ASSESSMENT OF MYOCARDIAL DEFORMATION DURING OFF PUMP CABG (OPCABG) USING SPECKLE TRACKING ECHOCARDIOGRAPHY

Thesis submitted for the partial fulfilment for the requirement of the Degree of DM (Cardiothoracic and vascular Anaesthesia)

BY

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DECLARATION

I hereby declare that this thesis entitled, **"Assessment of myocardial deformation during off pump CABG (OPCABG) using speckle tracking echocardiography"** has been prepared by me under the able supervision and guidance of **Dr. Suneel P.R and Dr. Unnikrishnan K.P,** Division of Cardiothoracic and Vascular Anaesthesia**,** Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram, Kerala.

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Dr. GarreSandeep

CONTENTS

INTRODUCTION

Introduction

Left ventricular (LV) dysfunction increases the risk of cardiovascular complication and death after cardiac[1] and non cardiac surgery[2]. Echocardiography is the most versatile and accessible imaging modality for assessment of cardiac function. Estimation of LV systolic function is a prime goal of echocardiography, performed for almost any indication. A number of parameters such as fractional shortening (FS), fractional area change (FAC), ejection fraction (EF) cardiac output (CO) have been developed to assess global LV function. Of them left ventricular ejection fraction (LVEF) is robust, clinically the most relevant and widely used parameter.

Despite their utility all of them have several limitations and are indirect measures of myocardial contractile function. Most of them are calculated making certain geometrical assumptions and all of them are influenced by factors such as LV loading conditions and heart rate. None of them are sensitive enough to detect subtle changes in the contractile function and therefore not suitable for detecting subclinical myocardial damage which may have major therapeutic and prognostic implications[3].

Off pump coronary artery bypass grafting (OPCABG) is popular as it avoids the complications associated with cardiopulmonary bypass (CPB). During OPCABG the heart is subjected to a lot of distortion due to positioning and the application of stabilization devices such as octopus, and star fish, may cause alterations in the loco-regional myocardial blood flow, impairing myocardial function. These changes may be too subtle to be picked up by the routine measures of myocardial function such as EF.

Speckle tracking echocardiography (STE) is a developing technique for the characterization and quantification of myocardial deformation. It is a grey-scale based technique which is angle-independent and permits a comprehensive assessment of myocardial deformation. Of the various parameters obtained using speckle tracking, global longitudinal strain (GLS) assesses the longitudinal function of the left ventricle which is due to contraction of the subendocardial muscle fibres. The subendocardial fibres are very sensitive to alterations in myocardial blood flow and is the first layer affected in myocardial ischemia. GLS is very sensitive and more effective than LVEF for monitoring myocardial function after OPCABG[4].

Myocardial deformation imaging offers a means to directly quantify the extent of myocardial contraction and promises to overcome many of the limitations of LVEF. There are no published studies employing STE obtained with TEE during the intraoperative period during OPCABG surgery. Due to the small number of cases being done as off pump and multiple challenges in obtaining adequate quality images during the surgery, the present study is only meant as a feasibility study. We decided to evaluate the Left Ventricle using STE for OPCABG to assess any subtle changes in myocardial contractility using GLS that may occur during and after OPCABG.

REVIEW OF LITERATURE

Review of literature

Assessment of left ventricular systolic function is one of the primary goals of echocardiography. Various parameters have been developed to accomplish this task. Fractional shortening (FS), fractional area change (FAC), ejection fraction (EF), cardiac output (CO) are used to assess global LV function, while regional wall motion abnormality (RWMA) assesses the regional function. Clinically Left ventricular ejection fraction (LVEF) is the most popular and widely used parameter.

Most of these assessment tools are not direct measures of myocardial systolic function and have several other limitations. They are calculated making some geometrical assumptions of the LV, are influenced by LV preload, afterload, heart rate and are also subjected to a lot of inter observer variation[5]. None of them are sensitive enough to detect subtle changes in the contractile function and therefore not suitable for detecting subclinical myocardial damage which may have major therapeutic and prognostic implications[3]. The utility of RWMA is also limited because passive motion of a noncontracting/ ischemic segment, due to tethering to adjacent contracting or non-ischemic segments cannot be reliably excluded.

The left ventricular myocardial structure is complex with the myocardial fibres organized in layers, forming a leftward helix in the subepicardium, which transitions to a rightward helix in the subendocardium. This fibre arrangement produces movements in three planes, longitudinal (mitral annulus to apex), radial (epicardium to endocardium), and circumferential (tangentially to epicardium) motions during systole and diastole[6]. During systole there is longitudinal and circumferential thinning and radial thickening, with opposite changes in diastole. The overall direction of LV rotation is clockwise at the base and counter clock wise at the apex (Figure 1). Using conventional TEE imaging this complex 3D cardiac motion cannot be appreciated. The mid esophageal (ME) or transgastric (TG) views can reveal the function of the middle layer of myocardium, the inward endocardial excursion (radial motion) and myocardial thickening. The longitudinal motion (ME views) and circumferential motion (TG views) are difficult to evaluate although they are important. Also the first myocardial layer affected by ischemia is the subendocardium, which accounts for the longitudinal motion[7]. In systole, radial thickening predominates (40%) which is accompanied by longitudinal shortening (14%)[8]. Most of these limitations can be overcome by assessing myocardial deformation using speckle tracking echocardiography (STE).

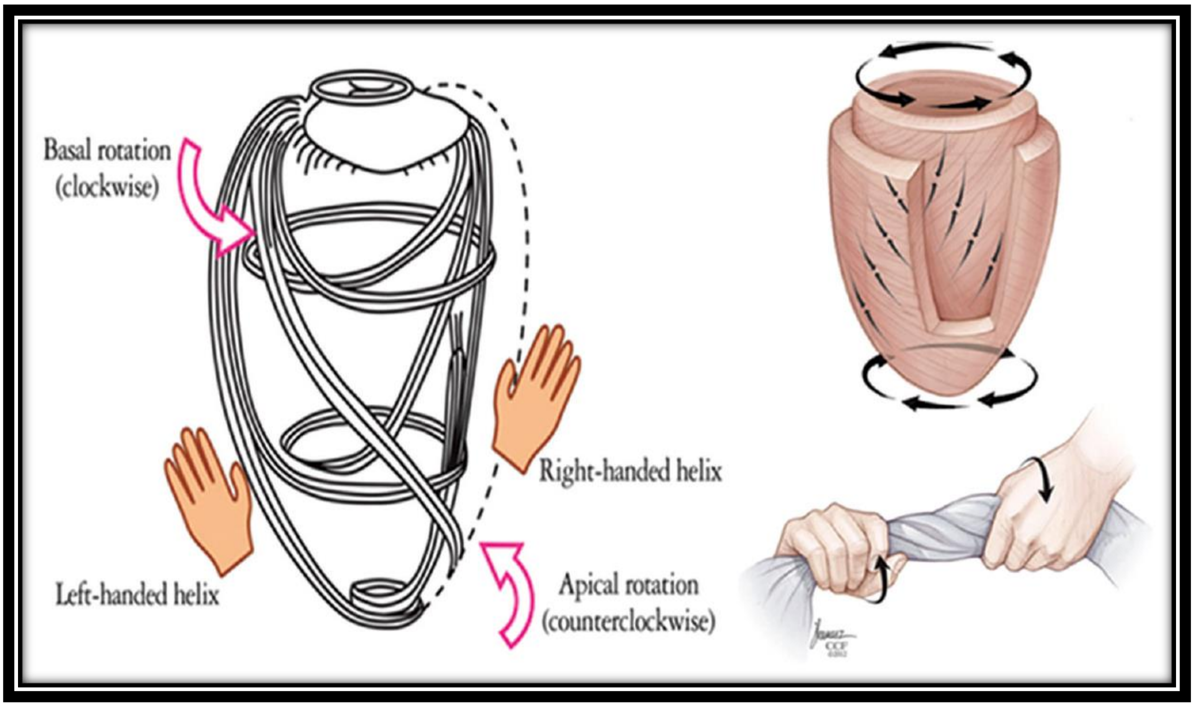

Figure 1: Arrangement of subepicardial layers in a leftward helix and subendocardial layers in a rightward helix leads to complex motion of the heart wherein there is clockwise rotation of the base and counterclockwise rotation of the apex of left ventricle (Sourced from: Cleveland Clinic Center for Medical Art & Photography © 2013.)

