OUTCOMES OF CORONARY ARTERY DISEASE PATIENTS WITH SEVERE LEFT VENTRICULAR DYSFUNCTION UNDERGOING SURGICAL MANAGEMENT

Thesis Submitted By

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Declaration

I, **Dr Srawanthi Ponnuru**, hereby declare that this thesis titled *"Outcomes of coronary artery disease patients with severe left ventricular dysfunction undergoing surgical management"* has been prepared by me under the capable supervision and guidance of

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Certificate

We hereby certify that this thesis titled

"Outcomes of coronary artery disease patients with severe left ventricular dysfunction undergoing surgical management" is the bonafide work of **Dr Srawanthi Ponnuru**, MCh CVTS resident, done under our guidance at Department of Cardiovascular and Thoracic Surgery at Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram.

She has shown keen interest in preparing this project.

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"Outcomes of coronary artery disease patients with severe left ventricular dysfunction undergoing surgical management"

Is the bonafide record of work done by **Dr Srawanthi Ponnuru**, MCh CVTS resident, done at Department of Cardiovascular and Thoracic surgery at Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram.

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30-08-2020
Thiruvananthapuram

Dr Srawanthi Ponnuru

CONTENTS

ABBREVIATIONS AND EXPANSIONS

CAD	CORONARY ARTERY DISEASE
SEV LVD	SEVERE LEFT VENTRICULAR DYSFUNCTION
CABG	CORONARY ARTERY BYPASS GRAFTING
EF	EJECTION FRACTION
MR	MITRAL REGURGITATION
LV	LEFT VENTRICLE
DM	DIABETES MELLITUS
HTN	HYPERTENSION
DLP	DYSLIPEDEMIA
G	GRAFTS
LAD	LEFT ANTERIOR DESCENDING ARTERY
OM	OBTUSE MARGINAL
RCA	RIGHT CORONARY ARTERY
CPB	CARDIOULMONARY BYPASS
LIMA	LEFT INTERNAL MAMMARY ARTERY

TITLE

Outcomes of *coronary artery disease patients with severe left ventricular dysfunction undergoing surgical management*

Synopsis

Background: CABG in patients with severe Left ventricular dysfunction has been shown to have survival advantage over medical therapy, but was historically associated with higher hospital mortality and morbidity. Preoperative severe left ventricular dysfunction in patients with coronary artery disease is a well-known risk factor for early and late outcomes after revascularization. In this high risk group of patients coronary artery bypass grafting with or without ventricular restoration remains a surgical challenge. Most of these studies in literature are from developed countries and on western patients. So this represents a need for a study on Indian population where the risk profile and socio economic status is different from the studies in literature.

Materials and methods : One hundred and forty six **(**146) consecutive patients who underwent CABG or CABG with ventricular restorative procedures or for coronary artery disease patients with severe left ventricular dysfunction between January 2010 and December 2014 are studied after considering inclusion and exclusion criteria.

Results and observations : Mean age of study population is 55.63± 8.74.The results of this study are encouraging with excellent mid term outcomes with 5 year survival reaching 84%. Our study had found to have a operative mortality of 5.47% and a early outcomes (within 30 days of surgery) was found to be 7.53%. significant improvement in postoperative Ejection fraction compared to Preoperative Ejection fraction 10.4± 5.84 (95%CI – 8.744 to 12.075, P<0.0001)

Conclusion: From our study we conclude that CABG and CABG with ventricular restorative procedures remain a viable option for patients with severe LV dysfunction , in view of better early outcomes and excellent midterm suvival probabality reaching standards of western studies who dominate the current literature

.There is a need for further larger studies and to maintain a central registry in India like in western world on patients with severe left ventricular dysfunction undergoing surgical management , thereby outcomes can be better understood and surgical management in Severe LVD patients can be encouraged.

INTRODUCTION

Despite the improvement in medical therapies and surgical techniques, the management of Patients with coronary artery disease with low ejection fraction remains challenging. Patients with low Ejection fraction are at higher risk of sudden death, Ventricular arrhythmia and worsening heart failure due to left ventricular dysfunction

CABG in patients with severe Left ventricular dysfunction has been shown to have survival advantage over medical therapy, but was historically associated with higher hospital mortality and morbidity. Advances in preoperative management, refinements in surgical techniques- use of coronary artery bypass grafting with or without ventricular restorative procedures, and advances in cardiac anaesthesia with improvement in intensive care all have resulted in decreased mortality rate in patients with low Ejection fraction (EF) undergoing surgical management(1).

Preoperative severe left ventricular dysfunction in patients with coronary artery disease is a well-known risk factor for early and late outcomes after revascularization. In this high risk group of patients coronary artery bypass grafting with or without ventricular restoration remains a surgical challenge(2) .In India studies done on patients with coronary artery disease and severe left ventricular dysfunction undergoing surgical management are their outcomes are less known . As per literature most of the studies on this high risk group are American based or European based studies. As surgical management of patients with Coronary artery disease with severe left ventricular dysfunction is a common in our institution, we find ourselves a need to verify the real outcomes of patients undergoing Coronary artery bypass grafting with or without ventricular restorative procedures for Coronary artery disease with severe Left ventricular dysfunction

AIM OF THE STUDY

Main aim of this work is to evaluate and analyze effects of preoperative variables , operative outcomes and postoperative critical care in coronary artery disease Patients with severe Left ventricular dysfunction underwent surgical management , So as to render surgical management in this high risk group more objective.

REVIEW OF LITERATURE

HISTORICAL NOTE:

Sones and Shirey developed coronary cine angiography at Cleveland clinic during early 1960 made possible direct identification of stenotic and occlusive coronary atherosclerotic lesions and laid foundation for Coronary artery surgery.

Montreal, Veinberg and Miller in 1951 reported direct implantation of Internal thoracic artery into the myocardium(3). Murrey and collegues in 1954 considered a direct surgical approach to Coronary artery disease (CAD) by experimenting anastomosis of ITA to a coronary artery(4). Longmire and colleagues at university of California in Losangeles reported a direct vision coronary endarterectomy without cardiopulmonary bypass(5). In 1961 senning reported patch grafting of stenotic coronary artery(6). Favaloro and Effler in May 1967 at the Cleveland clinic performed reversed saphenous vein bypass grafting(7). Milwaukee, Flemma Johnson in 1971 described the technique of sequential grafting(8) . Bilateral ITA grafting was performed by 1972.

DEVELOPMENT OF CORONARY ARTERY STENOSIS:

Atherosclerosis common form of arteriosclerosis, a process that occurs in coronary arteries consists of Focal intimal accumulation of lipids, complex carbohydrates, fibrous tissue blood and its products and deposits of calcium .There will be associated changes in Media.These Lipoid foci are converted into fibrous or hyaline connective tissue plaques(9). Stenotic lesions are produced when these fibrolipoid foci encroaches onto lumen of artery. On the luminal side of plaque ,episodically new material is deposited resulting in further narrowing, sometimes it leads to complete occlusion of coronary artery. Antegrade regional myocardial blood flow will develop with the development of collateral coronary flow(10). Suddenly Atherosclerotic plaque rupture

and thrombosis occur by haemorrhage within plaque, will increase or precipitate the coronary stenosis, thereby leading to Acute Myocardial infarction (MI) or Unstable angina pectoris.Following this process there will be rapid recanalization. Platelet aggregation over the ruptured plaque releases the Thromboxane A2 (potent Vasoconstrictor).Interrelationships among platelet aggregation, coronary spasm and atherosclerotic narrowing are important in development of Acute Myocardial infarction. 95% of patients with atherosclerotic complete occlusion had major stenosis in other 2 arteries. Left main coronary artery is majorly stenotic in 10-20% of patients. In the middle third of LAD and sometimes one or all branches of Obtuse marginal of circumflex artery may lie beneath muscle bridge. Severe atherosclerotic changes are typically less seen in these segments (11)

RISK FACTORS:

- Diabetes Mellitus, Hypertension, Hyperlipidemia , smoking, History of MI or a particularly stressful occupation or a lifestyle.
- Arterisclerosis is the cause of CSD,its presence anywhere in the circulatory system is a risk factor for CAD- H/o Transient cerebral ischemic attack or stroke, carotid bruits, Intermittent claudication indicative of peripheral vascular occlusive disease should be noted
- Thoracic and abdominal aortic aneurysm or occlusive disease.
- Pulmonary and renal function should be Evaluated

CLINICAL FEATURES AND DIAGNOSTIC CRITERIA

First suspicion of development of CAD ,when patient develops symptom complex of Angina pectoris or an Acute MI . Occasionally evidence of CAD by ECG changes due to silent MI, ECG changes in exercise stress test or patient may have sudden death. CAD occasionally may also be first suspected because of cardiomegaly on chest X rays and development of symptoms of chronic heart failure without any other obvious cause(12). On Physical examination findings are non specific.

Investigations to identify CAD- Non invasive tests and Invasive tests.(13,14)

Non Invasive tests:

- ECG
- Chest radiograph
- Echocardiography-Detects regional wall motion abnormalities, LV contractility and function and valvular status- assoiated MR,TR,AR .
- Contrast Enhanced Computed tomographic coronary angiography- Emerging as a promising technique in detecting Coronary artery disease, with increased temporal and spatial resolution suitable as an accurate and noninvasive technique to select candidates for CABG

Invasive tests:

- Coronary angiography
- LV Angiography

Patients with similar EFs may have variable exercise capacity, and these variations are prognostically important. Emphasizing on heart size alone is deceptive ,as it may remain normal in the presence of severe LV dysfunction.

M-Mode Parameters used to Assess Left ventricular systolic function- (15)

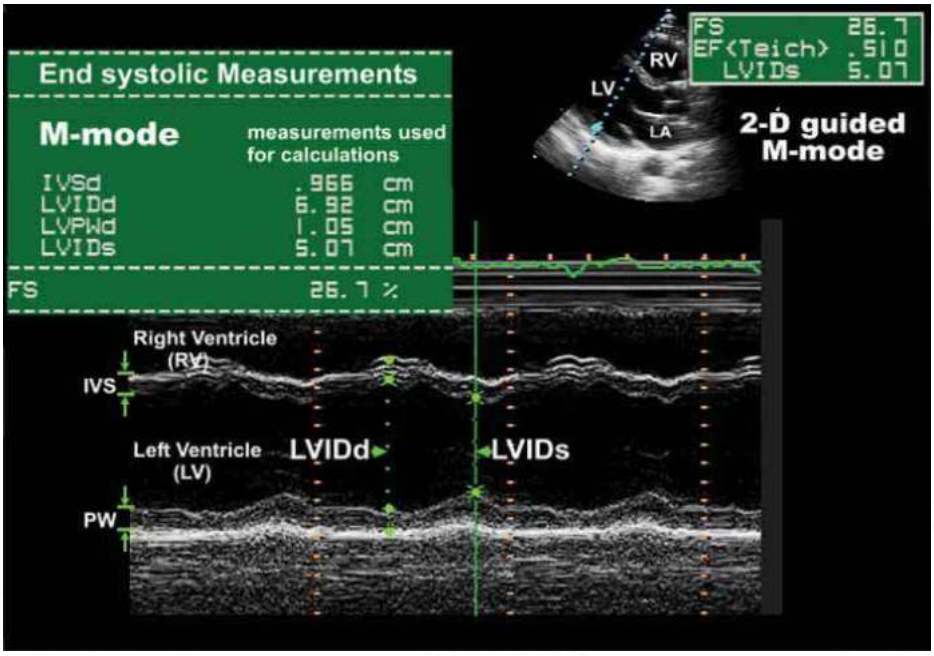
- LVID(LVIDs<3.7cm; LVIDd <5.6cm are normal)
- Left ventricular WT(wall thickness)
- % change in WT= (WT at end systole- WT at end diastole/ WT at end systole)
- Left ventricular volume
    - Prolate ellipse calculation : Volume= $\pi/3(LVIDd)^3$
    - Teichholz formula: Volume +[7/(2.5+LVIDd)]
- Ejection fraction : (EDV- ESV)/ EDV
- Fractional shortening(FS)(%) = (LVIDd-LVIDs)/ LVIDd
- Mitral valve E point – septal separation(normal >7mm)
- Left ventricular mass ($Mass_{LV}$) = $0.8x[1.04(IVS+PWT+ LVIDd)^3- (LVIDd)^3]+0.6g$

Doppler Indices of Left Ventricular Systolic Function

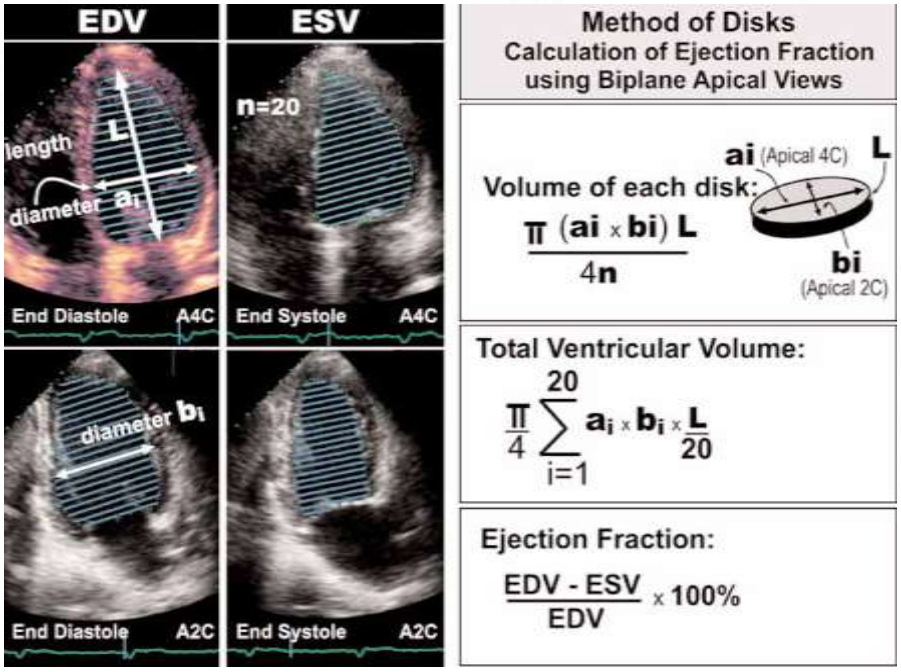
Traditional Doppler indices	*Newer Doppler indices*
$SV = VTI \times CSA = VTI \times \pi r^2$ $= VTI \times \pi D^2/4 = 0.785\ D^2 \times VTI$	TDI/DTI
Measurement sites: LVOT Left ventricular inflow (mitral valve) Pulmonary artery	
$CO = SV \times HR$ $CI = CO/body\ surface\ area$	TVI for left ventricular dyssynchrony
CW Doppler in mitral regurgitation: $dP/dt = 32/time\ (mmHg/s)$	Doppler strain imaging: strain and strain rate
Velocity/acceleration times, e.g., aortic flow/velocity acceleration, aortic ejection time	Left ventricular torsion by TDI

SV, stroke volume; VTI, velocity time integral; CSA, cross-sectional area; D, diameter; TDI, tissue Doppler imaging; DTI, Doppler tissue imaging; LVOT, left ventricular outflow; CO, cardiac output; HR, heart rate; CI, cardiac index; TVI, tissue velocity imaging; CW, continuous wave; dP/dT, rate of ventricular pressure rise.

