coronary artery was identified, the goal of management is revascularization.

Revascularization can be accomplished either by interventional techniques or by surgical management. Coronary artery Bypass Surgery is the corner stone of surgical management of coronary artery disease. Various techniques and modifications have emerged to promote best possible way of revascularizing the stenosed coronary arteries over the past century.

REVIEW OF LITERATURE

Coronary artery disease is the leading cause of death and severe disability not only in India, but also in various affluent countries and worldwide. Atherosclerosis with superimposed thrombosis, atherothrombosis is the leading cause of coronary artery disease as well as peripheral arterial disease and large artery related stroke (11). Stenotic atherosclerotic coronary artery disease causes narrowing of the coronary arteries due to thickening and loss of elasticity of arterial wall (12). When this stenosis compromises lumen of arterial wall, blood supply to the myocardium becomes limited.

In a normal heart, the balance between myocardial oxygen demand and supply is well maintained by various autoregulatory methods. Whereas, in stenosed coronary vessels, in its initial stages coronary flow reserve is affected. Coronary flow reserve means increase in coronary flow to improve oxygen supply during the times of demand. As disease progresses, stenosis increases reducing the lumen significantly to cause decreased or absent blood supply to the myocardium even at rest. Ischemic heart disease symptomatology extends from symptoms on exertion to acute coronary syndromes.

Since the initial description of angina pectoris in 18th century by Dr. John Hunter – Father of Modern Surgery, understanding of underlying pathobiology and pathogenesis of this condition has greatly improved (13,14). Ironically, he himself dies of sudden heart attack with autopsy revealing findings suggestive of ischemic heart disease (15). It is now well-established fact that, blockage of coronary artery responsible for ischemia or infarction has to be addressed and the compromised myocardium need to be revascularized.

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Myocardial revascularization is the gold standard management of coronary artery disease. It can be broadly classified as Percutaneous coronary intervention (PCI) and surgical revascularization. In the past century, both cardiology as well as cardiac surgical societies have seen significant progress in their fields to provide optimal blood flow to compromised myocardium. Currently, in the era of guideline directed management, very precise guidelines exist regarding the timing, choice and planning of revascularization strategy. Among these, Coronary Artery Bypass Surgery (CABG) still remains the fore runner of management in various indications of Coronary artery disease.

History of Coronary Artery Bypass Surgery:

Coronary artery bypass surgery (CABG) is the most common operation performed by adult cardiac surgeons worldwide. It is an open-heart surgery, in which stenosed coronary artery is bypassed using another conduit, so as to improve the coronary blood flow beyond the blocked segment (16). Currently, evidence suggests this operation can be safely performed either by using cardiopulmonary bypass or without bypass on a beating heart also termed Off pump CABG (OPCAB).

Although Alexis Carrel, a French surgeon, a Nobel laureate pioneered triangulation technique of vascular anastomosis as early as 1912, successful operations on coronary artery was possible only after mid 50's (17). As early as 1896, first heart operation was performed by Ludwig Rehn for stab wound of chest which resulted in right ventricular tear (18).

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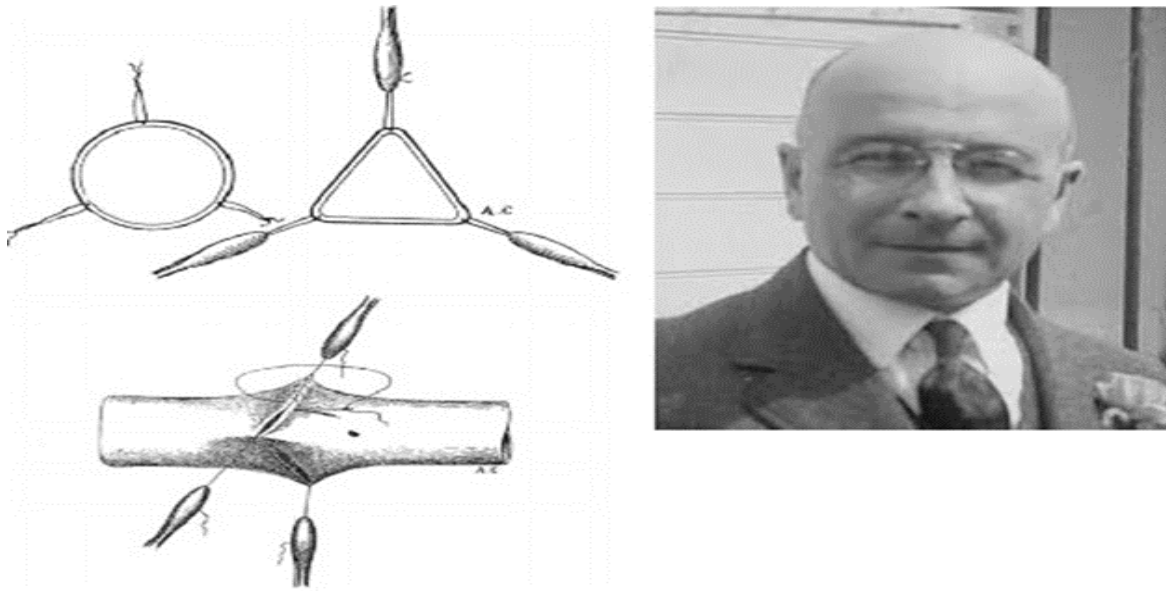


Figure.1: Alexis Carrel and his method of Triangulation technique.

Even though the pathophysiology of coronary artery disease was explained by Adam Hammer, that angina is a result of imbalance between myocardial oxygen demand and supply due to reduced blood supply to a particular segment of heart, there was no means to identify the location till 1960. Sones and Shirey at the Cleveland clinic developed very significant invention of coronary cineangiography to identify stenotic and occluded coronary arteries responsible for CAD and marked the foundation of modern-day CABG (19).

Multiple sporadic attempts to revascularize coronary arteries were performed till 1960. These earlier attempts were made feasible largely due to the invention of cardio pulmonary bypass by Dr John Gibbon – Father of CPB (20). Nevertheless, these were ineffective due to lack of proper and precise anatomic diagnosis till cineangiography was developed.

Even though CPB machine was invented by 1930, it was effectively used only by 1950s as a result of initial technical failures. Even though Alexis Carrel initially described CABG in 1910, Vineberg and Muller from McGill University, Canada were the first to implant Internal thoracic

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artery into LV myocardium for management of cardiac ischemia and angina in 1950 (21). Even though, this technique provided alternate blood supply to left ventricular myocardium, it was very little and not effective. Later, Murray and colleagues performed experimental studies on anastomosis of arterial grafts to coronary circulation by 1954 (22). At University of California, Los Angeles, series of patients undergoing coronary endarterectomy without CPB was reported by Longmire and colleagues in 1958 (23). First report of using saphenous vein harvest was given by Sidney Smith, where he anastomosed vein from the aorta to myocardium.

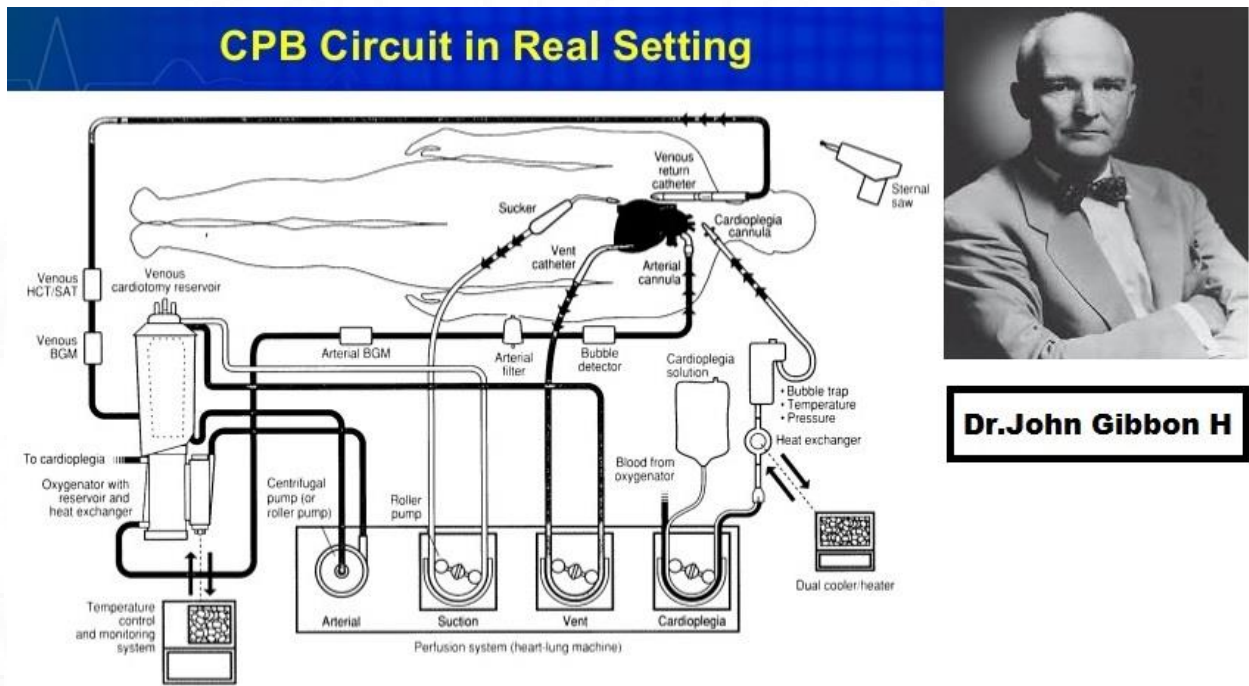


Figure.2: Dr. John Gibbon and Cardio Pulmonary Bypass setting in an operating theatre.

In 1961, Senning reported patch grafting of stenotic coronary artery with the use of cardiopulmonary bypass for the first time (24). By this time, Effler and colleagues at Cleveland clinic started pioneering work on CABG with the help of cineangiography (25). Goetz et.al were credited for performing first human coronary artery bypass operation in 1961. Even though, Kolesov in Leningrad performed first internal mammary artery (IMA) to left anterior descending

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(LAD) artery anastomosis in 1961 (26), it went largely unrecognized till 1968 when Green and colleagues re-reported this technique in New York. By 1971, Favaloro and Effler performed large series of reversed saphenous vein bypass grafting (27).

Evolution of CABG surgery was very rapid following this era. Large groups started reporting the success of these techniques along with invention of various new techniques. Sequential grafting of one vein to several distal coronary anastomosis was initially reported by Flemma, Johnson and Lepley in 1971, and further improvements in these techniques were reported by Bartley, Bigelow and Page in 1972 and Sewell in 1974. Beating heart bypass surgery was performed by Benetti, Calafiore and Subramanian as early as 1973. Subsequently, bilateral ITA grafting was also performed by 1970's (12).

As safety and efficacy of CABG became well established by 1980's, newer techniques emerged. Thoracoscopic harvesting of ITA was performed by 1998, which paved way for minimally invasive CABG procedures like minimally invasive direct coronary artery bypass surgery (MIDCAB) with left anterior thoracotomy incision, Robotic assisted CABG. Even endoscopic vein harvesting was made possible. Currently, CABG is widely performed either on CPB or Off CPB (OPCAB).

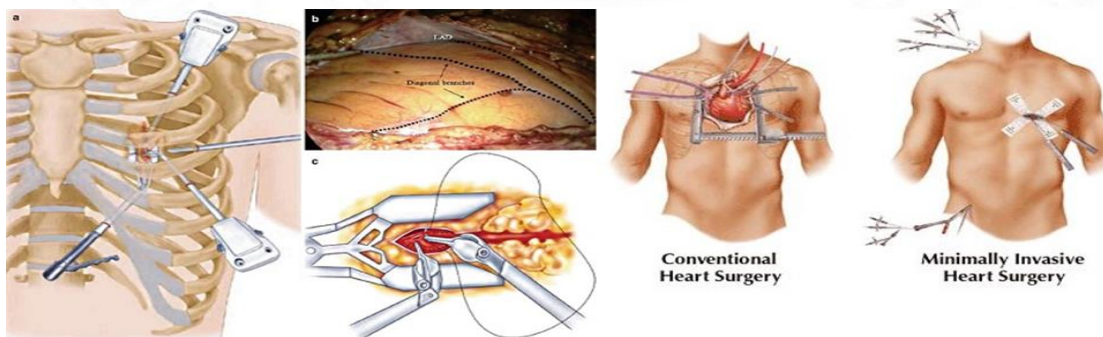


Figure.3: Illustrations of robotic assisted CABG and MIDCAB

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Morphology of Coronary artery stenosis (11):

Atherosclerosis with superimposed thrombosis, causing atherothrombosis is the main cause of coronary artery disease. Atherosclerosis is a chronic inflammatory disease of the arterial wall, which developed due to focal accumulations of lipid, carbohydrates, blood and blood products, fibrous tissues, calcium deposits in tunica intima with associated changes in media. These lesions typically develop at the sites of bifurcation of vessels and inner wall of curvatures which are characterized by low and oscillatory endothelial shear stress; and also, in the regions of preexisting intimal thickenings (28,29).

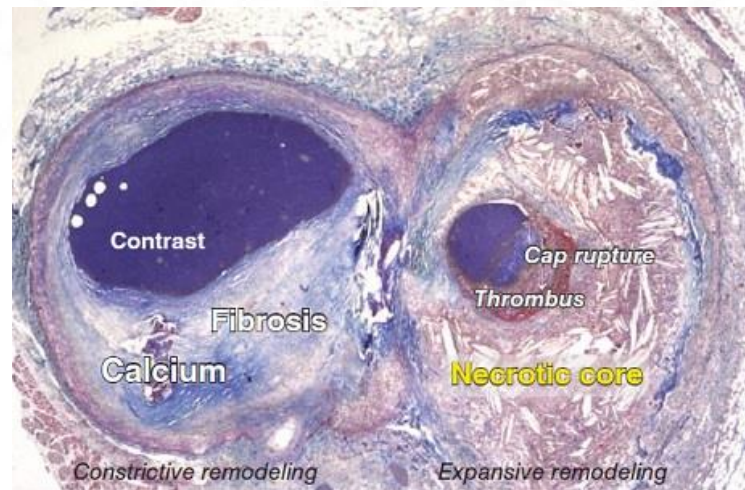


Figure.4: Histopathological section of coronary artery at bifurcation showing luminal narrowing due to acute and chronic processes.

These lipid foci with accumulation of various components form atherosclerotic lesions or plaques. These fibro lipid plaques are heterogenous in their size and composition. These plaques progress very slowly and speed of their progression varies greatly and it usually requires many years for these lesions to develop into advanced plaques to result in clinically significant disease. A pie chart showing typical composition of an advanced plaque.

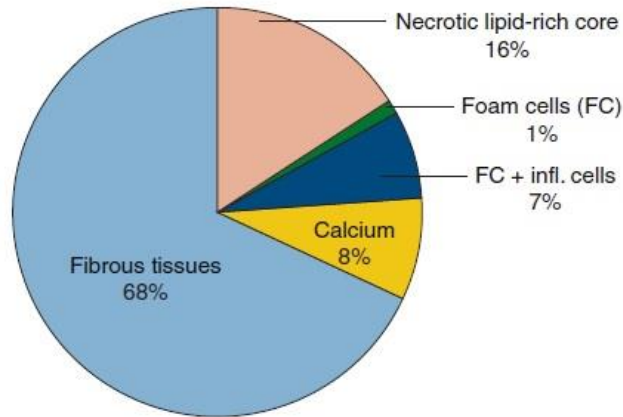
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Majority of these plaques remain asymptomatic with subclinical disease, but some of these plaques become thick over time encroaching onto lumen and become obstructive producing stenosis which causes anginal symptoms. Whereas, a few of these plaques become vulnerable causing atherothrombotic events like acute coronary syndromes which may end up in fatal heart attack.

Vulnerable plaques form symptomatic coronary thrombi mainly by two mechanisms. Majority of them, nearly 75% are caused by plaque rupture and other thrombi by plaque erosion. Plaque rupture is more common in men than women. The in-vitro model of rupture prone plaque typically consists of large, soft lipid rich necrotic core covered by thin and inflamed fibrous cap. Plaque vulnerability is determined by various factors like a) plaque size and remodeling, b) Necrotic core, c) Fibrous cap, d) Neovascularization and intraplaque hemorrhage, e) Perivascular inflammation, f) Spotty calcification. Of these factors, Necrotic core and fibrous cap are the most important factors governing plaque rupture.

Various modifiable and non-modifiable risk factors for atherosclerosis are well established like smoking, diabetes mellitus, hypertension, obesity, dyslipidemia, age, family history, certain types of hypercoagulable states (30). These factors are present in almost all patients who suffer from acute coronary syndromes in both men and women (31). But, the individual susceptibility to these risk factors is highly variable among different race of origin and also among within race and individual to individual. As a result of this, prediction of heart disease in population with these risk factors is limited. And surprisingly, initial coronary events occur in people with average or slightly elevated risk factor levels (32). And moreover, recurrences occur despite controlling these risk factors (33).

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Spectrum of clinical presentation of coronary artery disease depends on the underlying atherosclerotic lesion obstruction. When myocardium is deprived of blood supply in relation to its demand, myocardial necrosis ensues. In its milder or earlier stages, it affects only subendocardial portion, as this is more vulnerable to ischemia and results in a Non-ST elevation MI. In its most extreme form, it involves full thickness of ventricular wall resulting in Transmural MI.

This atherosclerotic process usually affects multiple coronary arteries. It usually affects proximal portion of the large coronary arteries, especially at or just beyond the bifurcation. Therefore, stenosis of main trunks like LAD, left circumflex artery (LCx) and right coronary artery (RCA) often involve first of secondary branches like diagonal 1 of LAD, obtuse marginal 1 of LCx, posterior descending artery of RCA. In approximately 10 – 20% of cases, left main coronary artery is diseased. Not uncommonly, diffuse disease with poor targets, not suitable for surgical revascularization are encountered (12).

Diagnostic tools to guide myocardial revascularization:

Most common clinical symptom in majority of patients with stable coronary disease is angina on exertion. This chest pain is centralized in location over the precordial area, characteristically described as pressure over the chest with radiation to left upper limb along the ulnar aspect of it and occasionally to the left side of neck. Angina typically comes up with exertion

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as crescendo – decrescendo pattern and relieves with rest or sublingual nitrates. Severity of angina is classified by Canadian Cardiovascular Society into four categories with class 4, being the most severe form, where patient develops chest pain even with mild activity or at rest.

When patient presents with Acute coronary syndromes, symptomatology slightly differs from stable coronary artery disease (SCAD). In unstable angina, pain comes up without any significant trigger or relationship with activity or exertion. Pain is typically of cardiac origin with radiation to left upper limb and associated findings. This pain also doesn't get relieved by rest or easily by nitrates.

Presentation of myocardial infarction (MI) is much more acute in origin with pain developed suddenly with associated perspiration, dyspnea, vomiting and sometimes even with loss of consciousness and death. It is easy to identify the patients with ACS if they have well known established risk factors or a prior history of cardiac events. In other cases, one or another initial non-invasive diagnostic modality is essential.

The most significant and foremost is electrocardiography (ECG). Abnormal ECG suggests ischemia or infarction, especially during acute events. Whereas, in patients with stable disease, it is normal in approximately 50% of the patients. During acute presentation, ECG helps in establishing initial diagnosis and localize territory of insult in most of the cases. In stable disease, stress ECG (Treadmill Test – TMT by modified Bruce protocol) is a very helpful screening diagnostic tool, as it is simple, non-invasive and inexpensive. In patients with significant stenosis and multivessel disease, it has high sensitivity and particularly seen with increasing age, severity of patient's disease and with magnitude of ST-segment shift. Positive stress test is an indication for coronary angiography.

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Coronary angiography is the gold standard investigation for assessment of coronary artery disease. It provides anatomical details and helps in decision making in management of either optimal medical therapy Vs Percutaneous coronary Intervention (PCI) Vs CABG. Angiography can be done either by conventional method or by CT imaging. Whereas, conventional traditional angiography has been used for long time as diagnostic modality, recently studies on non-invasive CT-coronary angiography to assess myocardial ischemia are under study.

Non-invasive methods:

In patients with stable CAD with angina, the likelihood of intermediate stenosis is more common than critical stenosis on imaging. In these patients, functional testing is critical to assess the extent of ischemia and the need for revascularization (34). Pre-operative functional testing can be carried out by invasive and non-invasive methods. In these patients, exercise ECG can have low sensitivity and hence non-invasive methods are recommended.

In patients with intermediate grade stenosis with no evidence of ischemia on non-invasive testing or multivessel disease, severity of lesion should be functionally assessed by coronary pressure derived fractional flow reserve (FFR). This FFR measurement can be done while performing coronary angiogram (CAG) or with coronary CT (CT-FFR). CT derived FFR and CT perfusion are possible approaches, with recent trials showing high correlation between CT-FFR and invasive FFR (35). Non randomized PLATFORM study (Prospective Longitudinal Trial of FFR-ct: Outcome and Resource impacts) showed that, by performing non-invasive CT and CT-FFR in patients with intermediate probability and chest pain, it reduced the number of patients undergoing normal invasive coronary angiography (36).

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In patients with extensive CAD with severe LV dysfunction, assessment of myocardial viability can be performed to select patients who can benefit from revascularization – Class IIb indication (LOE: B) (37). These can be achieved by various imaging modalities like

- A) Assess cellular integrity – 1. Myocardial contrast echocardiography 2. Single photon emission – CT(SPECT) 3. Late gadolinium enhancement cardiac magnetic resonance (LGE-CMR)
- B) Assess cellular metabolism – 18 FDG (Fluoro Deoxy Glucose) Positron Emission Tomography (18 FEG-PET)
- C) Assess contractile reserve – Dobutamine assays

The PARR-2 trial (PET and Recovery following Revascularization) done in patients with severe LV dysfunction, did not show superiority in terms of primary outcome of cardiac death, MI or recurrent hospital stay in patients managed with FDG-PET preoperatively over standard care (38). Even the viability sub study of STICH trial (Surgical Treatment for Ischemic Heart Failure) showed majority of patients with viable myocardium and failed to show significant association between myocardial viability and outcome on multivariate analysis (39).

Invasive methods:

Hemodynamic relevant stenosis is defined as $FFR \leq 0.75 - 0.80$ (40). DEFER trial has shown that revascularization can safely be deferred if $FFR > 0.75$ (41). FFR based assessment results in reclassification of the revascularization strategy in patients with intermediate stenosis. A recent meta-analysis revealed that revascularization for lesions of $FFR < 0.75$ reduce 1-year risk of major adverse cardiac events (MACE) (42).

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Another index to assess relevance in intermediate stenosis is instantaneous wave free ratio (iwFR). This is a resting index with comparable results between FFR and iFR. Two recent randomized trials, DEFINE-FLAIR trial and iFR-SWEDEHEART trial proposed revascularization if $FFR < 0.80$ or $iwFR \leq 0.89$. Both trials have similar primary outcomes in terms of death, MI and MACE in both iFR guided Vs FFR guided revascularization. Hence when evidence of ischemia is not available, FFR and iFR are recommended for assessment of hemodynamic relevance (Class I recommendation, LOE: A) (43,44).

Intravascular imaging of coronaries can be done by optical coherence tomography (OCT) or Intravascular ultrasound (IVUS). Their use is limited to certain indications only with IVUS superior to OCT. These imaging techniques should be considered to assess the severity of unprotected left main stenosis (COR: IIa, LOE: B).

Revascularization for stable coronary artery disease:

Gross indications for patients with stable coronary artery disease are those who have persistent symptoms, despite guideline directed medical therapy and for the improvement of prognosis (34). Detailed indications are provided in table.1. Since 1960, several studies have proved the efficacy of revascularization (PCI or CABG) over medical therapy in terms of relief of angina, use of anti-anginal medications, quality of life and improvement in exercise capacity during short-term and long-term follow up. In the recent era, follow up of FAME 2 study indicates improvement in angina in FFR guided PCI arm compared to medical therapy (45).

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Notable surgical trials like SYNTAX, FREEDOM (Future Revascularization Evaluation in Patients with Diabetes Mellitus), and EXCEL (Evaluation of XIENCE Versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) have consistently showed sustained improvement for revascularization strategies (PCI or CABG) on long-term follow up (46–48).

| Indications for revascularization in patients with stable angina or silent ischaemia | | | |
|--|--|--------------------|--------------------|
| Extent of CAD (anatomical and/or functional) | | Class ^a | Level ^b |
| For prognosis | Left main disease with stenosis >50%. ^{c 68–71} | I | A |
| | Proximal LAD stenosis >50%. ^{c 62,68,70,72} | I | A |
| | Two- or three-vessel disease with stenosis >50% with impaired LV function (LVEF ≤35%). ^{c 61,62,68,70,73–83} | I | A |
| | Large area of ischaemia detected by functional testing (>10% LV) or abnormal invasive FFR. ^{d 24,59,84–90} | I | B |
| | Single remaining patent coronary artery with stenosis >50%. ^c | I | C |
| For symptoms | Haemodynamically significant coronary stenosis ^c in the presence of limiting angina or angina equivalent, with insufficient response to optimized medical therapy. ^{e 24,63,91–97} | I | A |

CAD = coronary artery disease; FFR = fractional flow reserve; iwFR = instantaneous wave-free ratio; LAD = left anterior descending coronary artery; LV = left ventricular; LVEF = left ventricular ejection fraction.
^aClass of recommendation.
^bLevel of evidence.
^cWith documented ischaemia or a haemodynamically relevant lesion defined by FFR ≤0.80 or iwFR ≤0.89 (see section 3.2.1.1), or >90% stenosis in a major coronary vessel.
^dBased on FFR <0.75 indicating a prognostically relevant lesion (see section 3.2.1.1).
^eIn consideration of patient compliance and wishes in relation to the intensity of anti-anginal therapy.

Table.1: Indications for CABG in patients with stable coronary artery disease

CABG Vs Medical Therapy: Three early major randomized trials between 1972 and 1984, the Coronary Artery Surgery Study (CASS), the Veterans Administration Cooperative Study Group (VA), and the European Coronary Surgery Study (ECSS) have shown superiority of CABG over medical therapy in terms of long-term survival (49,50).

In 1994, a land mark meta-analysis of seven RCTs by Yusuf et.al in patients with SCAD and left main (LM) or triple vessel disease, demonstrated survival benefit in CABG group as compared to initial medical therapy with these benefits being corroborated in more recent studies also (51). A network meta-analysis of 100 trials with 93,553 patients, which compared initial

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medical therapy with revascularization strategy has reported improved survival and a reduced risk of MI among patients undergoing CABG as compared with initial medical treatment (52).

In the STICH trial, patients with severe LV dysfunction ($EF \leq 35\%$) secondary to coronary artery disease were randomized to either CABG or initial medical therapy. Their extended 10-year follow-up of this trial reported a significant reduction in all-cause and cardiovascular mortality in CABG group favouring surgical revascularization even in severe LV dysfunction group (53).

PCI Vs CABG:

Criteria to decide myocardial revascularization strategy either by percutaneous coronary intervention (PCI) or coronary artery bypass surgery (CABG) is governed by predicted risk of surgical mortality, the anatomical complexity of coronary disease, and the anticipated completeness of revascularization.

A) Predicted surgical mortality: Two scoring systems were developed, both based on clinical variables which estimate the operative in-hospital or 30-day mortality. These are the European System for Cardiac Operative Risk Evaluation (Euro SCORE II) and the Society of Thoracic Surgeons (STS) score. Euro SCORE II was developed to improve Euro SCORE I (54,55). Although, both these scoring systems have demonstrated their efficacy in specific cohorts of patients undergoing CABG, recent EACTS guidelines recommend calculation of STS score to assess in-hospital or 30 day mortality and in-hospital morbidity after CABG (COR: I, LOE: B) and Euro SCORE II calculation may be considered for the same purpose (COR: IIb, LOE: B).

To combine clinical and anatomical risk estimation, SYNTAX II score was developed, but it is less well investigated. Moreover, SYNTAX II score failed to predict outcome in EXCEL trial (56).

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B) Anatomical complexity of coronary artery disease:

One of the most significant randomized trial in the evolution of CABG surgery is SYNTAX (Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) study and development of SYNTAX score to grade the anatomical complexity of coronary disease in patients with left main disease or triple vessel disease (57). SYNTAX score was shown to be an independent predictor of long-term major adverse cardiac and cerebrovascular events (MACCE) and of death in patients treated with PCI but not CABG in this trial and also has been validated in various other cohorts (58).

In the SYNTAX trial, patients were categorized into strata based on SYNTAX score with low, intermediate, and high anatomical complexity. These strata identified patients who had similar outcomes with both PCI and CABG and those who derived significant benefit from CABG (59). They were stratified as low score (0-22), intermediate score (23-32), high SYNTAX score (\geq 33). Further, in a recent collaborative individual patient pooled analysis of randomized trials including 11,518 patients, these strata of the SYNTAX score identified outcomes of patients with respective to myocardial revascularization strategy as reflected in the original study (60).

However, minor concerns of bias and inter-individual variability in calculation of SYNTAX score can be minimized by adequate training. Recent guidelines recommend SYNTAX score calculation for patients with left main disease and multi-vessel disease for anatomical complexity and long-term risk of mortality and morbidity (COR: I, LOE: B).

C) Completeness of Revascularization:

Myocardial revascularization should be aimed to reduce residual ischemia. A sub study from COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug

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Evaluation) trial demonstrated superiority in terms of death and MI when ischemic myocardium was reduced to $\leq 5\%$ (61). A meta-analysis of 89,883 patients from various RCTs and observational studies revealed complete revascularization to be superior to incomplete revascularization in terms of long-term mortality, MI, and repeat myocardial revascularization (62).

Consistent results were obtained in a pooled analysis of patients from SYNTAX, BEST (Randomized Comparison of Coronary Artery Bypass Surgery and Everolimus-Eluting Stent Implantation in the Treatment of Patients with Multivessel Coronary Artery Disease), and PRECOMBAT (Premier of Randomized Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease) trials (63). Priority should be given for completeness of revascularization when deciding between PCI or CABG (COR: IIa, LOE: B).

In this era, surgical revascularization is driven by these factors supported by these largely studied randomized controlled trials. Recommendations for CABG in patients with SCAD with suitable coronary anatomy for either procedures (PCI or CABG) and low predicted surgical mortality.