There is an ever increasing number of patients with coronary artery disease (CAD) presenting for coronary artery bypass grafting (CABG). Off pump coronary artery bypass grafting (OPCABG) is popular in many centres as it avoids the complications associated with CPB.

Some studies have documented worsening of both systolic and diastolic function with cardioplegic arrest[9,10] and some show preservation of LV systolic and diastolic function following OPCABG[11]. However during OPCABG in order to properly visualise and graft the target vessels the heart has to be positioned in ways which distorts the normal anatomy of the heart and the cardiac valves. Also stabilization devices such as octopus, star fish are used during distal anastomoses to keep the area less mobile, facilitating the surgeon to perform grafting in a less mobile field. Use of stabilization devices may cause alteration in the loco regional myocardial blood flow, impairing myocardial function during the procedure. After grafting the stabilisation devices are removed and the heart is kept back in the normal position. The myocardial function may decrease during the procedure, and may come back to normal or even increase as bypass grafting has been done and better blood flow is expected in the post graft period. However these changes may be too subtle to be picked up by the routine measures of myocardial function such as EF. The subendocardial layer of the heart is the first to be affected by alterations in myocardial blood flow and hence GLS which measures the longitudinal motion of the heart, may be sensitive enough to pick up these changes during OPCABG.

Myocardial deformation imaging

The complex three dimensional motion of the heart cannot be appreciated by routine 2-D imaging of the heart. Myocardial deformation imaging offers a means to directly quantify the extent of myocardial motion in various planes.

Myocardial deformation imaging evaluates myocardial motion in 3directions / axes: Longitudinal shortening (from base to apex), Circumferential shortening (encircling the short axis of LV) and Radial thickening (transverse direction from endocardium to epicardium) (Figure 2).

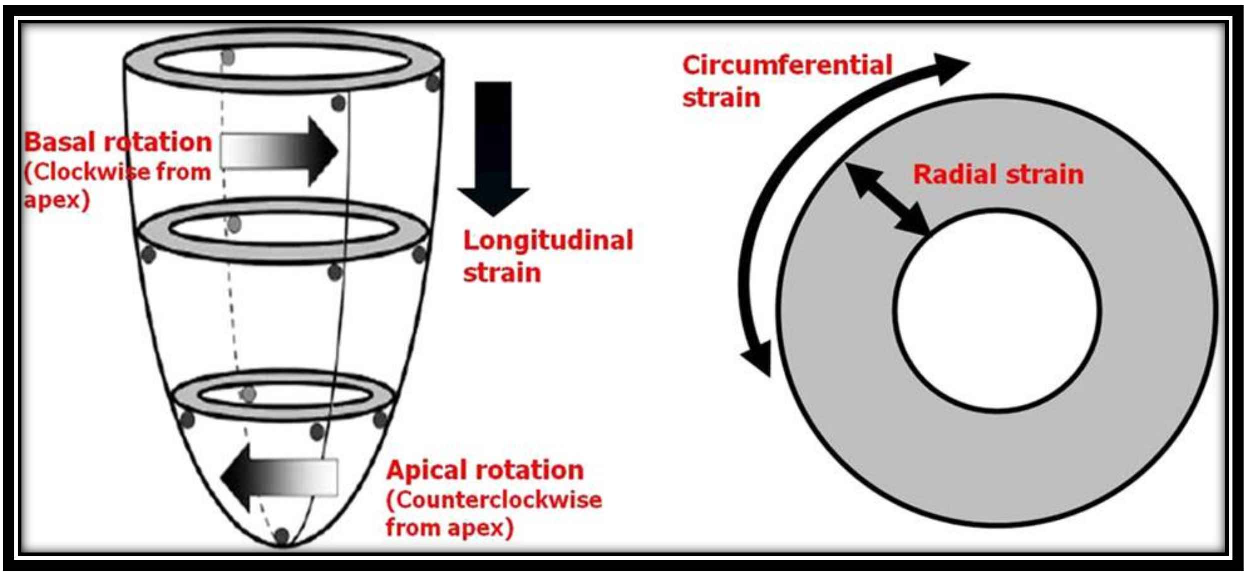

Figure 2: Different components of left ventricular myocardial deformation that can be measured by myocardial deformation imaging. (Indian heart journal 65 (2013) 117-123: How do I do it? Speckle tracking echocardiography[3])

Myocardial deformation parameters:

Strain (S or ∈): a dimensionless index, is the (systolic) deformation of a myocardial fibre, normalized to its original length:

$$\in \ = \frac{L-Lo}{Lo} \times 100 \ = \ \frac{\Delta L}{Lo} \times 100$$

Where ∈ = myocardial strain, L = length at end systole, L0 = initial length measured at end – diastole.

Based on the myocardial motion there are three types of strain:

- Radial strain relates to motion from the endocardium to the epicardium.
- Circumferential strain relates to motion along the circumference (curvature) of the left ventricle.
- Longitudinal strain relates to motion from the base to the LV apex.

Strain is positive when the systolic dimension increases (the myocardial fibre lengthens or thickens) and negative when the systolic dimension decreases (the myocardial fibre shortens or thins). Therefore, radial thickening is associated with positive strain (L > L0), whereas longitudinal shortening and circumferential thinning are associated with negative strain (L < L0).

Strain rate (SR): reflects how fast regional myocardial deformation (strain) occurs: i.e.; the rate at which shortening or lengthening is taking place and has a unit of sec-1.

$$SR = \in / \Delta t$$

Where SR = strain rate, ∈ = myocardial strain, Δt = time duration of the deformation.

For normal myocardium, SR reflects regional contractile function because it is relatively independent of heart rate, whereas systolic strain reflects changes in stroke volume(SV)[12]. Normal values for strain are −16% to −24% (longitudinal strain), +48% (radial strain), and −20% (circumferential strain)[13].

Strain and SR offer complementary information, and ideally both should be measured and evaluated. For example, prolonged contraction may yield normal strain despite low SR. Average longitudinal strain rate in healthy subjects is -1.10 ± 1.16 /sec [14].

SR showed good correlation with +dP/dt during isovolumic contraction (r = .74) and with −dP/dt during isovolumic relaxation (r = .67)[15]. Strain rate is load independent while Strain is load dependent. Abali G et al; showed that acute hypovolemia induced by withdrawal of 500 mL of blood from healthy subjects led to decreased longitudinal tissue Doppler imaging (TDI) strain, whereas SR remained unchanged[16]. Speckle tracking imaging (STI) strain is preload and afterload dependent; longitudinal strain decreased after hemodialysis in patients with end-stage renal disease, and radial strain increased immediately after AVR surgery to treat AS and decreased after AVR to treat AR[17]. It has been shown that intraoperative radial strain measurement by transesophageal echocardiography has a good reproducibility and allows quantitative assessment of regional ventricular function during OPCABG[18]. Strain rate can also detect ischemia with a good sensitivity and specificity[19].