2D guided M-mode measurements and derived indices. EF is an automatic calculation



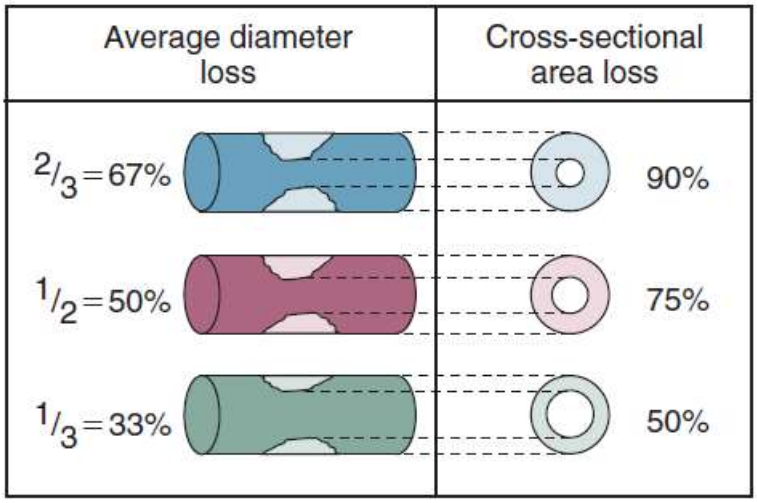
Modified SIMPSON'S method of calculating Ejection fraction



CORONARY ANGIOGRAPHY

Coronary angiograms gives detailed assessment of both the coronary ostia and the arteries from several angles(16). It also gives detailed assessment of all major and minor branches of the right and left coronary arterial systems. Some times angiography remains imperfect in visualizing the severity of stenotic lesion and diameter of vessels distal to stenotic lesions are underestimated. Assessment by external palpation of coronary arteries during operation or by probing of the open vessel cannot substitute for coronary angiography. Assessment of all coronary arterial branches carefully at the time of operation by surgeon rather than assume the coronary angiogram is a totally accurate is needed.

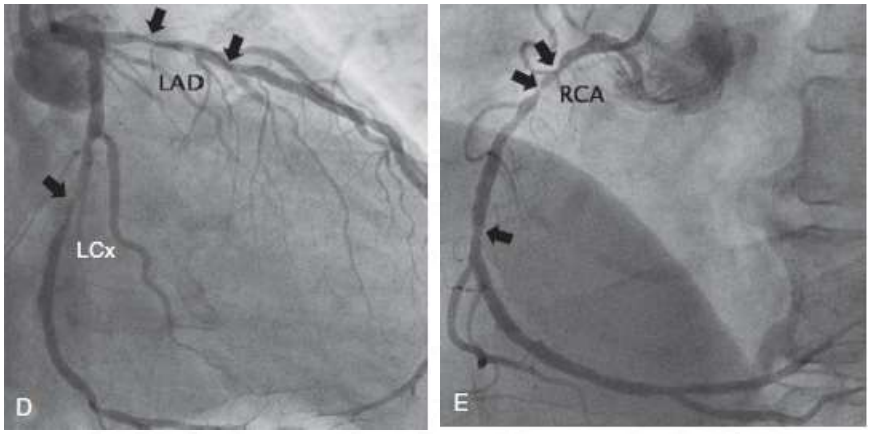
Diagrammatic representation of estimating severity of coronary artery stenosis by CAG



- Some consider those lesions with 70% or more diameter loss(90% or more cross sectional area loss) as important. (17)
- Extent of important coronary artery stenosis summarized conventionally as “single vessel”, ”Double vessel”, or “triple vessel” disease with involvement of Left main coronary artery or not.

-

Left and Right coronary systems with lesions evident on Coronary angiography(18)



TIMI GRADING SYSTEM(19)

Grade 0	Complete occlusion of infarct related artery
Grade 1	Some penetration of contrast material beyond the point of obstruction but without perfusion of distal coronary bed
Grade 2	Perfusion of entire infarct vessel into distal bed but with flow that is delayed compared with of normal artery
Grade 3	Full perfusion of infarct vessel with normal flow

TECHNIQUE OF OPERATION

- Extensive three system coronary artery disease is the most common entity in patients undergoing CABG, with important stenosis of four, five or six arteries. Many of these patients have impairment of LV function and with various comorbidities. (20)
- Surgical management of CAD has evolved from treatment primarily for patients with Good LV function to severe LV dysfunction undergoing elective operation to emergency surgeries(20,21). At present CABG with use of total CPB through a median sternotomy is the most widely used technique. Other approaches are Off Pump CABG, through small sternal, parasternal or thoracotomy incisions.
- To obtain *complete revascularisation* is the *prime objective of CABG* by bypassing all severe coronary stenosis in 2 major arterial trunks and branches having a diameter of about 1mm or more(22,23)
- In case of more vessels to be grafted, sequential grafting can be considered with a distal end to side to a relatively large vessel . Many studies suggested that sequential grafts are associated with higher mean flow and graft patency(24,25)

Bypass conduit options

Venous conduits	Arterial conduits	Alternative conduits
Great Saphenous vein Lesser Saphenous Vein Cephalic vein	Internal Mammary Artery Radial Artery Right Gastroepiploic artery Inferior epigastric artery	Biological: • SV allografts • Bovine ITA Synthetic-PTFE grafts

Coronary Artery Bypass Grafting with Cardiopulmonary bypass[20,23]

- Median sternotomy is made, at same time arterial and venous conduits are harvested
- LIMA and RIMA if needed is completely mobilized before pericardium is opened
- Heparin is administered, dissection of IMA is completed and then divided, checked for IMA flow and an bulldog clamp is applied
- Pericardium is opened and pericardial stay sutures taken . Aortic and Right Atrial wall or appendage purse string sutures were taken and cannulated and connected to arterial and venous limbs of CPB and CPB is established when target ACT is reached
- Purse string suture for cardioplegia cannula is taken and cannulated.
- Aorta Cross clamped and cardioplegia solution is infused, to achieve diastolic arrest of heart
- Heart is retracted out in pericardial cavity by the assisting surgeon and distal anastomosis of conduit to blocked coronary artery started

Principles of Coronary anastomosis

Use of 7-0 or 8-0 prolene

No touch technique

Attention to geometric distribution of sutures as the anastomosis is performed.

- Incision on coronary artery is made and is enlarged with affine angled scissors to a length of 4-6mm.
- Distal vein is bevelled so that the circumference of the opening is 20% longer than artery.
- Stitches in coronary artery artery are placed from intima to adventitia (inside out).
- Sutures in vein are placed slightly apart than those in the artery to create the desired cobra head configuration

- Care should be taken to avoid any inclusion of adventitia or debris in the suture line.
- Aortic cross clamp is removed. A partially occluding clamp is placed on the ascending aorta, aortic punch is used to make aortic openings
- Grafts are anastomosed to the aorta so that they are free of kinking or tension.

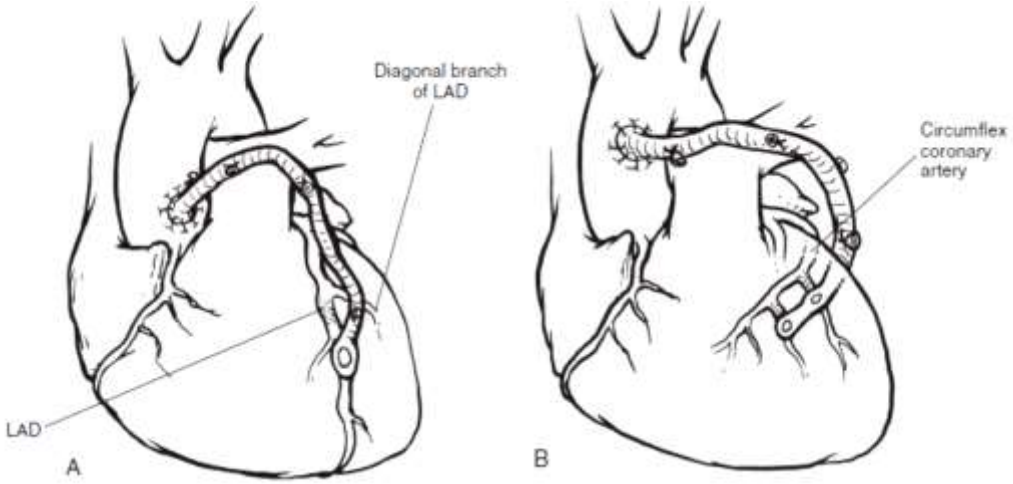
Principles of Proximal anastomosis

To ensure a perfect graft (i.e without torsion, tension or excessive redundancy)

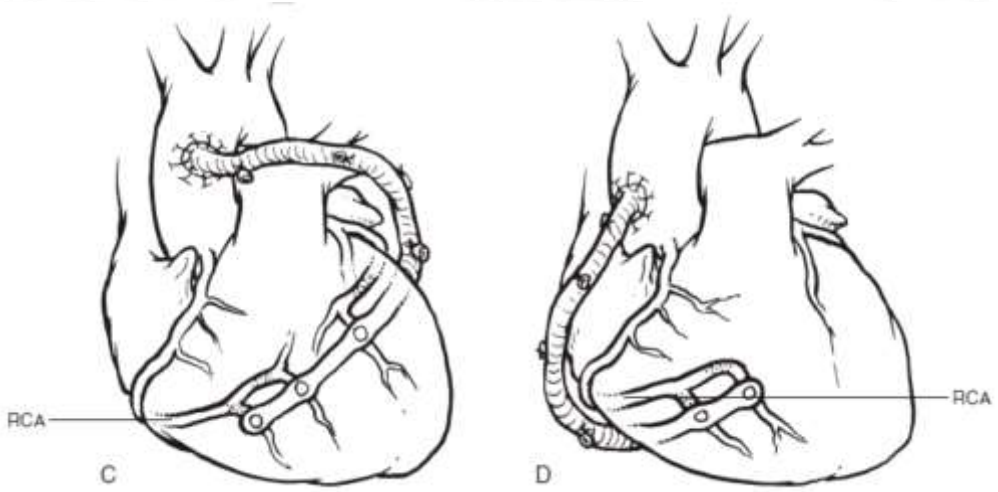
To minimize aortic manipulation

- Partially occluding clamp is then removed. Air is evacuated from ascending Aorta
- Once rewarming is completed and heart is beating well, CPB is discontinued and aortic and Venous cannulae are removed
- Remainder of operation is completed in a standard manner from haemostasis to sternal and skin closure

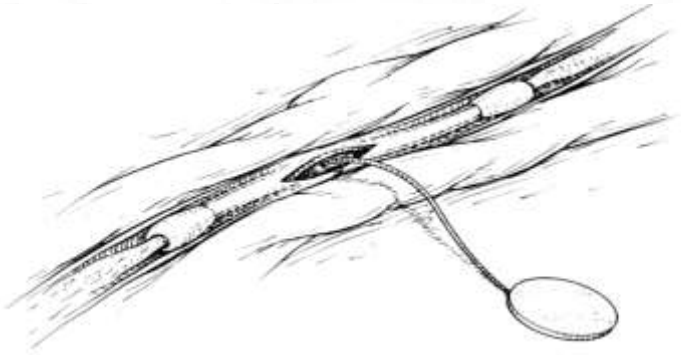
End to Side Anastomosis of Venous conduits to LAD and circumflex coronary arteries