While considering CABG over PCI, these aspects favour CABG:

A. Clinical characteristics

1. Diabetes
2. Severe LV dysfunction ($EF \leq 35\%$)
3. Contraindication to DAPT
4. Recurrent diffuse in-stent restenosis

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B. Anatomical and technical aspects

1. Multivessel disease with SYNTAX score ≥ 23
2. Anatomy not suitable for PCI and may result in incomplete revascularization
3. Severely calcified coronaries preventing lesion expansion

C. Need for concomitant interventions

1. Ascending Aortic pathology requiring surgery
2. Associated valvar or other cardiac pathology requiring surgery

| Recommendations according to extent of CAD | CABG | |
|---|--------------------|--------------------|
| | Class ^a | Level ^b |
| One-vessel CAD | | |
| Without proximal LAD stenosis. | IIb | C |
| With proximal LAD stenosis. ^{68,101,139–144} | I | A |
| Two-vessel CAD | | |
| Without proximal LAD stenosis. | IIb | C |
| With proximal LAD stenosis. ^{68,70,73} | I | B |
| Left main CAD | | |
| Left main disease with low SYNTAX score (0 - 22). ^{69,121,122,124,145–148} | I | A |
| Left main disease with intermediate SYNTAX score (23 - 32). ^{69,121,122,124,145–148} | I | A |
| Left main disease with high SYNTAX score (≥ 33). ^{c 69,121,122,124,146–148} | I | A |
| Three-vessel CAD without diabetes mellitus | | |
| Three-vessel disease with low SYNTAX score (0 - 22). ^{102,105,121,123,124,135,149} | I | A |
| Three-vessel disease with intermediate or high SYNTAX score (>22). ^{c 102,105,121,123,124,135,149} | I | A |
| Three-vessel CAD with diabetes mellitus | | |
| Three-vessel disease with low SYNTAX score 0–22. ^{102,105,121,123,124,135,150–157} | I | A |
| Three-vessel disease with intermediate or high SYNTAX score (>22). ^{c 102,105,121,123,124,135,150–157} | I | A |

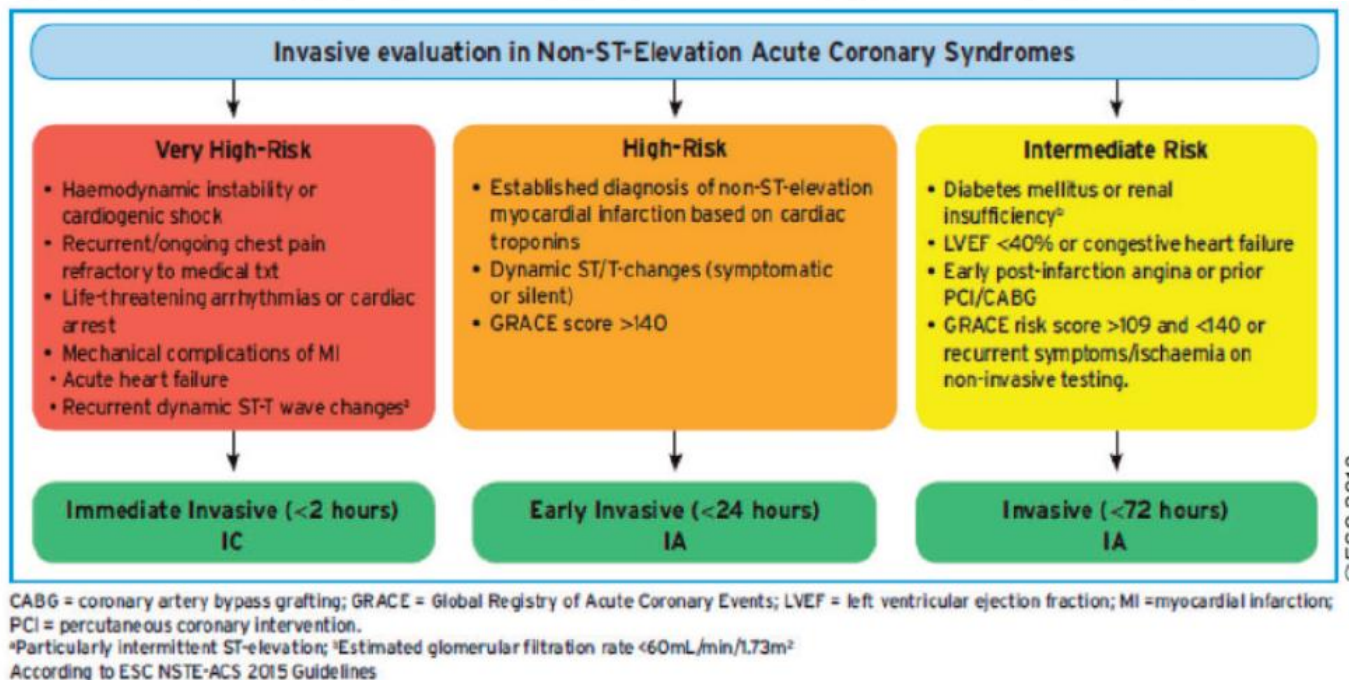
Table.2: Indications for CABG depending on the extent of CAD according to EACTS guidelines

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Revascularization in Non-ST elevation MI:

Current literature suggests an invasive strategy as the standard of care in high-risk patients who suffered from myocardial infarction (34). Patients presenting with Non-ST-elevation MI (NSTEMI) are risk stratified for the purpose of treatment strategy and timing of intervention. The benefit of invasive strategy was confined especially to biomarker positive patients and those with other high-risk factors and also has been shown to improve clinical outcomes (64).

In patients with multivessel disease, complete revascularization should be attempted depending on hemodynamic stability as the prognosis of patients with incomplete revascularization is worse. Two major concerns in surgical revascularization of patients with MI are myocardial stunning and risk of perioperative bleeding due to antiplatelet therapy or thrombolytic therapy during the acute episodes.



Risk stratification in patients presenting with NSTEMI

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It is estimated that perioperative bleeding complications with antiplatelets is > 10%, while the risk of ischemic events in patients while awaiting surgery and taking suboptimal antiplatelet therapy is < 0.1% (65). Hence, as per risk stratification, in those patients who are stabilized following this initial event, revascularization strategies are based on principles applied to SCAD (COR: I, LOE: B). This is supported by recent meta-analysis, in which individual patient's data analysis from the BEST, PRECOMABT, and SYNTAX trials of patients with stabilized NSTEMI-ACS and left main or multivessel disease, have shown 5-year incidence of primary outcome of composite death, MI or stroke to be significantly lower in CABG group as compared to PCI (66). There is no randomized comparison of CABG Vs PCI in NSTEMI group of patients exclusively.

Whereas, in patients with ongoing ischemia or hemodynamic instability, emergency CABG should be performed regardless of antiplatelet therapy and its consequences. In these circumstances, only infarct related artery should be revascularized especially in patients with cardiogenic shock. In cardiogenic shock, routine revascularization of non-IRA lesions is not recommended (COR: III, LOE: B).

Revascularization in ST elevation MI (STEMI):

In STEMI, primary modality of intervention is primary PCI. In case of delay, other methods of reperfusion therapy like thrombolysis are performed. The key issue in the management of STEMI is unexpected delays in the timely implementation of reperfusion therapy. Four major randomized trials have shown benefit of complete revascularization as compared to IRA only PCI in STEMI patients with multivessel disease (67). Though PCI is preferred in emergency setting, patients with Non-PCIable lesions to IRA and ongoing ischemia or large areas of compromised myocardium should be considered for CABG (COR: IIa, LOE: C). As with NSTEMI-ACS, routine

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revascularization (PCI or CABG) of non-IRA lesion is not recommended in the setting of cardiogenic shock (COR: III, LOE: B).

Myocardial Revascularization in patients with heart failure:

Chronic heart failure:

Even though, optimal revascularization strategy (PCI or CABG) is not defined for patients with heart failure secondary to ischemic heart disease with low ejection fraction (HFrEF), coronary revascularization has survival advantage as compared to medical therapy alone. Decision to choose revascularization strategy depends on the heart team.

The only randomized trial in patients of heart failure with reduced EF comparing revascularization strategy, STICH trial has compared revascularization with CABG to medical therapy alone. Trial results showed CABG can be performed with acceptable 30-day mortality (5.1%). Further, follow up over 10 years in STICHES study (STICH Extension Study) revealed significant survival benefit in patients with CABG combined with medical therapy as compared to medical therapy alone (53).

Major clinical trials comparing PCI Vs CABG have excluded patients with heart failure. Few observational studies however have proven superiority of CABG over PCI and effectiveness of PCI over medical therapy where surgical risk is high. In one propensity matched analysis, similar survival pattern was observed among both groups of PCI and CABG (68). Another recent observational study compared outcomes in patients with multivessel disease and LV dysfunction undergoing PCI or CABG, this study revealed significant reduction in mortality and low risk of MACE in CABG group as compared to PCI patients (69). These event trends were observed as early as during the first year and continued till 12 years post-surgery.

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Hence, CABG is recommended as first line management in patients with multivessel disease and acceptable mortality risk (COR: I, LOE: B), whereas PCI can be considered as acceptable alternate revascularization strategy in single or double vessel disease, when complete revascularization can be achieved. (COR: IIa, LOE: C). PCI is preferred in older patients without diabetes, where complete revascularization is possible, whereas CABG is preferred in younger patients with more extensive CAD or those with diabetes. CABG is associated with better long-term survival and reduced incidence of MACCE in patients with diabetes and LV moderate or severe dysfunction (EF <50%).

Ventricular reconstruction and aneurysm resection:

In patients with ischemic heart failure, Left ventricle is largely dilated secondary to myocardial dyskinesia, thinning and scar formation. Surgical ventricular restoration is performed either by LV wall plication, scar resection and LV wall reconstruction to restore physiological volume and achieve an elliptical shape of the LV. Wherein, aneurysmectomy is performed to prevent thromboembolic episodes and life-threatening ventricular arrhythmias. In cases of severe LV dilatation, fibrous scar is excised to prevent thrombus formation in akinetic aneurysmal segment and thereby preventing thromboembolism. The STICH trial comparing patients with isolated CABG and CABG combined with SVR did not reveal any difference in the primary outcome among both groups (70). Post-operative LV end-systolic volume index < 70 mL/m² in patients with CABG and SVR, showed better survival compared with CABG alone (71).

CABG with LV aneurysmectomy should be considered in patients with NYHA class III/IV, large LV aneurysm, large thrombus formation, or if the aneurysm is arrhythmogenic (COR: IIa,

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LOE: C). Only centers with expertise should consider surgical ventricular restoration during CABG procedure in specific patients (COR: Iib, LOE: B).

Acute heart failure and cardiogenic shock:

This is most commonly seen in patients who suffer from acute ST elevation myocardial infarction. The SHOCK (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock) trial demonstrated that, long-term survival is improved in patients who present in cardiogenic shock secondary to acute MI and underwent emergency revascularization with PCI or CABG as compared to initial aggressive medical therapy (72). Revascularization group showed reduced all-cause mortality at 6 months when compared to medically treated patients.

Similar survival rates were observed in a sub analysis of SHOCK trial which compares CABG Vs PCI revascularization strategy (73). Recent guidelines recommend emergency PCI or CABG of the culprit vessel in patients with cardiogenic shock due to STEMI or NSTEMI (COR: I, LOE: B). CABG should be considered if coronary anatomy is not amenable to PCI (COR: I, LOE: B).

Mechanical Circulatory Support:

Various short-term mechanical support devices like Intra-aortic balloon pump (IABP), veno-arterial extracorporeal membrane oxygenation (VA-ECMO), percutaneous left ventricular assist devices (pLVAD's) are used in refractory cardiogenic shock in acute MI.

The IABP-SHOCK II (Intra-aortic Balloon Pump in Cardiogenic Shock II) randomized trial, did not reduce 30-day mortality in patients with cardiogenic shock complicating acute MI, with no evidence of long-term benefit (74). A recent Cochrane review of seven trials showed no

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survival benefit in patients on IABPs, even though there was some beneficial effect on some hemodynamic parameters in the immediate period (75). Thus, guidelines do not recommend the routine use of IABPs in patients with cardiogenic shock complicating acute MI (COR: III, LOE: B).

Veno-arterial ECMO (VA-ECMO) provides superior circulatory support over IABP. A meta-analysis of observational studies in patients with cardiogenic shock post-ACS revealed better (33% higher) 30-day survival in patients with VA-ECMO as compared to IABP (76).

Even though percutaneous LVAD's are increasingly being used now a days to support cardiogenic shock, the evidence is bleak to support its use in patients with cardiogenic shock. Most commonly applied devices are Impella – a transaortic micro axial pump and Tandem Heart – a transeptal centrifugal assist device. As of today, there is very limited data available on surgically implanted left ventricular assist devices (34).

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Aim of the study:

To assess in-hospital complications and long-term outcomes during follow-up in patients who underwent coronary artery bypass surgery at our institution.

Objectives of the study:

1. To look into in-hospital mortality and evaluating risk-factors associated with same.
2. To observe long-term survival following surgery
3. To assess major adverse cardiac and cerebrovascular events (All-cause death, stroke, return of angina, myocardial infarction, re-intervention for ischemic symptoms) during follow-up at 12 months and 120 months post-surgery.
4. To individually assess risk factors associated with composite end-point of late mortality during follow up.
5. To find an association between risk factors of pre-operative myocardial infarction and stroke with post-operative recurrence of myocardial infarction and stroke respectively.
6. To ascertain freedom from re-intervention and freedom from symptom onset post-surgery

Hypothesis:

In the current era, CABG performed with LIMA and additional venous grafts have non-inferior outcomes in terms of survival and long-term MACCE.

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MATERIALS AND METHODS

Study setting:

This study was performed in the division of Adult cardiac surgery unit under Department of Cardio Vascular and Thoracic Surgery at Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram, India.

Sree Chitra Tirunal Institute for Medical Sciences and Technology – Department of Cardio Vascular and Thoracic Surgery:

Hospital wing serves as tertiary referral center for cardiovascular, thoracic and neurologic conditions. Department of Cardio Vascular and Thoracic surgery has three divisions – Adult cardiac surgery, Pediatric cardiac surgery, General Thoracic and Vascular surgery. Adult cardiac surgery has 14 ICU and 28 Ward beds with three state of the art operating rooms. Approximately 4 – 5 operations are performed every day with nearly 750 – 800 adult cardiac surgeries in a year. Most commonly performed operations include coronary artery bypass surgery and valve replacement surgeries.

Study Design:

This study is a retrospective observational cohort study in a defined set of patients. There is no prospective component in the study.

Study population:

All patients who underwent coronary artery bypass surgery in adult cardiac surgery unit of SCTIMST and who meet the inclusion criteria are included in the study.

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Study duration:

This retrospective cohort has patients who were operated during the period of January 2003 to December 2007.

Inclusion criteria:

1. All elective and emergency patients
2. All patients above the age of 18
3. All patients who have either undergone isolated CABG or associated with other valve intervention, but with predominant ischemic heart disease.

Exclusion criteria:

1. Patients under the age of 18
2. Patients in whom CABG was performed as concomitant procedure with predominant valve pathology
3. Patients with missing records or incomplete data
4. Patients with inadequate follow up period and data

DATA management:

Data collection: All the data will be collected by the principal investigator of the study

Data sources: Data will be collected from the institutional data base from the Medical Records Department. Patient's initial outpatient cardiology visit chart is accessed for initial presentation and comorbid details. Cardiology admission record is reviewed for coronary angiogram report. Detailed In-patient charts of cardiac surgery are utilized. Discharge summary, operation record, ICU charts, Perfusion charts are reviewed for data collection.

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Follow up data is collected from outpatient department visit charts following the discharge. Those patients who are advised to follow-up closer to their home are contacted through phone or post mail to gather survival data.

Data entry: All the collected data will be directly entered into principal investigator's personal computer using epidata software (Epi Data version 3.1). This data will be converted to Microsoft excel files for further statistical analysis and results.

Data measurement: Data will be collected in a defined manner as determined earlier by designed proforma. These are broadly categorized into pre-operative, operative, post-operative and follow-up groups.

1.Pre-operative characteristics:

Demographic data of all patients like age of the patient, gender and body surface area are collected. Body surface area is calculated using height and weight of the individual using a formula and collected from the perfusion chart.

Patient Co-morbid illness profile:

1. Patient smoking status – patients were categorized into four groups based on cigarette, cigar or beedi smoking.
 - a. Nonsmokers – who have never smoked in their life
 - b. Current smoker – Those who are actively smoking at the time of surgery or those who have stopped smoking within 3 months of their operation
 - c. Patients who have stopped smoking 3 months earlier than surgery but not later than 10 years prior

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d. Reformed smoker – Who have stopped smoking more than 10 years ago.

Tobacco chewing is not prominent in this region of country and hence it is not taken into account even though it is a risk factor for CABG. Calculation of pack years is more reliable than just smoking status, but it was limited as this is a retrospective analysis.

2. Obesity: Body mass index (BMI) calculated by weight in kilograms divided by height in m^2 is used to indicate obesity. In Indian population, $BMI \geq 30 \text{ kg/m}^2$ is considered obesity. Patients are divided into obese and non-obese groups.

3. Diabetes Mellitus: Patients are divided into three categories.

a. Non-diabetic individuals

b. Type I DM – Insulin dependent diabetes mellitus. Patients who were administering at least one form of insulin before the planned admission of surgery.

c. Type II DM – Patients who are exclusively only on oral hypoglycemic agents with diet control and not on any form on Insulin.

Diabetes is the most significant modifiable risk factor for the development of macrovascular and microvascular disease. It is not only a risk factor for coronary artery disease, but also for cerebrovascular disease (large-artery stroke) and peripheral arterial disease. It plays a significant role in microvascular disease and causes diabetic nephropathy, diabetic retinopathy, peripheral neuropathy, accelerated hypertension and even affects musculoskeletal system.

Patients with coronary artery disease who have diabetes mellitus have bad prognosis when compared to non-diabetes patients. This prognosis is much worse in patients who had history of MI, particularly with insulin dependent DM than type II DM. Multiple randomized controlled trials

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have proven benefit of CABG in the setting of Diabetic patients with multivessel disease with or without left main stenosis and irrespective SYNTAX score tertiles.

Most notable trials include FREEDOM trial, VACARDS trial, SYNTAX trial and BEST trial with few meta-analysis and propensity matched comparisons. The FREEDOM trial compared revascularization methods of PCI Vs CABG in patients with DM and multivessel disease but without LM stenosis. At 5 year follow up, CABG group had lower incidence of all-cause death, non-fatal MI and stroke as compared to PCI patients ($p=0.005$). Patients with type I DM had higher event rates. VACARDS (Veterans Affairs Coronary Artery Revascularization in Diabetes Study) also showed similar results with primary end-point of death and MI to be lower in CABG group Vs PCI group.

CARDia (Coronary Artery Revascularization in Diabetes) trial showed similar outcomes in CABG and PCI at 1-year primary outcome, but higher rate of revascularization in PCI group. In the sub analysis of SYNTAX trial with DM patients and multivessel disease, even though there was no difference in safety end point at 5 year follow up of CABG and PCI patients, there was significant higher rate of repeat revascularization in PCI group, even with low and intermediate SYNTAX score tertiles. Further MACCE incidence was higher in all diabetics of PCI and death was higher in type I DM of PCI group. Even the BEST trial had similar results with higher rate or primary end points in PCI group.

A meta-analysis (four RCT's) of patients with DM and multivessel disease comparing PCI Vs CABG suggested higher risk of death and MI in PCI group, but with lower incidence of stroke. A pooled analysis of 11,518 patients with multivessel or LM disease randomized to CABG or PCI, CABG patients had significant lower all-cause death than PCI group. This difference was evident

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in diabetes patients, but same could not be found in non-diabetes patients. This benefit of CABG over PCI is even seen in patients with ACS as evidenced in a recent population-based analysis.

4. Hypertension: Patients are divided into hypertensives and non-hypertensives. Patients are labelled hypertensive when they already have been diagnosed and on anti-hypertensive medications or newly diagnosed at initial OPD visit. Systolic blood pressure > 140 mm of Hg and diastolic blood pressure > 90 mm of Hg recorded at three different occasions is considered as newly diagnosed hypertension.

Hypertension combined with DM increases the risk of CAD.

5. Dyslipidemia: Majority of patients with CAD have dyslipidemia which usually surfaces on blood panel during the initial event of ACS or OPD visit. Dyslipidemia was defined as per prevailing guidelines during the study period with positive family history, total cholesterol levels > 200 mg/dl, Low density Lipoprotein (LDL) cholesterol > 100 mg/dl, statin use and other familial syndromes.
6. Hypothyroidism: Patients who have been diagnosed to be hypothyroid and on thyroxine supplementation. All patients are routinely performed thyroid profile (TSH, FT3, FT4), those with lower levels of FT3 and FT4 with usually elevated levels of TSH are considered hypothyroid and started on thyroid hormone supplementation.
7. Pre-operative Percutaneous Coronary Intervention (PCI) status: Many patients present initially with single or double vessel disease which is amenable to PCI, but later on they may develop multivessel disease or in-stent restenosis which requires CABG. Few patients present as ACS and PCI was carried out as a result of primary PCI or rescue PCI and so as to accomplish complete revascularization, referred for CABG. Though, PCI was not so widely used during the time of study (2003-2007), few patients have undergone PCI many

years prior to CABG and few before months. Some patients have failed PCI and referred for surgery.

8. Cerebro Vascular Accidents: Risk factors for CAD and cerebral macrovascular disease (large-artery stroke) are nearly identical with atherosclerosis as predominant pathophysiological mechanism. Hence, patients with CAD are always at risk of these events both pre-operatively and also post-operatively which severely affects their morbidity and mortality. Patients who had prior history of transient ischemic attacks, documented stroke – Ischemic or Hemorrhagic in nature with or without focal neurological deficit, seizure disorder are considered to have CVA in this study.

Patients with history of transient loss of consciousness, syncope or pre-syncope, history of undocumented stroke, history of cranial surgery for other causes, traumatic brain injuries are excluded to have CVA.

9. Peripheral Vascular Disease: As a part of macrovascular disease, peripheral arterial disease is one of the most common coexisting arterial disease seen with CAD. All patients are screened clinically for the presence of peripheral arterial disease through any history of claudication, peripheral signs of chronic peripheral arterial occlusive disease (PAOD) like loss of hair, brittle nails, active or healed arterial ulcers, stretched and shiny skin. All peripheral pulses are palpated and those with grade 2+ are considered normal. If any patient has above symptoms or signs with no palpable pulses or pulse with grade 1+, arterial doppler of lower limb arteries is performed and disease burden is assessed.

In patients with high risk of PAOD like DM and smokers, specific attention is given, as it will affect wound healing process of the saphenous vein harvested site in the

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lower limb. Upper limbs are usually less affected with peripheral arterial disease. History of bowel angina is also considered to rule out visceral artery stenosis. Our institute protocol is to perform CABG followed by management of PAOD in cases of peripheral artery critical stenosis.

10. Chronic Obstructive Pulmonary Disease (COPD): Patients with diagnosis of emphysema, chronic bronchitis or bronchial asthma are considered to have COPD. These patients are subjected to pulmonary function tests which reveal obstructive airway disease and pulmonologist opinion is taken to assess the surgical risk depending on the disease activity. Smoking and people working in environment of smoke (occupational hazard, air pollution) are more prone to develop COPD, with genetic and familial factors playing a minimal role.

Patients with chest X ray showing emphysematous changes are carefully monitored in the post-operative period. COPD patients pose a major challenge in regards to management of peri-operative ventilation, especially in patients with LV dysfunction. They tend to maintain low pO₂, higher NIV rates post extubation, increased rates of tachyarrhythmias to atrial fibrillation, prolonged ICU and ward stay with increased bronchodilator use.

All patients are adequately optimized before surgery to minimize the above adverse events, by breathing exercises, long-acting bronchodilator inhalers and nebulization following admission. We keep high threshold to initiate oral or parenteral steroid to minimize wound infection and sternal dehiscence rates.

11. Carotid Artery Disease: All patients are clinically screened for significant carotid artery stenosis. Any history of recurrent giddiness, syncope or pre-syncope on exertion in the absence of aortic valve disease necessitates duplex imaging of carotid arteries. All are

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examined for carotid bruit on auscultation. Presence of bruit requires imaging. In the absence of these features, likelihood of significant carotid artery stenosis is very low. Moreover, evidence also suggests that stenosis of carotid arteries is not a significant cause of stroke in the peri-operative stroke. Duplex imaging with > 50% stenosis is considered significant in the event of recent TIA/stroke within 6 months or > 70% in other asymptomatic patients.

Also included are patients with documented evidence of carotid stenosis during the evaluation of stroke. Patients who have significant carotid artery stenosis have undergone concomitant carotid endarterectomy with CABG.

12. Renal Function: Cardiopulmonary bypass incites systemic inflammatory response which can affect patients with decreased renal function. Prolonged CPB time carries higher risk compared to standard CPB time. This has particular relevance in patients who have undergone coronary angiogram recently and recovering from contrast induced nephropathy. A lot of other patients have mild subclinical renal damage due to their underlying comorbid illnesses like DM and hypertension.

For practical purposes, serum creatinine is considered as a marker for renal dysfunction. Normal serum creatinine level < 1.4 mg/dl. Any value above this is considered as renal dysfunction. Some patients have chronic kidney disease and dialysis dependent and carry a higher risk of renal damage. In our department, we usually delay elective CABG operation for three weeks following coronary angiogram to allow improvement in contrast induced nephropathy. Nephrologist opinion is sought for higher serum creatinine values and general nephroprotective measures like adequate hydration, avoiding

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nephrotoxic drugs, serial monitoring of serum creatinine and electrolytes in the immediate post-operative period are observed.

13. Nature of surgery: Patients are divided into whether primary CABG is being performed or Redo CABG. Redo CABG is considered only if patient has undergone earlier CABG, wherein other valve or intracardiac operation is not included.

Clinical Presentation details:

1. Initial presentation: Patients are classified into five categories depending on their initial presentation at the time of diagnosis of CAD.
 - A. Asymptomatic – These are patients who have no cardiac related symptoms, but who were detected during their routine health check-up (ECG and echo changes) or those patients while availing their fitness for pre-anesthetic checkup, to undergo major non-cardiac surgery.
 - B. Stable coronary artery disease: In stable coronary artery disease, patients present with cardiac symptoms on exertion. Most common symptom is angina on exertion which is classified according to Canadian cardiovascular society classification (CCS). Next common symptoms are dyspnea on exertion, palpitations and fatigue.
 - C. Unstable Angina (UA): UA is usually due to abrupt reduction in myocardial coronary blood flow as a result of nonocclusive coronary thrombosis. It can present in three forms: 1. Angina with minimal exertion, lasting > 20 min or rest angina, 2. New onset severe angina (CCS III or more), 3. Crescendo angina, angina which has worsened in severity and frequency as compared to angina earlier.

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D. Non-ST elevation MI: Acute MI is defined as presence of evidence of myocardial necrosis in the form of rise/fall of an acceptable cardiac biomarker (troponin or CK-MB) + evidence of myocardial ischemia by one of the following:

1. Symptoms of ischemia
2. ECG – new ST/T changes or new onset left bundle branch block (LBBB)
3. New pathologic Q waves on ECG
4. New regional wall motion abnormality on echo or new loss of myocardium on imaging.

When such acute MI is associated with ST depression (Non-ST elevation), it is termed as NSTEMI.

E. ST-elevation MI: When above acute MI changes are accompanied with ST elevation, it is termed as STEMI. This is most lethal form with complete occlusion of coronary vessel leading to transmural MI.

2. Symptomatic status at Operation: All patients with SCAD are started on optimal medical therapy before operation to control symptoms and prevent ACS. Patients with ACS are stabilized during the initial event and operated upon usually 3-6 weeks later. Patients symptomatic status is assessed at the time of admission for CABG in elective patients and their status just before operation in emergency patients.
3. Myocardial Infarction: Patients are divided into recent MI – MI occurring within three months of operation, and old MI – History of MI older than 3 months.
4. Recent MI: These patients are further categorized into type of MI – NSTEMI or STEMI
5. Old MI: Similar to recent MI, subdivided into NSTEMI or STEMI.

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6. Cardiogenic shock: This includes patients who are in refractory shock despite optimal intensive medical therapy (Inotropic supports and IABP [when necessary]) following acute MI, most commonly STEMI and have ongoing ischemia with anatomically non-PCIable lesion taken up for CABG.
7. Congestive cardiac failure: Patients who have sustained massive MI, but were successfully managed with medical therapy at the initial event; patients with recurrent episodes of ACS are more likely to develop chronic heart failure. These patients have fatigue and pedal edema as their predominant symptom and clinical signs of elevated jugular venous pulsations, pitting type of pedal edema, sometimes ascites, hepatomegaly, third heart sound S₃ and basal crepitations. Echo usually features global hypokinesia with moderate to severe LV dysfunction (EF < 40%).

TABLE 36–1. Canadian Cardiovascular Society Grading of Angina

| Class | Description of Stage |
|-------|---|
| I | Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation |
| II | Angina occurs on walking > 2 level blocks and climbing > 1 flight of ordinary stairs at normal pace and under normal conditions |
| III | Angina occurs on walking 1–2 level blocks and climbing 1 flight of ordinary stairs under normal conditions and at normal pace. |
| IV | Anginal symptoms may be present at rest. |

8. Symptomatic class: Patients presenting with angina are graded according to Canadian Cardiovascular Society (CCS) Grading for Angina into four grades. Those predominantly have dyspnea as their symptom are classified according to New York Heart Association (NYHA) classification.

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9. Diuretic therapy: Patients with moderate – severe LV dysfunction or chronic heart failure are started on diuretics to optimize preload before operation.
10. Family history of CAD: Patients with first degree relatives who suffered from history of CAD or sudden cardiac arrest are considered to have positive family history
11. Pre-operative Electrocardiography (ECG): Patient's ECG was categorized to a) Sinus Rhythm b) Atrial fibrillation c) Occasional ventricular premature complexes d) Right bundle branch block e) Left bundle branch block f) Paced rhythm g) Other rhythm patterns
12. Cardiomegaly: If the patient's chest X ray shows increased cardio-thoracic ratio (CTR > 0.5), it is considered as cardiomegaly
13. Two-dimensional echocardiography: Echo provides information on evidence of ischemia as regional wall motion abnormality (RWMA), biventricular function, mitral regurgitation and other cardiac conditions.
 - A. Left ventricular function: Assessed by LV ejection fraction
 - B. Grade of LV dysfunction: LV dysfunction is graded depending on EF. EF \geq 55% - Good LV function, EF 46 – 54% as mild LV dysfunction, EF 35-45% as moderate LV dysfunction, EF < 35% is considered to be severe LV dysfunction.
 - C. Mitral regurgitation: Grading of MR is done based on various echocardiographic criteria. Grade 0 – No MR, Grade 1+ or 1-2+ - Trivial MR, Grade 2+ - Mild MR, Grade 2-3+, 3+ - Moderate MR, Grade 3-4+,4+ - Severe MR.
 - D. Etiology of MR: Etiology is divided into 1. Ischemic MR 2. Rheumatic 3. Degenerative
 - E. RWMA: Presence of RWMA suggests evidence of ischemia
 - F. Territory affected: RWMA can affect anterior wall, posterior wall, lateral wall in basal, mid and apical segments

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Coronary angiogram details:

1. Number of stenotic vessels: In clinical scenario, hemodynamically significant stenosis is defined as
 - a. $\geq 70\%$ narrowing of luminal diameter of an epicardial stenosis measured in the “worst view” angiographic projection.
 - b. $\geq 50\%$ narrowing of luminal diameter of a left main stenosis.
 - c. 40% to 70% luminal narrowing of an epicardial stenosis with an abnormal FFR < 0.80 , which is consistent with inducible ischemia.

Number of vessels with the above defined narrowing are considered as stenosis.

2. Left main coronary artery (LMCA) disease: Left main disease with $> 50\%$ stenosis is considered as LMCA disease
3. Disease territory: Coronary artery disease is categorized into single vessel, double vessel and triple vessel disease depending on the territories involved rather than on the number of vessels affected.

Coronary anatomy has two major arterial systems - Left main coronary artery and right coronary artery. Left main coronary anatomy divides into left anterior descending artery (LAD) and left circumflex artery (LCx). LAD gives septal and diagonal branches. LCx gives rise to obtuse marginal branches and occasionally posterolateral branches. Occasionally left main trifurcates and gives Ramus intermedius in addition to LAD and LCx. RCA gives rise to posterior descending artery (PDA) which decided dominance of the system. It also often gives posterolateral branches (PLBs).

Operative characteristics:

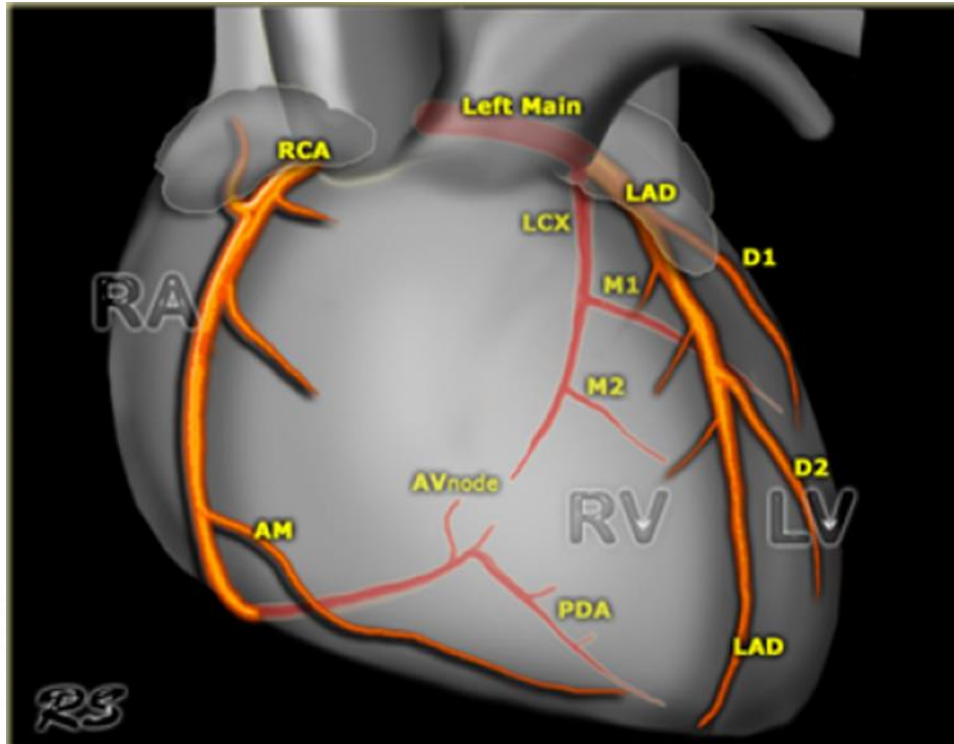


Figure.5: Coronary anatomy showing Left and Right major coronary systems and their branches

1. Surgery: Surgeries planned earlier in the OPD are considered elective. Other surgeries are considered as emergency operations

Surgical procedure: Following pre-incision antibiotic prophylaxis, primary median sternotomy is performed. Cardiopulmonary bypass is established by dual stage venous cannula into right atrium in cases of isolated CABG or bicaval cannulation in cases of additional intracardiac procedure with ascending aortic cannulation following adequate heparinization (ACT > 400). LV vent is introduced only in cases of additional aortic procedure or dilated sick hearts. Antegrade cold blood cardioplegia is administered through aortic root cannulation and topical ice-cold saline is applied.