Twist:

It is the instantaneous difference between apical and basal rotation. It has the unit of degree.

Torsion:

It is the LV twist normalised to distance, having the unit degree/cm.

Echocardiographically there are two techniques/methods to assess LV deformation noninvasively:

- Tissue Doppler imaging (TDI)
- Speckle-tracking imaging/ echocardiography (STI).

Tissue Doppler Imaging (TDI) Strain:

Measurements of strain by using TDI are derived by integrating SR over time (Fig 3). Myocardial tissue velocities are measured at 2 points relative to the transducer[20]. SR is estimated from the spatial velocity gradient described as:

$$SR = (va - vb)/d$$

where va − vb represents the difference in myocardial velocities at points a and b, and d represents distance between these points. Strain is derived by temporal integration of SR. Doppler derived strain is a sensitive means for detecting myocardial ischemia, also capable of correctly localizing the ischemia, as opposed to tissue velocity assessment[21]

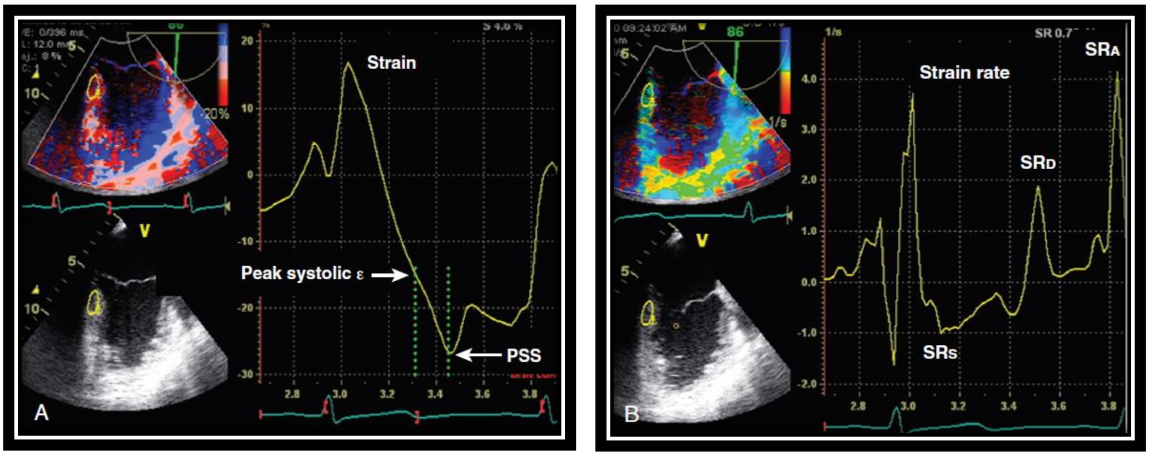

Figure 3: Measurement in Doppler strain echocardiography includes (A) peak systolic (SRS), early diastolic (SRD), late diastolic (SRA) strain rates, and (B) end-systolic strain. Strain recorded after aortic valve closure is called post systolic strain (PSS). (Kaplans cardiac anaesthesia for Cardiac and non cardiac surgery, seventh edition pg no:598)

However TDI strain is time consuming, technically demanding, and has important limitations.

- As it is a Doppler based technique, it is angle dependent and can only measure the component of motion parallel to the ultrasound beam, hence is of limited use with TEE.
- Only the axial component of strain aligned can be measured, thus it measures only longitudinal deformation from ME views and from the trans gastric short-axis window, radial deformation of the anterior or inferior walls[22] and circumferential deformation in the septum and lateral wall.
- Affected by tethering or translation.
- It is semi objective.

Because of these numerous limitations, it is not very popular and other methods to calculate myocardial strain have been developed.

Speckle Tracking Echocardiography (STE)

Speckle tracking echocardiography (STE) is a developing technique for the characterization and quantification of myocardial deformation. STE is a gray-scale based technique which is non- doppler angle-independent and permits more comprehensive assessment of myocardial deformation. When ultrasound interacts with myocardium it results in reflection and scattering generating a finely grey shaded speckled pattern. These speckles are equally distributed within the myocardium and function as acoustic markers, changing their position in accordance with the surrounding myocardial deformation or tissue motion. Movement of these speckles is tracked by STE software throughout the cardiac cycle and the software algorithm extracts displacement, velocity, strain and strain rate within the defined myocardial segment...

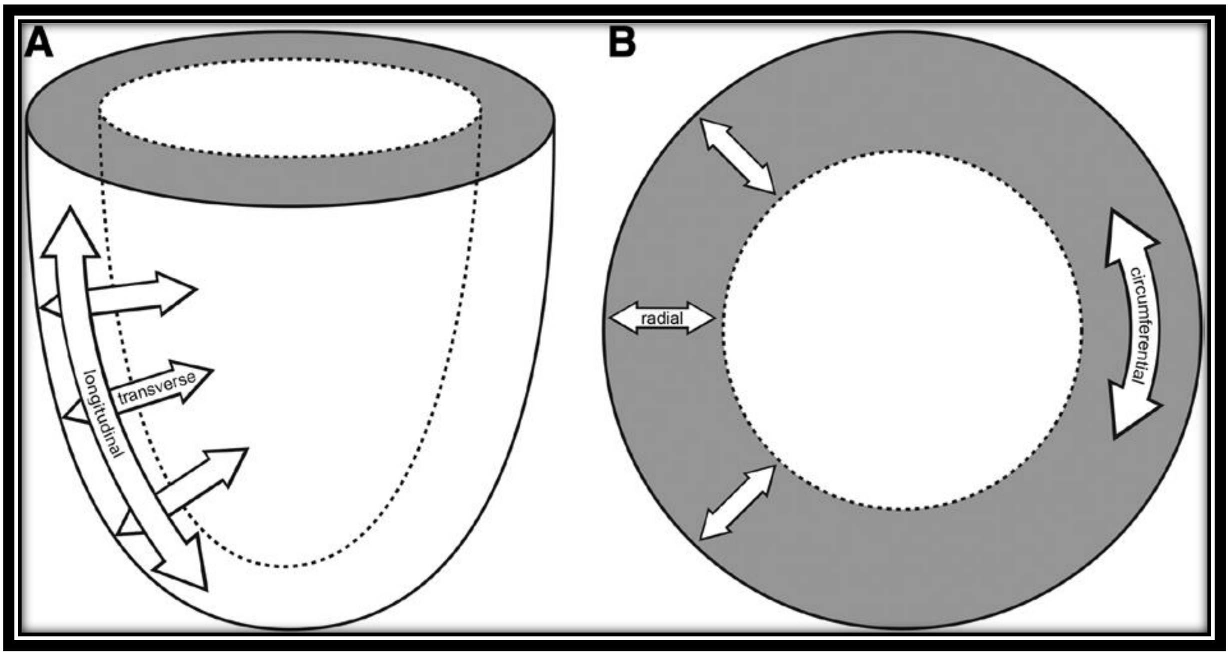

Figure 4: (A) Long-axis views of the left ventricle measure longitudinal (shortening) and transverse (thickening) strain. (B), Short-axis views of the left ventricle measure circumferential (shortening around the circular LV) and radial (thickening) strain (Cleveland Clinic Center for Medical Art & Photography © 2013)

From this data, the software automatically resolves the magnitude of myocardial deformation in different directions and generates strain and strain rate curves[20]. Speckle tracking strain is angle independent and it calculates deformation in two axes. Thus it measures longitudinal and transverse deformation from long-axis views, and radial and circumferential deformation from short-axis views (Fig 4). STE is less susceptible to tethering or translation artefacts, therefore ischemic myocardial segments which may demonstrate displacement and velocity due to tethering, but if deformation does not occur, regional strain and SR will be near zero, thus distinguishing active contraction from passive motion. It provides robust measurements of myocardial deformation with acceptable intraobserver and interobserver variability[23], which correlates with sonomicrometry in dogs under changing loading conditions and regional ischemia, and in humans measured by MRI tagging[24].