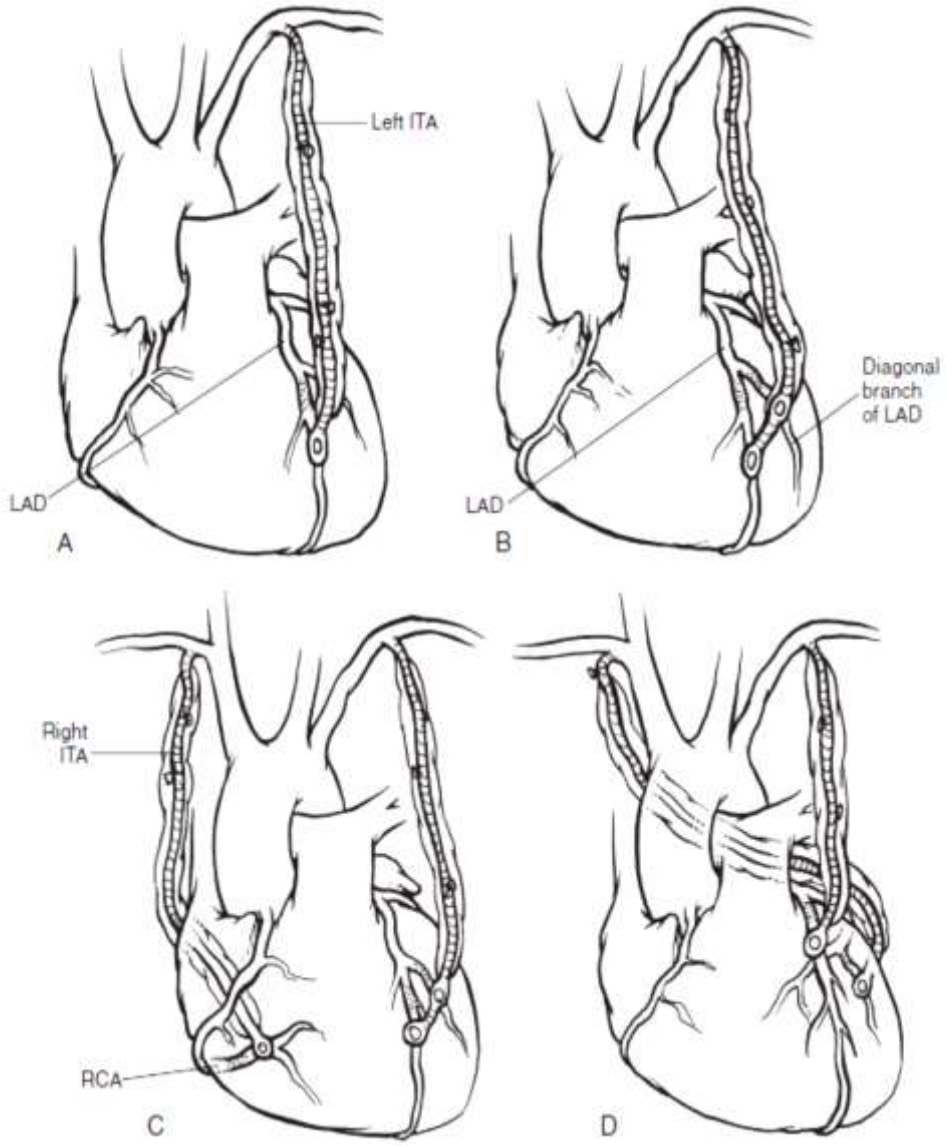
Sequential Anastomosis of venous conduits to circumflex and right side coronary arteries



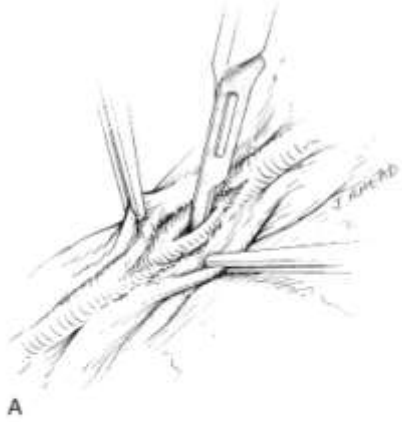
Intracoronary Shunt can be used to performing distal anastomosis

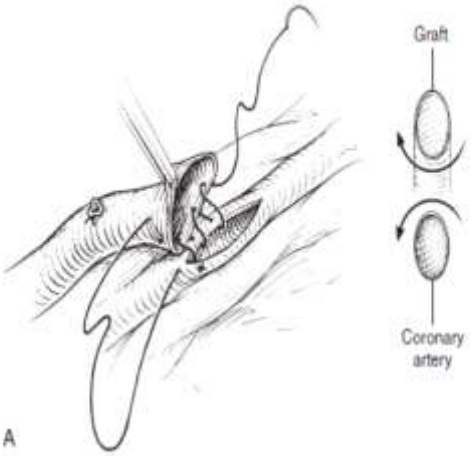


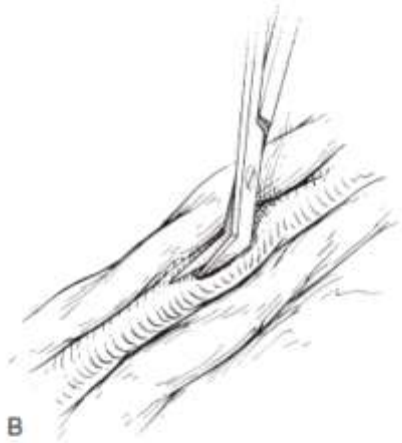
Combinations and configurations of Internal Thoracic Artery bypass grafts

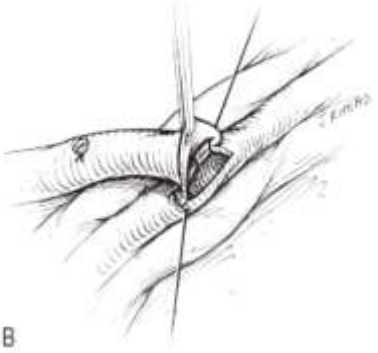


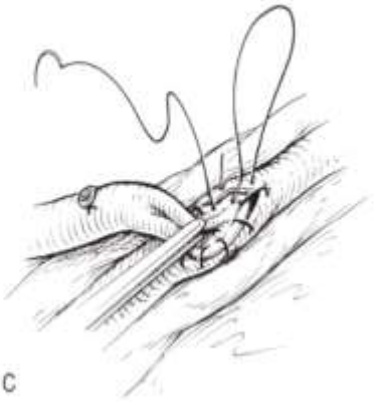
Technique of Distal coronary anastomosis











CORONARY ENDARTERECTOMY

Coronary Endarterectomy is a surgical procedure performed alongside CABG for the treatment of diffuse CAD. It involves an arteriotomy of the coronary artery and the excision of the atheromatous plaque occluding the vessel in order to revascularise the ischemic myocardium(29).Patients who had previous PCIs, elderly patients with multiple comorbidities, severe and diffuse atherosclerotic disease are at high operative risk and poor postoperative outcomes(27)

History of CE

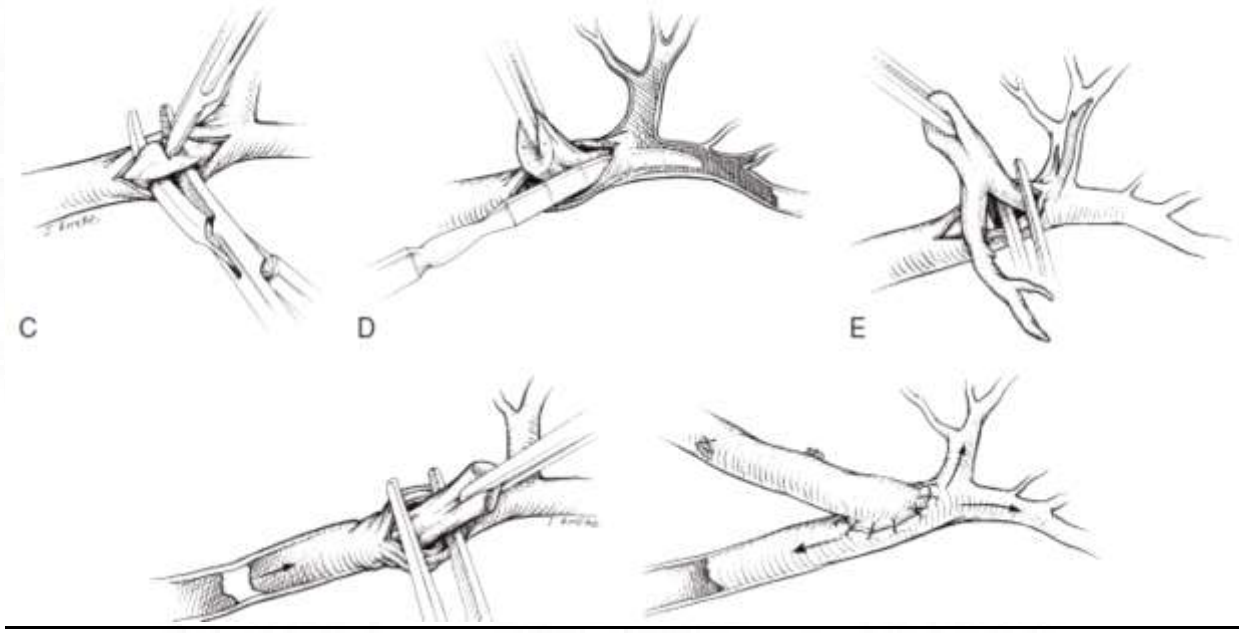
Charles Bailey was the first to successfully perform the procedure on two patients at Hahnemann Hospital in Philadelphia, USA, in October 1956 . Initially until 1960, CE was performed using a distal, blind, retrograde technique without heart-lung bypass (30.31). In 1958 antegrade endarterectomy was performed by Longmire and colleagues under direct vision, i.e. using the open technique for the first time (28). The benefit of CE was overshadowed by the observation that it was associated with high perioperative MI , postoperative morbidity and mortality rates (32,33). For historical reasons, it is worth mentioning Swayer in 1965 introduced , an alternative technique of endarterectomy using carbon dioxide .Other techniques such as laser, cardioplegia infusion and even a 'modified battery-powered toothbrush' were used to separate the atheroma from the vessel wall (34).

. **Open versus closed technique** : Two main techniques, namely open and closed, that can be used to perform the procedure (35). In open technique involves arteriotomy extends beyond the limits of the stenosis. Atherosclerotic plaque being lifted off under direct vision (32),then an on-lay patch anastomosis derived from IMA or SVG to the LAD is performed(35).

The open technique is more time consuming, lower likelihood of intimal flap formation and thereby less chance of causing residual obstruction compared to closed technique.

Closed technique involves a smaller arteriotomy to remove the atherosclerotic plaque In closed technique steady and gentle traction on the plaque applied both proximally and distally. By closed technique graft anastomosis is easier as incision is smaller and takes lesser time (35).In closed technique there is a likelihood of the occurrence of the snowplow effect, i.e. distal LAD and its side branches occlusion due to insufficient endarterectomy . In closed technique there is a chance of forming intimal flap which in turn can result in the occlusion of the lumen distally (35). Even though it is not entirely clear so far which is the optimal technique, the open technique appears to be a safer option

TECHNIQUE OF CORONARY ENDARTERECTOMY



LEFT VENTRICULAR ANEURYSMS

- Early and late distorsion of structure of heart are caused by large anterior myocardial infarction(36). Raised wall tension caused by adverse shape produces mechanical disadvantages and adverse remodelling .
- Most postinfarction LV scar involves Nonresectable septum ,and may result in an akinetic region or occasionally in a dyskinetic scar if there is no reperfusion.
- Cardiac output is not supported due to asynergic between the LV segments and may cause chronic heart failure, because remote non ischemic muscle may reduce the EF over years.
- Thrombolysis and percutaneous transluminal coronary angioplasty during infarction may salvage epicardial muscle and produce an akinetic segment due to which dyskinetic segments are rare. Conversely the only predictor of favourable outcome is considered to be dyskinesia (36,37).
- Both Akinetic and Aneurysmal (dyskinetic) segments were repaired with Endoventricular circular patch plasty (EVCPP) or DOR's procedure.
- Circular ventricular architechture will be restored by this technique by excluding septal scar by means of Laplace relationship. Reduces the cavity to restore wall tension towards normal and thereby improve hemodynamic satus Linear aneurysmectomy and septal inclusion produces higher mortality and less functional improvement.
- In EVCPP excludes the septum for post infarction anterior scar. By dealing with the extent of asynergy(noncontractile muscle)rather than presence or absence of dyskinesia ,improve the outcomes in patients with low Ejection Fraction (<35%)