Left internal mammary artery is harvested by opening left pleura in a pedicled fashion. Preferably, left great saphenous vein (unless significant PAOD, active wounds, implants or

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deformity) is harvested by no-touch open technique. Skip incisions are used in patients with mild PAOD and severely uncontrolled DM.

Distal anastomosis is performed to bypass significantly stenosed vessels using 7-0 polypropylene sutures in a continuous manner. LIMA is anastomosed to LAD artery. In cases where radial artery is used as conduit, it is usually anastomosed to major OM branch. Once distal anastomosis is completed, cross clamp is removed and proximal anastomosis is performed using 6-0 polypropylene suture. Patient is gradually weaned off CPB on inotropic supports whenever indicated.

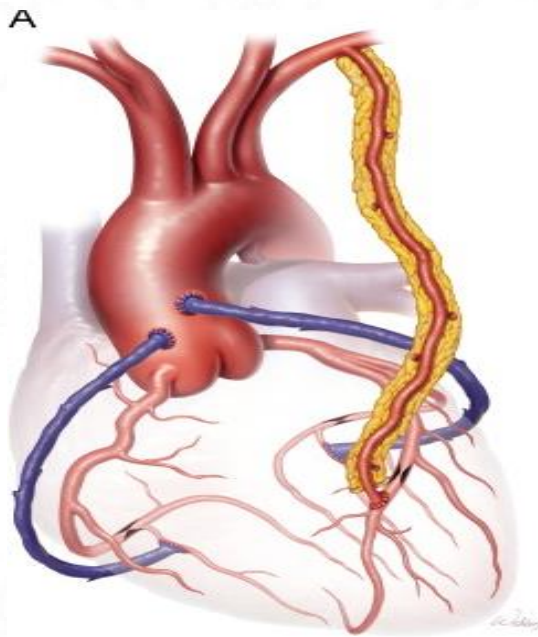


Figure.6: CABG surgery showing LIMA to LAD anastomosis and venous grafts to OM and RPDA branches. LAD-Left anterior descending artery, LIMA-Left internal mammary artery, OM-obtuse marginal branch, RPDA-right posterior descending artery.

CPB employs roller pumps and with membrane oxygenator. Cardioplegia is blood cardioplegia in St Thomas II solution (4:1) which is delivered at 4⁰C at 30 min intervals. There is no routine continuous ultrafiltration process unless the patient was in heart failure (Both acute and chronic).

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2. Total number of grafts placed – includes both arterial and venous grafts
3. Number of only venous grafts are collected
4. Depending on whether CPB and cardiac arrest was utilized for revascularization – patients are divided into three groups. A. ONCAB – those who underwent CABG on CPB and cardioplegic cardiac arrest. B. OPCAB – who underwent revascularization without CPB and cardioplegia. C. On pump beating heart – patients operated on CPB, but without cardioplegia.
5. Cardiopulmonary Bypass (CPB) time is measured in minutes
6. Aortic cross clamp time (ACC) is measured in minutes
7. Endarterectomy: This procedure involves removal of sclerotic intima from the critically narrowed coronary artery to make distal anastomosis feasible. It can be performed either by open technique or closed technique followed by direct anastomosis or vein patch anastomosis.
8. Additional procedures: procedures like mitral valve repair, mitral valve replacement, aortic valve replacement, atrial septal defect closure, LV apical plication – Thinned out and scarred LV is plicated usually at the apex, ventricular septal rupture repair, Dor procedure, ventricular septal defect closure and other adult congenital heart surgery procedures. Patients with combined procedures.

In-hospital post-operative complications:

1. Reoperation: Patients who were re-explored in the immediate post-operative period depending on the etiology such as mediastinal bleeding, unexplained hypotension, sudden

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cardiac arrest or malignant refractory arrhythmias probably secondary to acute graft occlusion.

Significant post-operative bleeding for re-exploration is considered when bleeding is more than 400 ml/hr for 1 hr, 300 ml/hr for 2 hrs., 200 ml/hr for 4 hrs.

2. Post-operative abnormal rhythm: It varies from sinus rhythm to occasional ectopics to persistent arrhythmias. Patients were assigned to 1. Atrial fibrillation 2. Occasional ventricular ectopics 3. Persistent atrial or ventricular ectopics – electrophysiology study followed by ablation 4. Implantable Cardioverter Defibrillator (ICD) implantation for Refractory ventricular arrhythmias.
3. Direct Cardioversion: If patient was given electrical cardioversion for hemodynamically unstable AF or medically refractory AF, unstable ventricular tachycardia or ventricular fibrillation
4. Peri-operative MI: Those who sustained MI post-surgery with new ST-T changes or new onset LBBB with elevation of cardiac enzymes.
5. Post-operative renal dysfunction: Renal dysfunction is defined by the same criteria as pre-operative renal function. This is most common complication following CABG surgery. Patients with pre-operative renal dysfunction are more likely to worsen following surgery. Patients with serum creatinine > 1.4 mg/dl are considered to have dysfunction with few patients requiring dialysis (usually peritoneal dialysis).
6. Cerebro Vascular Accidents: Categorized to have experienced none, mild transient ischemic attacks and with gross focal neurological deficits.

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7. Left ventricular support: Patients who were not be able to wean CPB despite maximal inotropic supports and maximal possible surgical revascularization intraoperatively are placed on intraaortic balloon pump (IABP) to provide LV support in the immediate post-operative period. Also included are patients who suffer severe myocardial depression due to post-op MI or recurrent refractory arrhythmias or aborted cardiac arrest in the ICU.
8. Uncontrolled sugars: Patients only with prior diagnosis of DM are included if they satisfy the following criteria. Patients with type I DM requiring more than one type of Insulin formulation with persistently elevated sugars (> 200 mg/dl x 3 days despite on Insulin) or type II DM patients requiring insulin to control sugars despite their pre-operative doses of oral hypoglycemic agents.
9. Deep surgical site infection (SSI): Patients developing deep SSI within six months following surgery are classified depending on the received management. They are classified into a. conservative management b. Daily dressings followed by debridement and resuturing of the skin and subcutaneous tissues. c. Debridement and rewiring of the sternum d. Flap reconstruction: Most commonly used flap is bilateral pectoralis major flap reconstruction. Vacuum suction dressings were used as and when necessary till adequate healthy granulation tissue appeared and infection is eliminated. Our routine practice is to perform procedure once the wound is free of pathogens.
10. In-hospital mortality: Patients who die during the same admission of surgery irrespective of number of days from the operation.
11. Causes of mortality: Causes are defined as 1. Cardiogenic shock – secondary to myocardial dysfunction 2. Septic shock – secondary to ventilator or hospital acquired pneumonia 3. Septic shock as a result of other sepsis like mediastinal sepsis, necrotizing infection of

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thigh, urinary sepsis. 4. Malignant arrhythmias – unresponsive to DC version and pharmacotherapy 5. Deep SSI – leading to secondary hemorrhage secondary to erosion of grafts or myocardial surface or other blood vessels. 6. Stroke – Massive ischemic or hemorrhagic stroke which may lead to malignant stroke with herniation of brain contents. 7. Sudden unexplained cardiac death 8. Renal failure 9. Acute mesenteric ischemia secondary to persistent low cardiac output in a previously compromised visceral circulation.

Follow-up data:

1. Aneurysm association: Atherosclerosis can affect other major large arteries and can cause aneurysmal disease. Aortic aneurysms of thoracic and abdominal aorta are followed up.
2. Major non-cardiac morbidity: Major comorbidity like malignancy and hepatic dysfunction are followed up
3. Major surgical intervention: Major intervention such as Infra renal aortic aneurysm repair, thoracoabdominal aortic aneurysm repair, PAOD intervention, treatment of malignancy like surgery or radiotherapy.
4. Latest year of follow up.
5. Symptoms during the follow up are divided as angina, dyspnea, failure, ACS, stroke, giddiness / presyncope / syncope
6. Year of first symptom onset
7. Stroke on follow up as ischemic or hemorrhagic stroke
8. Year of suffering stroke
9. Acute coronary syndrome during follow up

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10. Year of ACS
11. Any additional neurological dysfunction as seizures, Parkinson's disease, Alzheimer's disease, Psychiatric illness, Degenerative brain disease
12. Symptom status at last follow up
13. Functional classification during the last follow up
14. ECG during the last follow up
15. Any intervention for arrhythmias
16. Echo follow up: LV function and its grade, RWMA and territory
17. Diagnostic modality for symptomatic status – coronary CT, conventional CAG, TMT
18. TMT if performed – positive for inducible ischemia
19. Year of investigation performed
20. Patency of grafts – whether all grafts are patent, only arterial graft is occluded or only venous grafts are blocked or both grafts are blocked.
21. Number of grafts blocked and no. of grafts patent
22. LIMA arterial graft patency
23. Re-intervention for symptom status or stenosed vessels
24. Year of re-intervention
25. Current status of patient – Alive or death
26. Year of death
27. Cause of death – cardiac or non-cardiac.

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Data Analysis and statistical methods:

Collected data in excel sheet is entered into SPSS software (IBM, India) and Med Calc software. All continuous variables are assessed for mean with standard deviation and categorical variables are assessed by percentage. Significant association of continuous variables are assessed by students t test and for categorical variables, chi-square test and paired t test were applied. Survival curves, freedom from MACCE survival, freedom from reintervention was assessed by Kaplan-Meier curves. Significant difference among survival between the years was assessed by log rank p value. P value of less than 0.05 is considered as statistically significant. Risk factors for in-hospital mortality and long-term MACC events was assessed by calculating Relative risk with 95% confidence interval limits.

ANALYSIS AND RESULTS

Patients who underwent coronary artery bypass surgery from January 2003 to December 2017 at adult cardiac surgery department of our institution were analyzed. A total of 1705 patients were operated during this period. Year wise distribution of patients are given below. There were almost equal number of patients from 2005 to 2007, with slightly less numbers during 2003 and 2004.

| Year | 2003 | 2004 | 2005 | 2006 | 2007 | Total |
|------------------------|-------------|-------------|-------------|-------------|-------------|--------------|
| No. of patients | 316 | 281 | 360 | 373 | 375 | 1705 |

Demographic characteristics:

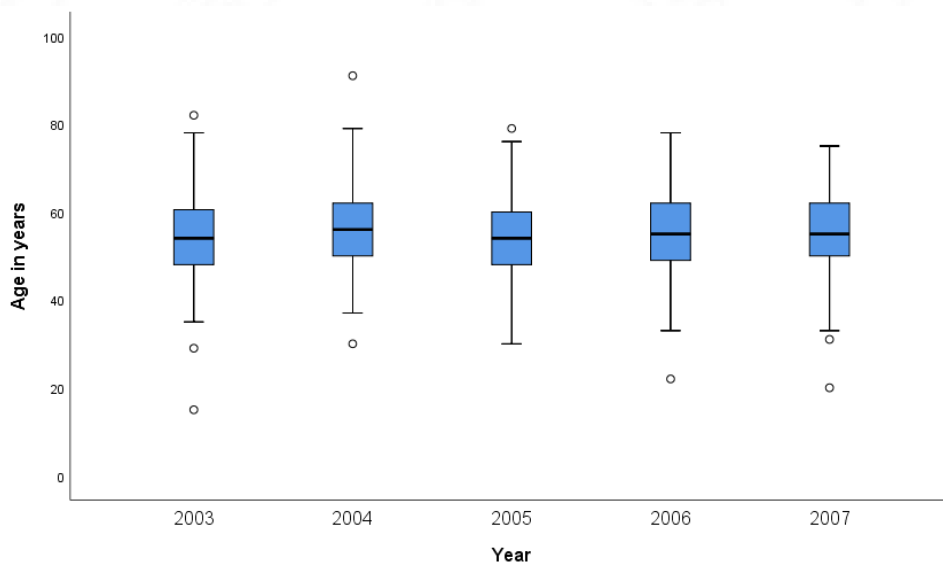


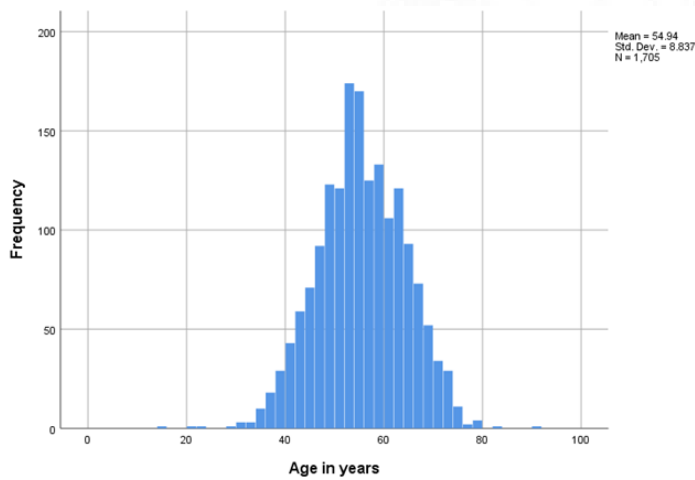
Figure.7: Mean age of patients across the years

Age: Mean age of patients was 55 years. There was no significant difference among age groups of patients across the years.

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| | 2003 | 2004 | 2005 | 2006 | 2007 | Total | P value |
|-----|-------------|-------------|-------------|------------|-------------|-------------|---------|
| Age | 55 (9) | 56 (9) | 54 (9) | 55 (8) | 55 (9) | 55 (9) | 0.053 |
| BSA | 1.67 (0.16) | 1.67 (0.14) | 1.68 (0.14) | 1.7 (0.15) | 1.68 (0.15) | 1.68 (0.15) | 0.113 |

Table.3: Mean age (in years) and BSA (m²) over the years. BSA – Body surface area.



| Age in years | N (%) |
|--------------|-------------|
| ≤45 | 240 (14.1) |
| 46 - 60 | 1007 (59.1) |
| 61 - 75 | 450 (26.4) |
| >75 | 8 (0.5) |
| Total | 1705 (100) |

Figure.8: Histogram showing distribution of age of all patients

The mean body surface area of all patients was 1.68 m². The surface area of patients across the years was similar. Further patients were classified into different age groups with majority of patients between 45 – 60 years age and least above the 75 yrs. of age.

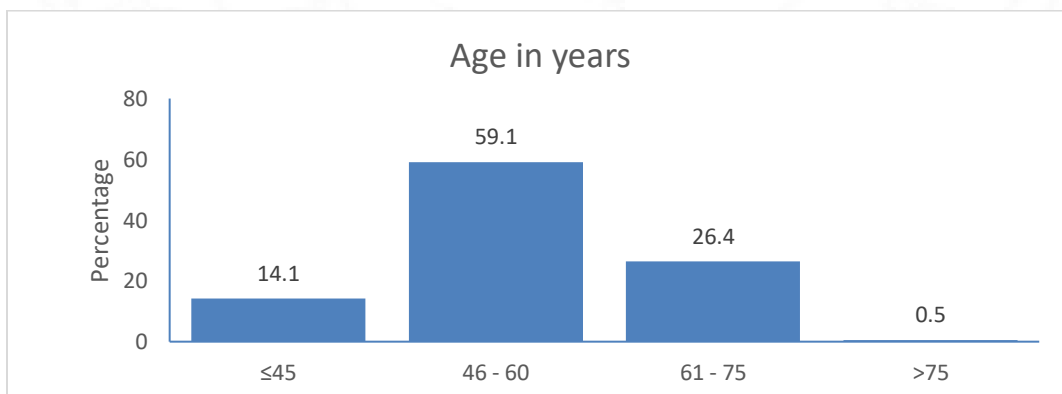


Figure.9: Bar diagram comparison of various age groups.

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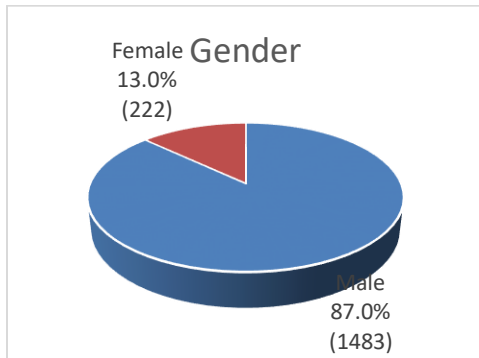


Figure.10: Pie chart showing gender distribution of patients

Gender: Majority of patients were males with only 13% of females of all study patients.

Patient co-morbidities:

Smoking: Even though majority of patients were non-smokers, 22.5% (383) of patients had history of smoking during or within three months of operation. Only 95 (5.6%) patients were reformed smokers.

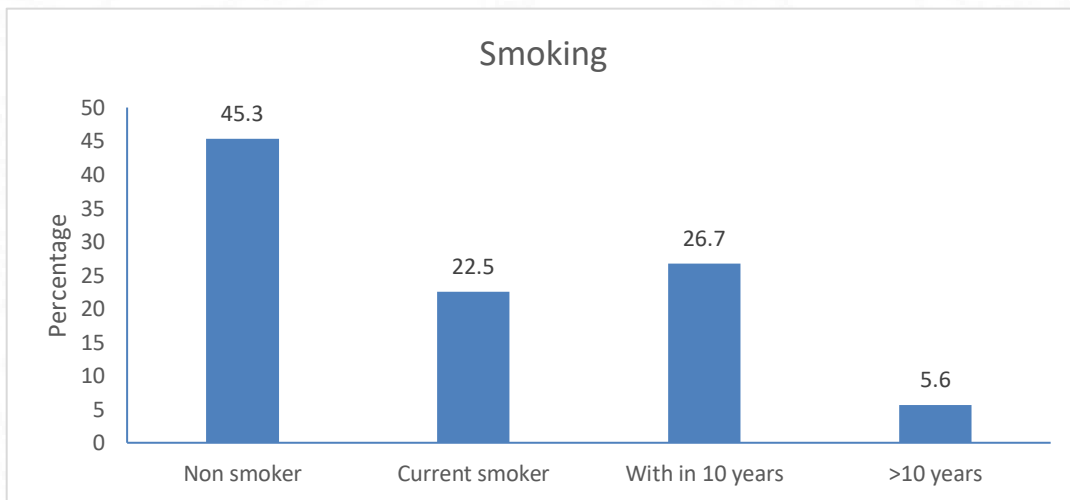


Figure.11: Patient distribution with regard to different patterns of smoking

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Obesity was less prevalent with only 370 patients (21.7%). Hypertension and dyslipidemia were very common with more than 50% of the patients, 1007 (59.1%) and 1113 (65.3%) respectively.

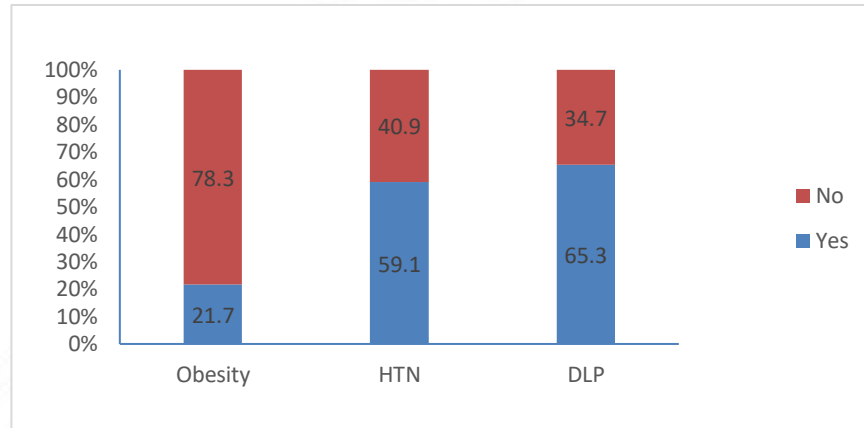


Figure.12: Prevalence of obesity, hypertension and dyslipidemia among operated patients for CABG

As a part of atherosclerotic coronary artery disease presence of associated large artery disease like carotid artery disease, peripheral arterial occlusive disease and cerebrovascular disease is not uncommon. Presence of these conditions in our patients are depicted in this bar diagram.

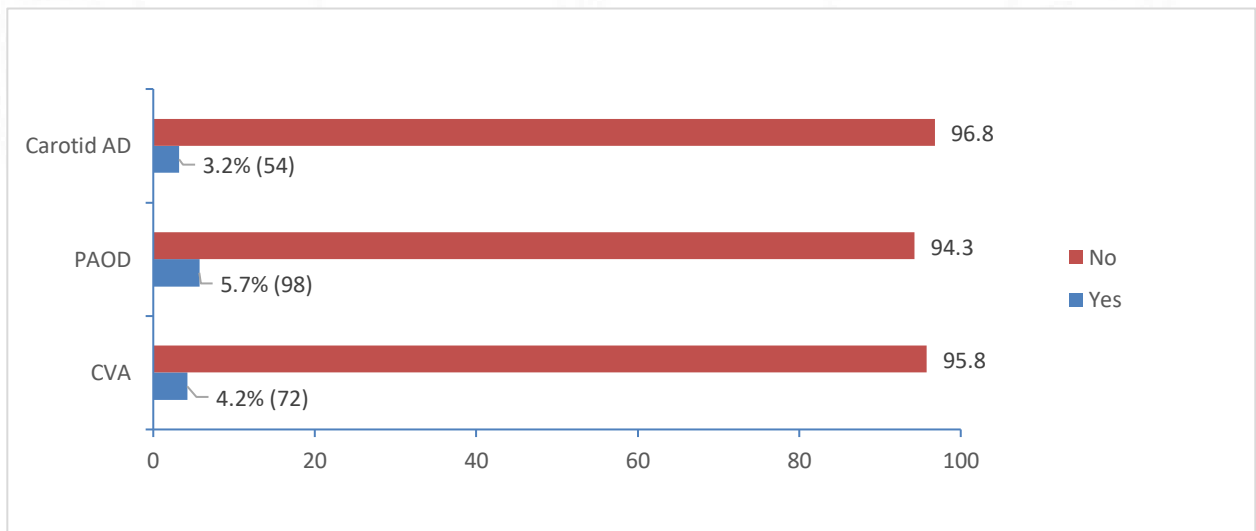


Figure.13: Presence of other large artery disease and CVA in patients. AD - Arterial disease,

CVA – Cerebro Vascular Accident, PAOD – Peripheral Arterial Occlusive Disease.

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Hypothyroidism was less prevalent among patients with only 29 patients (1.7%). Renal dysfunction with serum creatinine > 1.4 mg/dl was seen in 339 patients (19.9%). COPD was observed in 89 patients (5.2%).

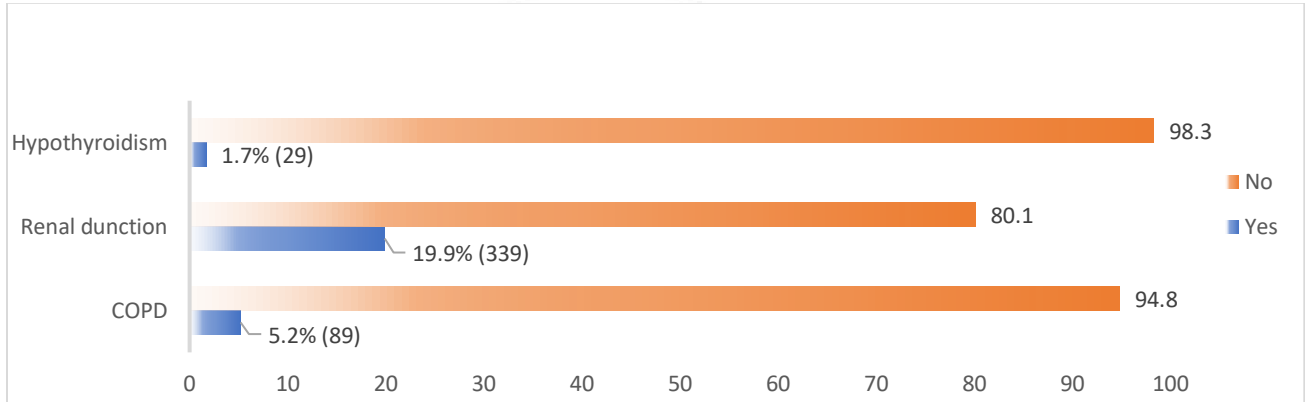


Figure.14: Co-morbid profile of COPD, hypothyroidism and renal dysfunction in patients. COPD – Chronic Obstructive Pulmonary Disease.

Diabetes Mellitus:

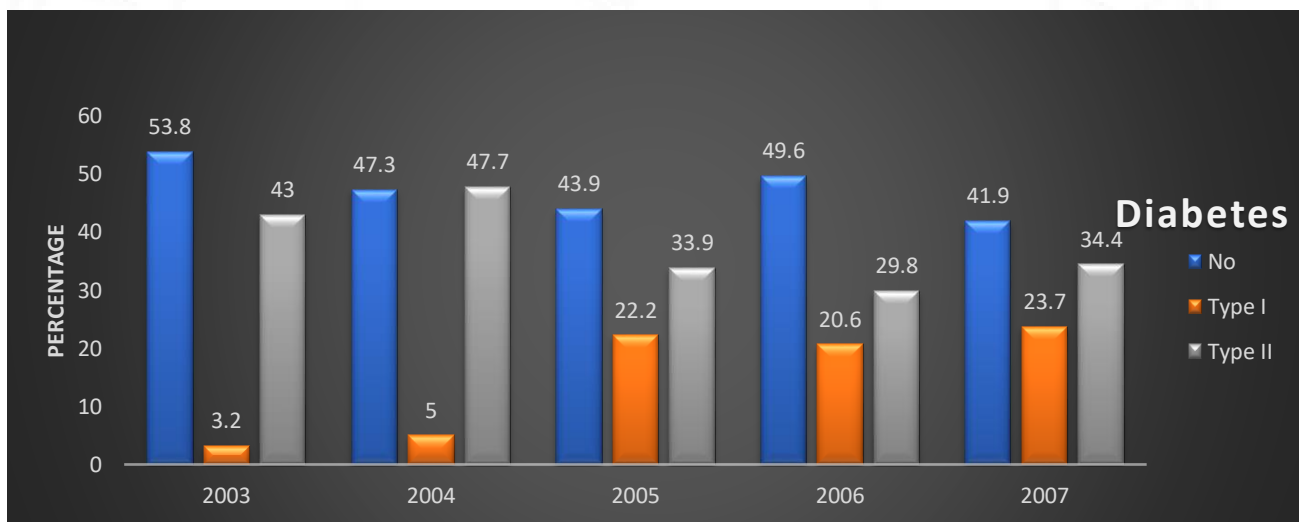


Figure.15: Distribution of presence and type of diabetes in CABG patients over the study years.

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Around 902 (52.9%) of total patients suffered from diabetes. Of this, 37.1% (632) had predominantly type II DM (Non-insulin dependent DM) and rest 15.8% (270) had Insulin dependent DM (Type I). During the initial years of study, type II DM was more common than type I DM.

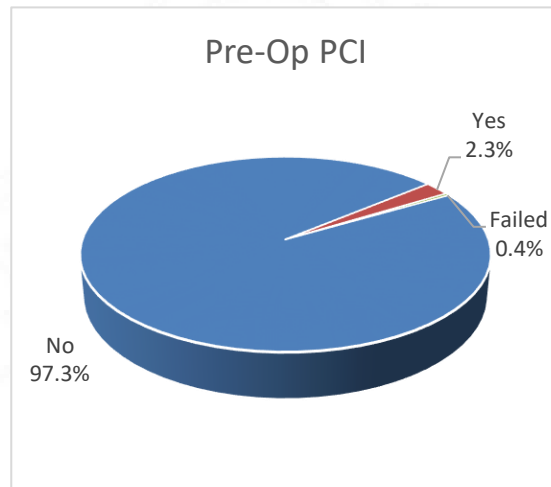


Figure.16: Pre-operative intervention rate before CABG

As few as only 40 patients have undergone percutaneous coronary intervention before CABG. Few cases of these were within few months before operation, whereas others have developed recent CAD years after their initial intervention. Only six patients (0.4%) had failed attempts to PCI. All patients underwent CABG as primary cardiac surgery for the first time except six patients (0.2%) who had prior cardiac operation in the form of CABG or valve intervention.

Pre-operative clinical characteristics:

Initial presentation: Majority of patients (66.5%) presented with stable coronary artery disease (SCAD), and altogether proportion of patients presenting with ACS at the first visit was 31.5%. Trend over years had similar presentation with more patients presenting with SCAD.

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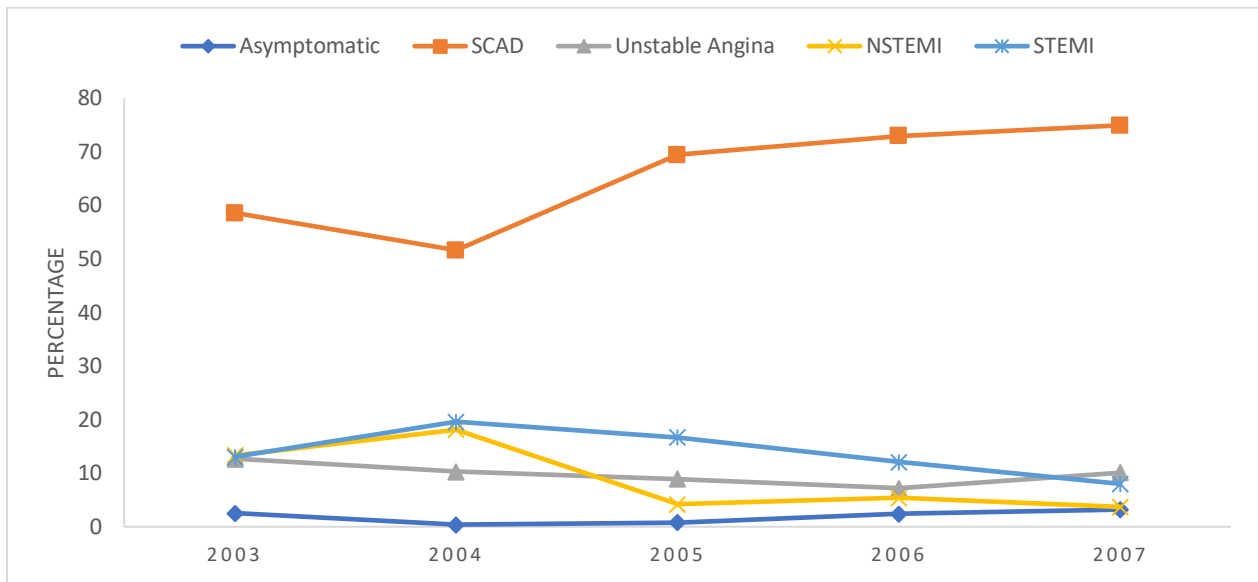


Figure.17: Trend of initial presentation of CAD for CABG patients over years.