Limitations of STE

- STE is highly dependent on the quality of the 2-D echocardiographic images, hence good 2-D images are a must for performing STE.
- Acoustic shadowing and reverberations interfere with frame-by-frame tracking that decrease accuracy of measurement.
- Speckle-tracking uses lower frame rates (typically 50 to 90 frames/s) than TDI strain, which may compromise the ability to capture rapid events during the cardiac cycle.
- Under sampling occurs in tachycardia because optimal frame rate should be less than 100 frames/sec.
- As image analysis requires some operator-dependent functions, such as positioning of the region of interest and approval of myocardial tracking, this technique is semi objective.

But despite these limitations, speckle-tracking provides a simpler, more reproducible, and angle-independent technique to estimate strain in the operating room and serves as the best option for assessing intraoperative regional myocardial function.

Myocardial Deformation in Ischemic Heart Disease

Fall in the LVEF represents a relatively late stage in the development of myocardial dysfunction when sufficient myocardial damage has already occurred. Detection of the myocardial dysfunction in the early, subclinical stage may have significant diagnostic and therapeutic implications and appears to be one of the most promising indications for STE. Subendocardium is responsible for the longitudinal motion of the heart and it is the first layer to be affected by ischemia. Hence, Global longitudinal strain (GLS) is the first parameter to be decreased by myocardial ischemia. Geyer H et al[25]; showed that strain measurements provide an early indication of subendocardial ischemia. Yang ZR et al[26]; showed that in patients with coronary artery disease, longitudinal segmental strain cut-offs of −14.1% and −6.65% detected ischemic and infarcted myocardial segments, respectively. Patients with recent anterior wall myocardial infarction demonstrate reduced radial and longitudinal strain, while greater reduction in circumferential strain is seen if LVEF is reduced[26,27].

Left ventricular (LV) systolic function is a powerful predictor of cardiovascular outcome[28], Left ventricular ejection fraction (EF) is popularly used to access the LV function. Julien Ternacle et al[29]; found that despite a fair correlation between LVEF and global strain (∈), 40% of patients with preserved LVEF (LVEF ≥50%) had abnormal global strain (∈ > - 16%). In patients with preserved LVEF, NTproBNP level, heart failure symptoms, and the need for prolonged inotropic support after surgery were greater when global strain was impaired. Also despite similar EuroSCORE the rate of postoperative death was 2.4- fold more in patients with preserved LVEF when global strain was impaired. Multivariate analysis showed that global strain is an independent predictor for early postoperative mortality after adjustment to EuroSCORE. This highlights the importance of GLS over LVEF for risk stratification in patients undergoing cardiac surgery.

OPCABG is widely popular nowadays as it avoids the complications associated with CPB. Francesca D'Auria et al[4]; studied the changes in myocardial function after OPCABG using transthoracic echocardiography (TTE) and found that Longitudinal strain (LS) increased at 3 and 6 months after OPCABG. However, the LVEF, left ventricular end-diastolic dimension, and stroke volume measured by TTE were not significantly changed after OPCABG treatment during the 6 months of follow-up. Strong correlation between coronary lesion in angiography imaging and the corresponding heart zone with a reduction in global and segmental LS was found.

These studies show the importance of speckle tracking echocardiography in picking up early insults of myocardial ischemia, before the other conventional parameters such as EF are impaired. During OPCABG the positioning and application of stabilization devices on the heart during grafting may compromise the regional blood flow altering myocardial contraction, which may or may not improve post revascularisation. STE has not been studied with TEE during the intraoperative period for assessing the myocardial deformation during OPCABG. The mechanical effects of distortion during positioning and application of stabilisation devices has not been studied, hence we chose to study GLS and regional strain for patients undergoing OPCABG using TEE.

AIMS & OBJECTIVES

Aims and Objectives

1. To assess the feasibility of performing intraoperative speckle tracking echocardiography (STE) using Transesophageal echocardiography (TEE) in patients undergoing Off pump coronary artery bypass grafting (OPCABG).
2. To assess the changes in LV strain during and after grafting in OPCABG.

MATERIALS & METHODS

Materials and Methods

This prospective observational study was conducted in the Department of Cardiovascular and Thoracic Anaesthesia, SCTIMST, a tertiary care referral centre, after approval from the Technical advisory committee (TAC) and Institutional Ethics Committee (IEC).

28 patients who were scheduled for elective off pump coronary artery bypass grafting (OPCABG) were included in this feasibility study. During the preoperative anaesthesia check-up (PAC) patient was educated about the study protocol and informed consent was obtained.

Inclusion criteria:

1. Adult patients undergoing elective OPCABG.
2. Patients in Sinus rhythm.

Exclusion criteria:

1. Patients refusing to participate in the study.
2. Patients who had contraindications to TEE probe placement like esophageal strictures, esophageal varices, esophageal tumours, gastric ulcer, previous esophagectomy, esophageal diverticulum, tracheoesophageal fistula, previous bariatric surgery, hiatus hernia, large descending thoracic aortic aneurysm, unilateral vocal cord paralysis, esophageal varices, post radiation therapy.
3. Undergoing redo Surgeries
4. Emergency surgeries.
5. Patients receiving pre-operative inotropes.
6. Poor 2d echocardiographic image quality.
7. Patients converted from off pump to on pump CABG due to hemodynamic instability.

Study protocol:

Upon arrival in the operating room, standard monitoring including ECG, invasive blood pressure measurement and pulse oximetry were established. Patient was pre-oxygenated and anaesthesia induced using titrated doses of Fentanyl: 5-10 mcg/kg, Midazolam 0.05 – 0.1mg/kg, Propofol – 0.5– 1mg/kg, and pancuronium 0.1 mg/ kg. Trachea was intubated with an appropriate size endotracheal tube. After anesthesia induction, a triple lumen central venous catheter, temperature probe (Nasopharyngeal) multi planar TEE probe (IE33, Philips Medical Systems, Bothell, WA) were inserted. Anesthesia was maintained with air + oxugen + sevoflurane targeted to a MAC of 0.7-1. The systolic/ diastolic and mean arterial blood pressure, central venous pressure, heart rate were monitored throughout the procedure.

We targeted the mean arterial blood pressure (MAP) to ≥ 70 mmHg. Hypotension was treated with titrated increments of phenylephrine 50mcg boluses. If multiple doses of phenylephrine were required, the patient was started on an infusion of nor adrenaline starting at 0.05 mcg/kg/min. Use of additional inotropic support was left to the discretion of the individual practitioner. The data of inotrope use was also collected. Atrial pacing was employed in case of fall in heart rate of less than 60 beats per minute.