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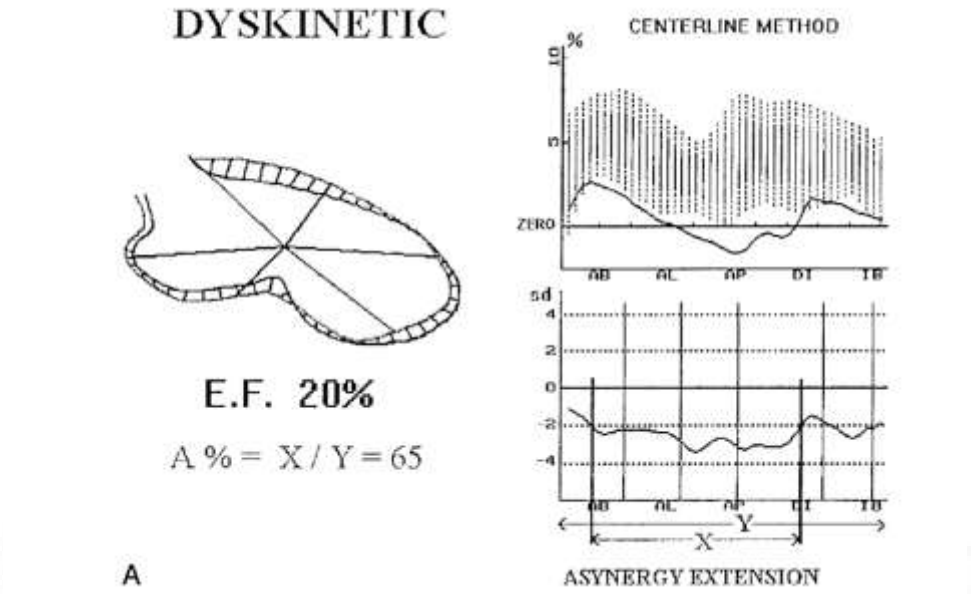
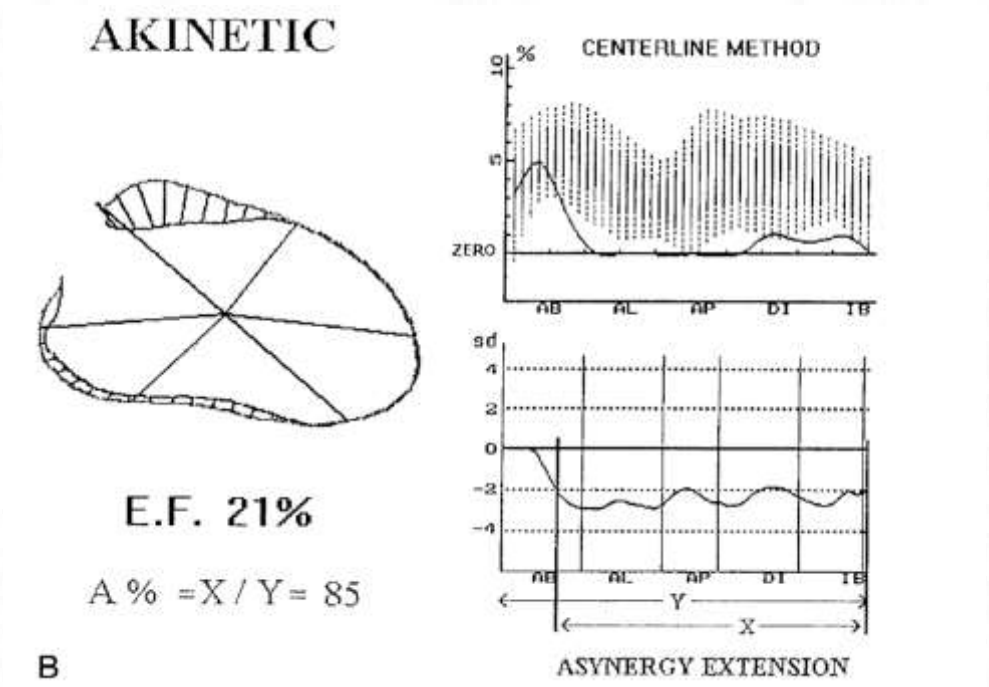


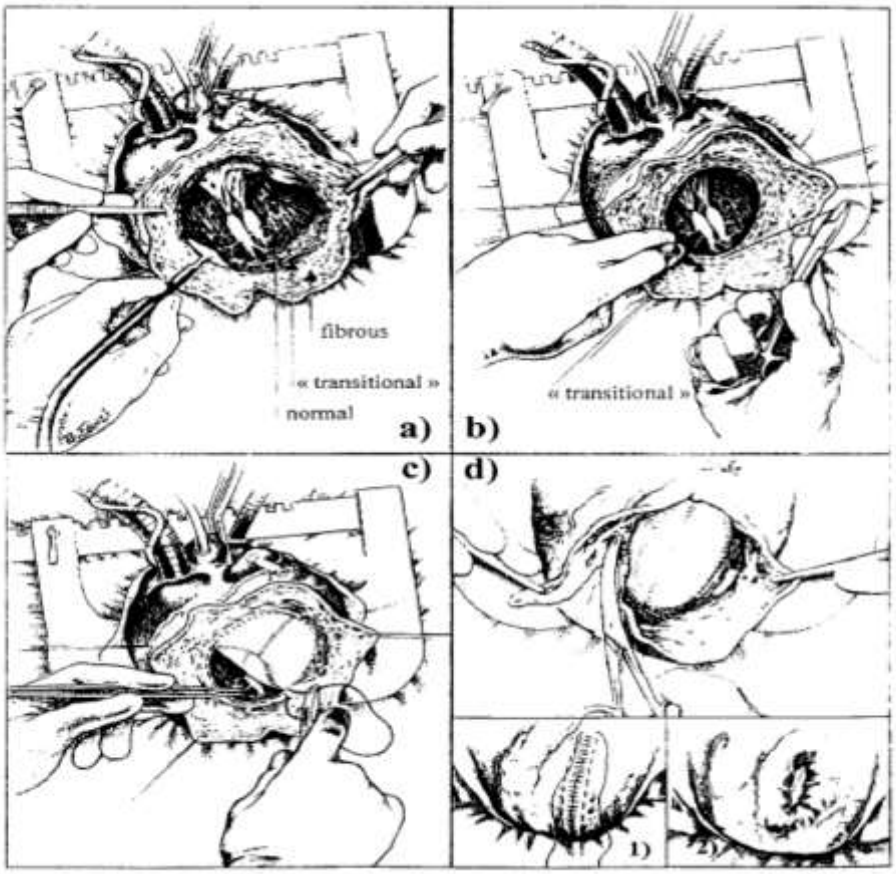


Examples of preoperative centerline analysis in dyskinetic and Akinetic LV aneurysms.vertical lines indicate extent of asynergy.

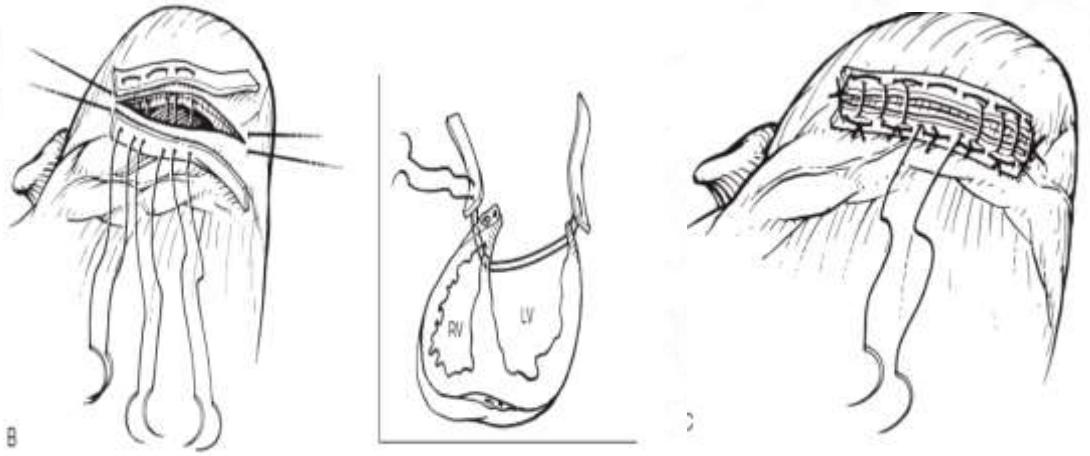
Surgical technique of DOR's Procedure/ EVCPP [38,39] :

- Procedure was performed with crystalloid cardioplegia or cold blood cardioplegia. For coronary revascularization IMA and Saphenous grafts will be used.
- LV is then opened in the center of the anterior depressed area produced by aspirating the vent catheter. Clots if present are removed.
- Junction between scarred and normal muscle will be much clearly defined in dyskinetic aneurysms than the akinetic segments. In the open ventricle, fibrous endocardial scar determines the border zone between the total fibrous tissue and the beginning of the muscular tissue. The endocardial scar is mobilized and resected.
- An endoventricular circular suture is placed with a prolene /monofilament nonabsorbable suture to restore the neck of the contracting ventricle to be retained and thereby provide a normal oval curvature of the ventricle. Between normal and scarred tissue a circular suture is passed in the fibrous tissue above transition zone and the neck of aneurysm closed with a Dacron patch or autologous endocardial tissue.
- The patch that is used to rebuild ventricle is tailored to the dimensions of new artificial neck in both vertical and horizontal diameters
- .A hemicircular autologous patch modeled from the septal scar with a septal hinge can be used to close the artificial neck and restore the circularity of the cavity.
- Almost half of the septum and the posterior wall upto the root of the posterior papillary muscle are excluded.The excluded tissue of LV aneurysmal wall is folded to reinforce the suture line. Direct suture of septum is avoided to protect the revascularised LAD

DOR's PROCEDURE or EVCPP

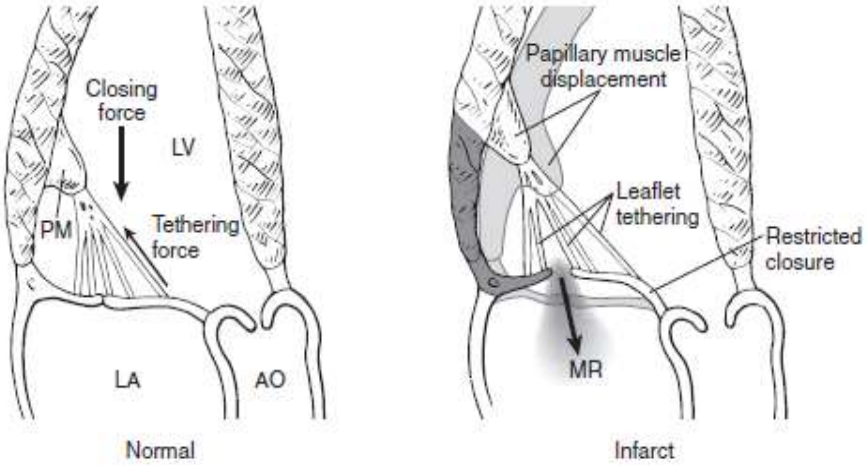


Linear Plication of LV aneurysm



ISCHEMIC MITRAL REGURGITATION:

- MR due to prior Myocardial infarction associated with normal mitral valve leaflets and chordae is defined as Ischemic Mitral regurgitation (40).
- MR results from an unbalance between increased tethering forces and reduced closing forces due to LV remodelling, the papillary muscles are displaced apically, posterior, and laterally.
- Increased tethering forces in results from incomplete closure of normal mitral leaflets. Reduction in LV contractility and global LV dyssynchrony , systolic annular contraction alteration , reduced synchronicity of two papillary muscles results in reduced closing forces of mitral leaflets thereby leads to MR(41)
- The pathophysiological process then becomes self-perpetuating as resultant MR leads to ventricular dilatation which, in turn, leads to further papillary muscle displacement, annular enlargement, and then further MR(42)



Left – Normal Balance of forces acting on Mitral leaflets in systole.Right-Effect of Papillary muscle displacement, dark shading indicates Infero basal infarction

In cases of Ischemic cardiomyopathy the role of CABG in improving the outcomes had been established by STICH(Surgical Treatment for Ischemic Heart Failure) trial (43) and STICHES(surgical treatment for Ischemic heart failure Extension Study) (44)trial.83% of cardiovascular disease mortality is caused by Ischemic heart disease and stroke.

In India Ischemic heart disease affects the population atleast a decade earlier and in the most productive years mid life years compare to western population(45).In Urban population Ischemic heart disease increased by 7 fold and in rural population quadrapuled in recent years(46).

The incidence of STEMI (ST segment elevation MI) is more than NSTEMI(non ST segment elevation MI) or Unstable angina in India. In India there are also longer delay before admissions to hospital and between admission and reperfusion therapy.Therefore Indian patients with ACS(Acute coronary syndrome) have higher morbidity and mortality than high income countries.(47,48). All the above factors mentioned could increase the prevalence of Ischemic cardiomyopathy and Low Ejection fractions(EF) in Indian patients.

There are studies which show CABG improves survival in patients with Ischemic acrdiomyopathy but these are based on reports from developed countries. Due to poor socioeconomic status , lack of equality in healthcare delivery and differences in risk profile and lack of access to optimal health care are some of the factors which make conclusion or reports of studies from developed countries irrelevant to Indian population. So, In Indian population it is important to check for the outcomes of CABG and other associated ventricular restoration procedures of Ischemic cardiomyopathy with low ejection fraction

2018 EACTS GUIDELINES FOR SEVERE LEFT VENTRICULAR DYSFUNCTION OR HEART FAILURE

2018 ESC7EACT5 Guidelines on myocardial revascu larization

Recommendations on revascularizations in patients with chronic heart failure and systolic left ventricular dysfunction (ejection fraction

Recommendations	Class of recommendation	Level of evidence
In patients with severe left ventricular systolic dysfunction and CAD suitable for intervention, myocardial revascularization is recommended	I	B
CABG is recommended as the first revascularization strategy choice in patients with multivessel disease and acceptable surgical risk	I	B
In patients with one- or two-vessel disease, PCI should be considered as an alternative to CABG when complete revascularization can be achieved	IIa	C
In patients with three-vessel disease, PO should be considered based on the evaluation by the Heart Team of the patient's coronary anatomy, the expected completeness of revascularization, diabetes status and comorbidities	IIa	C
Left ventricular aneurysmectomy during CABG should be considered in patients with NYHA class III/IV, large left ventricular aneurysm, large thrombus formation, or if the aneurysm is the origin of arrhythmias	IIa	C
Surgical ventricular restoration during CABG may be considered in selected patients treated in centers with expertise	IIb	B

Note: CAD=coronary artery disease: CABG=coronary artery bypass graft; NYHA=New York Heart Association; PG =percutaneous coronary intervention

2017 ACC/AHA GUIDELINES FOR CORONARY REVASCULARIZATION IN PATIENTS WITH LEFT VENTRICULAR DYSFUNCTION

ACC/AATS/AH A/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients with Stable Ischemic Heart Disease

Revascularization to improve survival compared with medical therapy in the anatomic setting of left ventricular dysfunction

Recommendations	Class of recommendation	Level of evidence
CABG - ejection fraction 35% to 50%	IIa	B
CABG - ejection fraction <35% without significant left main CAD	IIb	B
PCI	Insufficient data	N/A

2013 ACCF/AHA Guideline for the Management of Heart Failure: Executive Summary - Recommendations for Stage C HFpEF - Updated in 2017

Recommendations	Class of recommendation	Level of evidence
CABG or PCI is indicated for HF patients on GDMT with angina and suitable coronary anatomy, especially significant left main stenosis or left main equivalent	I	C
CABG to improve survival is reasonable in patients with mild to moderate left ventricular systolic dysfunction and significant multivessel CAD or proximal LAD stenosis when viable myocardium is present	IIa	B
CABG is reasonable to improve morbidity and mortality for patients with severe left ventricular dysfunction (ejection fraction <35%) and significant CAD	IIa	B
CABG may be considered in patients with ischemic heart disease, severe left ventricular systolic dysfunction and operable coronary anatomy, regardless of whether a viable myocardium is present	IIb	B

Note: CAD=coronary artery disease: CABG=coronary artery bypass graft GDMT=guideline-directed medial therapy: LAD=left anterior descending artery; PCI percutaneous coronary intervention

MATERIALS AND METHODS

The present study was approved by institute research and ethics committee .It was conducted in department of cardiothoracic and vascular surgery, Shree Chitra Tirunal Institute of Medical Sciences and Technology,Trivandrum.This study was conducted in a period from 1st January 2010 to 31st December 2014 .Data was collected from hospital database

STUDY DESIGN

Single center retrospective observational study.