But the symptomatic status at the time of operation is slightly variable as compared to initial presentation. There is statistically significant association between the initial symptomatic status and symptom status at the time of operation.

| | | Initial Presentation | | | | | Total |
|----------------------------|--------------|----------------------|------|-----------------|--------|-------|-------|
| | | Asymptomatic | SCAD | Unstable Angina | NSTEMI | STEMI | |
| Current symptomatic status | Asymptomatic | 31 | 67 | 12 | 32 | 24 | 166 |
| | SCAD | 1 | 1031 | 134 | 102 | 186 | 1454 |
| | Unstable | 0 | 26 | 18 | 4 | 11 | 59 |
| | NSTEMI | 0 | 4 | 2 | 4 | 1 | 11 |
| | STEMI | 1 | 5 | 0 | 0 | 9 | 15 |
| | Total | 33 | 1133 | 166 | 142 | 231 | 1705 |

p < 0.001

Table.4: Correlation of symptom status at their initial presentation and current symptom status

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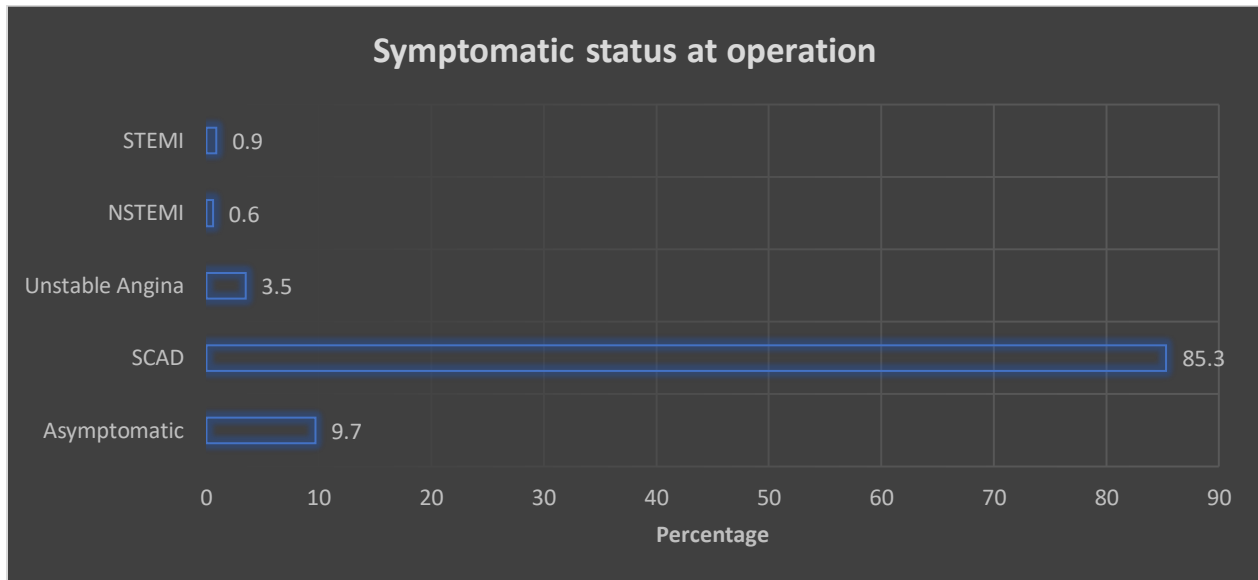


Figure.18: Distribution of patients with regard to symptom status at the time of operation

| | Initial Symptomatic status | | Current symptomatic status | |
|-----------------|----------------------------|------|----------------------------|------|
| | n | % | n | % |
| Asymptomatic | 33 | 1.9 | 166 | 9.7 |
| SCAD | 1133 | 66.5 | 1454 | 85.3 |
| Unstable Angina | 166 | 9.7 | 59 | 3.5 |
| NSTEMI | 142 | 8.3 | 11 | 0.6 |
| STEMI | 231 | 13.5 | 15 | 0.9 |

Myocardial Infarction: Around 52.7% of patients (n=898) suffered from myocardial infarction before undergoing operation. There was a gradual rise in the incidence of ACS over the years from 2003 to 2007. Among those who had MI, more than two-thirds, had history of old MI (MI occurred more than 3 months earlier) [n=584,34.3%] with other thirds suffering from recent MI [n=314,18.4%].

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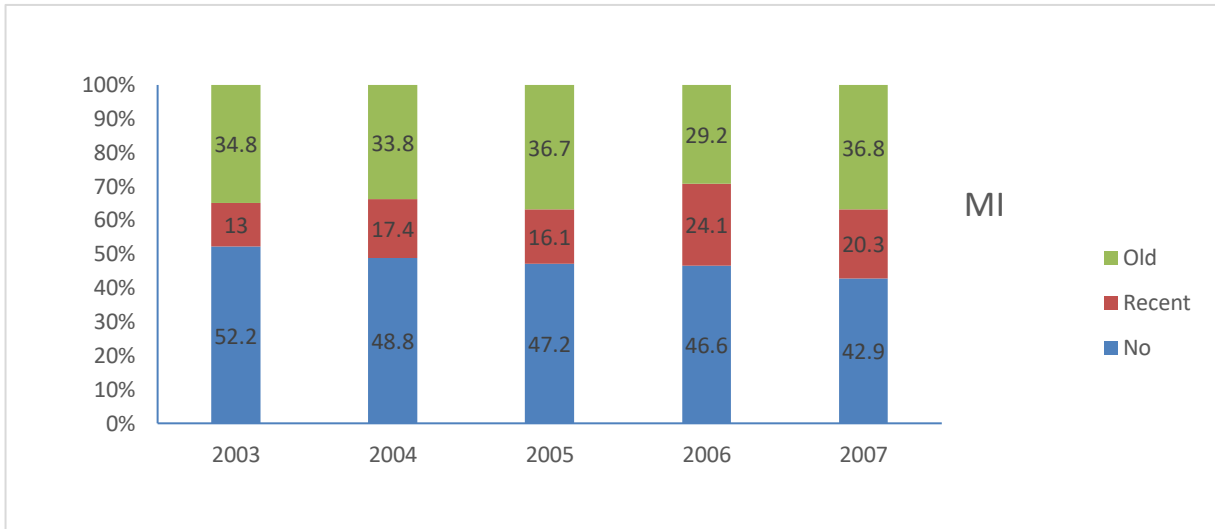


Figure.19: Distribution of MI over the years with slight increase in incidence in the recent years

Sub analysis of recent and old MI into NSTEMI and STEMI revealed that STEMI was more common than NSTEMI in both during recent and old MI.

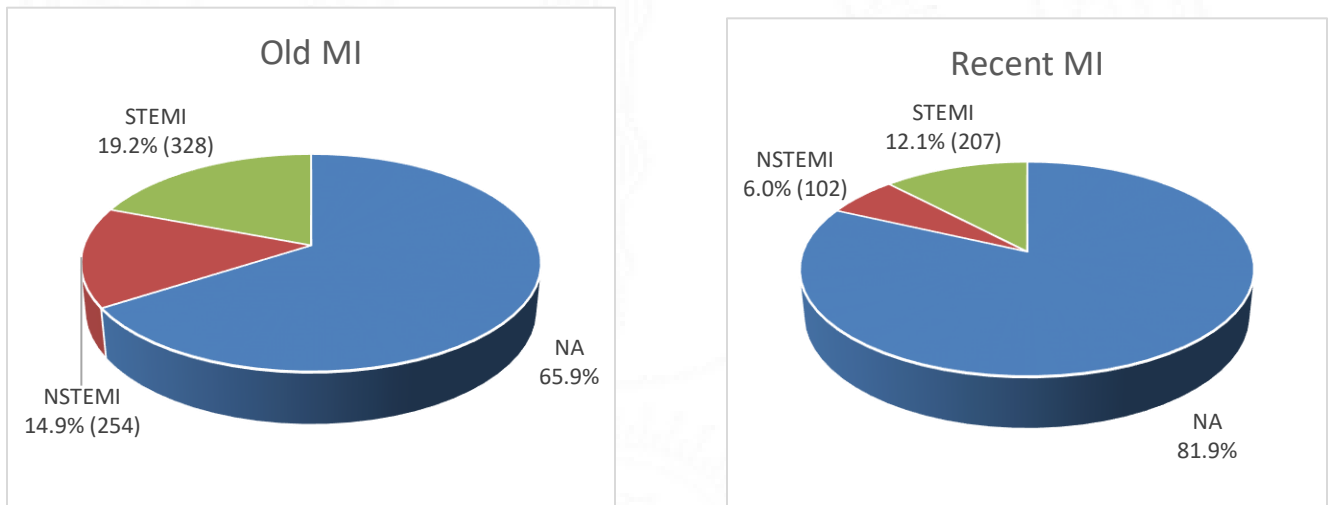


Figure.20: Pie charts depicting the distribution of NSTEMI and STEMI in recent and old MI group

Associated clinical features: Diuretic therapy [n=75,4.4%] was initiated for all cases of failure in both acute and chronic failure patients. Majority of patients were in functional class II and III,

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[1233 (72.3%) and 395 (23.2%)] respectively with least patients belonging to FC IV, the most severe form.

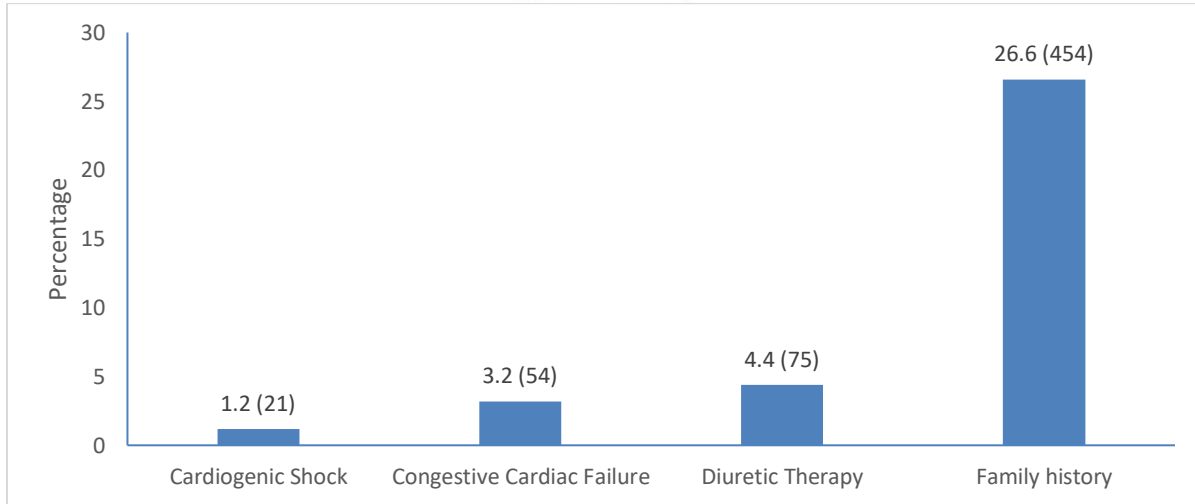


Figure.21: Incidence of associated conditions at the initial presentation

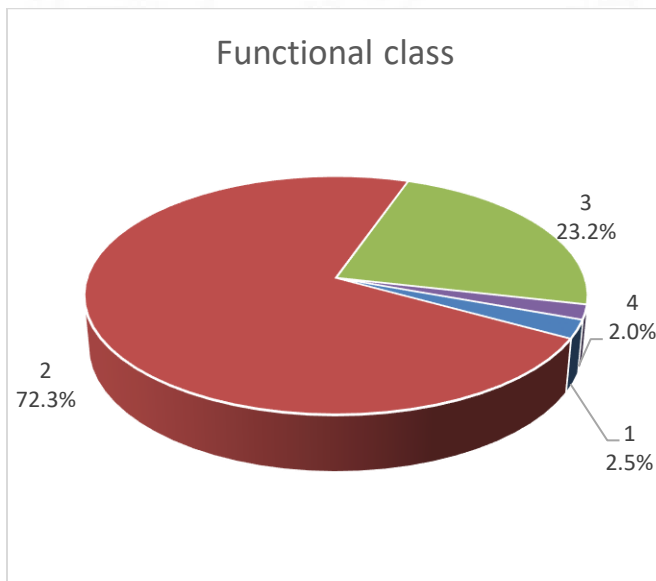


Figure.22: Pie-chart showing distribution of functional class of patients.

Wall motion abnormality was present in 759 patients (44.5%). Around 142 patients operated for surgery had cardiomegaly.

In-hospital and long-term outcomes of CABG – A single center experience.

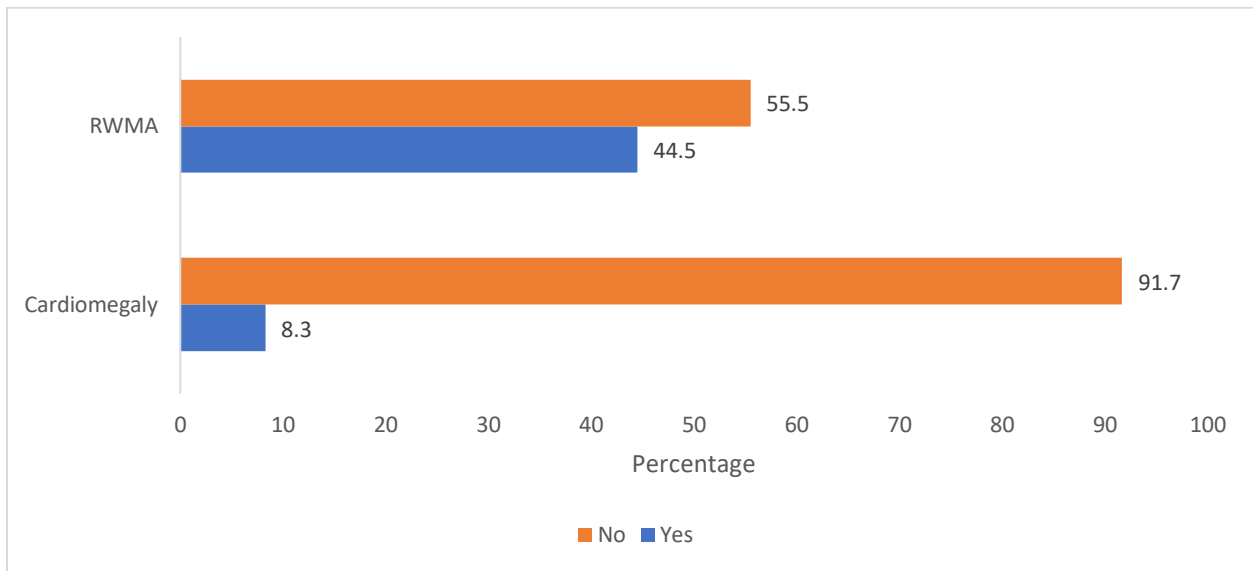


Figure.23: Bar diagram showing the presence of cardiomegaly and RWMA in CABG patients.

Left Ventricular function:

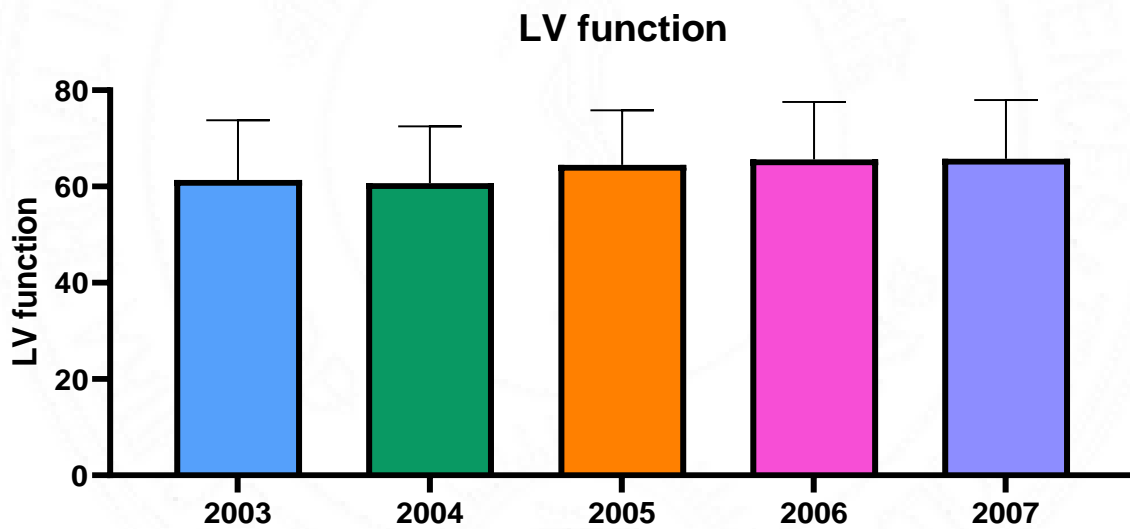


Figure.24: Box and puncture graph showing mean LV function values over the years.

Mean LV function was slightly better during the latter years of study with mean value of $64\% \pm 12\%$ during the all five years of study.

In-hospital and long-term outcomes of CABG – A single center experience.

LV dysfunction (mild to severe) was observed in 394 patients which are around 23.1% of study population. Majority of patients had good LV function with EF \geq 55% in the pre-operative period.

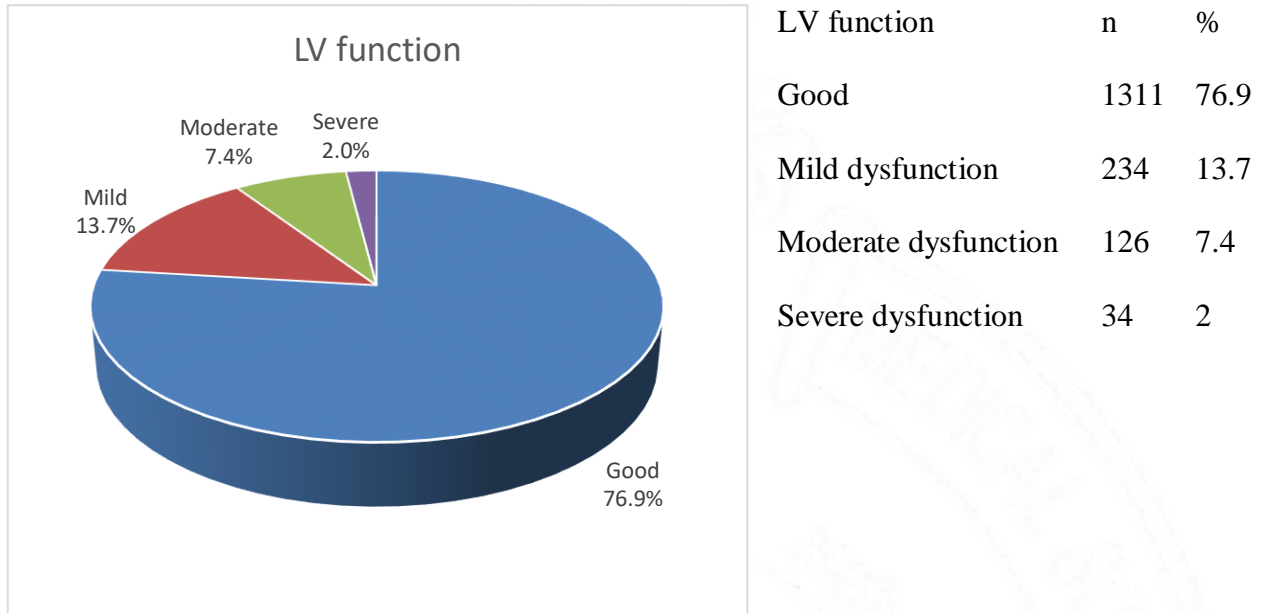


Figure.25: Distribution of left ventricular function

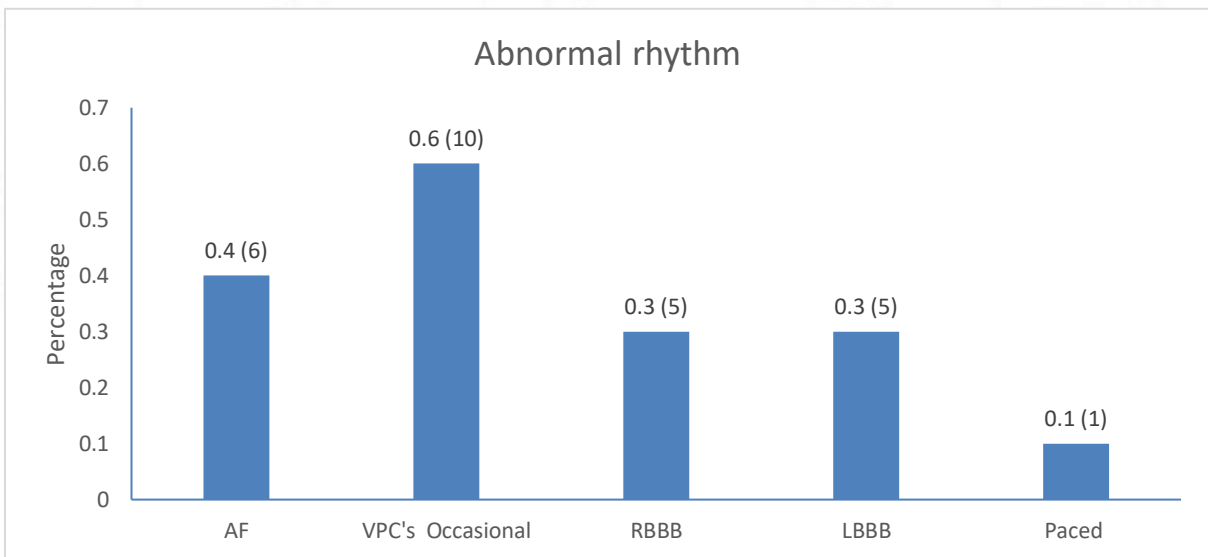


Figure.26: Distribution of abnormal rhythm pattern in the pre-operative period

In-hospital and long-term outcomes of CABG – A single center experience.

Where 98.7% (1678) patients had normal sinus rhythm at the time of operation, remaining 1.3% (27) patients had some form of rhythm disturbance in the form of atrial fibrillation, occasional VPC's with few patients having bundle branch blocks and paced rhythm.

Mitral regurgitation: MR is present in 1040 patients (61%), but majority of them had trivial to mild MR. Moderate to severe MR was seen in 88 (5.2%) patients. Almost all patients who had MR was secondary to ischemic nature with only two patients who had rheumatic pathology associated with CAD.

| Severity of MR | n | % |
|----------------|-----|------|
| 0 | 665 | 39 |
| 1 | 609 | 35.7 |
| 2 | 343 | 20.1 |
| 3 | 78 | 4.6 |
| 4 | 10 | 0.6 |

Coronary angiogram (CAG) characteristics:

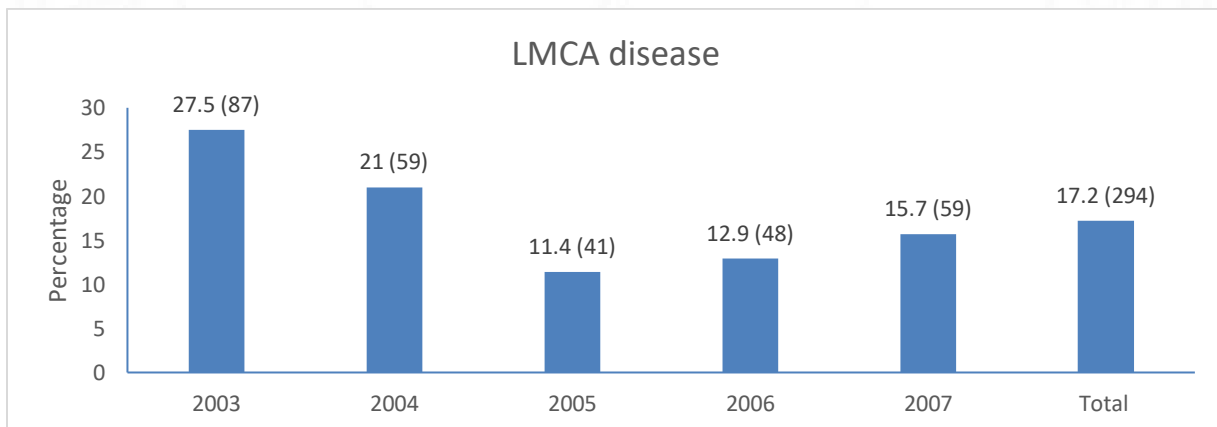


Figure.27: Left main coronary artery disease incidence over the years.

In-hospital and long-term outcomes of CABG – A single center experience.

The average number of vessels with critical stenosis was four over all the years in all patients. Left main disease was present in 294 patients (17.2%) and the pattern over the years revealed decreasing trend in cases with more proportion of LMCA diseased patients in the initial years.

Triple vessel disease was common with more than two-thirds of all patients in all the years.

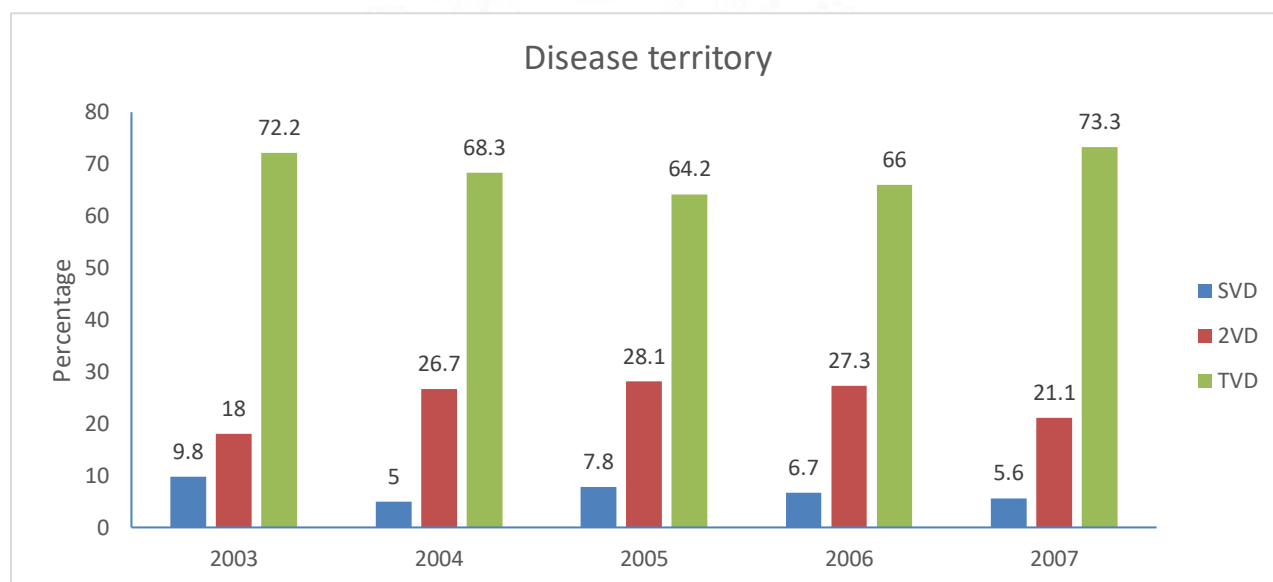


Figure.28: Disease territory distribution over the years. SVD – Single vessel disease, TVD – Triple vessel disease, 2VD – Double vessel disease.

| Disease territory | 2003 | | 2004 | | 2005 | | 2006 | | 2007 | | Total | | p |
|-------------------|------|------|------|------|------|------|------|------|------|------|-------|------|-------|
| | N | % | N | % | N | % | N | % | N | % | N | % | |
| SVD | 31 | 9.8 | 14 | 5 | 28 | 7.8 | 25 | 6.7 | 21 | 5.6 | 119 | 7 | 0.008 |
| 2VD | 57 | 18 | 75 | 26.7 | 101 | 28.1 | 102 | 27.3 | 79 | 21.1 | 414 | 24.3 | |
| TVD | 228 | 72.2 | 192 | 68.3 | 231 | 64.2 | 246 | 66 | 275 | 73.3 | 1172 | 68.7 | |

In-hospital and long-term outcomes of CABG – A single center experience.

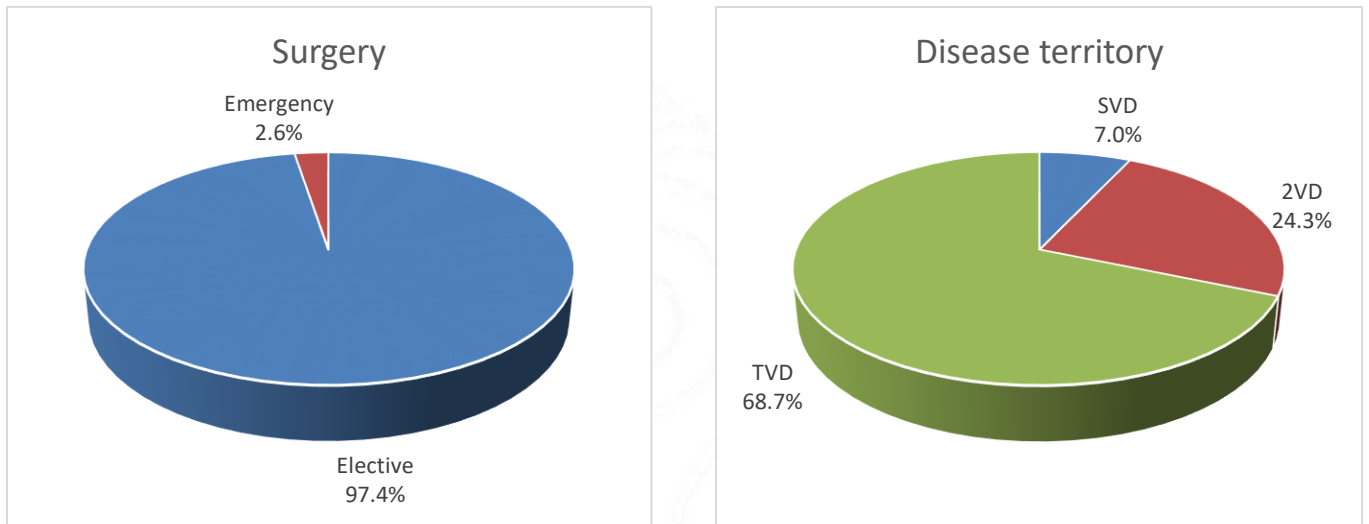


Figure.29: Disease territory and nature of surgery in all the patients.

Intraoperative characteristics:

About 44 patients (2.6%) underwent operation as emergency operation, where as other operations were performed on an elective basis.

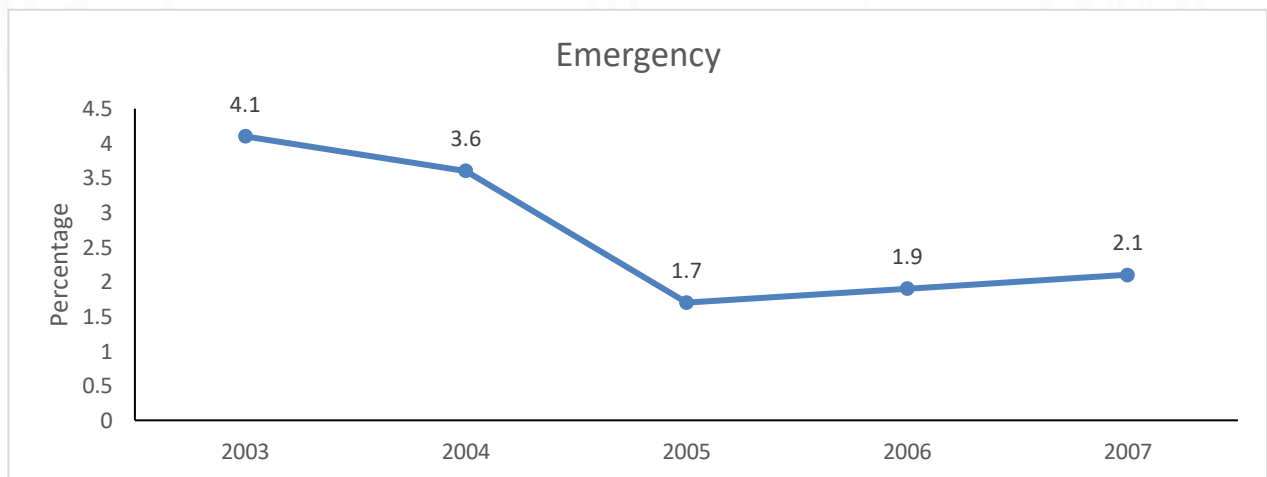
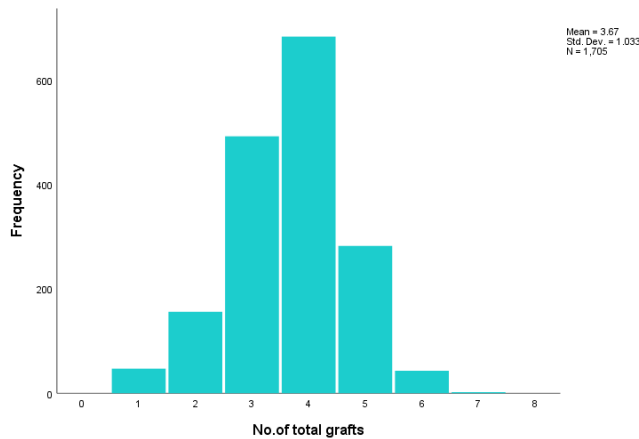


Figure.30: Emergency operation trend over the years.