Echocardiographic image acquisition was performed using the iE33 workstation (Philips Medical Systems, Andover, MA, USA) with transesophageal X7–3t transducers. Images were acquiered pre CABG, during LAD grafting, post OPCABG.

Pre CABG

Comprehensive routine 2D examination was performed and the echocardiographic images acquired at stable hemodynamic function (+/- 20% 0f baseline HR and mean BP).

Imaging for Speckle tracking echocardiography

Can be divided into:

- Image acquisition
- Image analysis

Image acquisition for speckle tracking was done in the following manner:

- The image sector was narrowed, focussed on LV and frame rate kept between 40 – 90 frames/sec.
- Optimal 2D echocardiographic images were obtained, ensuring that the entire left ventricle along with the endocardium was visualised throughout the cardiac cycle without any foreshortening.
- An Electrocardiogram (ECG) with a clearly defined P waves and QRS complexes was obtained along with the echocardiographic loops.
- Collection of mid esophageal long axis (ME LAX), 4 – chamber (ME 4C) and 2-chamber (ME 2C) echocardiographic clips with a similar heart rate (within 10 beats/min) were obtained during breath holding.
- Minimum of three cardiac cycles were acquired for each loop.

Surgical procedure

A traditional sternotomy was performed and all conduits (venous and LIMA) are harvested as for traditional CABG. Patient was heparinised (3mg/kg) and after achieving an activated clotting time (ACT) of > 300seconds grafting of the vessels was started.

Sequence of anastomosis

Our surgeon began by grafting the lateral wall vessels, followed by inferior wall vessels and finally anterior wall vessels.

Positioning of the heart for target vessel grafting

For lateral LV wall vessels (Obtuse Marginals, Posterolateral branches of right coronary artery) the OR table was placed in Trendelenburg position and the table rotated toward the right. This will allow gravity to displace heart to the right and apex anteriorly. In case of hemodynamic compromise due to right heart compression, the right pleural space was opened to allow the heart to move toward the right pleural space. Octopus was placed in the required position and grafting begun after stable hemodynamics were achieved.

For inferior LV wall vessels (distal RCA and PDA) the OR table was placed in trendlenburg position, few mops kept under the heart and the apex slightly verticalised to expose the target vessels in the centre of the operative field and an octopus applied.

For anterior LV wall vessels (LAD, Diagonal, Ramus), few mops were kept under the heart and octopus applied in the desired region. Our surgeon always grafted the left internal mammary artery (LIMA) to the left anterior descending (LAD) artery.

During LAD Grafting

With the heart positioned for LAD grafting and octopus stabiliser in situ, and after stable hemodynamics were achieved, TEE images of the LV were acquired in ME LAX, ME 4C, ME 2C views.

Post CABG

Along with the routine analysis of the heart post CABG, images were acquired for speckle tracking as described above.

Image analysis

Quantification and analysis of 2D images was routinely performed on echocardiography monitor in the Operation theatre (OT) complex. Left ventricular ejection fraction (LVEF) and cardiac output (CO) were calculated pre and post CABG

For speckle tracking image analysis was done in the following way

- Longitudinal strain quantification was performed offline using a dedicated software package CMQ (Cardiac motion quantification) analysis package available with QLAB 9 (Philips Medical Systems – Andover, MA, USA) on a personal computer (PC) in the OT complex.
- Images were transferred to the PC, QLAB 9 software launched, image opened in the application and CMQ selected as the technique for analysis.
- The mid esophageal LAX (ME LAX) image was analysed first by selection of three tracking points on the end diastolic frame:
    1. At the mitral annulus near the PML
    2. At the junction of anteroseptal wall with aortic annuli.
    3. At the apex
- The software automatically generates a region of interest (ROI) to include the entire myocardial thickness.
- The ROI was manually adjusted as required to include the entire myocardium only, avoiding the pericardium.
- The software then tracks the myocardial speckles frame-by-frame and generates moving images displaying the tracking.
- Inspection of the moving image was done to determine the adequacy of tracking.

- The quality of tracking was visually assessed during motion playback and if necessary the width of the region of interest was adjusted to the wall thickness.
- Once satisfactory tracking was achieved, the same was approved.
- The software then divides the LV myocardium into six segments and generates segmental and global longitudinal strain. (Fig 5)
- A color-coded parametric image that provides quick, visual impression of the extent of segmental myocardial deformation was also generated.

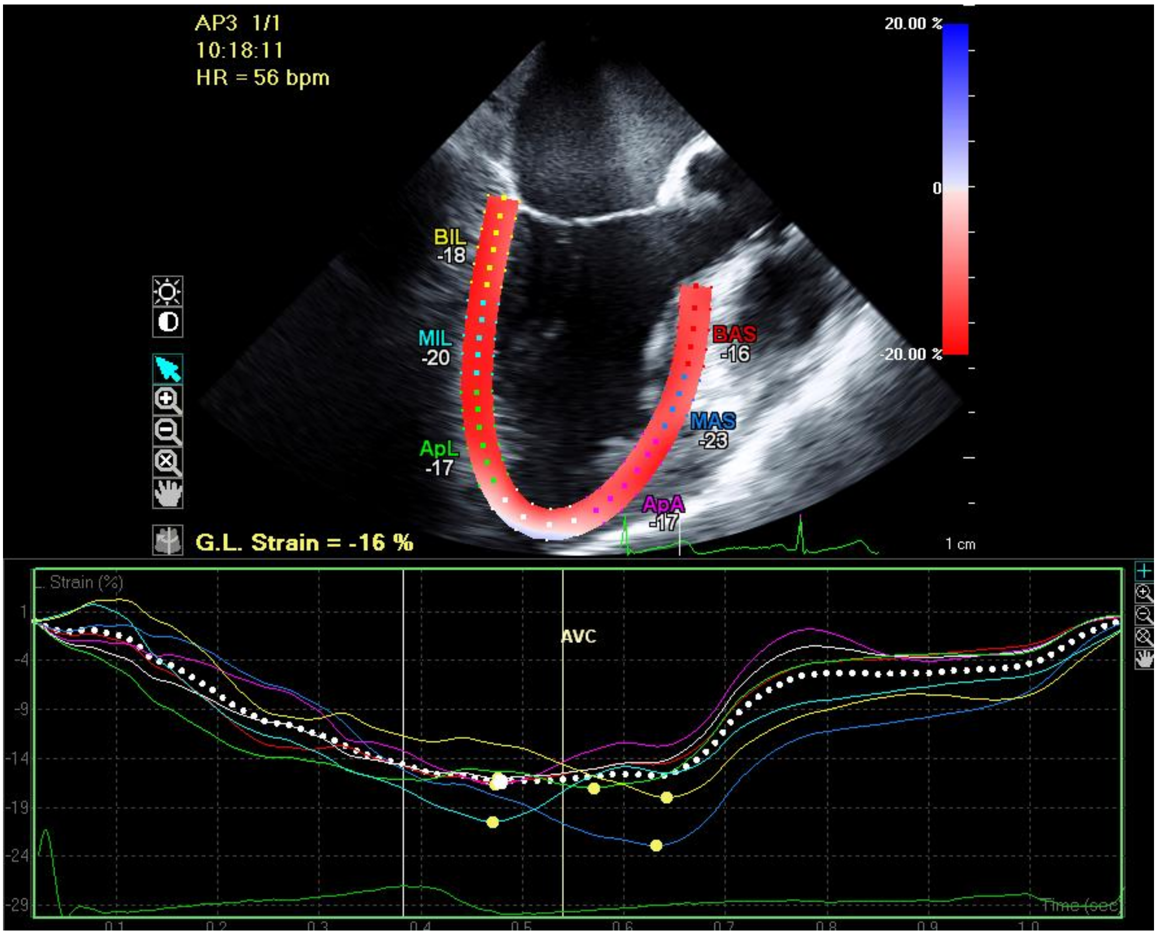

Figure 5: Mid-esophageal long axis echocardiographic view of pt no 9 depicting the left ventricle (LV), where the myocardial walls are divided into six segments distinguished by color-coded labels. Segmental strain measurements are shown adjacent to each segment. BAS – basal anteroseptal, MAS –mid anteroseptal, ApA – apical anterior, BIL – basal inferolateral, MIL – mid inferolateral, ApL – apical lateral.