POPULATION

146 consecutive patients who underwent CABG or CABG with ventricular restorative procedures or for coronary artery disease patients with severe left ventricular dysfunction between January 2010 and December 2014

INCLUSION CRITERIA

- 146 consecutive patients who had undergone Surgical management for coronary artery disease with severe Left ventricular dysfunction (EF $\leq$ 35%) , and patients with Ischemic Mitral regurgitation from January 2010 to December 2014

EXCLUSION CRITERIA

- Patients who underwent Previous cardiac surgery now with Coronary artery disease with severe Left ventricular dysfunction
- Rheumatic or degenerative valvular disease now with Coronary artery disease with

severe left ventricular dysfunction .

- Patients whose data is neither available in database nor able to contact telephonically will be excluded from the study.

APPROVAL FROM TECHNICAL ADVISORY COMMITTEE (TAC):

TAC approval was obtained before commencing the study.

APPROVAL FROM INSTITUTIONAL ETHICS COMMITTEE (IEC):

IEC approval was taken before commencing the study.

METHODOLOGY

Patients who satisfied the inclusion criteria were included in the study. Data was collected with a semi structured questionnaire from hospital records and analysed . Pre-operative details, immediate post surgery echocardiography parameters, follow up details were collected, so that every one had a minimum follow up period of 5 years from hospital records. Present survival status as on December 2019 was collected by contacting telephonically. Data was analysed after consultation with the statistician.

Following Data of variables were collected for study

Demographic data :

Serial number:

Age :

Gender :

Preoperative Data :

Symptoms- Dyspnoea- NYHA I/II/III/IV

Angina-NYHA I/II/III/IV

H/O Chronic stable angina/Acute coronary syndrome

H/O Heart failure

H/O Pulmonary disease

H/O Cerebrovascular disease

H/O Renal failure/ Chronic Kidney disease

H/O Liver/Gastrointestinal disease

H/O Diabetes, Hypertension, Smoking, Hyperlipidemia

H/O Peripheral vascular disease

Family History -coronary artery disease/Peripheral vascular disease/Thoracoabdominal aneurysm

H/o cardiac surgeries:

Preoperative Procedures- PCI

Preoperative ventilation-

Emergency/Elective

Preoperative Investigations

2D ECHO- Ejection fraction

Regional wall motion abnormality

Valvular status- Mitral regurgitation, Aortic regurgitation

LV Size, Scar/Aneurysms

Coronary angiogram-

Number of Vessels involved

Left Main Involvement

PCI for any involved vessel

ECG- Arrhythmias

Intraoperative Data :

Procedure executed

On pump CABG/Off Pump CABG

Number of grafts

Endarterectomy

Internal Mammary artery,Radial Artery use

LV wall reconstruction

Valvular Repair/replacement

CPB time

Aortic cross clamp time

Use Of IABP- Preop/postoperatively

Postoperative Data:

Postoperative ICU stay

Postoperative Ventilation status – Duration of Ventilation

Postoperative need of IABP

Need for renal replacement /Dialysis

Inotrope score

Postoperative arrhythmias

Postoperative Hospital stay

Postoperative Infections:

Deep Sternal Infections/Superficial SSI

Respiratory Infections

Blood Infections

In hospital Mortality

Cause of mortality

Postop ECHO- EF, ventricular function, RWMA, Valve function

Follow UP

Follow up Symptoms-class

Post op follow up echo- Ventricular function, Ejection fraction, RWMA, Valve function/status

Readmission with signs of failure

Readmission for Re-CAG /Cath studies

Readmission for Redo CABG

Readmission for any other cause other than cardiac

Mortality- cause of mortality

Date of death

STATISTICAL ANALYSIS:

Kaplan meier survival analysis was performed to assess the overall survival rate.

Survival rate was compared across the Preoperative 2D Echo EF

Early mortality (<30days) and Late Follow up survival time were considered as primary outcome variables.

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Non normally distributed quantitative variables were summarized by median and interquartile range (IQR). Data was also represented using appropriate diagrams like bar diagram, pie diagram and box plots.

All Quantitative variables were checked for normal distribution within each category of explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro-wilk test was also conducted to assess normal distribution. Shapiro wilk test p value of >0.05 was considered as normal distribution.

For normally distributed Quantitative parameters the mean values were compared between study groups using ANOVA (>2 groups). For non-normally distributed Quantitative parameters, Medians and Interquartile range (IQR) were compared between study groups using Kruskal Wallis test (> 2 groups). For non-normally distributed, association between quantitative explanatory and outcome variables was assessed by calculating spearman correlation (r_s)coefficient and the data was represented in a scatter diagram.

Categorical outcomes were compared between study groups using Chi square test /Fisher's Exact test (If the overall sample size was < 20 or if the expected number in any one of the cells is < 5, Fisher's exact test was used.)

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

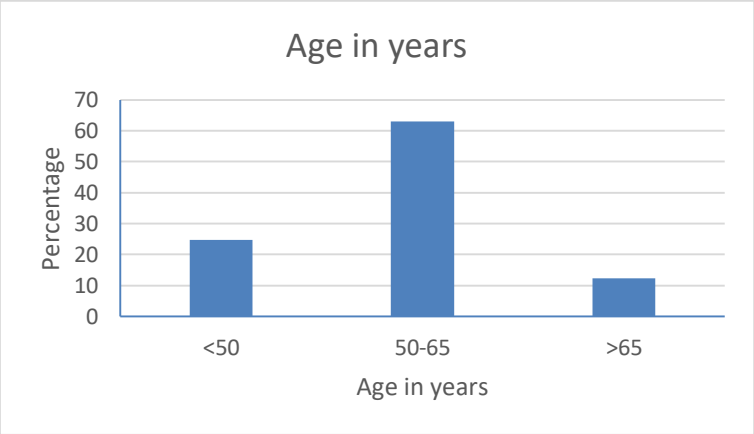
OBSERVATION AND RESULTS

Result:

A total of **146** subjects were included in the final analysis

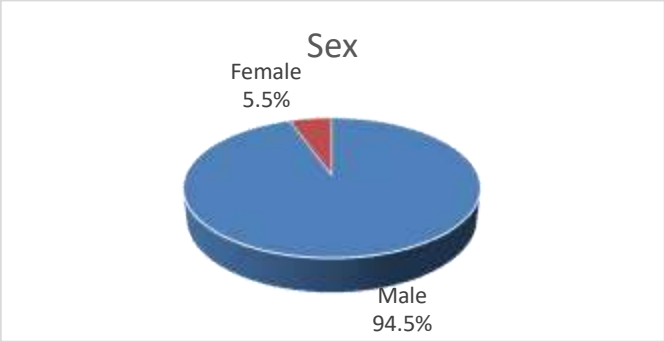
Descriptive analysis of age in study population (N= 146)

Age in years	Frequency	Percent
<50	36	24.7
50-65	92	63
>65	18	12.3
Total	146	100



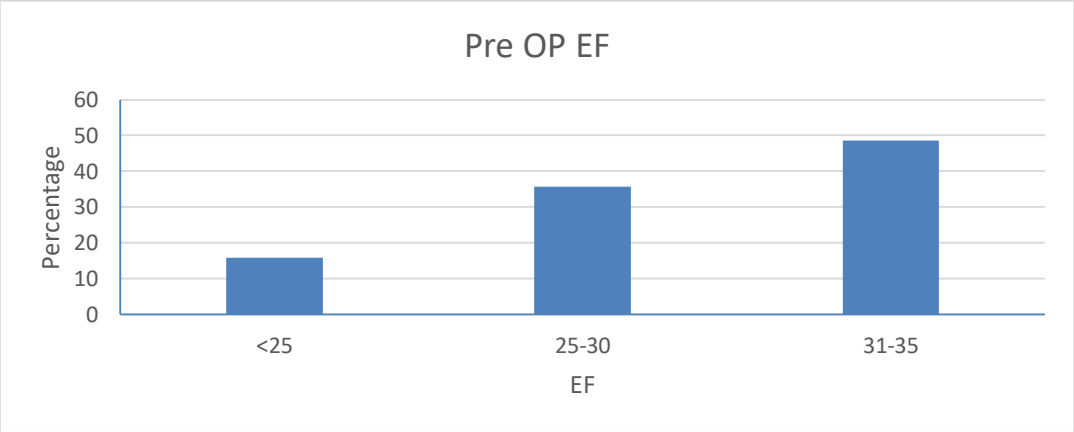
Descriptive analysis of gender in the study population (N=146)

Gender	Frequency	Percentages
Male	138	94.52%
Female	8	5.48%



Descriptive Analysis of Preop 2D ECHO EF

Pre OP 2D Echo EF	Frequency	Percent
<25	23	15.8
25-30	52	35.6
31-35	71	48.6
Total	146	100



Descriptive Analysis of Emergency and Elective procedures done

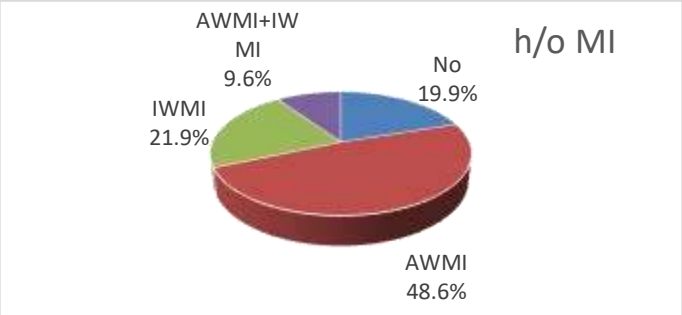
emergency/elective	Frequency	Percent
Emergency	4	2.7
Elective	142	97.3
Total	146	100

Descriptive Analysis of Preoperative Symptoms as per NYHA class

Symptoms Dyspnoea class(NYHA)	Frequency	Percent	Angina-NYHA class	Frequency	Percent
0	29	19.9	0	26	17.8
2	71	48.6	2	59	40.4
3	43	29.5	3	55	37.7
4	3	2.1	4	6	4.1
Total	146	100	Total	146	100

Descriptive Analysis of Preop Myocardial Infarction

H/o MI	Frequency	Percent
No	29	19.9
AWMI	71	48.6
IWMI	32	21.9
AWMI+IWMI	14	9.6
Total	146	100



Descriptive Analysis of Number of vessels involved according to CAG

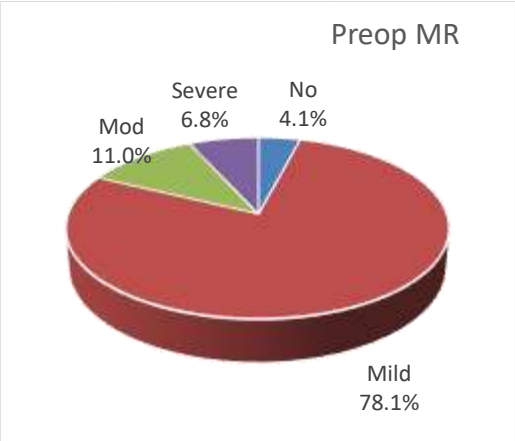
Number of vessels involved	Frequency	Percent
SVD	1	0.7
DVD	3	2.1
TVD	115	78.8
LMCA+DVD	3	2.1
LMCA+TVD	24	16.4
Total	146	100

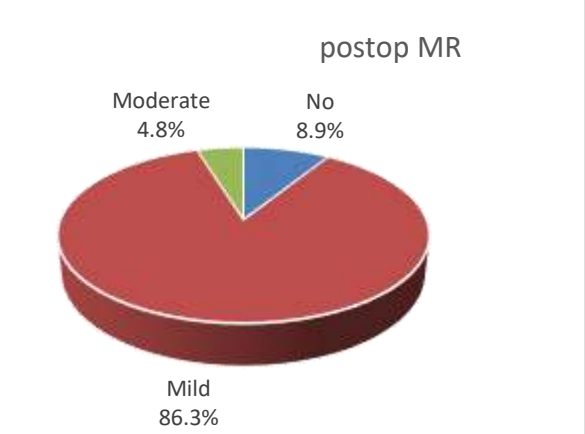
Descriptive Analysis of Preoperative Mitral Regurgitation

Preop Mitral Regurgitation	Frequency	Percent
No	6	4.1
Mild	114	78.1
Moderate	16	11
Severe	10	6.8
Total	146	100