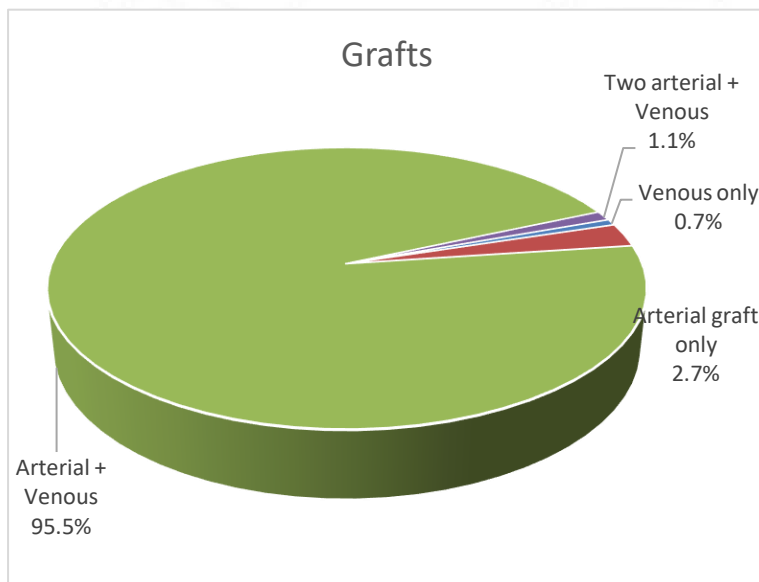
In-hospital and long-term outcomes of CABG – A single center experience.



Grafting of vessels: Majority of patients had 3-5 grafts.

| No. of total grafts | Frequency | Percent |
|---------------------|-----------|---------|
| 1 | 47 | 2.8 |
| 2 | 156 | 9.1 |
| 3 | 492 | 28.9 |
| 4 | 683 | 40.1 |
| 5 | 282 | 16.5 |
| 6 | 43 | 2.5 |
| 7 | 2 | 0.1 |
| Total | 1705 | 100 |

Figure.31: Histogram showing distribution of grafts



| Grafts | Frequency | Percent |
|-----------------------|-----------|---------|
| Venous only | 12 | 0.7 |
| Arterial graft only | 46 | 2.7 |
| Arterial + Venous | 1628 | 95.5 |
| Two arterial + Venous | 19 | 1.1 |
| Total | 1705 | 100 |

Figure.32: Graft conduit pattern in all patients with CABG.

Majority of patients received one arterial, almost always LIMA with additional venous grafts in 95.5% (1628) of the study population. Exclusive arterial grafts were performed in 46 patients with only venous grafts in 12 patients. 19 patients received two arterial grafts with venous

In-hospital and long-term outcomes of CABG – A single center experience.

grafts. Two arterial grafts are most commonly LIMA with right internal mammary artery or radial artery.

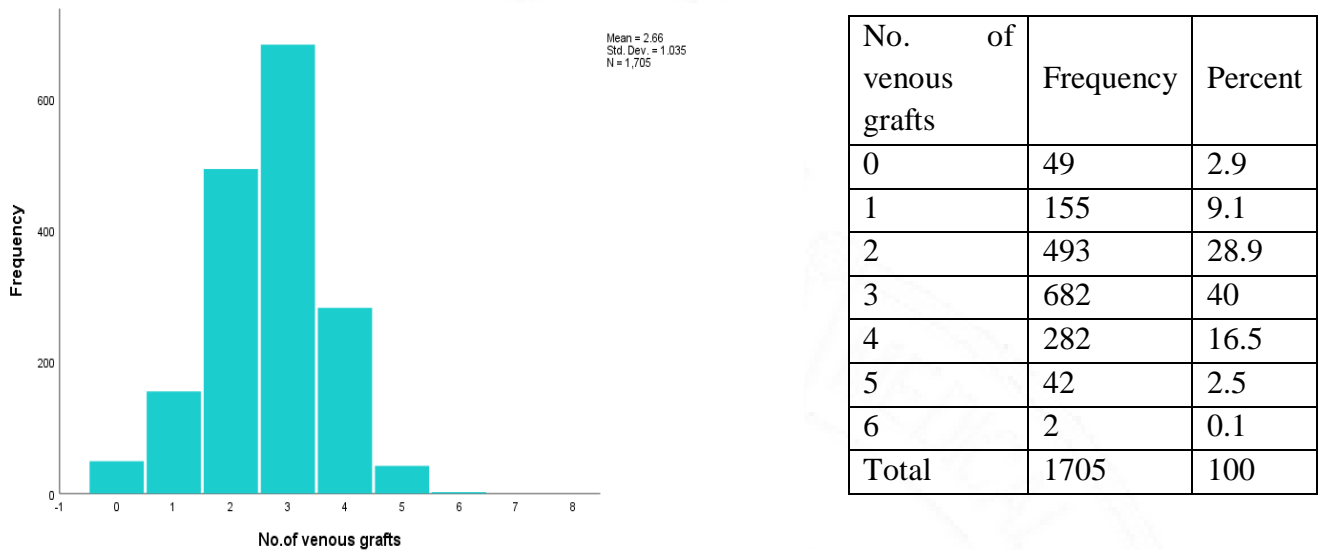


Figure.33: Histogram showing the distribution of venous grafts

Majority of patients received more than one venous graft with approximately 2-4 additional venous grafts (75%).

Even though large group of patients (72.2%) underwent complete revascularization with grafts to stenotic vessels, around 474 (27.8%) of patients had incomplete revascularization.

All operations were predominantly performed on cardiopulmonary bypass, few patients [n=51,3%] were operated off pump and as little as six patients were operated on pump beating heart without cardioplegic arrest. Mean cardiopulmonary bypass time was 91.3 ± 30.4 min and aortic cross clamp time was 51.4 ± 19.5 min.

In-hospital and long-term outcomes of CABG – A single center experience.

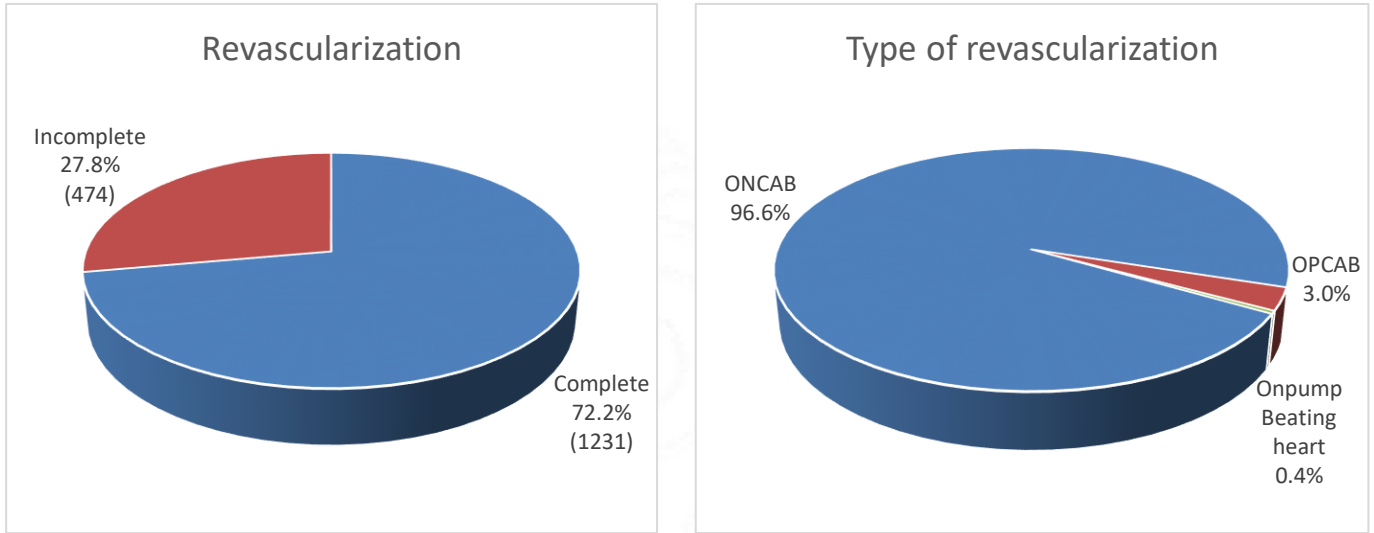


Figure.34: Pie-chart showing revascularization completeness and type of revascularization for significant stenotic vessels.

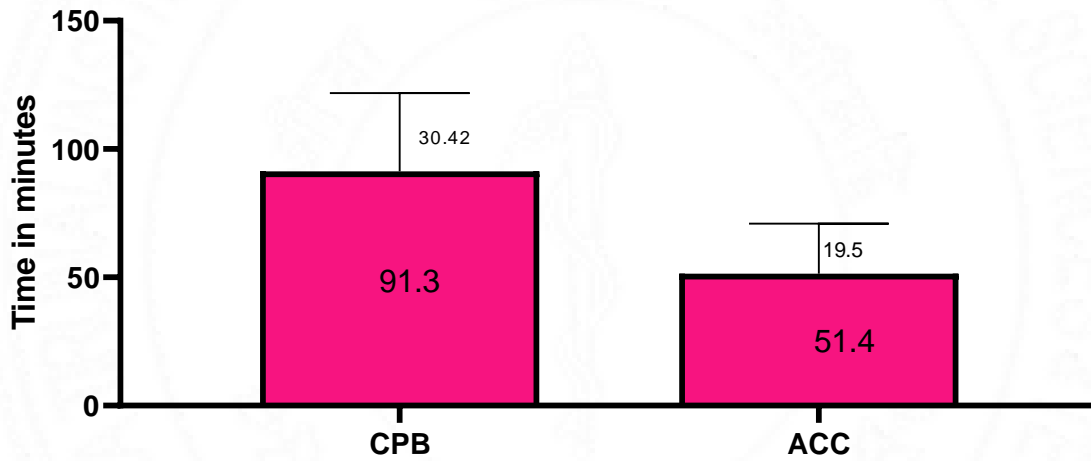


Figure.35: Box and puncture chart showing mean CPB and ACC times. ACC – Aortic cross clamp time. CPB – Cardiopulmonary bypass time.

Endarterectomy was performed in around 10-20% of patients every year with 16.5% (282) patients receiving the procedure overall.

In-hospital and long-term outcomes of CABG – A single center experience.

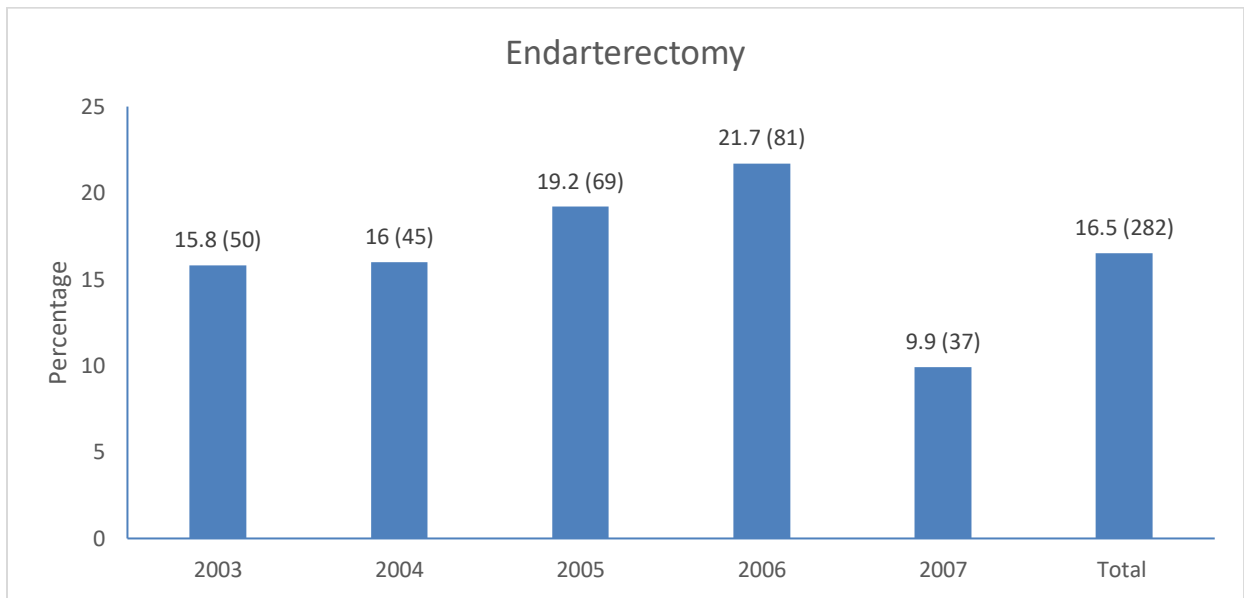


Figure.36: Yearly performance of endarterectomy procedures during CABG surgery

Additional intracardiac operations in association with CABG was performed in 4.2% (71) patients. Distribution of various additional procedures are shown in horizontal bar diagram.

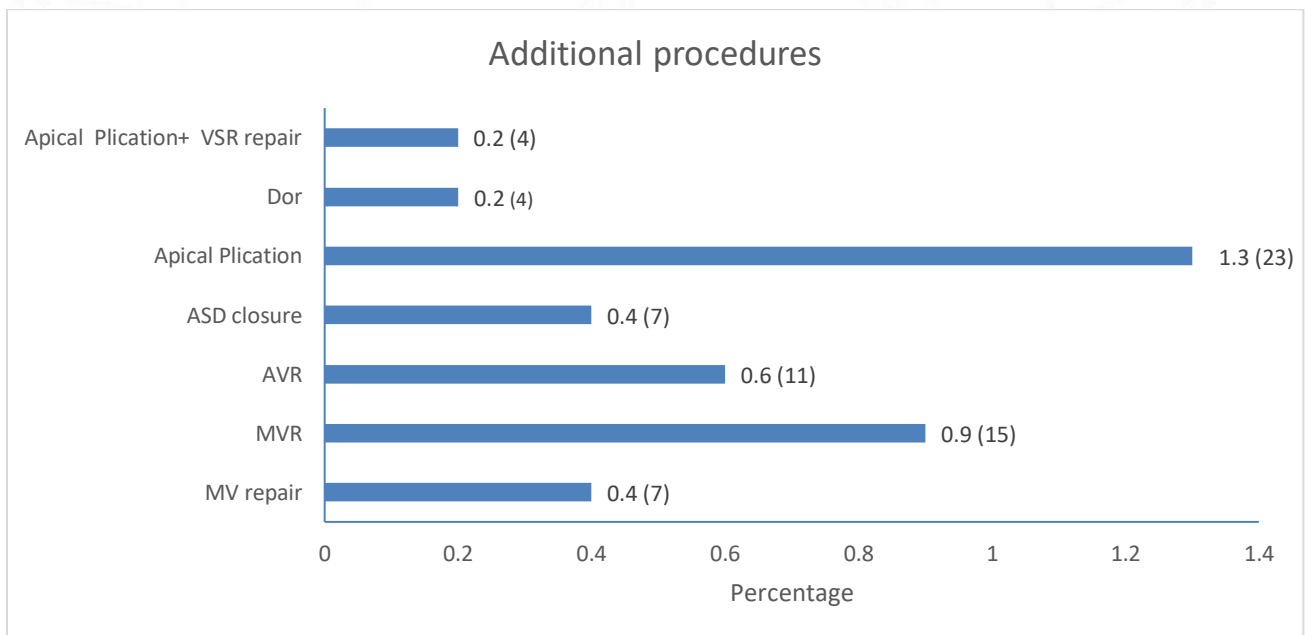


Figure.37: Various additional procedures performed in addition to CABG (primary operation).

In-hospital and long-term outcomes of CABG – A single center experience.

In-hospital post-operative complications:

Only 33 patients (2%) underwent re-exploration in the immediate post-operative period. Of which, 30 patients (1.8%) were reoperated for significant bleeding. Only three patients had unexplained hypotension in the immediate post-operative period and on re-exploration, found to have graft occlusion.

Atrial fibrillation is the most common form of arrhythmia in the immediate post-operative period [n=86,5%], followed by occasional ventricular premature complexes and persistent blocks as in the pre-operative period. There were no new onset bundle branch blocks. For recurrent arrhythmias, two patients underwent radiofrequency ablation and two were implanted with intracardiac cardioverter and defibrillator.

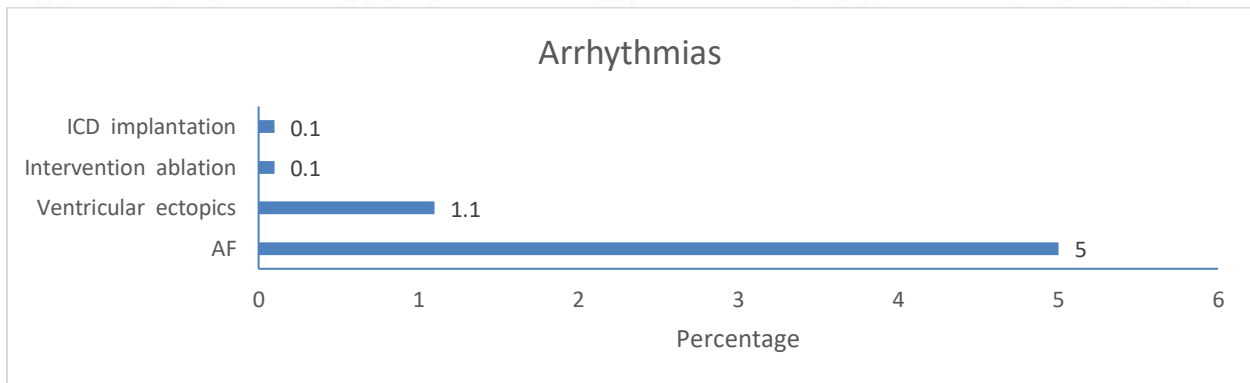


Figure.38: Various form of arrhythmias and associated intervention for refractory arrhythmias

In patients who were hemodynamically unstable and refractory to medical therapy, direct cardioversion was attempted in five patients for AF and seven patients for ventricular arrhythmias. Incidence of peri-operative MI, cerebrovascular incidents, post-operative renal dysfunction, left ventricular support, uncontrolled sugars, deep sternal wound infection are given in the table below.

In-hospital and long-term outcomes of CABG – A single center experience.

| Variable | N, % |
|----------------------------------|-------------|
| Peri-operative MI | |
| No | 1694 (99.4) |
| Yes | 11 (0.6) |
| Post-operative renal dysfunction | |
| No | 1269 (74.4) |
| Yes | 423 (24.8) |
| Dialysis | 13 (0.8) |
| CVA | |
| No | 1696 (99.5) |
| Yes | 9 (0.5) |
| Left ventricular support | |
| No | 1690 (99.1) |
| Yes | 15 (0.9) |
| Uncontrolled sugars | |
| No | 1388 (81.4) |
| Yes | 317 (18.6) |
| Deep SSI | |
| No | 1630 (95.6) |
| Conservative | 32 (1.9) |
| Debridement & rewiring | 14 (0.8) |
| Flap reconstruction | 9 (0.5) |
| Debridement & resuturing | 20 (1.2) |
| Early mortality | |
| No | 1665 (97.7) |
| Yes | 40 (2.3) |

Table.6: Post-operative in hospital complications in patients of CABG

In-hospital and long-term outcomes of CABG – A single center experience.

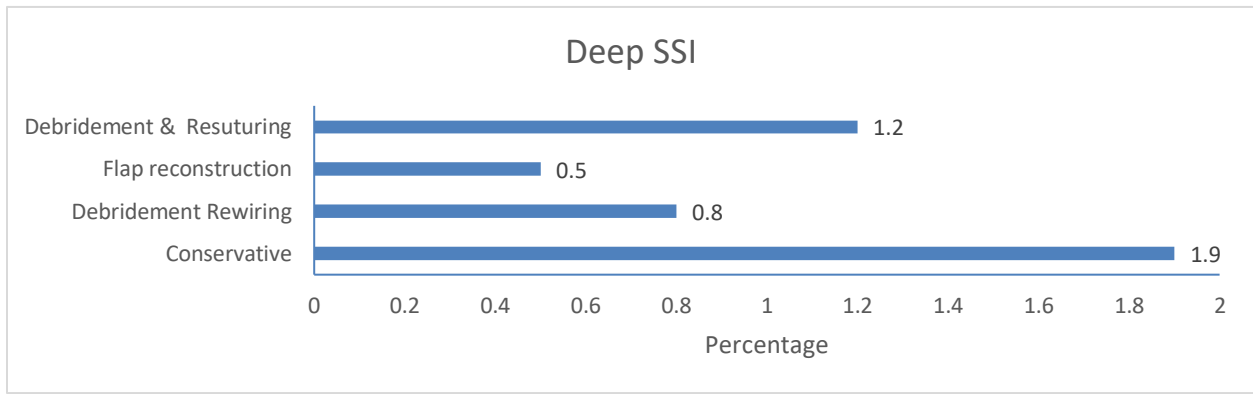


Figure.39: Management of deep surgical site infection.

Deep surgical site infection with mediastinitis was seen in 75 patients (4.4%). Majority were managed conservatively, and others required debridement with resuturing or rewiring. Very few underwent (n=9) underwent flap reconstruction due to complete destruction of sternum.

Forty patients suffered from in-hospital death. Yearly trend and various causes of in-hospital mortality was shown under. Most common cause of early mortality was cardiogenic shock with nearly half of patients followed by renal failure and sepsis as next common causes.

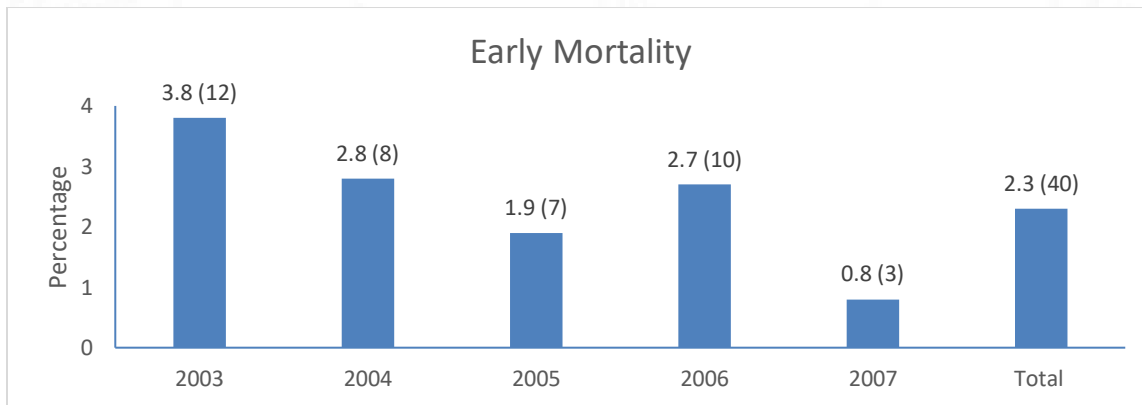


Figure.40: Yearly trend on in-hospital mortality among CABG patients.

In-hospital and long-term outcomes of CABG – A single center experience.

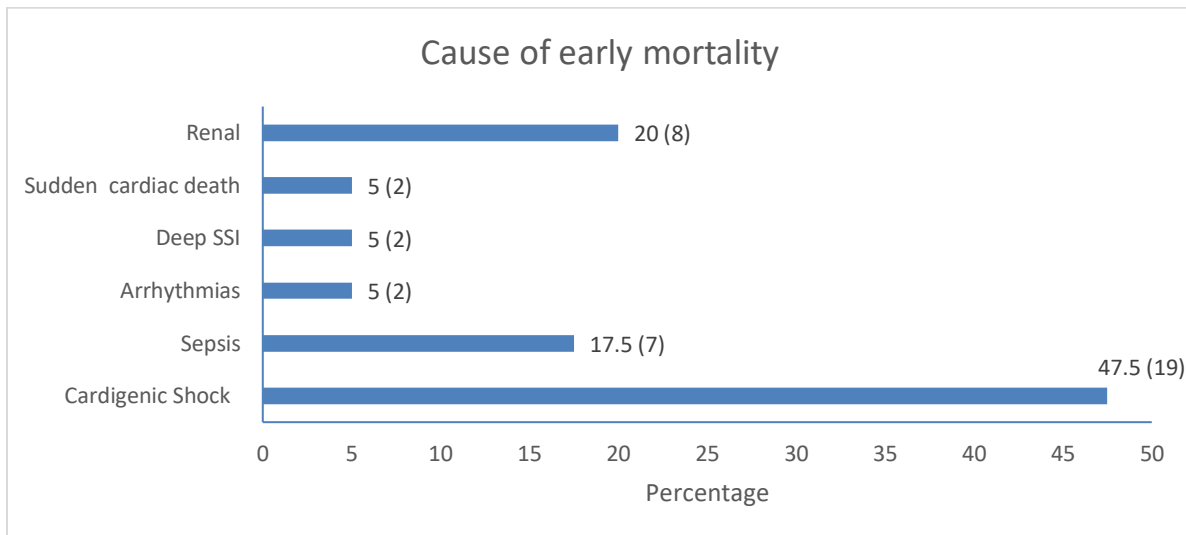


Figure.41: Various causes of in-hospital mortality among operated patients

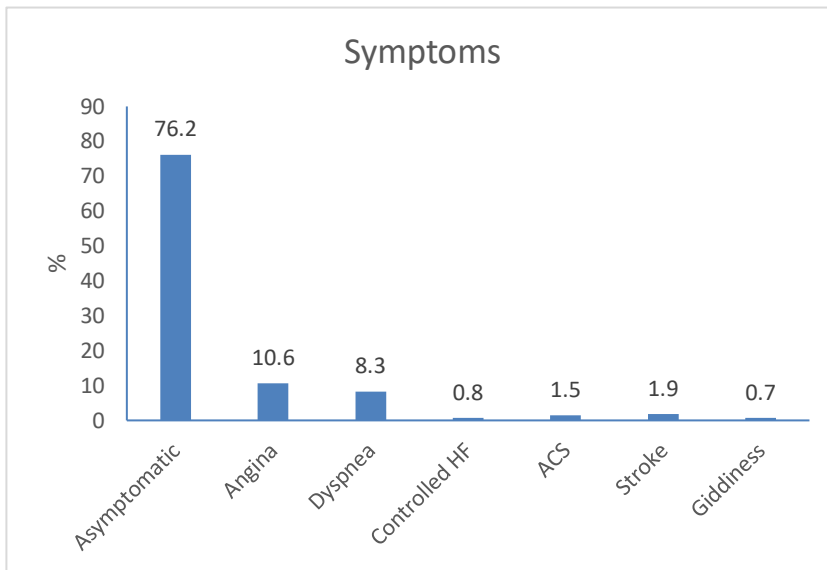
Follow-up of patients: Mean follow up duration of patients over 10 years is 7.7 ± 2.6 years.

On follow-up, seven patients (0.4%) developed large-artery aneurysm either as abdominal aortic aneurysm most commonly, while others developed thoracoabdominal aneurysm. Major co-morbid illnesses in the form of hepatic disorders like chronic hepatitis or liver failure was seen in 11 patients and life-threatening malignancy in eight patients.

Subsequently, due to these co-morbid illnesses, these patients underwent major surgical procedures like infra renal abdominal aortic aneurysm repair (IRAAA = 6), Thoraco abdominal aneurysm repair (n=1), intervention for PAOD (n=5) and treatment for malignancy (surgery or radiotherapy or chemotherapy) in eight patients.

During their follow up, more than 75% patients remained asymptomatic. Less than 25% of patients developed symptoms with more commonly angina and dyspnea as their initial symptom. Few patients developed stroke or acute coronary syndromes as their initial presentation.

In-hospital and long-term outcomes of CABG – A single center experience.



| Symptoms | Frequency | Percent |
|---------------|-------------|------------|
| Asymptomatic | 1269 | 76.2 |
| Angina | 176 | 10.6 |
| Dyspnea | 138 | 8.3 |
| Controlled HF | 13 | 0.8 |
| ACS | 25 | 1.5 |
| Stroke | 32 | 1.9 |
| Giddiness | 12 | 0.7 |
| Total | 1665 | 100 |

Figure.42: Symptomatic status of patients during follow – up.

Symptomatic status of patients at their last follow-up

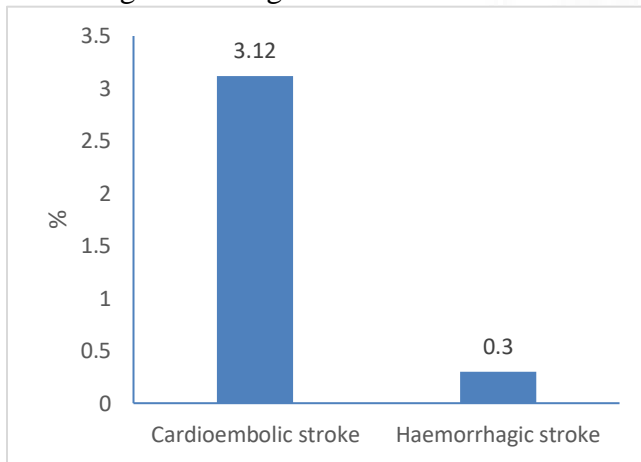
was similar with slight improvement in asymptomatic status. While other patients have worsened dyspnea (n=180) and heart failure (n=35). Proportion of patients with symptomatic status at their latest follow up is as follows:

| Symptom status | N | % |
|----------------|------|------|
| Asymptomatic | 1263 | 75.8 |
| Angina | 159 | 9.5 |
| Dyspnea | 180 | 10.8 |
| Controlled HF | 35 | 2.1 |
| Fatigue | 1 | 0.6 |

Table. 7: Symptom status of patients at the latest follow-up.

In-hospital and long-term outcomes of CABG – A single center experience.

Stroke: One of the major conditions which affects patient long-term morbidity and mortality with decreased quality of life. Over 10 year follow up, stroke event rate was 3.7% (N=57). Most commonly, stroke was of embolic in origin with 91.2% (n=52) with few patients 8.8% (n=5) sustaining hemorrhagic stroke.



| Stroke | N (%) | Type of stroke | N (%) |
|--------|-------------|----------------------|-----------|
| Yes | 57 (3.4) | Cardioembolic stroke | 52 (3.12) |
| No | 1608 (96.6) | Haemorrhagic stroke | 5 (0.3) |
| Total | 1665 (100) | Total | 57 (3.4) |

Figure.43: Stroke recurrence during follow-up.

Acute coronary syndromes: Out of 1665 patients on follow-up, 32 patients (1.9%) developed acute coronary syndromes. Within ACS patients, more patients suffered from myocardial infarction (n=28) with few developing unstable angina (n=4).

Functional class at follow-up: Majority of patients belonged to FC I, with few patients in FC II.

Few patients developed additional neurological conditions like seizures (n=8), Parkinson’s disease (n=5), Alzheimer’s disease (n=3), Psychiatric illness (n=1) and degenerative brain disease (n=1).

In-hospital and long-term outcomes of CABG – A single center experience.

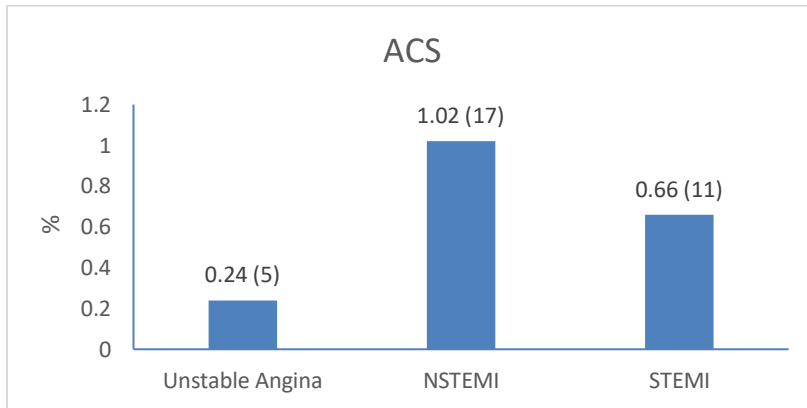
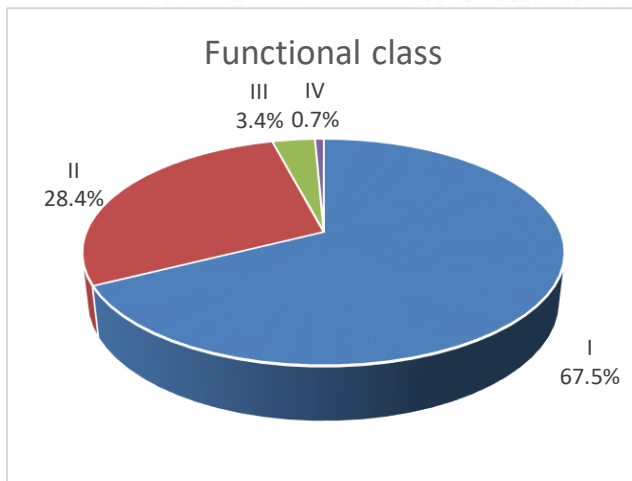


Figure.44: Bar diagram showing the distribution of ACS on follow up. ACS-Acute coronary syndromes, NSTEMI-Non-ST elevation MI, STEMI-ST elevation MI.



| Functional class | N (%) |
|------------------|-------------|
| 1 | 1125 (67.6) |
| 2 | 473 (28.4) |
| 3 | 56 (3.4) |
| 4 | 11 (0.7) |
| Total | 1665 (100) |

Figure.45: Distribution of patients as per functional classification of symptoms.