- The same process was then repeated for the mid esophageal four chamber (ME4C) image (Fig 6) by marking the following tracking points:
    1. At the medial end of the mitral annlus
    2. At the lateral end of the lateral annulus
    3. At the apex.

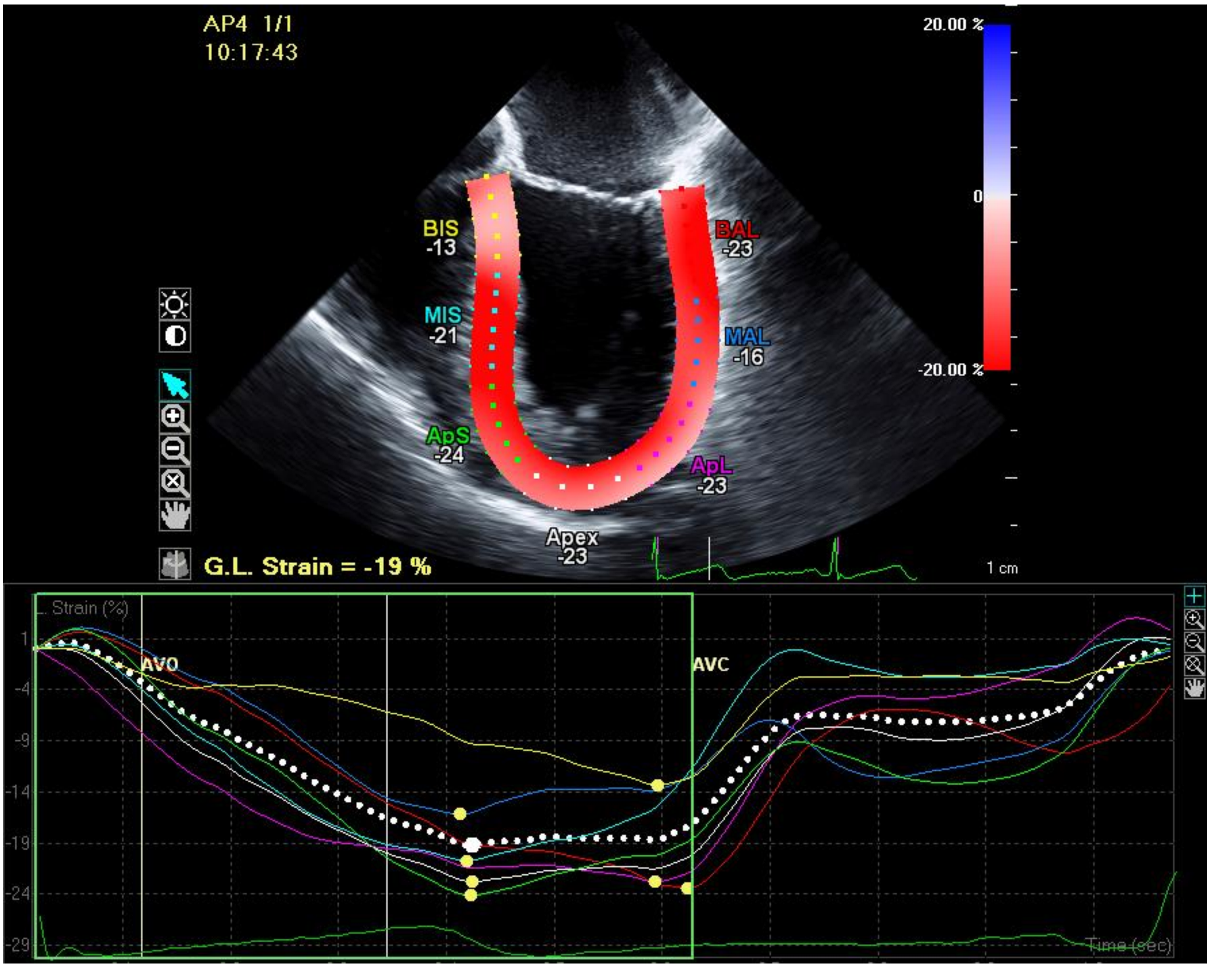

Figure 6: Mid-esophageal four - chamber echocardiographic view of patient no 9 depicting the left ventricle (LV), where the myocardial walls are divided into six segments distinguished by color-coded labels. Segmental strain measurements are shown adjacent to each segment. BAL – basal anterolateral, MAL – mid anterolateral, ApL – Apical lateral, BIS – basal inferoseptal, MIS – mid inferoseptal, ApS – Apical septal.

- The process was then repeated for the mid esophageal two chamber (ME2C) image (Fig 7) by marking the following tracking points:
    1. At the medial end of the mitral annulus
    2. At the lateral end of the lateral annulus
    3. At the apex.