Descriptive analysis of Postoperative Mitral regurgitation

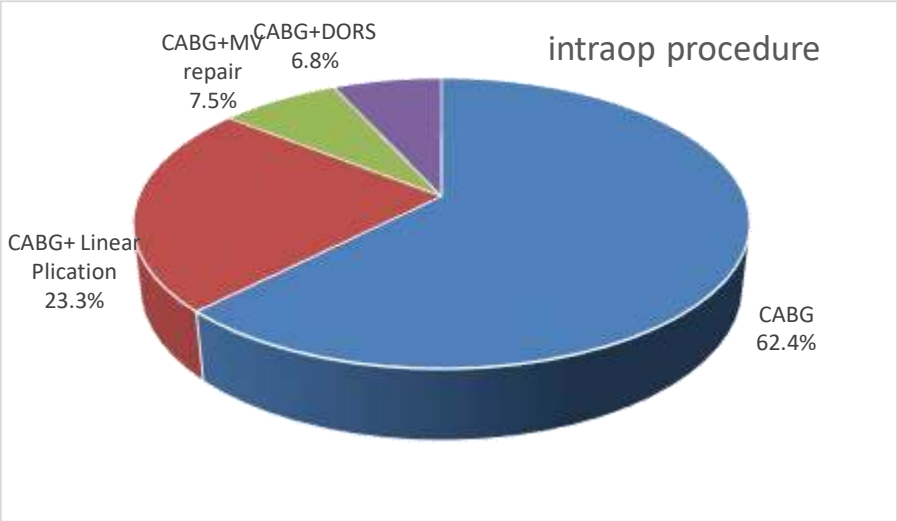
Postop Mitral Regurgitation	Frequency	Percent
No	13	8.9
Mild	126	86.3
Moderate	7	4.8
Total	146	100





Descriptive Analysis of Intraoperative procedure performed

intraop procedure	Frequency	Percent
CABG	91	62.3
CABG+ Linear Plication	34	23.3
CABG+MV repair	11	7.5
CABG+DORS	10	6.8
Total	146	100

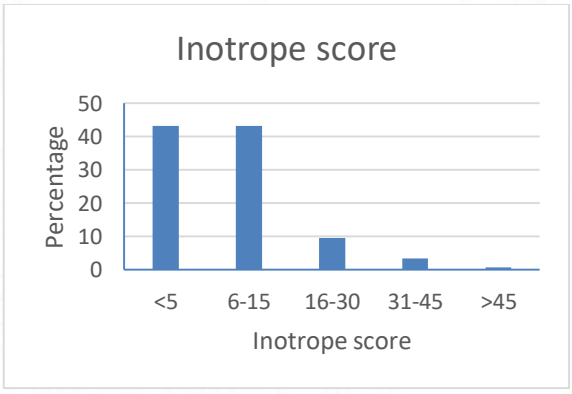


Descriptive Analysis of Number of Grafts used during CABG

Number of grafts	Frequency	Percent
1G	1	0.7
2G	3	2.1
3G	25	17.1
4G	54	37
5G	47	32.2
6G	15	10.3
7G	1	0.7
Total	146	100

Descriptive Analysis of Postoperative Inotrope score

Inotrope score	Frequency	Percent
<5	63	43.2
6-15	63	43.2
16-30	14	9.6
31-45	5	3.4
>45	1	0.7
Total	146	100



Descriptive analysis of Arrhythmias in postoperative patients

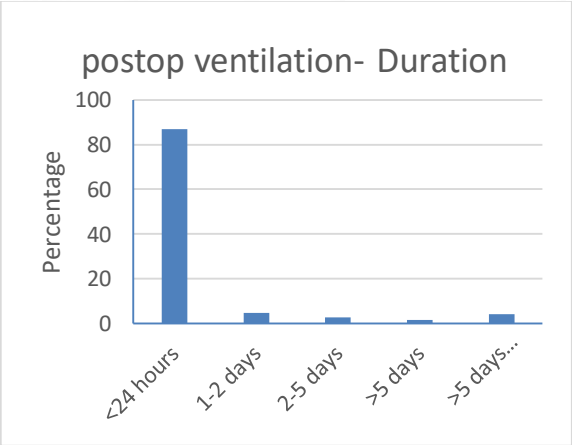
postop arrythmias	Frequency	Percent
No	83	56.8
AF	23	15.8
VPC	34	23.3
AF+VPC	6	4.1
Total	146	100

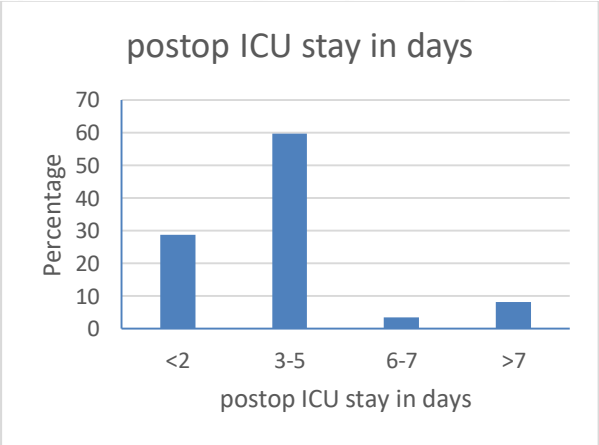
Descriptive analysis of postoperative Ventilation

postop ventilation- Duration	Frequency	Percent
<24 hours	127	87
1-2 days	7	4.8
2-5 days	4	2.7
>5 days	2	1.4
>5 days +tracheostomy	6	4.1
Total	146	100

Descriptive analysis of postoperative ICU stay

postop ICU stay in days	Frequency	Percent
<2	42	28.8
3-5	87	59.6
6-7	5	3.4
>7	12	8.2
Total	146	100





Descriptive analysis of frequency of various variables considered in study

Variable	Frequency	% of n (n=146)
h/o heart failure	31	21.2
h/o pulm disease	18	12.3
h/o CVA/syncope	4	2.7
H/o CKD	29	19.9
h/o AKI recovered	7	4.8
DM	84	57.5
HTN	90	61.6
Smoking	76	52.1
DLP	61	41.8
PVD	9	6.2
family h/o CAD/PVD/Thoraco abdominal aneurysm	37	25.3
preop PCI	15	10.3
preop ventilation	2	1.4
Left Main involvement	27	18.5
ON Pump CABG	144	98.6
Endarterectomy	8	5.5
LIMA	141	96.6
postop inf- SSI(deep/superfical)	9	6.2
Post op-resp inf	12	8.2
postop blood inf	1	0.7
postop urine inf	3	2.1
IABP	14	9.6
postop Dialysis/RRT	3	2.1
Follow up - reinterventions	38	26
B blockers	114	78.1
ACE inhibitors	78	53.4
Antiplatelet	126	86.3

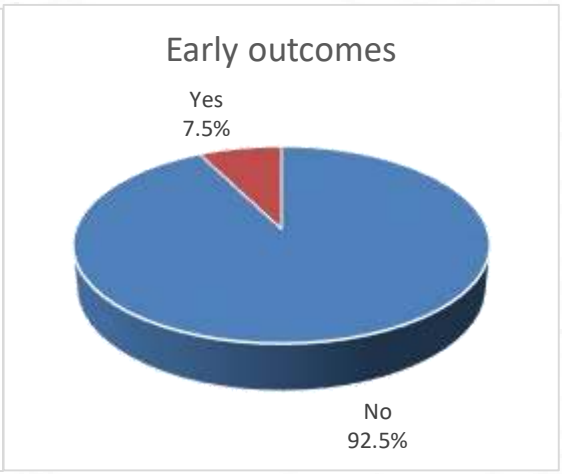
	Mean	Std. Deviation	Minimum	Maximum	Median	Q1	Q3
preop 2D ECHO-EF	29.5	4.8	17	35	30	27	33
Age	55.6	8.8	38	81	56	49.75	61
Hospital stay	10.6	6.0	2	45	9	8	10
postop stay	7.8	4.8	1	36	7	6	8
preop S creat	1.2	0.3	0.7	2.4	1.1	1	1.4
postop S Creat	1.4	0.4	0.7	3.5	1.3	1.1	1.6
CPB time	124.3	38.4	0	261	118	98.75	144
ACC time	67.5	27.0	0	162	60.5	49	81
postop echo- EF	39.9	9.0	17	76	40	35	45
postop ICU stay	4.0	3.3	1	22	3	2	4
Inotrope score	10.1	8.1	0	46	7.75	5	10.25
Duration of survival in months	64.6	35.9	0	118	73	42.75	90.25

Descriptive Analysis of Operative Mortality

Operative mortality	Frequency	Percent
No	138	94.5
Yes	8	5.5
Total	146	100

Descriptive Analysis of Early Outcomes (<30days mortality)

Early outcomes(<30days postop)	Frequency	Percent
No	135	92.5
Yes	11	7.5
Total	146	100



Parameter		Preoperative 2D Echo EF (%)			Chi square	P Value
		<25 (N=23)	25-30(N=52)	31-35(N=71)		
Gender	Male(N=138)	22 (15.9%)	47 (34.05%)	69 (50%)	2.746	0.253
	Female(N=8)	1 (12.5%)	5 (62.5%)	2 (25%)		
Intraoperative procedure	CABG (N=91)	13 (57%)	34 (5%)	44 (62%)	3.372	0.761
	CABG+ LV linear plication (N=34)	4 (17%)	12 (23%)	18 (25%)		
	CABG+DOR's Procedure(N=10)	3 (13%)	3 (5.8%)	4 (5.6%)		
	CABG+MV repair(N=11)	3 (13%)	3 (5.8%)	5 (7%)		
Inotrope score	<5 (N= 63)	9 (39%)	20 (39%)	34 (48%)	3.043	0.718
	6-15(N=63)	9 (39%)	25(48%)	29 (41%)		
	16-30(N= 14)	3(13%)	5 (9.6%)	6 (8.5%)		
	31-45(N= 5)	2 (8.7%)	2 (3.8%)	1 (1.4%)		
	>45 (N=1)	0 (0%)	0 (0%)	1 (1.4%)		
Postoperativ ventilation	<24hrs (N= 127)	19(14.9%)	48 (38%)	60 (47.2%)	3.210	0.782
	24-48hrs(N= 6)	2 (33.3 %)	1 (20%)	3 (12.5%)		
	2days-5days(N= 4)	1 (16.7%)	1 (20%)	3 (25%)		
	>5days(N=8)	1 (50%)	2 (60%)	5 (62.5%)		
IABP	Yes (N= 14)	3 (13%)	3 (5.8%)	8 (11%)	1.422	0.491
	No (N= 132)	20 (87%)	49 (94%)	63 (89%		
Early outcomes (<30 days mortality)	Alive (N=135)	19 (83%)	51 (98%)	65 (92%)	5.643	0.059
	Dead (N= 11)	4 (17%)	1 (1.9%)	6 (8.5%)		
Follow up admissions	Yes (N=32)	5(21.73%)	11 (21.2%)	16 (22.53%)	0.034	0.983
	No (N=114)	18 (78.3%)	41 (78.8%)	55 (77.46%)		
Follow up survival	<1 year(N= 26)	7 (30%)	5 (9.6%)	14 (20%)	6.479	0.372
	1-3 years (N= 9)	1 (4.3%)	5 (9.6%)	3 (4.2%)		
	3-5 years (N= 11)	1 (4.3%)	4 (7.7%)	6 (8.5%)		
	>5 years (N= 100)	14 (61%)	38 (73%)	48 (68%)		

Comparision of Preop 2D ECHO EF and Postoperative 2D ECHO EF

Parameter	Mean ± SD	Median	Minimum	Maximum	95% C. I	
					Lower	Upper
Preop 2D Echo-EF	29.51 ± 4.84	30.00	17.00	35.00	28.72	30.31
Postop 2D Echo EF	39.92± 9	40.00	17.00	76.00	38.44	41.39

Difference	10.410
Standard error	0.846
95% CI	8.744 to 12.075
t-statistic	12.309
DF	290
Significance level	**P < 0.0001**

Comparision of preop S creatinine and postop S.creatinine

Parameter	Mean ± SD	Median	Minimum	Maximum	95% C. I	
					Lower	Upper
Preop S Creat	1.21 ± 0.33	1.10	0.70	2.40	1.15	1.26
Postop S Creat	1.39 ± 0.44	1.30	0.70	3.50	1.32	1.46

Difference	0.180
Standard error	0.046
95% CI	0.0904 to 0.2696
t-statistic	3.954
DF	290
Significance level	**P =0.0001**

Analysis of factors effecting Postoperative stay

Parameter		Mean number of days	Median number of days IQR	(P value)
SSI(deep/Superficial)(N= 146)	Yes (N=9)	14.77+/- 11.7	7	<0.0001
	No(N=137)	7.36 +/- 3.56	6	
Respiratory Infections (N=146)	Yes(N=12)	16.66 +/- 9.19	16	<0.0001
	No (N=134)	7.05+/- 3.27	6	
Blood infection(N=146)	Yes(N=1)	8	8	0.95
	No(N=145)	7.82+/- 4.78	7	
Urine infection(N=146)	Yes(N=3)	16.66+/-10.01	16	= 0.001
	No(N=143)	7.63+/- 4.49	7	
IABP(N=146)	Yes (N=14)	8.35+/- 6.94	6	<0.0001
	No (N=132)	3.56+/-2.23	3	
Postoperative ventilation (N= 146)	<24hrs(N=127)	3.21+/- 1.35	2	<0.001
	24-48hrs(N=7)	5.00+/- 2.449	5	
	2-5days(N=4)	7.00+/- 4.23	6	
	>5days(N=8)	15.00+/-9.899	8	
Postop Arrhythmias	No (N= 83)	3.14+/- 1.463	2	<0.001
	AF(N= 23)	5.00+/- 4.348	4	
	VPCs(N=34)	4.91+/- 4.508	4	
	AF+ VPCs(N=6)	7.67+/-4.761	6	
Inotrope score	<5(N=47)	2.92+/-1.004	2	0.0003
	6-15 (N= 63)	4.42+/-3.65	4	
	16-30 (N=14)	6.64+/- 5.22	5	
	31-45(N=5)	6+/-5.61	5	
	>45(N=1)	2+/-1	2	