Latest ECG at follow up showed predominantly sinus rhythm (n=1540), more common abnormal rhythm patterns include VPC's and bundle branch blocks. Atrial fibrillation was seen in only 20 patients (1.2%) on follow-up. Bundle branch blocks constitute around 3.1% of total patients and nearly one-third of patients with abnormal rhythm. Apart from RBBB and LBBB of common block variants, few had fascicular blocks and complete heart blocks.

In-hospital and long-term outcomes of CABG – A single center experience.

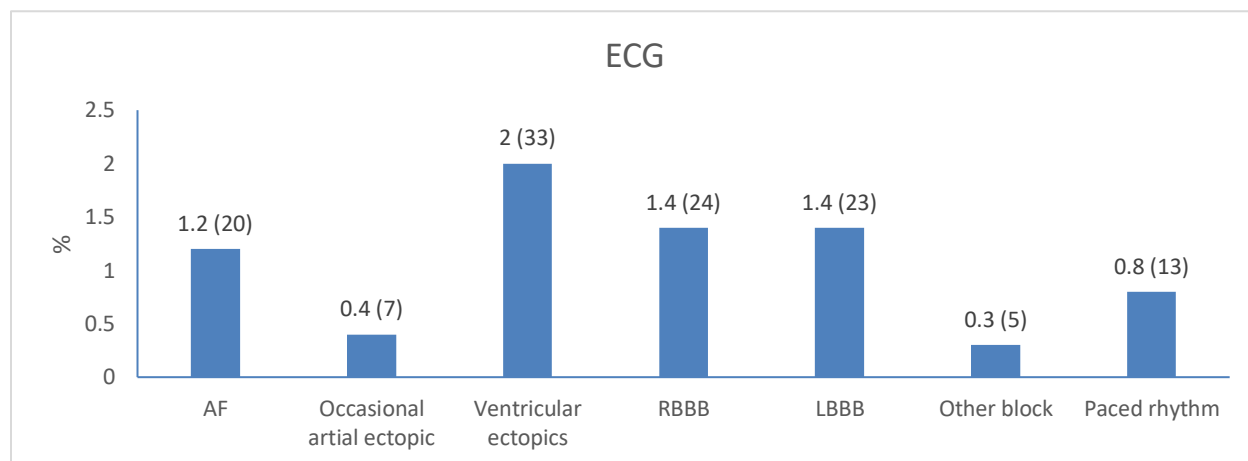


Figure.46: Percentage of patients with abnormal rhythm during their last follow-up. AF-atrial fibrillation, LBBB-left bundle branch block, RBBB-right bundle branch block.

Various methods of intervention performed in the above patients include permanent pacemaker insertion (n=11), intracardiac cardioverter defibrillator (n=3), radiofrequency ablation (n=2), cardiac resynchronization therapy (n=2).

Of 123 patients, who were evaluated for symptomatic angina or ACS, treadmill test was performed in 27 patients, coronary CT in 17 patients and conventional angiogram was performed in 79 patients. Among the 27 patients of TMT, only five patients tested positive for inducible ischemia and continued further evaluation of the disease.

Among the patients who underwent angiographic evaluation, pattern of graft patency is summarized as below.

| Patency of grafts | Frequency | Percent |
|--------------------------|-----------|---------|
| All grafts patent | 27 | 28.1 |
| Arterial block only | 6 | 6.2 |
| Venous block Only | 51 | 53.1 |
| Both arterial and venous | 12 | 12.5 |

Table.8: Angiographic information on graft patency

In-hospital and long-term outcomes of CABG – A single center experience.

Only 18 patients had LIMA arterial occlusion, with all others having LIMA arterial patent. A total of 47 patients underwent re-intervention in the form of PCI or CABG. Five patients underwent CABG, whereas others underwent PCI. Disease recurrence was mainly in the form of native vessel disease rather than stenosis of the grafted vessels.



COMPARATIVE ANALYSIS

Correlation between Pre-operative and post-operative renal dysfunction:

Among 339 patients who had pre-operative renal dysfunction, 161 patients persisted to have renal dysfunction post-operatively. Only 275 patients developed renal dysfunction in the immediate post-operative period. There is statistically significant relationship for the development of post-operative renal dysfunction in patients with prior renal dysfunction.

| Renal dysfunction | | Pre-operative | | | | Total | |
|-------------------|-----|---------------|------|-----|------|-------|------|
| | | No | | Yes | | | |
| | | N | % | N | % | N | % |
| Post-operative | No | 1091 | 79.9 | 178 | 52.5 | 1269 | 74.4 |
| | Yes | 275 | 20.1 | 161 | 47.5 | 436 | 25.6 |
| Total | | 1366 | 100 | 339 | 100 | 1705 | 100 |

P < 0.001

Table. 9: Relationship between the pre-operative and post-operative renal dysfunction.

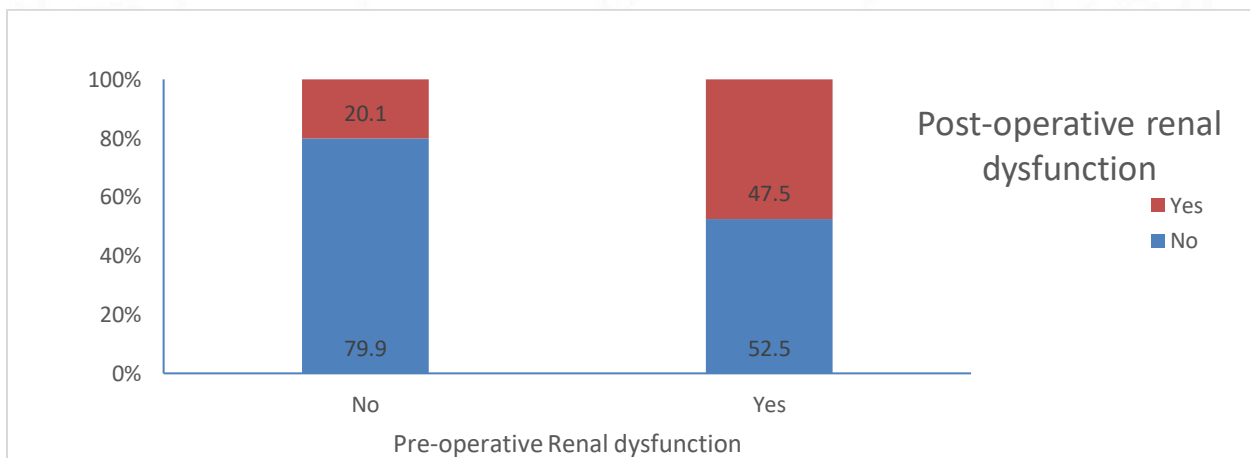


Figure.47: Bar-diagram depicting the proportion of patients developing or persisting renal dysfunction in the immediate post-op period.

In-hospital and long-term outcomes of CABG – A single center experience.

Correlation between pre-operative DM and post-operative uncontrolled sugars:

| Pre-Op Diabetes | Uncontrolled sugars | | | | Total | |
|--------------------|---------------------|------|-----|------|-------|-----|
| | No | | Yes | | N | % |
| | N | % | N | % | | |
| No | 781 | 97.3 | 22 | 2.7 | 803 | 100 |
| Type I | 119 | 44.1 | 151 | 55.9 | 270 | 100 |
| Type II | 488 | 77.2 | 144 | 22.8 | 632 | 100 |
| Total | 1388 | 81.4 | 317 | 18.6 | 1705 | 100 |

$P < 0.001$ Table.10: Relation between pre-operative presence and type of diabetes mellitus and uncontrolled sugars in the post-operative period.

Among 902 patients with pre-operative DM, only 317 patients (18.6%) developed uncontrolled sugars in the immediate post-operative period. More than half of patients had type I DM pre-operatively. As few as 22 patients developed uncontrolled sugars during recovery without pre-operative history of DM. There exists statistically significant relationship in patients with pre-operative DM and uncontrolled sugars in the immediate post-operative period.

Correlation between pre-operative DM and deep surgical site infection:

| Pre-Op Diabetes | Deep surgical site infection | | | | Total | |
|--------------------|------------------------------|------|-----|------|-------|-----|
| | No | | Yes | | N | % |
| | N | % | N | % | | |
| No | 786 | 97.9 | 17 | 2.1 | 803 | 100 |
| Type I | 241 | 89.3 | 29 | 10.7 | 270 | 100 |
| Type II | 603 | 95.4 | 29 | 4.6 | 632 | 100 |
| Total | 1630 | 95.6 | 75 | 4.4 | 1705 | 100 |

$P < 0.001$. Table.11: Correlation between presence of pre-operative Diabetes Mellitus and development of deep SSI in the post-operative period.

In-hospital and long-term outcomes of CABG – A single center experience.

Deep SSI was seen in 72 patients. There was significant correlation between the development of deep SSI and pre-operative DM status ($p < 0.001$). Out of 75 patients, 58 patients had DM and moreover there appears to be strong relation between type I DM than type II DM [29 patients of 270 (10.7%) Vs 29 patients of 632 (4.6%)].

Predictive risk factors for early mortality:

| | | Early mortality | | | | Total | | p | RR | 95 % CI for RR | |
|----------------------------|-----------------------------------|-----------------|------|------|------|-------|-----|------------------|-------|----------------|-------|
| | | Yes | | No | | | | | | L | U |
| | | n | % | n | % | | | | | | |
| Obesity | | 14 | 3.8 | 356 | 96.2 | 370 | 100 | 0.039 | 1.94 | 1.03 | 3.68 |
| Gender | Female | 12 | 5.4 | 210 | 94.6 | 222 | 100 | 0.001 | 2.86 | 1.48 | 5.55 |
| | Male | 28 | 1.9 | 1455 | 98.1 | 1483 | 100 | | | | |
| Diabetes Mellitus | | 25 | 2.8 | 877 | 97.2 | 902 | 100 | 0.219 | 1.48 | 0.79 | 2.79 |
| Hypertension | | 27 | 2.7 | 980 | 97.3 | 1007 | 100 | 0.272 | 1.44 | 0.75 | 2.77 |
| Dyslipidemia | | 35 | 3.1 | 1078 | 96.9 | 1113 | 100 | 0.003 | 3.72 | 1.47 | 9.45 |
| Pre-op CVA | | 3 | 4.2 | 69 | 95.8 | 72 | 100 | 0.297 | 1.84 | 0.58 | 5.82 |
| COPD | | 5 | 5.6 | 84 | 94.4 | 89 | 100 | 0.036 | 2.59 | 1.04 | 6.46 |
| Renal dysfunction | | 11 | 3.2 | 328 | 96.8 | 339 | 100 | 0.222 | 1.53 | 0.77 | 3.03 |
| Initial Presentation | ACS | 12 | 2.2 | 527 | 97.8 | 539 | 100 | 0.824 | 0.93 | 0.48 | 1.81 |
| | SCAD | 28 | 2.4 | 1138 | 97.6 | 1166 | 100 | | | | |
| Myocardial Infarction | | 25 | 2.8 | 873 | 97.2 | 898 | 100 | 0.208 | 1.50 | 0.80 | 2.82 |
| Cardiogenic shock | | 6 | 28.6 | 15 | 71.4 | 21 | 100 | <0.001 | 14.15 | 6.66 | 30.07 |
| Congestive cardiac failure | | 11 | 20.4 | 43 | 79.6 | 54 | 100 | <0.001 | 11.60 | 6.12 | 21.97 |
| Functional class | III - IV | 23 | 5.4 | 406 | 94.6 | 429 | 100 | <0.001 | 4.02 | 2.17 | 7.46 |
| | I - II | 17 | 1.3 | 1259 | 98.7 | 1276 | 100 | | | | |
| LV function | Moderate to severe LV dysfunction | 9 | 5.6 | 151 | 94.4 | 160 | 100 | 0.004 | 2.80 | 1.36 | 5.78 |
| | Good LV | 31 | 2 | 1514 | 98 | 1545 | 100 | | | | |
| Mitral Regurgitation | Moderate to severe | 8 | 9.1 | 80 | 90.9 | 88 | 100 | <0.001 | 4.59 | 2.18 | 9.67 |
| | Mild | 32 | 2 | 1585 | 98 | 1617 | 100 | | | | |
| RWMA | | 17 | 2.2 | 742 | 97.8 | 759 | 100 | 0.795 | 0.92 | 0.50 | 1.71 |
| LMCA disease | | 6 | 2 | 288 | 98 | 294 | 100 | 0.704 | 0.85 | 0.36 | 2.00 |
| Disease territory | SVD | 1 | 0.8 | 118 | 99.2 | 119 | 100 | | | | |

In-hospital and long-term outcomes of CABG – A single center experience.

| | | | | | | | | | | | |
|-----------------------|-----------|----|------|------|------|------|-----|------------------|-------|-------|-------|
| | 2VD | 7 | 1.7 | 407 | 98.3 | 414 | 100 | 0.258 | | | |
| | TVD | 32 | 2.7 | 1140 | 97.3 | 1172 | 100 | | | | |
| Surgery | Elective | 31 | 1.9 | 1630 | 98.1 | 1661 | 100 | <0.001 | 0.09 | 0.05 | 0.18 |
| | Emergency | 9 | 20.5 | 35 | 79.5 | 44 | 100 | | | | |
| Endarterectomy | | 9 | 3.2 | 273 | 96.8 | 282 | 100 | 0.305 | 1.47 | 0.71 | 3.04 |
| Additional procedures | | 4 | 5.6 | 67 | 94.4 | 71 | 100 | 0.062 | 2.56 | 0.94 | 6.99 |
| Reoperation | | 3 | 9.7 | 28 | 90.3 | 31 | 100 | 0.006 | 4.38 | 1.43 | 13.44 |
| LV support | | 9 | 60 | 6 | 40 | 15 | 100 | <0.001 | 32.71 | 19.05 | 56.17 |
| Uncontrolled sugars | | 14 | 4.4 | 303 | 95.6 | 317 | 100 | 0.007 | 2.36 | 1.25 | 4.46 |
| Deep SSI | | 8 | 10.7 | 67 | 89.3 | 75 | 100 | <0.001 | 5.43 | 2.59 | 11.38 |

Table. 12: Various pre-operative factors associated with early mortality. ACS-Acute coronary syndrome, COPD-Chronic obstructive pulmonary disease, CVA-Cerebrovascular accident, LMCA-Left main coronary disease, LV-Left ventricle, MR-Mitral regurgitation, SCAD-Stable coronary artery disease, SSI-surgical site infection, SVD-Single vessel disease, 2VD-Double vessel disease.

| | Early mortality | | p |
|----------------|-----------------|--------------|--------------|
| | No | Yes | |
| | Mean (SD) | Mean (SD) | |
| Age (in years) | 54.8 (8.8) | 61.6 (9.2) | 0.600 |
| CPB time (min) | 91.0 (30.3) | 104.4 (32.6) | 0.001 |
| ACC time (min) | 51.3 (19.4) | 57.5 (21.1) | 0.001 |

Table. 13: Association of continuous variables like age, CPB time and ACC time with early mortality. ACC-Aortic cross clamp, CPB-Cardiopulmonary bypass time.

Various factors were assessed to predict risk factors for early mortality. Of the variables studied, demographic and comorbid illnesses like female gender, obesity, chronic obstructive pulmonary disease, dyslipidemia is found to have significant association to predict early mortality. Clinical characteristics like cardiogenic shock or congestive cardiac failure at the time of operation carries high risk for early mortality. Functional class III-IV at presentation and associated moderate to severe MR is associated with early mortality. Other factors like emergency operation,

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reoperation for acute graft occlusion, left ventricular support like IABP, uncontrolled sugars and deep SSI also favoured early mortality.

Risk factors for MACCE (Major adverse cardiac and cerebrovascular events):

| | | MACCE | | | | Total | | p | RR | 95 % CI | |
|----------------------------|-----------------------------------|-------|------|------|------|-------|-----|--------------|------|---------|------|
| | | Yes | | No | | | | | | for RR | |
| | | n | % | n | % | | | | | L | U |
| Obesity | | 31 | 8.7 | 325 | 91.3 | 356 | 100 | 0.660 | 0.92 | 0.63 | 1.34 |
| Gender | Female | 20 | 9.5 | 190 | 90.5 | 210 | 100 | 0.909 | 1.03 | 0.66 | 1.61 |
| | Male | 135 | 9.3 | 1320 | 90.7 | 1455 | 100 | | | | |
| Diabetes | | 95 | 10.8 | 782 | 89.2 | 877 | 100 | 0.024 | 1.42 | 1.05 | 1.94 |
| Hypertension | | 99 | 10.1 | 881 | 89.9 | 980 | 100 | 0.183 | 1.24 | 0.90 | 1.69 |
| Dyslipidemia | | 114 | 10.6 | 964 | 89.4 | 1078 | 100 | 0.016 | 1.51 | 1.08 | 2.13 |
| Pre-op CVA | | 14 | 20.3 | 55 | 79.7 | 69 | 100 | 0.001 | 2.30 | 1.40 | 3.76 |
| COPD | | 9 | 10.7 | 75 | 89.3 | 84 | 100 | 0.649 | 1.16 | 0.61 | 2.19 |
| Pre-op Renal dysfunction | | 39 | 11.9 | 289 | 88.1 | 328 | 100 | 0.073 | 1.37 | 0.97 | 1.93 |
| Initial Presentation | ACS | 40 | 7.6 | 487 | 92.4 | 527 | 100 | 0.100 | 0.75 | 0.53 | 1.06 |
| | SCAD | 115 | 10.1 | 1023 | 89.9 | 1138 | 100 | | | | |
| Pre-op MI | | 88 | 10.1 | 785 | 89.9 | 873 | 100 | 0.256 | 1.19 | 0.88 | 1.61 |
| Cardiogenic shock | | 1 | 6.7 | 14 | 93.3 | 15 | 100 | 0.723 | 0.71 | 0.11 | 4.77 |
| Congestive cardiac failure | | 10 | 23.3 | 33 | 76.7 | 43 | 100 | 0.001 | 2.60 | 1.48 | 4.58 |
| Functional class | III – IV | 41 | 10.1 | 365 | 89.9 | 406 | 100 | 0.529 | 1.12 | 0.80 | 1.57 |
| | I - II | 114 | 9.1 | 1145 | 90.9 | 1259 | 100 | | | | |
| LV function | Moderate to severe LV dysfunction | 17 | 11.3 | 134 | 88.7 | 151 | 100 | 0.387 | 1.24 | 0.77 | 1.99 |
| | Good | 138 | 9.1 | 1376 | 90.9 | 1514 | 100 | | | | |
| Mitral Regurgitation | Moderate to severe | 16 | 20 | 64 | 80 | 80 | 100 | 0.001 | 2.28 | 1.43 | 3.64 |
| | Mild | 139 | 8.8 | 1446 | 91.2 | 1585 | 100 | | | | |
| RWMA | | 63 | 8.5 | 679 | 91.5 | 742 | 100 | 0.303 | 0.85 | 0.63 | 1.16 |
| LMCA disease | | 25 | 8.7 | 263 | 91.3 | 288 | 100 | 0.686 | 0.92 | 0.61 | 1.38 |
| Disease territory | SVD | 8 | 6.8 | 110 | 93.2 | 118 | 100 | | | | |
| | 2VD | 31 | 7.6 | 376 | 92.4 | 407 | 100 | 0.193 | | | |
| | TVD | 116 | 10.2 | 1024 | 89.8 | 1140 | 100 | | | | |

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| | | | | | | | | | | | |
|-----------------------|-----------|-----|------|------|------|------|-----|------------------|------|------|------|
| Surgery | Elective | 153 | 9.4 | 1477 | 90.6 | 1630 | 100 | 0.459 | 1.64 | 0.42 | 6.36 |
| | Emergency | 2 | 5.7 | 33 | 94.3 | 35 | 100 | | | | |
| Endarterectomy | | 31 | 11.4 | 242 | 88.6 | 273 | 100 | 0.203 | 1.28 | 0.88 | 1.85 |
| Additional procedures | | 15 | 22.4 | 52 | 77.6 | 67 | 100 | <0.001 | 2.56 | 1.59 | 4.10 |
| Reoperation | | 3 | 10.7 | 25 | 89.3 | 28 | 100 | 0.796 | 1.15 | 0.39 | 3.40 |
| Uncontrolled sugars | | 40 | 13.2 | 263 | 86.8 | 303 | 100 | 0.010 | 1.56 | 1.12 | 2.19 |
| Deep SSI | | 9 | 13.4 | 58 | 86.6 | 67 | 100 | 0.236 | 1.47 | 0.79 | 2.75 |

Table. 14: Various pre-operative factors associated with MACCE (major adverse cardiac and cerebrovascular events). ACS-Acute coronary syndrome, COPD-Chronic obstructive pulmonary disease, CVA-Cerebrovascular accident, LMCA-Left main coronary disease, LV-Left ventricle, MR-Mitral regurgitation, SCAD-Stable coronary artery disease, SSI-surgical site infection, SVD-Single vessel disease, 2VD-Double vessel disease.

| | MACCE | | p |
|----------------|-------------|-------------|------------------|
| | No | Yes | |
| | Mean (SD) | Mean (SD) | |
| Age (years) | 54.8 (8.7) | 54.4 (9.3) | <0.001 |
| CPB time (min) | 90.2 (29.7) | 98.7 (34.9) | 0.006 |
| ACC time (min) | 50.8 (18.6) | 56.1 (26.1) | 0.046 |

Table. 15: Association of continuous variables like age, CPB time and ACC time with MACCE events. ACC-Aortic cross clamp, CPB-Cardiopulmonary bypass time.

Among the factors assessed for risk during the 10-yr follow up, age of the patient, pre-operative diabetes mellitus, dyslipidemia and CVA are associated with increased risk for MACCE. Congestive cardiac failure at the time of operation and associated moderate to severe mitral regurgitation also confer additional risk. Prolonged CPB and ACC times and performance of additional surgical procedures along with CABG and post-operative uncontrolled sugars are among the other factors associated with increased risk of MACCE.

SURVIVAL ANALYSIS:

Major adverse cardiac and cerebrovascular events (MACCE): MACCE event rate was calculated over the mean follow-up period of 7.8 years in the 10-year follow up. It includes composite death (all-cause death), Stroke, Acute coronary events, revascularization with PCI or CABG.

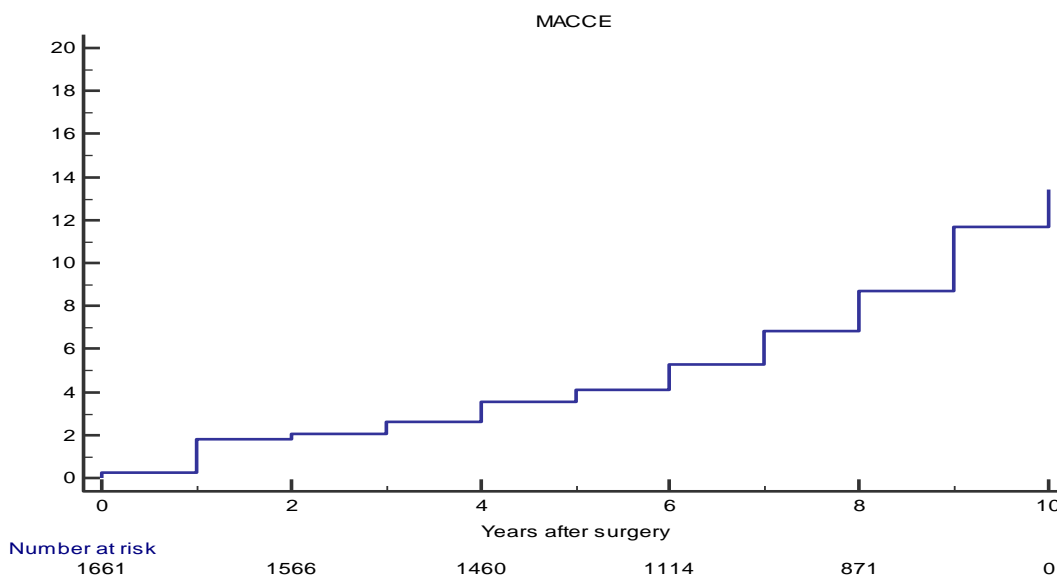


Figure. 48: KM-curve showing MACCE event rate over 10 year follow up.

Cumulative MACC event rate at 10 years was 15.8% (n=155). Even though cumulative event rates were low (< 3.4%) initially during the first 8 years, by 10 years, event rate was 15.8%.

Further event rates were classified based on duration from operation into four groups.

| | <1 year | | 1-3 years | | 3-5 years | | 5-10 years | | Total | |
|----------------|---------|------|-----------|------|-----------|------|------------|------|-------|-----|
| | n | % | n | % | n | % | n | % | n | % |
| Stroke | 10 | 17.5 | 7 | 12.3 | 15 | 26.3 | 25 | 43.9 | 57 | 100 |
| ACS | 5 | 15.6 | 3 | 9.4 | 3 | 9.4 | 21 | 65.6 | 32 | 100 |
| Reintervention | 5 | 10.6 | 3 | 6.4 | 3 | 6.4 | 36 | 76.6 | 47 | 100 |
| Mortality | 4 | 10.5 | 8 | 21.1 | 1 | 2.6 | 25 | 65.8 | 38 | 100 |
| MACCE | 27 | 17.4 | 16 | 10.3 | 21 | 13.5 | 91 | 58.7 | 155 | 100 |

Table. 16: Group wise distribution of various MACC events from the time of operation.

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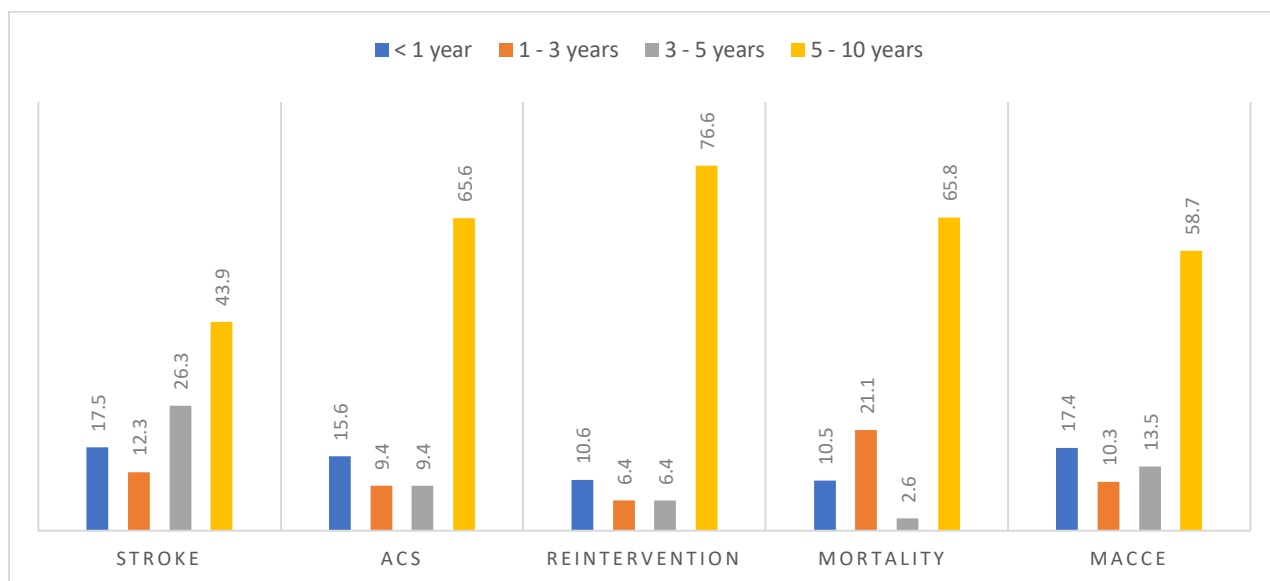


Figure.49: Bar diagram comparing various MACC events in the four-time frames from the time of operation.

MACC events were more commonly seen 5-10 years after the operation with gross event rate of 5.6% followed by during the first year (1.6%) and later during 3-5 years duration (1.2%). It appears to be least during 1-3-year period.

Year-wise distribution of MACCE is shown in the KM curve below with significant difference in event rate among the years with more events occurring in the latter years (log rank $p=0.023$). Also assessed was MACCE free survival rate in each year.

| Year | MACCE | | No MACCE | | Total sample size |
|---------|-------|-------|----------|-------|-------------------|
| | N | % | N | % | |
| 2003 | 16 | 5.26 | 288 | 94.74 | 304 |
| 2004 | 21 | 7.69 | 252 | 92.31 | 273 |
| 2005 | 35 | 9.92 | 318 | 90.08 | 353 |
| 2006 | 43 | 11.85 | 320 | 88.15 | 363 |
| 2007 | 40 | 10.75 | 332 | 89.25 | 372 |
| Overall | 155 | 9.31 | 1510 | 90.69 | 1665 |

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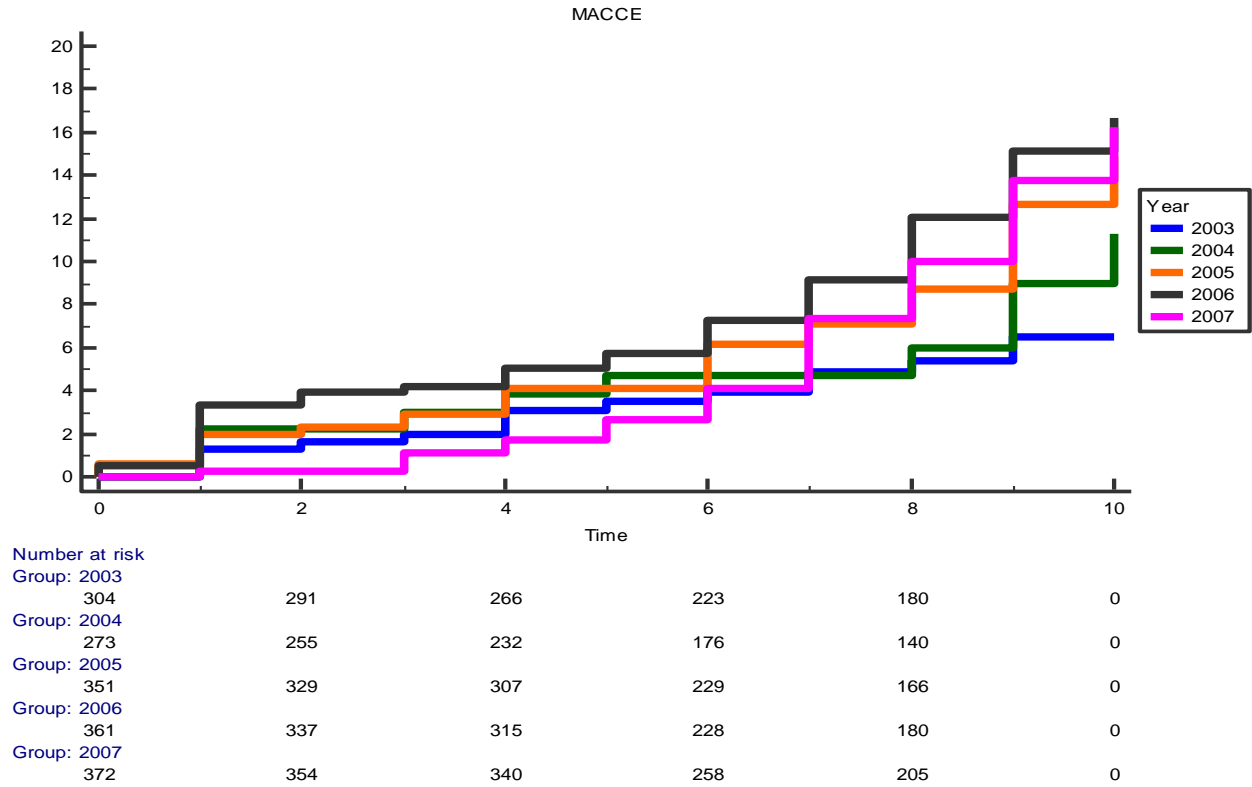


Figure.50: Kaplan-Meier curve showing the MACCE event rate in respective years.