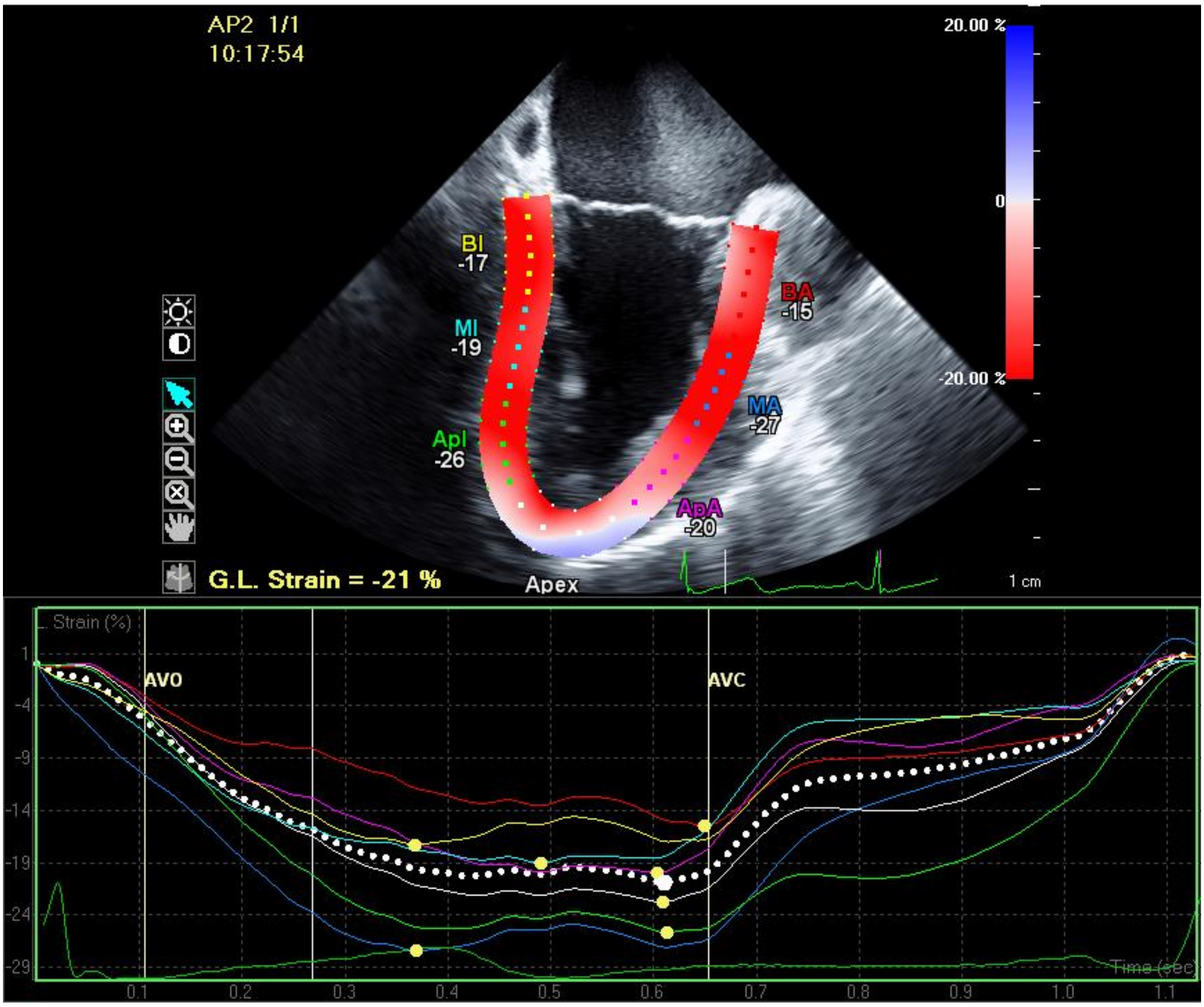

Figure 7: Mid-esophageal two - chamber echocardiographic view of pt no 9 depicting the left ventricle (LV), where the myocardial walls are divided into six segments distinguished by color-coded labels. Segmental strain measurements are shown adjacent to each segment. BA – basal anterior, MA – mid anterior, ApA – apical anterio, BI – basal inferio, MI – mid inferio, ApI – apical inferior.

- The strain values for all the segments were averaged to obtain the global longitudinal strain (GLS).
- Bull's eye display of the regional and global longitudinal strain was obtained (Fig 8).

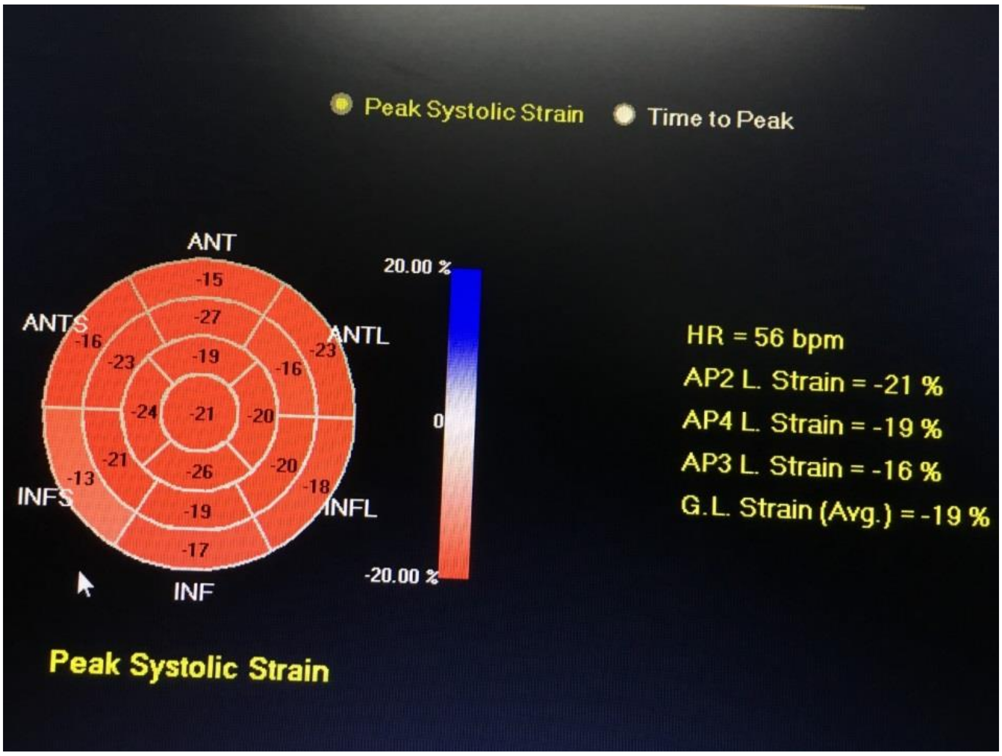

Figure 8: Bulls eye image of pt no 9 showing regional strain values of 17 segemnets of LV. The GLS of LV is obtained by averaging the regional longitudinal strain of all the segments and is displayed to the left of the picture.

Statistical analysis

Qualitative data was expressed as number of observations (percentage). Quantitative variables were expressed as mean ± SD. Difference between the preoperative and intraoperative values, intraoperative and postoperative values and preoperative and postoperative values was analysed using students t – test. p Value of < 0.05 was considered to be statistically significant. Statistical analysis was performed using IBM SPSS software version 21 for windows.

RESULTS

RESULTS

Twenty eight patients scheduled for elective off pump coronary artery bypass grafting (OPCABG) were included in this prospective observational study.

Demographic parameters

The mean, standard deviation and the range of values of the demographic parameters of all the patients in the study were analyzed and are represented in a table 1. There were 24 male and four female patients with a mean age of 59.3 years and weight 66 kg. Five patients had history of acute coronary syndrome, 64% were hypertensive and 53% were diabetic.

Table 1: Demographic and echocardiographic parameters

No. of patients	28
Age (years)	59.3 ± 6.5
Weight (Kg)	65.9 ± 12.3
Males	24 (85)
Females	4 (15)
H/O ACS	5 (17)
H/O Hypertension	18 (64)
H/O Diabetes mellitus	15 (53)
Preoperative EF (%)	55.9 ± 9.7
Preoperative CO (L/min)	3.4 ± 0.9
Preoperative GLS (%)	-15.5 ± 3.0
No of grafts	2.5 (1-4)

Data expressed as mean ± SD or as n (%) or average (range)

The average preoperative EF was 56% and the preoperative GLS was – 15.5%. The number of coronary arteries involved varied from single vessel disease to triple vessel disease and the number of grafts kept ranged from 1 – 4. 3 patients received a single graft, which was LIMA to LAD, 12 received two grafts, 12 received three grafts and one patient received 4 grafts. The left internal mammary artery (LIMA) was always anastomosed to the LAD.

During the course of the study while doing the analysis it was found that images of patients with pacing could not be analyzed correctly with the QLAB9 software. The software detects the pacing spike as the R wave of the QRS complex and all the calculations are automatically made by the software from one pacing spike to the next instead of R-R. Hence the timing of systole and diastole detected by the software differed from the actual mechanical systole and diastole resulting in erratic strain values. Therefore patients whose images had pacing spikes were excluded from the results.