Analysis of CPB time and ACC time in study population(N=146)

Parameter (N=146)	Mean ± SD	Median	Minimum	Maximum	95% C. I
CPB Time	124.32 ± 38.26	118.00	67.00	261.00	124.32+/- 6.228
ACC Time	67.45 ± 26.89	61.00	29.00	162.00	67.65+/- 4.37

Univariate analysis of Inotrope score and CPB time

		CPB time		
Inotrope score	**N**	**Mean**	**SD**	**P value**
<5	63	114.08	34.034	
6-15	63	124.13	34.534	
16-30	14	157.57	49.610	**<0.001**
31-45	5	151.20	41.457	
>45	1	183.00	.	
Total	146	124.33	38.396	

Univariate analysis of Inotrope score and ACC time

		ACC time		P Value
Inotrope score	**N**	**Mean**	**SD**	
<5	63	61.00	22.876	
6-15	63	71.87	27.706	
16-30	14	77.14	25.225	**0.124**
31-45	5	67.80	54.993	
>45	1	59.00	.	
Total	146	67.46	26.992	

Comparision of Preop 2D Echo EF effect on Inotrope score

Inotrope score	Pre OP EF						Total		p
	<25		25-30		31-35				
	N	%	N	%	N	%	n	%	
<5	9	39	20	39	34	48	63	43	**0.718**
6-15	9	39	25	48	29	41	63	43	
16-30	3	13	5	9.6	6	8.5	14	9.6	
31-45	2	8.7	2	3.8	1	1.4	5	3.4	
>45	0	0	0	0	1	1.4	1	0.7	
Total	23	100	52	100	71	100	146	100	

Comparision of Inotrope score and effect on Early outcomes

Inotrope score	Early outcomes				Total		P value
	Alive		Dead				
	N	%	N	%	N	%	
<5	63	46.7	0	0	63	43.2	**<0.001**
6-15	61	45.2	2	18.2	63	43.2	
16-30	8	5.9	6	54.5	14	9.6	
31-45	3	2.2	2	18.2	5	3.4	
>45	0	0	1	9.1	1	0.7	
Total	135	100	11	100	146	100	

Early Outcomes – Univariate Analysis with various parameters

Parameter	Early outcomes		Chi square	Fisher exact P value
	Alive (N=135)	Dead (N=11)		
Gender				
Male (N= 138)	**128 (94.81%)**	**10 (90.9%)**	**0.2996**	**0.5841**
Female (N= 8)	**7 (5.18%)**	**1 (9.09%)**		
DM				
Yes	78 (57.8%)	6 (54.5%)	0.043	0.835
No	57 (42.2%)	5 (45.5%)		
HTN				
Yes	85 (63.0%)	5 (45.5%)	1.319	0.251
No	50 (37.0%)	6 (54.5%)		
Smoking				
Yes	69 (51.1%)	7 (63.6%)	0.639	0.424
No	66 (48.9%)	4 (36.4%)		
DLP				
Yes	55 (40.7%)	6 (54.5%)	0.797	0.372
No	80 (59.3%)	5 (45.5%)		
H/o Heart Failure				
Yes (N=30)	29(21.48%)	1(9.09%)	0.956	0.461
No (N= 116)	106(78.52%)	10(90.91%		
Emergency/elective				
Elective	132(97.77%)	10 (90.9%)	1.800	0.179
Emergency	3 (2.22%)	1 (9.09%)		
OP CABG/On Pump CABG				
On pump	134(99.26%)	10(90.91%)	5.249	0.145
Off Pump	1(0.74%)	1(9.09%)		

Intraop procedure	Early outcomes				P value
	Alive (N=135)		Dead (N= 11)		
	n	%	n	%	
CABG	82	60.7	9	81.8	0.305
CABG+ Linear Plication	34	25.2	0	0	
CABG+MV repair	10	7.4	1	9.1	
CABG+DORS	9	6.7	1	9.1	

Number of Grafts	Early Outcomes		Chi square	P value
	Alive (N=135)	Dead (N=11)		
2G	3 (2.22%)	1 (9.09%)	2.753	0.599
3G	23 (17.04%)	2 (18.18%)		
4G	49 (36.3%)	5 (45.45%)		
5G	45 (33.33%)	2 (18.18%)		
6G	15(11%)	1 (9.09%)		

IABP	Early outcomes				P value
	Alive (N=135)		Dead (N=11)		
	n	%	n	%	
No (N= 132)	129	95.6	3	27.3	<0.001
Yes (N=14)	6	4.4	8	72.7	

Inotrope score	Early mortality				P value
	Alive (N=135)		Dead (N=11)		
	n	%	n	%	
<5 (N= 63)	63	46.7	0	0	<0.001
6-15 (N= 63)	61	45.2	2	18.2	
16-30 (N=14)	8	5.9	6	54.5	
31-45 (N=5)	3	2.2	2	18.2	
>45 (N=1)	0	0	1	9.1	

postop ventilation	Early mortality				P value
	Alive (N=135)		Dead (N=11)		
	n	%	n	%	
<24 hours (N=127)	125	98.4	2	1.6	<0.001
1-2 days(N=7)	4	57.1	3	42.9	
2-5 days (N=4)	1	25.0	3	75.0	
>5 days (N=2)	0	0.0	2	100.0	
>5 days +tracheostomy(N=6)	5	83.3	1	16.7	

Endarterectomy	Early mortality				P value
	Alive (N=135)		Dead (N=11)		
	n	%	n	%	
No (N=138)	127	92.0	11	8.0	0.406
Yes (N=8)	8	100.0	0	0.0	

Postoperative arrhythmias	Early mortality				P value
	Alive (N=135)		Dead (N=11)		
	n	%	n	%	
No (N=83)	81	60	2	18.18	0.007
Yes (N=63)	54	40	9	81.2	

Follow up readmissions

Total No of patients who had undergone readmission (N)=38 from 135 alive patients

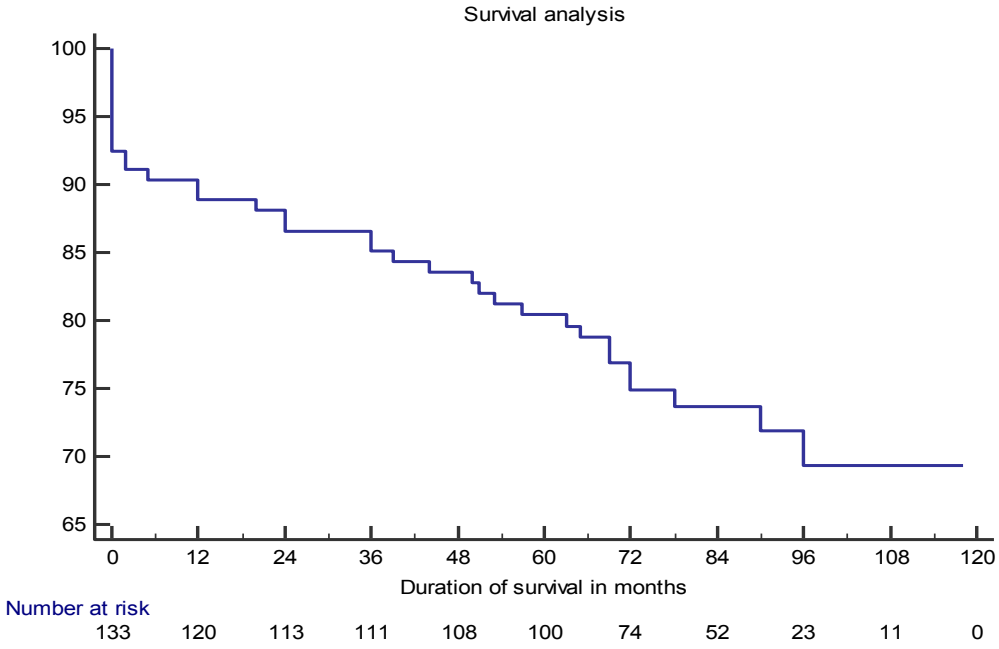
Cause For readmission	N =38 (%)	% of Alive patients under follow up (N=135)
Heart failure	10 (26.3%)	7.47%
CAG and PCI	9(23%)	6.66%
ICD	2 (5.26%)	1.48%
Holter	4 (10.52%)	2.96%
Infections(SSI)	6 (15.78%)	4.44%
CVA	2 (5.26%)	1.48%
PE drainage	1 (2.63%)	0.74%
Dyselectrolemia	2 (5.26%)	1.48%
Other surgeries	2 (5.26%)	1.48%

	N=38	Alive patients under follow up (N=135)
Readmission from cardiac cause	26 (68.42%)	26(19.25%)
Readmission from non cardiac cause	12 (31.57)	12(8.8%)
Total	38 (100%)	38 (2.81%)

Survival Analysis

Number of events		Number censored		Total sample size
N	**%**	**N**	**%**	
36	24.66	110	75.34	146
Mean survival time in months				
Mean	SE	95% CI for the mean		
94.221	3.523	87.315 to 101.127		

Kaplan-Meier curves of overall survival probability

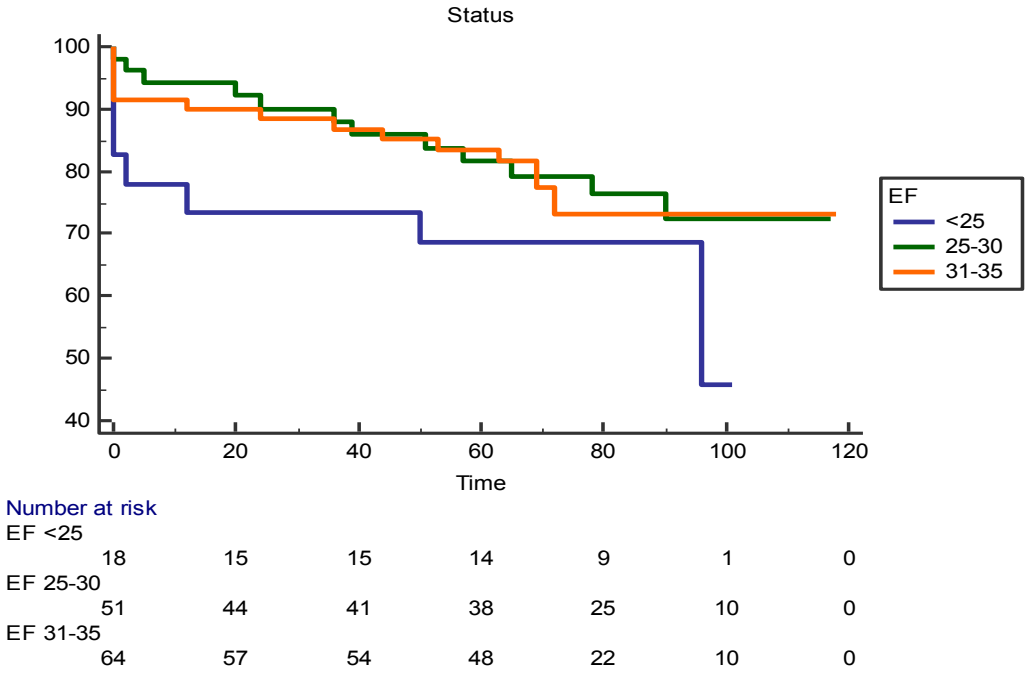


Ejection fraction	Number of events		Number censored		Total sample size
	N	%	N	%	
<25	8	34.78	15	65.22	23
25-30	12	23.08	40	76.92	52
31-35	16	22.54	55	77.46	71
Overall	36	24.66	110	75.34	146

EF	Mean survival time in months		
	Mean	SE	95% CI for the mean
<25	71.6	9.2	53.660 to 89.590
25-30	97.0	5.2	86.683 to 107.245
31-35	83.8	4.0	75.998 to 91.641
Overall	94.2	3.5	87.315 to 101.127

Comparison of survival curves (Logrank test)	
Chi-squared	1.8997
DF	2
p	P = 0.3868

Kaplan-Meier curves comparing survival time and preop EF

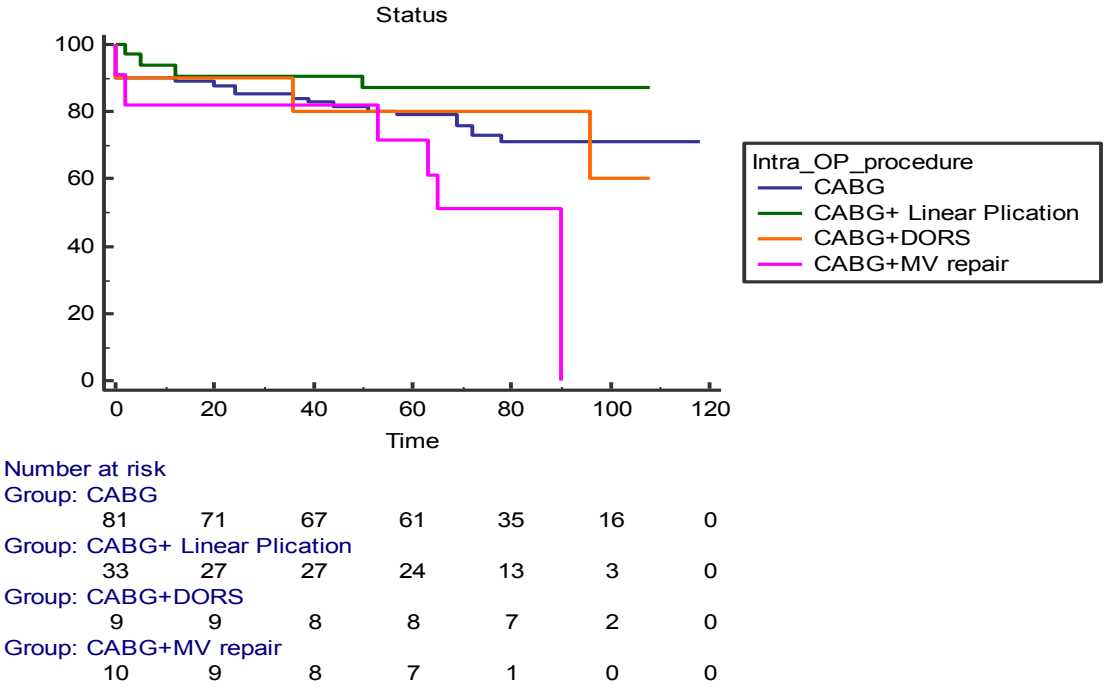


Operative procedure	Number of events		Number censored		Total sample size
	N	%	N	%	
CABG	23	25.27	68	74.73	91
CABG+ Linear Plication	4	11.76	30	88.24	34
CABG+DORS	3	30	7	70	10
CABG+MV repair	6	54.55	5	45.45	11
Overall	36	24.66	110	75.34	146