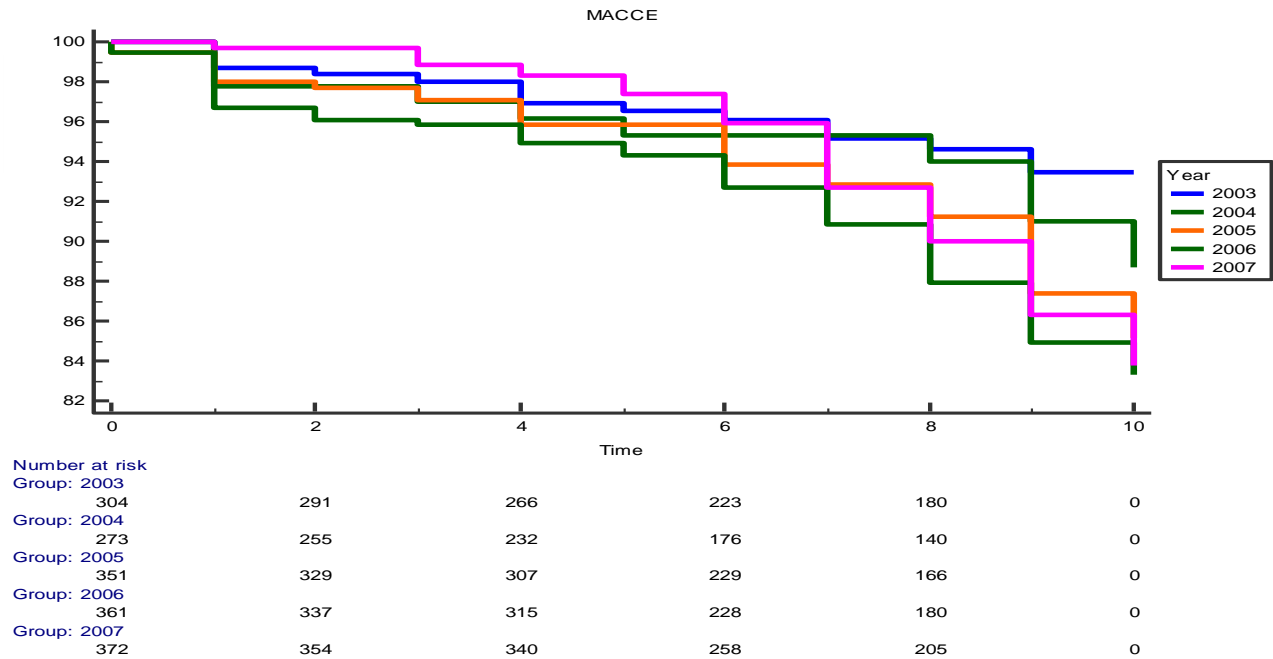


Figure.51: MACCE free survival in the study population during follow-up.

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| Comparison of survival curves (Log rank test) | |
|---|--------|
| Chi-squared | 11.302 |
| DF | 4 |
| p | 0.023 |

Freedom from Reintervention: Reintervention in the form of percutaneous coronary intervention or CABG during the follow-up is considered as MACC event. A total of 47 patients underwent one form of intervention during the follow-up period. Re-intervention free survival is shown as under.

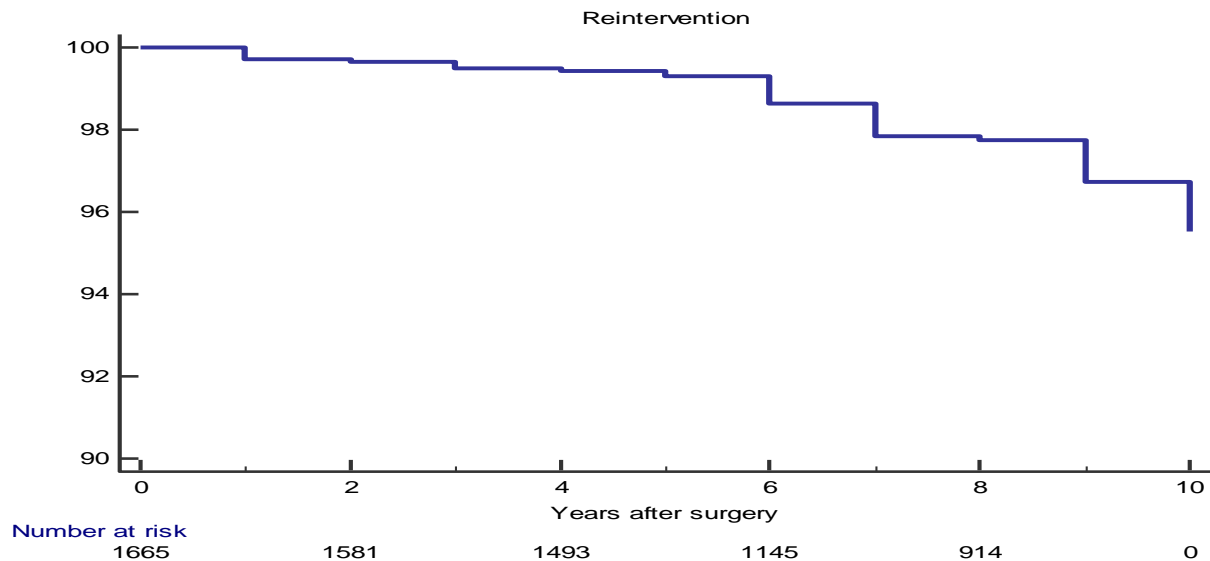


Figure.52: Re-intervention free survival rate shown in KM curve.

Freedom from re-intervention at 2-year and 5-year 99.6% and 99.3% respectively. Freedom gradually reduced to 97.7% at 8 years and 95.5% by 10 years of follow-up.

Symptom free survival: Of 1665 patients on follow-up, 32.6% patients (n=544) developed symptoms at various time duration from the time of operation. Symptom free survival at 1 year was 97.8%, 2-year and 5-year was 96.6% and 89.5% respectively. Symptom free survival

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significantly reduced to 78.4% by 8-year from the time of operation and more than half of patients developed symptoms at the end of 10-year follow-up with only 49.4 % of patients free of symptoms.

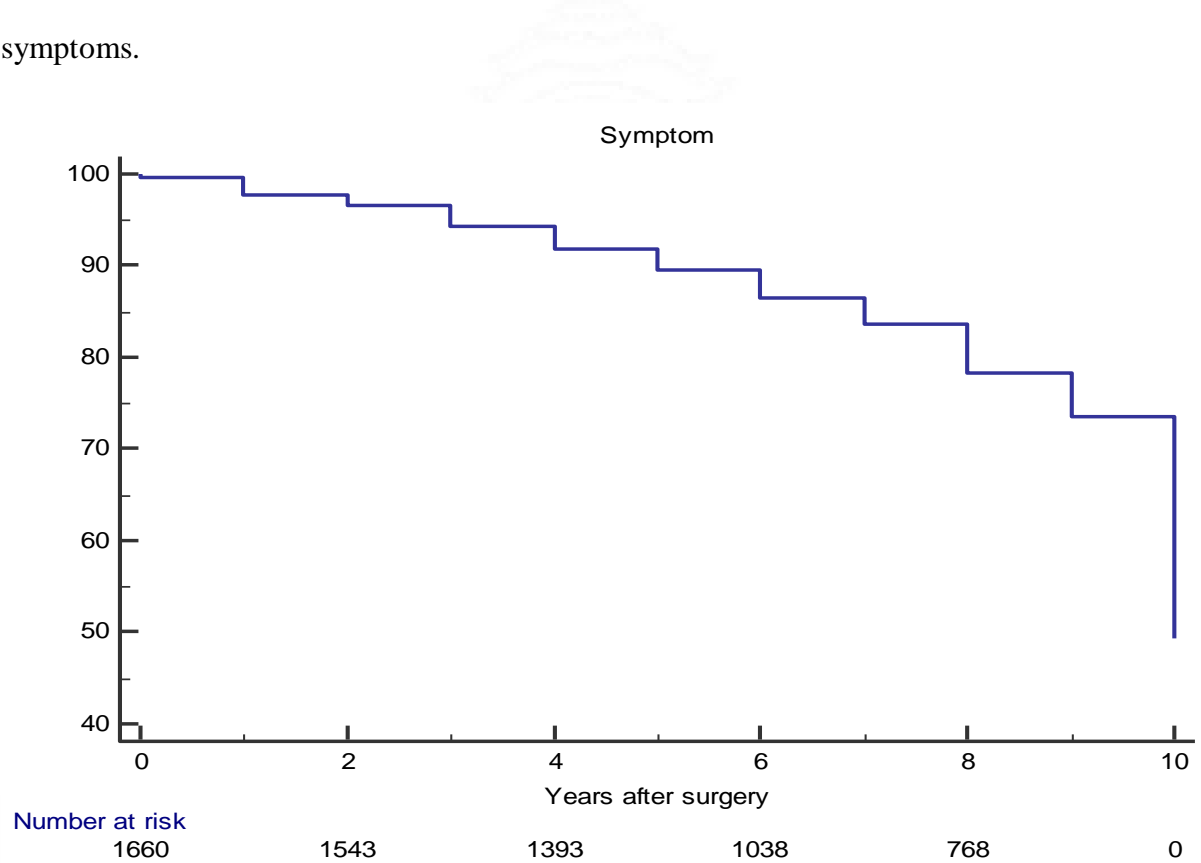


Figure.53: Kaplan-Meier survival curve showing patients with freedom from symptom onset.

Survival Analysis:

Mean follow up period was 7.8 ± 2.7 years over the 10-year follow-up period. During survival analysis, there were total 78 deaths, of which 40 patients had in-hospital mortality. Year wise distribution of deaths (includes in-hospital and late mortality) is shown in table below.

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| Year | Death | | Alive | | Total sample size |
|---------|-------|------|-------|-------|-------------------|
| | N | % | N | % | |
| 2003 | 13 | 4.11 | 303 | 95.89 | 316 |
| 2004 | 12 | 4.27 | 269 | 95.73 | 281 |
| 2005 | 20 | 5.56 | 340 | 94.44 | 360 |
| 2006 | 20 | 5.36 | 353 | 94.64 | 373 |
| 2007 | 13 | 3.47 | 362 | 96.53 | 375 |
| Overall | 78 | 4.57 | 1627 | 95.43 | 1705 |

Table. 17: Year wise distribution of survival status including in-hospital deaths.

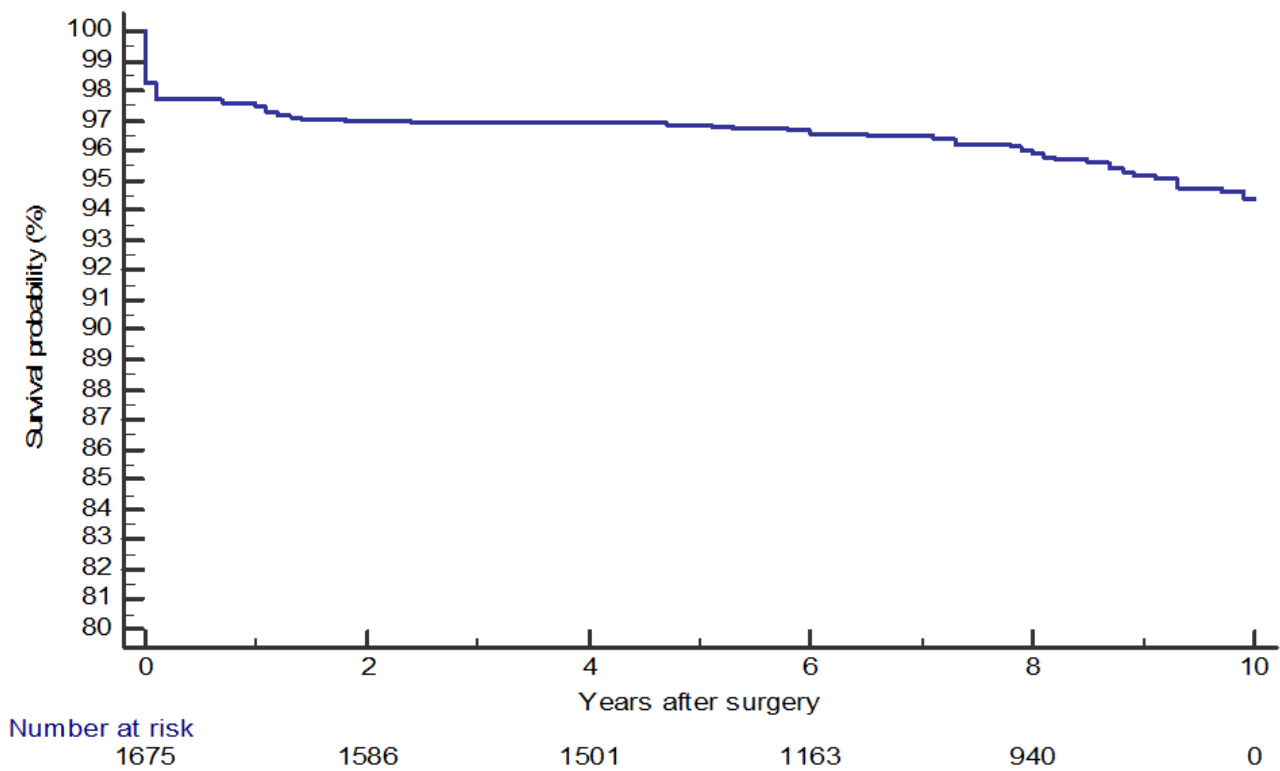


Figure.54: Kaplan-Meier survival curve for 10 years of CABG patients.

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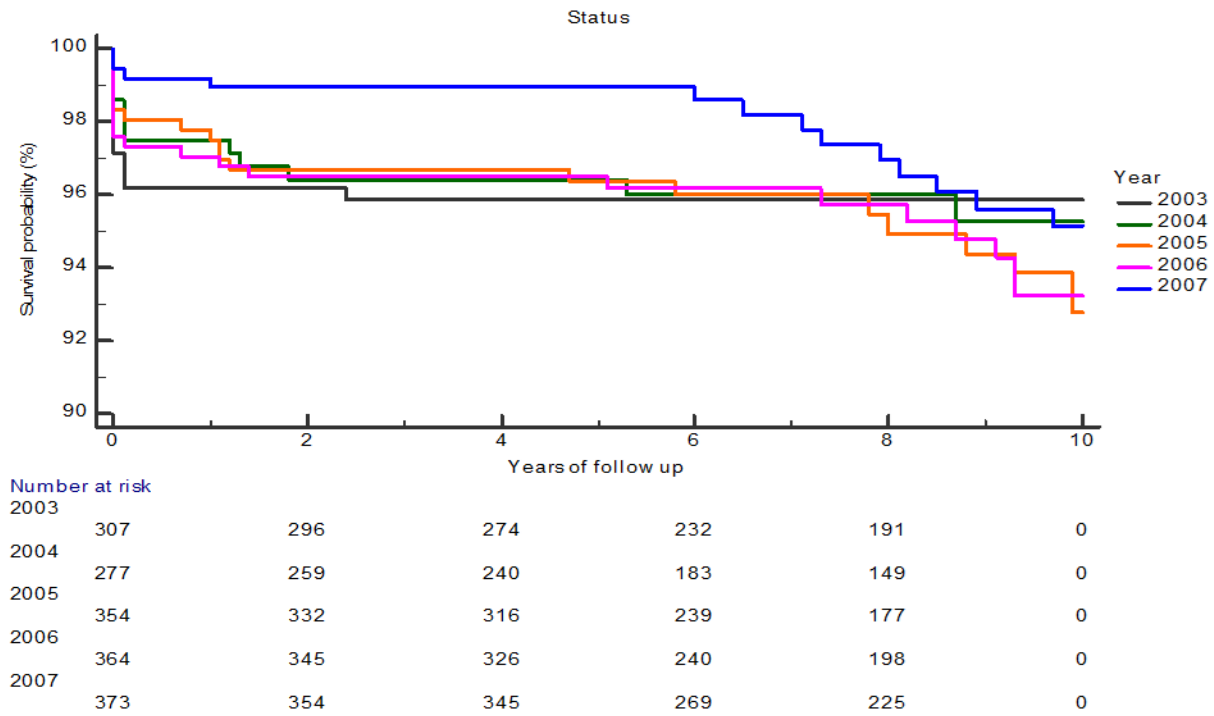


Figure.55: Year-wise Kaplan-Meier survival curve of all patients of CABG. (log rank p=0.564)

| Comparison of survival curves (Log rank test) | |
|---|--------|
| Chi-squared | 2.9652 |
| DF | 4 |
| p | 0.564 |

Overall actuarial survival rate at 10 years was 94.4%. Survival rates at 1 year and 5 year was 97.5% and 96.8% respectively. At 6-year and 8-year follow up, survival rate was 96.6% and 95.9%. Year-wise calculation of survival rate did not reveal any significant difference of survival across the years (log rank p=0.564).

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DISCUSSION

Demographic characteristics:

Mean age of patients in the study group was 55 ± 9 years with majority of patients less than 60 years of age. Age group of patients was more or less similar as compared to other studies(77). International registries have their mean age of patients close to 65 years as seen in large Danish registry(78) and in two prominent trials – SYNTAX and EXCEL trials (59,79). The effect of age on clinical outcomes has been studied in a large multi-center retrospective study, where patients less than 60 years of age are observed to have lower adverse events compared to older people (80). Mean body surface area was not studied as a parameter to assess risk. Our study group had similar BSA across the years with no significant difference.

Females were 13% of the total patients. Our group has slightly less female population as compared to other study groups. A comparison of male and female patients undergoing CABG at 1-year follow up revealed that recovery over time was similar in both with respect to physical, social and emotional well-being with health related quality of life slightly inferior among women as compared to men (81). In our study, female gender is associated with risk factor of early mortality.

Co-morbid illnesses:

Even though patients with history of smoking are above 50%, only 22.5% (383) patients were active smokers at the time of operation. Few non-randomized studies looking at the effect of smoking on patient outcomes have inconsistent results. Study by Benedetto et.al showed that smoking cessation before the operation reduces pulmonary complications(82) and further smoking

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cessation program should be embarked. Similar findings were seen earlier in another study where smoking is associated with significant pulmonary complications with no effect on mortality (83). Another study by Saxena et.al showed that smoking is not associated with early mortality, however is associated with increased pulmonary complications and reduced long term survival (84).

In our study, number of active smokers were comparable to literature, we have considered active smokers as smoking within 3 months of operation, whereas many studies have defined them as smoking within 4 weeks. According to this definition, we had very few patients. Hence, as it might not be able to perform comparison analysis, this variable was not studied.

Obesity defined as BMI > 30 kg/m², was seen in small group of patients (21.7%). Literature suggests that body size is not a risk factor for CABG related early mortality (85). But, BMI as high as ≥ 40 Kg/m² is an independent risk factor for duration of hospital stay and development of infection (86). Compared to a study done in north India, our prevalence of obesity was much lower (21.7% Vs 50.8%) (87).

Hypertension is one of the most common significant risk factors seen in patients undergoing CABG. Incidence of hypertension in our study (59.1%) is similar to literature (88). Prevalence studies on hypertension in India (87) have shown it to be higher than our study (70.9% Vs 59.1%) . In EUROSCORE trial, looking at risk factors in European population, their incidence was close to 50% with highest among German population (54). Incidence of hypertension is a powerful prognostic factor of early and late clinical outcome. Pre-operative beta blockers or ACE inhibitors are initiated in all patients to improve outcome of CABG, in particular those with history of MI, heart failure or LV dysfunction (89). There is mild trend towards decrease in incidence of hypertension post-surgery.

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Dyslipidemia or hyperlipidemia is a very important risk factor for atherosclerosis and thereby CAD. All patients are started on statin therapy at the immediate diagnosis of CAD. Our prevalence is higher 65.3% of CABG patients with much higher rates seen in North Indian population (80.5%) (87). Direct comparison with other studies couldn't be done as definitions differ across various groups. Post-surgery, Statins have been shown to reduce the progression of native artery atherosclerosis, slow the process of vein graft disease, and reduce adverse cardiovascular events (89). Recent guidelines and studies (include trials) suggest usage of high dose statins (Atorva 80 mg or Rosuva 20 mg) rather than medium and lose dose statins (90,91).

Associated peripheral arterial diseases like carotid artery disease and lower extremity PAOD are common associations with CAD. Incidence of carotid artery disease in this study was 3.2% which is less as compared to patient population of SYNTAX and EXCEL trials (92). However, evidence so far does not suggest carotid artery disease is a significant risk factor for peri-operative stroke (93).

Peripheral extremity arterial disease was seen in 5.7% of patients. Recent ESC guidelines report the incidence to be between 7-16% and it carries worse prognosis (34). Recent retrospective multicentric study revealed greater incidence of stroke, acute kidney disease, and limb ischemia following CABG in patients with peripheral arterial disease (94). It is also an independent risk factor for late mortality (95).

Incidence of pre-operative CVA (4.2%) was comparable to other literature as in Danish population registry (5.5%) (78), in SYNTAX (6.7%) and in EXCEL trial (6.4%) (92). Hypothyroidism is relatively rare to be seen in association with CABG and few studies have shown subclinical hypothyroidism to be associated with cardiovascular morbidity and mortality. Chronic

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obstructive pulmonary disease is commonly seen in relation to chronic smoking habits of patients. Incidence in this study was 5.2% which is less compared to American population whose range is between 7-10%, whereas EUROSCORE trial has similar incidence of 3-5% (54,92).

Pre-operative renal dysfunction was seen in around 20% of the patients (S. creatinine > 1.4 mg/dl). Various trials have considered renal dysfunction with serum creatinine levels to be higher than 1.7 mg/dl or > 2 mg/dl and hence their incidence was roughly around 2-4%. Since our cut-off value for definition was lower, this could have led to higher incidence. Moreover, majority of patients with dysfunction had creatinine levels between 1.4 – 1.8 mg/dl.

Diabetes mellitus is a major risk factor predisposing patients to CAD and has several implications in selecting the nature of revascularization strategy with its variable effect on early and late post-operative major morbidity and mortality. Incidence of DM in this study was 52.9% (n=902), which is similar to a study (47.5%) done to assess the prevalence of cardiovascular risk factors in patients undergoing CABG surgery in north Indian population (87). Western data had significantly less incidence of DM as seen in various studies like northern England – 34.4%, Danish registry – 13%, EUROSCORE study – 25%, SYNTAX group – 26.1%, EXCEL group – 27.1% (54,78,92,96). However, studies with Egyptian population – 51.6% and south Asian population – 45.7% reflected similar incidence of DM (77,97). Higher incidence of DM in India is probably related to genetic predilection to abnormalities in glucose homeostasis.

Patients with coronary artery disease present with various clinical syndromes initially at the time of diagnosis. Most common presentation was with stable coronary artery disease. All the patients are initiated on optimal medical therapy before operation. Because of this, many patient's symptomatic status improved with 166 patients in asymptomatic status as compared to 33 at their

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initial presentation. Similarly, around 300 patients with ACS at their presentation were optimized to SCAD by the time of presentation. As few as 26 patients were having acute MI at the time of operation.

At our institution, patients with history of MI (including recent or old) is significantly higher (52.7%) as opposed to other registries. Incidence of MI in northern England registry was 44.7% (96) and Danish registry was 51%, whereas in large trials based in US, reported incidence was 21-24%. This higher incidence of MI in Indian population may be secondary to presentation during the initial event of ACS due to ignorance of initial stable cardiac symptoms; development of new ACS in a SCAD patient while awaiting operation; lack of accessibility to specialty care and thereby increased waiting time for the operation; referral to higher center following stabilization of initial hemodynamic status.

Timing of CABG following acute MI has been largely debated. Prior evidence suggested performance of surgery 5-7 days following the event. Our institution protocol was to delay surgery for three weeks for the initial episode to stabilize to avoid myocardial depression during the peri-operative period. CABG performed within 10 days of acute MI was associated with significant mortality especially in elderly patients and those with severe LV dysfunction (98). If operated within one day carries highest mortality as per other study (99). But recent studies are revealing improved outcomes if operated even within 48 hrs. (100).

However, some patients remain hemodynamically unstable or with on-going ischemia and require emergency operation. Few patients are in cardiogenic shock at the time of operation. Our study had 21 (1.2%) patients with shock. Comparison with other studies, incidence is slightly lower probably related to large number of patients unable to reach hospital before timely intervention.

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Congestive cardiac failure, secondary to chronic ischemic heart failure is another condition at the time of operation. Incidence in our study (3.2%) was less as compared to European and US based studies, where incidence ranges from 5-15%. All these patients are started on diuretic therapy before the operation.

In 454 patients (26.6%), family history was positive for CAD or MI. In contrast to prevalence study of north India, it is significantly low (26.6% Vs 54.5%). Study group in EXCEL trial also had very strong family history (62.9%) and in SYNTAX group, it was comparable to our study (29.5% Vs 26.6%).

Severe LV dysfunction with EF < 35% was found in only 34 patients (2%) of the study group. This incidence is very low as compared to various registries. This may be probably due to significant proportion of patients dying with only a smaller number of patients who were getting operated, while incidence might be slightly higher in CAD patients.

Moderate to severe mitral regurgitation secondary to CAD has been extensively studied. In this study incidence of moderate to severe MR was less as compared to western registries. Whereas, trivial to mild MR was present in almost all patients. This mild MR can be just an incidental finding also without any significant implications.

Reported incidence of significant LMCA stenosis was 2.5-17.5% in various presentations (101) across the literature. LMCA disease in this study was 17.2%.

Multivessel disease (68.7%) was more common in our study than double vessel (24.3%) or single vessel disease. Single vessel and double vessel diseases were considered for CABG as they are not amenable to PCI. Superiority of CABG over PCI is well established in various trials.

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Emergency operations constituted around 2.6% of all operations. In EUROSCORE study performed in various European countries, emergency operations were between 2-4.5% of all surgeries (54).

Almost all cases received at least one arterial graft, the most common anastomosis being left internal mammary artery to left anterior descending artery. Advantages of LIMA and its anastomosis to LAD has been proven earlier to provide superior early and late survival and better event-free survival after the operation (102). The long-term patency rate of arterial bypass conduits is very high, with 85% to 95% of grafts free of significant stenosis at 7 to 10 years (103). Its long-term patency rates are attributed to various physiological, anatomic, and hemodynamic characteristics(104).

Causes of occlusion of the arterial bypass grafts remain controversial. Competitive flow of the target vessel with moderate stenosis might lead to decreased antegrade flow in the arterial graft which might lead to graft occlusion. A study looking into these factors revealed that the degree of stenosis in the native vessel is a major predictor of internal mammary artery bypass graft patency. Also, IMA should be used cautiously in the treatment of native vessels with only mild or moderate stenosis (105).

The superiority of LIMA to LAD graft late patency as compared to SVG was shown as early as 1985. Its superiority persists even today despite multiple advances to improve vein graft performance. The superior patency of the ITA becomes even more prominent with longer follow-up. An angiographic study on patency rates for the LIMA and SVG at 10 and 15 years performed in symptomatic post-CABG patients, revealed higher patency rates in LIMA to be 95 and 88%, respectively, as compared to SVG rates of 61 and 32% at the same time (106).

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Another angiographic study published recently with 13 year follow up showed perfect patency was 96.8% for LIMA and 17.5% for SVG, which show that the majority of patent SVG had atheroma and the arterial grafts were normal. Nevertheless, patency rate of SVG was 82.5% with luminal irregularities (107). A recent meta-analysis of 52 studies revealed that overall graft patency was higher in the LCA than in the RCA system for both asymptomatic and symptomatic patients (108). Hence arterial grafting with IMA to the LAD system is recommended (COR: I, LOE: B).

Venous grafts were extensively studied as second conduit of choice. When compared at 1-year post surgery, there was no difference in angiographic patency between radial artery grafts and saphenous vein grafts in men (109). But however long-term patency studies suggested superior radial artery patency as compared to SVG and hence radial artery is the second conduit of choice in high grade stenosis (COR: I, LOE: B). There is sparse data on the clinical outcomes comparing LIMA with venous graft and TAR, one of such study have suggested that LIMA + venous grafts can be superior to total arterial revascularization in terms of MACCE (110). Second arterial graft should be considered depending on the patient's life expectancy, risk factors for sternal wound complications, coronary anatomy, degree of target vessel stenosis, graft quality, and surgical expertise (34).

When IMA is used as conduit, Skeletonized IMA dissection is recommended in patients with a high risk of sternal wound infection (COR: I, LOE: B). During venous harvest, Endoscopic vein harvesting, if performed by experienced surgeons, should be considered to reduce the incidence of wound complications (COR: IIa, LOE: A) and no-touch technique to be used during open harvesting (COR: IIa, LOE: B).

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Recent guidelines recommend complete myocardial revascularization (COR: I, LOE: B). But sometimes, complete revascularization is not achieved due to procedural difficulties. Incomplete revascularization in our study was 27.8% as compared to a study (22.7%) which looked into outcomes of patients with incomplete revascularization(IR) (111). Their study revealed that the impact of IR on the survival is marginal, if only one territory is ungrafted in patients receiving LIMA to LAD graft. If two territories are not vascularized, survival is reduced. In contrast, if surgery is performed off-pump, survival is affected even one territory is left behind.

In our study, predominantly all surgeries were performed on bypass with minimal fraction of 3% (n=51) were operated off pump when they needed only one or two anterior grafts. Several randomized trials compared outcomes of patients operated on or off pump. Literature is variable in terms of outcomes with each strategy and region. In Randomized On/Off Bypass (ROOBY) trial at 1-year outcomes, there were no significant treatment-related differences with regard to the short-term clinical outcomes, but patients in the off-pump group had a higher rate of the 1-year composite outcome than those in the on-pump group (112). Further follow-up in this randomized trial, off-pump CABG led to lower rates of 5-year survival and event-free survival than on-pump CABG (113).

Multiple meta-analysis was performed on this strategy. Filardo et.al in their meta-analyses concluded that evidence from RCTs showed no differences between the techniques. When observational studies are combined for analysis, indicated that off-pump CABG offers lower short-term mortality but poorer long-term survival (114). Study by smart et.al including six studies concluded that Statistically, on-pump CABG appeared to offer superior long-term survival, although the clinical significance of this may be more uncertain (115). A more recent meta-analysis

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with 104 trials by Guadino et.al revealed that OPCABG is associated with a higher incidence of incomplete revascularization, an increased need for repeated revascularization, and decreased midterm survival compared with ONCABG. Surgeon inexperience in OPCABG is associated with late mortality (116).

In this study, on an average patient received 3-4 grafts (mean 3.67). Mean cardiopulmonary bypass time (CPB) and aortic cross clamp times are slightly higher. This may be due to the significant proportion of patients undergoing endarterectomy and additional cardiac procedures. Endarterectomy was performed in 16.5% of patients. This is slightly higher as compared to other centers.

Post-operative complications:

Post-operative atrial fibrillation is an important risk factor for morbidity and mortality. Atrial fibrillation is the most common arrhythmia following coronary artery bypass surgery. Its incidence is variable roughly ranging from 5 – 40% across the studies (117,118). In this study, our incidence was 5% closer to the lower limit. We have adopted AF preventive strategies by initiation of beta-blocker therapy as early as inotropic supports have been taken off in the immediate post-operative period. AF is an independent predictor of many adverse outcomes, like increased risk of stroke, reoperation for bleeding, infection, renal or respiratory failure, cardiac arrest, cerebral complications, need for permanent pacemaker placement, and a 2-fold increase in all-cause 30-day and 6-month mortality (119).

Recent meta-analysis on new onset postoperative atrial fibrillation revealed that presence of AF in post CABG patients is associated with increased long-term risk of stroke compared with patients without new onset AF (120). Recent guidelines suggest perioperative beta blocker therapy

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for the prevention of post-operative AF in CABG surgery (COR: I, LOE: B). Restoration of sinus rhythm by electrical cardioversion or antiarrhythmic drugs is recommended in post-operative AF with hemodynamic instability (COR: I, LOE: C).

Role of warfarin at discharge is associated with reduced long-term mortality (121). Anticoagulation treatment with warfarin or non-vitamin K antagonist oral anticoagulants (NOACs) for stroke prevention should be based on using the CHA₂DS₂-VASc [Cardiac failure, Hypertension, Age >_75 (Doubled), Diabetes, Stroke (Doubled) – Vascular disease, Age 65–74 and Sex category (Female)] score. Individual assessment of patients should be carried out for the duration and timing of anticoagulants.

Reoperation for acute bleeding for CABG patients is a dreaded complication which increases morbidity and mortality with prolonged risk of infection, ICU stay and hospital stay (122). Incidence of reoperation for bleeding in our series was 1.8%, which largely corroborates with incidence as per various studies (123). Reported incidence varies from 2.2 – 4.2% (124).

In our institution, Reno protective measures are employed in patients with pre-operative renal dysfunction and patients who develop in the immediate post-operative period as creatinine > 1.5 mg/dl. All these patients are adequately hydrated and nephrotoxic antibiotics and analgesics are avoided. Dose modifications of Ecosprin from 150 mg to 75 mg is made and Tab. N-Acetyl cysteine and Tab. Sodium bicarbonate are administered till creatinine values returns to normal. Daily twice monitoring of s. creatinine levels are done. Patients with features of low urine output are initiated on furosemide infusion and intermittent bolus of a combination of Torsemide + Aminophylline + Mannitol is administered. Low renal dose of Dopamine infusion was started in the absence of response.

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Patients who fail to respond to these above measures with worsening renal function are started on dialysis. Mode of dialysis is dictated by the hemodynamic status of the patient, hemodialysis being the preferred modality as far as possible.

Post-operative kidney injury continues to be an important predictor of early and late mortality. Patients above 65 years of age with underlying CKD, may require lifetime renal replacement therapy. Identifying these at-risk individuals and proactive early intervention to optimize outcomes is extremely important (125).

Post-operative renal dysfunction was seen in 25.6% (n=436) of patients. Preoperative renal dysfunction is common in the CABG population and carries important prognostic importance. An STS, nation-based study revealed that operative mortality is higher as renal function declines. Mortality was 1.3% for those with normal renal function to 9.3% for patients with severe dysfunction not on dialysis and 9.0% for those who were dialysis dependent (126).

Another nation based study found that a small increase in the postoperative serum creatinine level was associated with an almost three-fold increase in the long-term risk of end stage renal disease in CABG patients (127). Similar to the above studies, we found corroboratively that patients who developed post-operative renal dysfunction had renal dysfunction pre-operatively ($p < 0.001$). Furthermore, among patients with pre-operative renal dysfunction (n=339), around 178 patients (52.5%) did not continue to be in renal dysfunction group post-operatively. This significant proportion can be likely due to two reasons – pre-operative renal status was assessed within 3 weeks of operation, which could have normalized by the time of operation and secondly, aggressive employment of reno protective strategies could have led to this effect.

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All our patient data is well corroborative with the earlier performed demographic analysis at our institution (128).

Early Mortality:

In-hospital or early mortality in our series was 2.3%. The 30-day mortality according to Society of Thoracic Surgeons (STS) database was 2.3% for isolated coronary artery bypass surgeries (129). Similar 30-day mortality rates ranging between 1% to 4% have been reported in various other large cardiac surgery data sets (130). A gender based CABG study in south India, close to our institution also reports similar early mortality rates around 3.2% (131). Surprisingly few registries based in Spain and Poland reported slightly higher in-hospital mortality rates [4-8%] (132,133).

Although there is slight variability among various factors studied, most of the studies show consistent association with mortality across the studies. Among demographic parameters, age was not found to have significant association in predicting early mortality. Female gender was associated with early mortality ($p < 0.001$; OR: 2.86; 95% CI: 1.48-5.55). Female gender has been consistently shown to predict increased in-hospital mortality in various studies (77,133,134). A large STS database study in their multivariate analysis indicated that women were at higher risk for OM than men (OR: 1.61, 95% CI - 1.40 to 1.84) (135). A recent meta-analysis had also showed a similar trend with OR of 1.36. Most common reasons hypothesized for this trend are the smaller diameter of coronary arteries and the less frequent use of LIMA grafts and bilateral internal mammary grafts (136).

Although multiple studies have shown that comparison of obese and non-obese patients early mortality was similar (137), our study found to have twice the risk for early mortality in

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obese patients ($p=0.039$, OR: 1.94, 95% CI 1.03-3.68). In another US based study found that morbid obesity is an independent predictor for late mortality but not early mortality (138). But, in our study, we did not find any association with late mortality. This finding in our population could have been due to decreased incidence of obesity in normal population and its presence could place these group of patients at high risk of DM, infection and pulmonary complications.

Diabetes mellitus was not found to predict risk for early mortality in this study. Similar findings were seen in few studies which found similar mortality rates among diabetic and non-diabetic patients (139,140). DM has been shown to have significant impact on long-term outcomes in various trials and non-randomized studies.

Hypertension was not found to have an association with early mortality. Dyslipidemia is associated with both early mortality as well as late MACC events. We found relative risk of 3.72 (95% CI: 1.47-9.45) for early mortality in patients with dyslipidemia ($p=0.003$). Similar association with early mortality was seen in a study from south India (131). This association could be due to high prevalence of dyslipidemia in our study population.

Patients with chronic obstructive pulmonary disease are a high-risk population for CABG. In this study, COPD carries a relative risk of 2.59 (95% CI: 1.04-6.46) for early mortality as compared to non-COPD patients. Many studies have found no association with early mortality, even though incidence of pulmonary complications, length of hospital stay and development of new onset post-operative atrial fibrillation are increasingly found in these patients (141). One study with similar demographic profile in India has shown its association with early mortality (131). But if COPD patients present with ACS and severe CAD, they carry higher risk of long-term and short-term death and postoperative infections (142). Another study stated that similar morbidity and

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mortality was seen in patients with or without COPD, when they were treated with off-pump CABG (143). In a recent propensity matched analysis of patients from EXCEL trial, COPD was independently associated with poor prognosis after LMCA disease revascularization (144).

There was no significant association with pre-operative renal dysfunction, initial presentation as acute coronary syndromes or past history of MI to early mortality.

Cardiogenic shock is one of the most dreadful complications following acute myocardial infarction, which is an indication for emergent CABG, where PCI is not amenable. SHOCK trial results demonstrated that long-term outcomes are better with revascularization with reduced 6-month all-cause mortality (72). In this study, cardiogenic shock is significantly associated with early mortality [$p < 0.001$, (RR:14.15, 95% CI: 6.66-30.07)].

Davierwala et.al found that emergency CABG in these patients was associated with high 30-day mortality, and is independently predicted by severe preoperative hemodynamic instability and presence of STEMI and satisfactory long-term survival is observed in patients who survived the operation, demonstrating the benefit of emergency CABG (145). Early surgical intervention when performed is associated with significant 1-year survival benefits and improvements in functional class (146). There appears to be higher rates of permanent stroke and mortality in patients with an unresponsive pre-operative neurologic state following CABG for cardiogenic shock (147).

Presence of pre-operative congestive cardiac failure predicts early mortality ($p < 0.001$). it carries a relative risk of 11.6 with (95% CI: 6.12-21.97). Results of STICH trial have clearly demonstrated the benefit of surgical revascularization in patients with ischemic heart failure with reduced EF with acceptable 30-day mortality (5.1%) (148). In our series, we found high early

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mortality in this group, this may be probably related to inadequate control of failure before the operation. A history of HF was an important risk factor for poor short-term and long-term outcomes after CABG regardless of preoperative EF. Reduced EF doubled the risk of early death after CABG (149).

Our study revealed significant association of patients having functional class III-IV at the time of operation to early mortality ($p=0.004$, RR:4.02, 95% CI: 2.17-7.46). This poor functional class almost always correlate with poor LV function with $EF \leq 45\%$. Similarly, patients with moderate to severe LV dysfunction independently predicted the risk for early mortality ($p<.001$). Patients with severe dysfunction carries 2.8 times higher risk of mortality as compared to patients with mild dysfunction and good LV function (95% CI: 1.36-5.78).

Many trials and observational studies have superiority of survival in CABG as compared to medical therapy alone in patients with ischemic cardiomyopathy. A retrospective study from south India by Jose et.al found that CABG in ischemic cardiomyopathy was associated with high early composite outcomes. But, survival rate at 5-year follow-up was good. Failure to improvement in LV function was a strong predictor of late mortality (150). In another study by Nardi et.al, found that complete revascularization and IMA grafting are associated with high freedom from MI and excellent long-term results can be expected in patients with low LVEF (≤ 0.35). Aggressive management of arrhythmias, diabetes, and renal dysfunction is necessary to improve long-term survival (151).

Higher early compared to late mortality after coronary revascularization was seen in another study (152). Few studies quoted that $EF \leq 35\%$ was not predictor of in-hospital mortality in patients underwent CABG (153).

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Moderate to severe mitral regurgitation carries 4.6 times relative risk of early mortality ($p < 0.001$, RR: 4.6, 95% CI: 2.18-9.67) in our study. MR was also shown to be an independent predictor of long-term adverse outcome in our study [$p = 0.001$, RR: 2.28, 95% CI: 1.43-3.64]. Literature is replete with studies on the concept of management of MR with CABG. When ischemic MR is associated with reduced EF (40% or less), there was an increase in cardiac-related deaths and events, and MR promotes left ventricular remodeling (154). In patients with moderate IMR, improvement in functional class was seen either by CABG alone or CABG with MV repair. Early and intermediate-term mortality rates were similar in both groups (155). Further, addition of MV surgery increased the risk of early mortality and complications (156).

Recent CTSN (Cardiothoracic Surgical Trials Network) trial showed that additional surgical MV repair to CABG made no significant difference to survival, overall reduction of adverse events, or LV reverse remodeling at 2 years. Further, repair group was shown to have increased ICU and hospital stay and perioperative morbidity, including neurological complications and supraventricular arrhythmias (157). Recent EACTS guidelines suggest MV surgery is indicated in patients with severe secondary MR undergoing CABG and LVEF $> 30\%$ (COR: I, LOE: C) and MV surgery should be considered in symptomatic patients with severe secondary MR and LVEF $< 30\%$, but with evidence of myocardial viability and an option for surgical revascularization (COR: IIa, LOE: C) (34).

Presence of wall motion abnormality did not reveal any association with early mortality (RR: 0.92, 95% CI: 0.92-1.71). Left main coronary disease or presence of triple vessel disease (multi vessel disease) did not confer additional risk of early mortality. Elective operation was seen to be protective against early mortality [$p < 0.001$, RR: 0.09, 95% CI: 0.05-0.18]. Early mortality

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rate in emergency surgery was higher than elective surgery (20% Vs 1.9%). However, it was not found to be an independent predictor of in-hospital mortality. Our mortality rates are comparable to other series in literature (158). This early mortality is particularly more in elderly population as compared to younger patients, but however substantial improvement is noticed with particular addressal of long-term renal failure and heart failure (159). Despite these risks, long-term survival is acceptable in emergency operations and as such, these are justified in most patients (160).

Additional intracardiac procedures or coronary endarterectomy did not increase the risk of early mortality in our study (RR: 0.062 and 0.305) respectively.

Prolonged cardiopulmonary bypass time and aortic cross clamp time are significantly associated with early mortality ($p=0.01$). This can be expected as this will lead to prolonged myocardial suppression and delayed recovery of hemodynamic status. Added to that, any comorbid illness in the patient will predispose to increased risk of mortality. In this study, mean CPB time in patients with early mortality was 104.4 min ($p=0.001$) and mean ACC time was 57.5 min ($p=0.001$). Similar findings with increased mortality and increased ROC curves was noticed with prolonged CPB and ACC time in an Egyptian study (77).

Few post-operative complications further aggravate the risk for in-hospital mortality. The most important ones are re-exploration for bleeding, LV support in the form of IABP, Post-operative new onset AF, uncontrolled sugars and deep SSI in our study. In our study, re-exploration was carried out for either bleeding or acute graft occlusion. Re-exploration for sudden unexplained hypotension or cardiac arrest in the absence of other obvious causes is considered as acute graft occlusion and it had significant association with early mortality ($p=0.006$, RR:4.38, 95% CI: 1.43-13.44).

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Re-exploration for bleeding is a lethal and morbid complication of cardiac surgery (161). Many studies support risk of early mortality following re-exploration for bleeding, although we couldn't find such association in our study (131). Excessive bleeding leading to re-exploration is associated with a two-fold increased early postoperative mortality rate (162).

Various risk factors associated with in-hospital mortality for bleeding have been identified as older age, smaller BMI, emergency cases, 5 or more distal anastomoses, preoperative aspirin and heparin for on-pump cases. If re-exploration time is prolonged, they are at higher risk of complications. Hence early re-exploration should be encouraged (163,164). Our institution policy is directed by early return to OR for re-exploration in cases of bleeding with low-threshold and this might be cause for our low mortality in bleeding cases. This is also supported by a study in south India where early re-exploration reduced morbidity and mortality (165).

Post-operative LV support in the form of IABP carries a relative risk of 32.7 compared to those without requiring support ($p < 0.001$, 95% CI: 19.05-56.17). Similar results were found in study by Verma et.al (131). While the recent IABP-SHOCK II trial in patients with acute MI complicated by cardiogenic shock, revealed no difference in 30-day mortality between patients randomized to receive an IABP versus those who were not (166). A meta-analysis revealed that in patients with AMI without CS, IABP may reduce the 30-day and 6-month mortality rate (167).

In our study, DM was more common and mere presence of it did not result in increased early mortality. However, those patients who developed uncontrolled sugars in the post-operative period are at greater risk for early mortality ($p = 0.007$, RR: 2.36, 95% CI: 1.25-4.46). Further these group of patients were also at increased risk of developing deep surgical site infections

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(mediastinitis). Deep SSI itself was an independent predictor of in-hospital mortality (RR: 5.43,95% CI: 2.59-11.38).

Multiple studies looked into factors causing deep SSI and their effect of patient outcomes. An analysis of 42 studies diabetes mellitus and obesity are by far the chief preoperative risk factors (168). In other study, risk factors identified were older age, obesity, COPD, DM, critical preoperative state, postoperative vasopressive support, transfusion or prolonged ventilation and Bilateral IMA use in female patients (169). Also identified were re-thoracotomy for bleeding and sternum instability as independent predictors for an increased sternal SSI rate (170). SSI after CABG can be reduced using evidence-based practice and structured problem-solving to identify risk factors (171).

MACCE:

Major adverse cardiac and cerebrovascular events define the long-term morbidity and mortality of revascularization strategies. Various randomized trials and non-randomized studies have led to the development of guidelines to choose optimal strategy of revascularization. In patients with multivessel disease and high SYNTAX scores with diabetes mellitus or left main coronary disease, CABG is the preferred revascularization strategy (34,172).

In our study, over a mean follow-up period of 7.8 years, cumulative MACC event rate was 15.8% at 10 years. The event rate is slightly lower in our study, when seen with other major registries or comparative trials with almost similar population. Further, we noticed that MACCE rate was highest 5-10 years after the surgery and during the first year following operation.

Post-operative stroke on follow-up remains the most devastating complications of cardiac surgery. Its incidence roughly ranges between 1.6-5.2% (173). We had similar incidence in our

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study with 3.7%. Majority of stroke was seen as cardioembolic stroke rather than hemorrhagic stroke.

Acute coronary syndromes during follow-up was seen in 32 patients (1.9%). This low incidence can be due to significant drop rate during follow up. It might also indicate that one arterial (LIMA to LAD) and other venous grafts could provide good freedom from MI at 10-year follow-up. This could not be concluded due to lack of angiographic evidence and incomplete follow-up.

These late MACC events are affected by both patient-related and procedure related factors. Development of post-CABG angina recurrence, MI, need for reintervention, and cardiac-related mortality are largely dependent on the progression rate of native coronary atherosclerosis after surgery and the development of graft failure. Procedure-related factors that influence long-term outcomes include completeness of revascularization, myocardial protection, and selection of bypass conduits.

Various pre-operative and post-operative characteristics affect and predict the occurrence of long-term MACCE. Among the variables assessed on logistic regression analysis, we found that pre-operative diabetes mellitus, dyslipidemia, history of CVA, congestive cardiac failure at presentation, moderate to severe mitral regurgitation, prolonged CPB and ACC times, performance of additional intracardiac procedures, uncontrolled sugars in the immediate post-operative period are known to independently predict the MACC events.

Diabetes mellitus is associated with significant long-term MACC events ($p=0.024$). These patients have relative risk of 1.42 (95% CI: 1.05-1.94). Similar study by Kamel et.al also found similar association (77). FREEDOM trial has proven superiority of CABG over PCI in patients

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with multivessel disease and diabetes with respect to primary endpoints (174). A study assessing risk in terms of HbA1c in relation to type 2 diabetes found that HbA1c 6.1-7.0% was associated with a lower risk of MACE and unstable angina and lower risk of death when HbA1c \leq 6.0% (175).

Another published study in JACC from Sweden stated that patients with insulin dependent DM were at high risk for death or MACE during medium-term follow-up. They also further observed that elevated preoperative HbA1c levels with poor glycemic control were significantly associated with an increased risk for all-cause mortality or MACE and was more than double that in patients with type 1 DM who had adequate glycemic control (176). Hence higher HbA_{1c} was associated with reduced long-term survival (177,178).

In our study, even though HbA1c levels were not collected, DM was seen to have significant association. Furthermore, patients who developed uncontrolled sugars in the post-operative period had 1.56 times risk compared to those who had controlled sugars (95% CI: 1.12-2.19). These set of patients are likely to represent those with higher levels of HbA1c and inadequate glycemic control conferring risk of long-term MACCE.

Dyslipidemia was seen to be associated with both in-hospital and long-term MACCE (p=0.016, RR:1.51; 95% CI: 1.08-2.13). This long-term association could be explained through risk of on-going atherosclerosis in this subgroup of patients.

Pre-operative stroke has been shown to have increased predilection for long-term MACCE in our study [p=0.001, RR:2.30, 95% CI: 1.40-3.76]. In a nation-wide data analysis study of 62,104 patients in UK, pre-operative stroke influenced mortality, postoperative stroke and prolonged length of stay. Further, they also mentioned that the time interval between stroke and CABG did

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not influence mortality or prolonged length of stay. But, if longer time interval is present before operation, mild increase in risk of postoperative stroke was seen. In particular, when MI occurred in pre-operative stroke patients, risk of death is increased (179). Study by Kamel et.al also found association of adverse events with prior stroke or CVA.

This increased risk could be due to two reasons. First, these patients carry inherent risk of developing stroke later due to on-going atherosclerotic risk factors or other comorbidities predisposing them to be at higher risk than other patients, secondly our study also includes patients with CABG and other intracardiac interventions like valve management or intracardiac defect closure which might have placed them at non-CABG related risk. Few others could have developed secondary to arrhythmias also.

Ischemic heart failure carries a relative risk of 2.60 (95% CI: 1.48-4.58) for long-term adverse events. Survival benefit of surgical revascularization over medical therapy has been proven by STICH trial and extended STICH study (53,180).

Though functional class severity and moderate to severe LV dysfunction had association with early mortality, they did not predict long-term adverse outcomes. Performance of additional procedures confer a relative risk of 2.56 times when compared to isolated CABG alone. These patients either comprised of valve procedures or operations for mechanical complications of CABG. Patients with additional valve procedures could have developed adverse events in relation to their anticoagulation or degenerative changes. Patients with procedures for mechanical complications constitute sicker group with expected poor outcomes and increased long-term adverse events.

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Similar to risk for early mortality, prolonged CPB and ACC times are associated with significant MACCE ($p=0.006$ & $p=0.046$) respectively. This can be partly attributed to additional procedures required along with CABG.

Freedom from reintervention rate at 10-year follow up was 95.5%. Freedom level in our study is better than seen with other trials. However, freedom from symptom onset was as low as 49.4% by 10 years. This low freedom rate could be due to inclusion of all symptoms (apart from angina) and subjective variability of assessment of symptomatic status.

CONCLUSION

A total of 1705 consecutive patients who underwent coronary artery bypass surgery (CABG) were retrospectively studied. Mean age of patients was 55 ± 8.8 years. Patient's comorbid profile was similar to our previous analysis and to other study performed in south Indian population, with minor deflections from a north Indian study.

Among comorbidities, Diabetes Mellitus (52.9%), Hypertension (59.1%) and Dyslipidemia (65.3%) are quite prevalent with more than half of patients. Obesity was less prevalent in our study patients as compared to north Indian population (21.7%). Renal dysfunction was more prevalent (19.9%). Majority of patients (66.5%) presented with stable coronary artery disease and 31.5% presented with acute coronary syndromes, whereas 52.7% (n=898) patients had history of myocardial infarction.

Coronary angiogram revealed 294 (17.2%) patients to have left main coronary disease and about 68.7% had triple vessel disease. Almost all operations (96.6%) were performed on CPB on an elective basis (97.4%). Bypass grafting pattern was predominantly one arterial (LIMA-LAD) + other venous grafts in 95.5% cases with only 0.7% receiving purely venous anastomosis. Mean grafts in a patient were 2.66 ± 1.03 . 16.5% of patients received coronary endarterectomy and additional intracardiac procedures were performed in 71 (4.2%) patients.

The most common post-operative complications in this study are re-exploration for bleeding (1.8%), atrial fibrillation (5%), renal dysfunction [25.6% (dialysis dependent=0.8%)], uncontrolled sugars (18.6%), deep surgical site infection (4.4%). Forty patients (2.3%) suffered from in-hospital mortality with cardiogenic shock, renal failure and sepsis being the most common causes of death.

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Obesity, female gender, dyslipidemia, cardiogenic shock and congestive cardiac failure at operation, Functional class III-IV, moderate to severe LV dysfunction, moderate to severe mitral regurgitation, prolonged CPB and ACC times, post-operative IABP support, uncontrolled sugars and development of deep SSI predicted risk factors for early mortality.

Mean follow-up period was 7.7 ± 2.6 years. Long-term MACCE (composite death, stroke, myocardial infarction, reintervention) at 10 years was 15.8% with majority of events occurring within 1 year or 5-10 years following operation. Patient's age, DM, dyslipidemia, pre-operative CVA, congestive cardiac failure, moderate to severe MR, prolonged CPB and ACC times, additional intracardiac procedure along with CABG and post-operative uncontrolled sugars were independently associated with long-term MACCE events.

Post-operative stroke and acute coronary syndromes were seen in 3.7% and 1.9% (crude event rate) of patients during 10-year follow up. Survival of freedom from re-intervention was 95.5% at 10-years and more than 50% of patients developed symptoms by 10 years. Overall cumulative actuarial survival at 10 years was 94.4%. Survival rates at 1 year and 5 year were 97.5% and 96.8% respectively.

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In-hospital and long-term outcomes of CABG – A single center experience.

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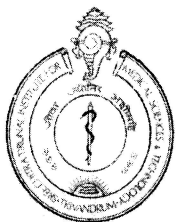
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Sources included in the report



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SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM – 695011, INDIA

16

TAC Registration No: SCT-/S/2018/853

Date: 21.11.2018

Project title: MID AND LONG TERM RESULTS OF CORONARY ARTERY BYPASS SURGERY – A SINGLE CENTER EXPERIENCE.

| |
|--|
| Principal Investigator: |
| Dr. Sameer MD, Resident, Department of CVTS, SCTIMST Degree: MBBS, M.S, MRCS(L) |
| Co-Principal Investigator(s) |
| Dr. Binu K.R, Assistant Professor, Department of CVTS, SCTIMST Degree: MBBS, M.S, M.Ch (CVTS) |
| Dr. Jaya Kumar. K, Professor and Head, Department of CVTS, SCTIMST Degree: MBBS, M.S, M.Ch (CVTS) |
| Dr. Harikrishnan.S, Professor, Department of Cardiology, SCTIMST Degree : MBBS,M.D,D.M (Cardiology) |

Members who participated in the TAC meeting on 03/11/2018

Dr. Rupa Sreedhar (Chairperson)
Dr. Prasantakumar Dash
Dr. Krishna Kumar K
Dr. Sankara Sarma P
Dr. Ashalatha. R
Dr. Bijulal S
Dr. Jayadevan ER
Dr. Syam K
Dr. Sanjay G
Dr. Varghese T. Panicker
Dr. K. Shivakumar (Member Secretary)

Dr. Syam K, Dr. Prasantakumar Dash, Dr. Rupa Sreedhar, Dr. Varghese T. Panicker, Dr. Krishna Kumar K and Dr. Sanjay G stayed away from the proceedings when the projects in which they are involved as investigator were discussed (# 844,845,846,849,852,856,857).

Risk Classification of the project (Minimum/ Moderate/ High): Minimum

Requirement of DSMB: No

Recommended members of DSMB: Not applicable

Recommendations of TAC:

Recommended for consideration of IEC in the light of the responses received from the investigator

The PI may note that there can be no additions / alterations in the documents approved by TAC when they are submitted to the IEC.

Signature of the Member Secretary, TAC (Clinical Studies)

Note for IEC

Copy of the investigator's responses to questions/suggestions from TAC is attached (Appendix-1).



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया

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

SCT/IEC/1331/FEBRUARY-2019

18.02.2019

Dr. Sameer MD
Resident
Department of CVTS
SCTIMST, Thiruvananthapuram

Dear Dr. Sameer,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "MID AND LONG TERM RESULTS OF CORONARY ARTERY BYPASS SURGERY – A SINGLE CENTER EXPERIENCE (IEC/1331)" on 16th February, 2019.

The following documents were reviewed:

1. *Covering Letter addressed to the Chairman, IEC, SCTIMST with checklist*
2. *TAC Approval Letter*
3. *IEC Application Form*
4. *Declaration form*
5. *Project Proposal*
6. *Proforma*
7. *CV of Principal Investigator and Co-Principal Investigators*

The following members of the Ethics Committee were present at the meeting held on 16th February, 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. Rema M. N | MD | Female | Basic Medical Scientist | No |
| 3. | Dr. Kala Kesavan. P | MBBS, MD | Female | Basic Medical Scientist | No |
| 4. | Dr. Harikrishna Varma PR | Ph.D(Materials Science) | Male | Medical Technology | Yes |
| 5. | Dr. Christina George | MD Psychiatry | Female | Clinician | No |
| 6. | Dr. S S Giri Sankar | LL.M. Ph.D. | Male | Legal Expert | No |
| 7. | Dr. Aneesh V Pillai | BA. LLB (Hons.), LLM, Ph. D, SET (Law) | Male | Legal Expert | No |
| 8. | Dr. P. Manickam | BSMS, MSc (Epid), PhD | Male | Health Science Expert/ Social Scientist | No |
| 9. | Mr. Satheesh Chandran | MSW, PGDPM | Male | Lay person/ NGO/ Social Scientist | No |
| 10. | Dr. Harikrishnan S | MD, DM (Cardiology) DNB (Cardiology) | Male | Clinician | Yes |
| 11. | 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

DATA COLLECTION SHEET

Demographics:

Serial No.

Date of surgery

Month of surgery

Year

Age

Gender: 0-male,1-female

BSA

Clinical characteristics:

Co-Morbidities

Smoking # 0-No, 1-Current, 2-within 10 years, 3-more than 10 years

Obesity # 0-No, 1-Yes

Diabetes # 0-No, 1-Type I, 2-Type II.

Hypertension # 0-No, 1-Yes.

Dyslipidemia # 0-No, 1-Yes.

Hypothyroidism # 0-No, 1-Yes.

Pre-Op PCI # 0-No, 1-Yes, 2-Failed.

Cerebrovascular Accident # 0-No, 1-Yes.

Peripheral Vascular Disease # 0-No, 1-Yes.

Chronic Obstructive Pulmonary disease # 0-No, 1-Yes.

Carotid artery disease # 0-No, 1-Yes.

Renal dysfunction # 0-No, 1-Creatinine >1.4mg/dl, 2-Dialysis dependent

Surgery-CABG # 0-Primary, 1-Redo CABG.

Clinical Presentation:

Initial presentation # 0-Asymptomatic, 1- SCAD, 2-Unstable angina, 3-NSTEMI, 4-STEMI.

Current symptomatic status # 0-Asymptomatic, 1- SCAD, 2-Unstable angina, 3-NSTEMI, 4-STEMI.

MI # 0-No, 1-Recent, 2-Old.

Recent MI # 0-N/A, 1-NSTEMI, 2-STEMI

Old MI # 0-N/A, 1-NSTEMI, 2-STEMI

Cardiogenic shock # 0-No, 1-Yes

Congestive cardiac failure # 0-No, 1-Yes

NYHA class symptoms ##

Diuretic therapy # 0-No, 1-Yes

Family history of CAD # 0-No, 1-Yes

ECG # 0-SR, 1-AF, 2-VPC's occasional, 3-RBBB, 4-LBBB, 5-Paced Rhythm, 6-Other.

CXR-Cardiomegaly # 0-No, 1-Yes.

ECHO:

LV function-EF ##

Grading of LV function # 0-Good LV, 1-Mild LVD, 2-Moderate LVD, 3-Severe LVD.

MR # 0-No, 1-Trivial, 2-Mild, 3-Moderate, 4-Severe.

Cause of MR # 0-No, 1-Ischemic, 2-Rheumatic, 3-Degenerative

RWMA # 0-No, 1-Yes

Territory _____

CAG characteristics at presentation:

Number of stenotic vessels: #

LMCA disease # 0-No, 1-Yes

Diseases territories # 1-SVD, 2-2VD, 3-TVD

Operative characteristics:

Surgery # 1-Elective, 2-Emergency

Number of total grafts #

Number of venous grafts #

Type of revascularization # 1-ONCAB, 2-OPCAB, 3-Onpump beating heart

CPB time ###

ACC time ###

Endarterectomy # 0-No, 1-Yes.

Additional procedures # 0-None, 1-MV repair, 2-MVR, 3-AVR, 4-ASD closure, 5-Apical plication, 6-VSR Repair, 7-Dor, 8-VSD closure and other procedures, 9-5+6.

Intrahospital complications:

Reoperation # 0-No, 1-Bleeding, 2-Acute graft occlusion-hypotension/arrhythmia

Arrhythmias # 1-No, 2-AF, 3-Ventricular ectopics, 4-Intervention-ablation, 5-ICD Implantation.

DC version # 1-No, 2-For AF, 3-For ventricular arrhythmias/VT.

Perioperative MI # 1-No, 2-Yes.

Postoperative renal dysfunction # 1-No, 2-Yes, 3-Dialysis

CVA - # 1-No, 2-Transient, 3-FND

LV support - IABP # 1-No, 2-Yes

Uncontrolled sugars # 1-No, 2-Yes

Deep SSI # 1-No, 2-Conservative, 3-Debridement & rewiring, 4-Flap reconstruction, 5-Debridement & resuturing.

Early mortality # 1-No, 2-Yes

Cause of mortality # 1-No, 2-Cardiogenic shock, 3-Sepsis-pneumonia, 4-Sepsis-Other, 5-Arrhythmias, 6-Deep SSI – sec He, 7-Stroke, 8-Sudden cardiac death, 9-Renal, 10-Acute Mesenteric Ischemia.

Post-operative follows up:

Aneurysm Association # 1-No, 2-Yes

Post-Op Major Morbidity # 1-No, 2-Hepatic dysfunction, 3-Malignancy

Post-Op major intervention # 0-None, 1-IRAA Repair, 2-TAAA Repair, 3-PAOD intervention, 4-Malignancy treatment – Surgery or CRT.

Latest follow up ##

Symptoms # 1-Asymptomatic, 2-Angina, 3-Dyspnea, 4-Failure, 5-ACS, 6-Stroke, 7-giddiness/presyncope/syncope, 8-Others.

Year of symptom onset #####

CVA # 1-None, 2-Cardioembolic stroke, 3-Haemorrhagic stroke

Year of stroke #####

ACS # 1-None, 2-Unstable Angina, 3-NSTEMI, 4-STEMI.

Year of ACS #####

Additional Neurological dysfunction # 0-None, 1-Seizures, 2-Parkinson's disease, 3-Alzheimer's disease, 4-Pshychiatric illness, 5-Degenerative brain disease.

Symptomatic status at last follow up # 1-Asymptomatic, 2-Angina, 3-Dyspnea, 4-Controlled HF, 5-Fatigue, 6-others.

NYHA class @ last follow up #

ECG changes # 1-SR, 2-AF/Flutter, 3-Occasional atrial ectopics, 4-Ventricular ectopics, 5-RBBB, 6-LBBB, 7-other block, 8-Paced rhythm

Intervention for arrhythmias # 1-None, 2-Ablation, 3-ICD, 4-PPI

ECHO

LV function-EF ##

Grading of LV function # 0-Good LV, 1-Mild LVD, 2-Moderate LVD, 3-Severe LVD.

RWMA # 1-No, 2-Yes

Territory _____

Diagnostic modality # 1-None, 2-CT CAG, 3-Conventional CAG, 4-TMT

TMT # 1-Negative, 2-Positive

Year performed #####

Patency of grafts # 1-Not applicable, 2-All patent, 3-Arterial block only, 4-Venous block only, 5-Both

Number of grafts blocked #

Number of grafts patent #

Venous grafts blocked #

LIMA arterial graft patency # 1-Patent, 2-Blocked

Re-intervention # 1- Optimal Medical Therapy, 2-PCI, 3-Re-CABG

Year of re-intervention #####

Re-reintervention # 1-Optimal Medical Therapy, 2-PCI, 3-CABG

Year of re-intervention ####

Current status # 1-Alive, 2-Death

Year of Death ####

Cause of death # 1-None, 2-Cardiac, 3-Noncardiac