Operative Procedure	Mean survival time in months		
	Mean	SE	95% CI for the mean
CABG	86.324	4.072	78.343 to 94.305
CABG+ Linear Plication	97.31	5.561	86.411 to 108.208
CABG+DORS	87.6	11.485	65.090 to 110.110
CABG+MV repair	64.716	10.963	43.228 to 86.203
Overall	94.221	3.523	87.315 to 101.127

Comparison of survival curves (Logrank test)	
Chi-squared	8.097
DF	3
p	**P = 0.044**

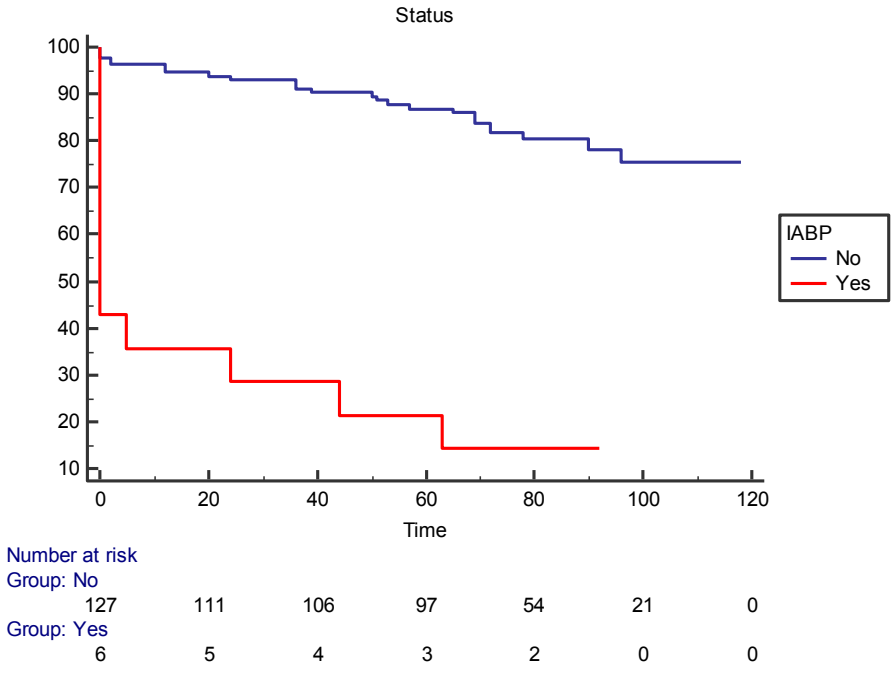
Kaplan –Meier curves comparing surving time and Operative procedure



IABP	Number of events		Number censored		Total sample size
	N	%	N	%	
No	24	18.18	108	81.82	132
Yes	12	85.71	2	14.29	14
Overall	36	24.66	110	75.34	146

IABP	Mean survival time in months		
	Mean	SE	95% CI for the mean
No	101.586	3.091	95.527 to 107.644
Yes	22.857	9.069	5.082 to 40.632
Overall	94.221	3.523	87.315 to 101.127

Comparison of survival curves (Logrank test)	
Chi-squared	60.4297
DF	1
p	**P < 0.0001**



DISCUSSION

- A Total of 146 consecutive patients who had undergone surgical management for coronary artery disease with severe left dysfunction were studied which represents 4.5% (146 of 3110) of all patients who had undergone CABG and other ventricular restorative procedures performed.
- In our study we found that CABG or CABG with ventricular restorative procedures had an excellent mid term outcomes with 5 year survival reaching 84%. Our study had found to have a operative mortality of 5.47% and a early outcomes (within 30 days of surgery) was found to be 7.53%.
- Operative mortality and early outcomes (<30 day mortality) is comparable to other studies conducted in western world (44,50),whereas studies conducted in India on patients with severe left ventricular dysfunction reached 11.62% of operative mortality and a higher early mortality (49).
- IABP, higher inotropic score,prolonged ventilation were identified as significant risk factors for Early mortality.
- There is no correlation with preoperative risk factors (DM,HTN,smoking,DLP) or history of congestive heart failure or History of PCI with early outcomes. Whereas other studies showed a correlation with preoperative risk factors and H/o congestive heart failure.(44,49,51).
- There is a significant improvement in postoperative Ejection fraction compared to Preoperative Ejection fraction (95%CI – 8.744 to 12.075, P<0.0001). Significant improvement in postoperative Ejection fraction could be reason for better early and mid term outcomes.

- In this study Patients with severe LV dysfunction it was found that developing postoperative respiratory and Surgical site infections ,requirement of IABP, higher inotropic score ,need for prolonged ventilation ,postoperative arrhythmias are having significant correlation with postoperative ICU stay, which were not analysed neither in landmark studies like STICH trial (43) or STICHES trial(44) , nor in Studies done in Indian popuplation (49) with respect to postoperative ICU stay
- Subgrouping in preoperative EF (<25%,25-30%,>31-35% groups) doesnot show any correlation in postoperative requirement of higher inotropic doses ,need for postoperative ventilation, IABP,early mortality,follow up survival time or follow up readmissions or reinterventions. Similar correlations were studied in Saeed Davoodi et al study(51).
- Usage of Left internal mammary artery (LIMA) to bypass LAD in 96.6% of patients. The survival advantage of using LIMA even in patients with severe left ventricular dysfunction was shown in Popovic B et al. study.(53). This could be one of the reasons for excellent midterm outcomes reaching survival probability upto 83%.
- This study also shows significant improvement in Ischemic MR compared to preoperative MR . This could be one of the reasons for achieving better early outcomes.
- Another reason for excellent mid term outcomes could be age of population ,49.3% of population are <55 years of age.
- In this study majority of patients (98.6%) coronary anastamosis was done under CPB.As per landmark studies (ROOBY ,ROOBY-FS trials) (56,57) Onpump CABG provides complete revascularisation .This could be one of the reasons for better early and mid term outcomes.
- CABG and other associated ventricular restorative procedures are thought to be difficult

in Indian population,due to diffuse nature of disease,tendency for early calcification (54,55).In this study 5.5 % of patients requires coronary endarterectomy.

- On Follow up midterm survival probability was found to be slightly more in patients undergoing CABG with ventricular restorative procedures than in patients who had undergone CABG alone .
- Readmissions on follow up i.e, 68% of readmissions / 19.25% of alive patients under follow up. Cardiac causes are the predominant reason for readmission , but the rate of readmission in our study shows less than other studies done on Indian population(49) and also comparable and better than other landmark studies(43,44)
- There is no system of public reporting of cardiac surgery results nor a central registry or a database in India through which data of patients with severe left dysfunction undergoing surgical management was known. This study is second of its kind in India which was studied on patients with severe left ventricular dysfunction who had undergone surgical management which gives on insight onto need for further studies on a large scale by which

CONCLUSION

- From our study we conclude that CABG and CABG with ventricular restorative procedures remain a viable option for patients with severe LV dysfunction , in view of better early outcomes and excellent midterm suvival probabality reaching standards of western studies.
- There is no system of public reporting of cardiac surgery results nor a central registry or a database in India through which data of patients with severe left dysfunction undergoing surgical management was known.
- This study is second of its kind in India which was studied on patients with severe left ventricular dysfunction who had undergone surgical management which gives an encouraging results on survival probability and is comparable in outcomes with western patients who dominate the current literature on surgical mangement in severe LV dysfunction , thereby suggesting CABG is a viable option in severe LVD patients even in Indian scenario.
- There is a need for further larger studies and to maintain a central registry in India like in western world on patients with severe left ventricular dysfunction undergoing surgical management , thereby outcomes can be better understood and surgical management in Severe LVD patients can be encouraged.

LIMITATIONS

- As it is retrospective study there may chance of potential biases ,and the results might be affected by confounding variables which are unmeasured, detection bias.
- Follow up coronary angiograms are performed only in patients who are symptomatic due to economic constraints. The exact patency of coronary grafts in many patients was not assessed

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श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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Institutional Ethics Committee

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

SCT/IEC/1507 /DECEMBER-2019 07.01.2020

Dr. Srawanthi Ponnuru
Senior Resident
Department of CVTS
SCTIMST, Thiruvananthapuram

Dear Dr. Srawanthi Ponnuru,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "OUTCOMES OF CORONARY ARTERY DISEASE PATIENTS WITH SEVERE LEFT VENTRICULAR DYSFUNCTION UNDERGOING SURGICAL MANAGEMENT (IEC/1507)" on 21st December, 2019.

The following documents were reviewed:

Original submission

1. *Covering letter addressed to the Chairman, IEC, SCTIMST with checklist*
2. *Full proposal*
3. *IEC Application Form*
4. *Proforma*
5. *TAC Approval letter*
6. *Telephone Recruitment Script in English and Malayalam*
7. *Patient Information Sheet*
8. *CV of Principal Investigator and Co-Principal Investigators*

Revised submission

1. *Covering letter addressed to the Chairman, IEC, SCTIMST with checklist*
2. *Full proposal*
3. *IEC Application Form*
4. *Proforma*
5. *Telephone Recruitment Script in English and Malayalam*
6. *Patient Information Sheet*
7. *CV of Principal Investigator and Co-Principal Investigators*

The following members of the Ethics Committee were present at the meeting held on 21st December, 2019 at G. Parthasarathi Board Room, AMCHSS, SCTIMST

SL No	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1	Dr. R V G Menon	M Tech, PhD	Male	Lay Person (Chairman)	No
2	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
3	Dr. K R S Krishnan	M.E., Ph.D.	Male	Medical Technology	Yes
4	Dr. Anand Kumar A	MD, DM	Male	Clinician	No
5	Dr. Rema M. N	MD	Female	Basic Medical Scientist	No
6	Dr. Harikrishna Varma PR	Ph.D(Materials Science)	Male	Medical Technology	Yes
7	Dr. V. Raman Kutty	M D, M Phil, M P H	Male	Health Sciences Expert/Clinician	Yes
8	Dr. P. Manickam	BSMS, MSc (Epid) ,PhD	Male	Health Science Expert/ Social Scientist	No
9	Dr. Aneesh V Pillai	BA. LLB (Hons.), LLM, Ph. D, SET (Law)	Male	Legal Expert	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

PROFORMA

Demographic data :

Serial number:

Age :

Gender :

Preoperative Data :

Symptoms- Dyspnoea- NYHA I/II/III/IV

Angina-NYHA I/II/III/IV

H/O Chronic stable angina/Acute coronary syndrome

H/O Heart failure

H/O Pulmonary disease

H/O Cerebrovascular disease

H/O Renal failure/ Chronic Kidney disease

H/O Liver/Gastrointestinal disease

H/O Diabetes, Hypertension, Smoking, Hyperlipidemia

H/O Peripheral vascular disease

Family History -coronary artery disease/Peripheral vascular disease/Thoracoabdominal aneurysm

H/o cardiac surgeries:

Preoperative Procedures- PCI

Preoperative ventilation-

Emergency/Elective

Preoperative Investigations

2D ECHO- Ejection fraction

Regional wall motion abnormality

Valvular status- Mitral regurgitation, Aortic regurgitation

LV Size

Scar/Aneurysms

Coronary angiogram-

Number of Vessels involved

Left Main Involvement

PCI for any involved vessel

ECG- Arrhythmias

Intraoperative Data :

Procedure executed

On pump CABG/Off Pump CABG

Number of grafts

Endarterectomy

Internal Mammary artery,Radial Artery use

LV wall reconstruction

Valvular Repair/replacement

CPB time

Aortic cross clamp time

Use Of IABP- Preop/postoperatively

Postoperative Data:

Postoperative ICU stay

Postoperative Ventilation status – Duration of Ventilation

Postoperative need of IABP

Need for renal replacement /Dialysis

Inotrope score

Postoperative arrhythmias

Postoperative Hospital stay

Postoperative Infections:

- Deep Sternal Infections/Superficial SSI
- Respiratory Infections
- Blood Infections

In hospital Mortality

Cause of mortality

Postop ECHO- EF, ventricular function, RWMA, Valve function

Follow UP

Follow up Symptoms-class

Post op follow up echo- Ventricular function, Ejection fraction, RWMA, Valve function/status

Readmission with signs of failure

Readmission for Re-CAG /Cath studies

Readmission for Redo CABG

Readmission for any other cause other than cardiac

Mortality- cause of mortality

- Date of death

Document Information

Analyzed document	Srawanthi Thesis.docx (D78349235)
Submitted	8/30/2020 8:47:00 AM
Submitted by	Dr Jayakumar zk
Submitter email	jk@sctimst.ac.in
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Sources included in the report

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