13 patients required pacing during grafting which was extended into the immediate post-operative period, hence the analysis of these patients was excluded from results. So the remaining 15 patient's results are reported for comparison between the pre, intra and post-operative periods.

Table 2: Data of patients without pacing (n=15)

Parameter	Pre operative	Post operative	p Value
Ejection Fraction (%)	54.9±9.1	54.1±9	0.639
Cardiac Output (L/Min)	3.27±0.86	3.44±0.98	0.409
Data reported as mean ± SD, p Value < 0.05 is significant.			

Table 3: Global longitudinal strain

Pre operative	Intra operative	Post operative	Pre vs Intra operative	Intra vs post operative	Pre vs post operative
			p Value		
-15.8±3.46	-13.8±2.73	-14.8±3.25	**0.0131**	0.296	0.282
Data reported as mean ± SD, p Value < 0.05 is significant					

Global LV function:

There was no statistically significant difference between preoperative and postoperative 2-D indices of global LV function such as ejection fraction and cardiac output as shown in table 2. The mean global longitudinal strain (GLS) was -15.8%, -13.8%, -14.8% in the preoperative, intraoperative and postoperative periods respectively. There was statistically significant difference in GLS in the pre vs intraoperative period while it was not significant in intra vs postoperative or pre vs postoperative periods as shown in table 3. GLS increased in the intraoperative period, which normalized post grafting.

Regional LV strain

Strain was measured in each of the 17 LV segments during the preoperative, intraoperative and postoperative periods (Table 3). There was significant increase in strain in the basal anterolateral (BAL), basal inferolateral (BIL), basal inferior (BIW), basal infero septal (BIS), mid anterolateral (MAL), mid inferior (MIW) walls when the heart was positioned for LAD grafting. Strain normalized in all the above segments after grafting and there was no significant change in strain postoperatively when compared to preoperative strain.

Table 3: Regioanl LV strain

Segment	Pre operative	Intra operative	Post operative	Difference of pre and intra operative	Difference of intra and post operative	Difference of pre and post operative
	Mean±S.D	Mean±S.D	Mean±S.D	p-value		
BAW	-14.3±5.89	-14.6±6.41	-13.5±6.81	0.905	0.546285	0.6859427
BAL	-15.85±5.99	-11.9±4.45	-14±4.18	**0.026**	0.147237	0.653418
BIL	-12.78±3.74	-9.26±5.66	-14.15±4.75	**0.03711**	**0.015175**	0.288412
BIW	-14.26±7.23	-5.46±10.5	-11.2±5.38	**0.00059**	**0.038858**	0.05
BIS	-9.8±4.29	-14.8±3.44	-12.4±4.40	**0.004916**	0.274954	0.242123
BAS	-11.2±6.71	-10.8±7.25	-13.2±7.82	0.896096	0.244703	0.43109
MAW	-14.8±8.75	-13.4±4.06	-14±9.18	0.535043	0.822541	0.810315
MAL	-17.4±6.66	-12.5±4.32	-16.1±5.98	**0.034083**	0.066899	0.424366
MIL	-17±5.04	-14.4±4.73	-17.4±6.11	0.207184	0.050375	0.825643
MIW	-17.2±5.87	-13.1±4.42	-13.46±8.52	**0.03915**	0.893833	0.151081
MIS	-16±5.83	-13.2±5.09	-14.33±7.97	0.138283	0.637657	0.560351
MAS	-16.46±4.65	-14.6±8.00	-17±4.92	0.446711	0.298523	0.750032
AW	-20.4±4.73	-19.4±5.91	-17.46±6.90	0.472945	0.410933	0.175407
LW	-17.53±6.54	-15.1±6.58	-16.6±5.80	0.381515	0.488793	0.686473
IW	-21.53±6.91	-19.5±7.69	-13.73±13.9	0.390247	0.20492	0.082343
SW	-19.2±9.02	-21.1±9.39	-22.13±6.05	0.522115	0.770138	0.17858
APEX	-19.06±4.96	-18.1±4.88	-17.86±5.01	0.531745	0.893597	0.391285

DISCUSSION

Discussion

Performing CABG without the support of cardiopulmonary bypass eliminates the need for aortic cannulation and cross clamp and reduces the systemic inflammatory response. The benefits of off pump CABG versus on pump CABG has been continually debated for the last 25 years. With no hard clinical data to back up either of these surgical techniques, the decision to operate on or off pump is left to the discretion of the individual surgeon[30]. Our surgeon opts for OPCABG when there are less number of grafts required (generally ≤ 3), usually involving the LAD and/or LCX territory and when the patient does not have severe LV dysfunction or LMCA disease. OPCABG cases account for approximately 20% of all CABG cases done by our surgeon.

OPCABG involves displacement of the heart and compression of the ventricular walls to facilitate distal anastomosis. Such cardiac manipulation may result in severe fall in cardiac output, hemodynamic derangements[31], arrhythmia, and may precipitate myocardial ischemia. Early detection of myocardial ischemia is the challenge that the anesthesiologist faces during the OPCAB procedure. ECG is not a sensitive tool during OPCAB, as the relationship of the heart to the surface electrodes continually changes during the procedure. The shape and amplitude of the ECG is affected by these positional changes of the heart. When the heart is completely verticalized, the diagnostic accuracy of ECG is minimal[32].

New segmental wall motion abnormality (SWMA) has been considered a reliable means to detect intraoperative myocardial ischemia and may precede the occurrence of ECG changes[33]. The question of whether TEE can detect new SWMA during OPCABG has been studied before[34]. There are challenges with the use of TEE in OPCABG. The presence of air surrounding the heart, the use of the posterior pericardial stitch by the surgeon and the use of surgical pads below the heart to elevate the heart, all can impair the images provided by TEE.

It is generally conceded that without the use of specialized adjuncts, the heart cannot be visualized with transgastric views by TEE. Therefore the midesophageal views offer the best sonologic window to the heart during OPCABG[35]. The placement of epicardial stabiliser devices are known to reduce the number of readable LV segments and the number of unreadable segments is most for placement of stabilizer for LAD and circumflex territories[34] Placement of LV epicardial stabilizer itself can induce the SWMA. When the SWMAs occur in the territory of the stenotic vessel it becomes all the more important to distinguish whether the detected SWMA is induced by ischemia or is a temporary effect from cardiac displacement. Detection of SWMA in the transesophageal views by TEE cannot be further confirmed by viewing the transgastric views as these views are unavailable at that time. Therefore to prevent undue overdiagnosis of myocardial ischemia, studies have applied stringent criteria for diagnosis of myocardial ischemia during OPCABG. SWMA is diagnosed when the segments that are being studied develop large degree of wall motion abnormality or when there is a fall in the wall motion score by two or more grades in two or more territories vascularized by the target vessel. Such application of stringent criteria may make the regional wall motion scoring less sensitive to detect ischemia. The epicardial stabiliser makes wall motion scoring difficult by immobilizing the epicardial surface where as the myocardial thickening and the endocardial movement are not affected as long as there is no myocardial ischemia. Regional LV function assessed by endocardial excursion and radial thickening are subjective and significant interobserver variability in the interpretation of regional function has been documented[36]. Myocardial deformation during systole occurs in several axes (i.e, radially, longitudinally and circumferentially), whereas conventional methods only assess the inward motion or radial thickening which corresponds to the radial component. Accordingly radial strain correlates well with wall motion score (WMS), while longitudinal strain correlates poorly[36]. Whenever there is myocardial ischemia, the first layer to be affected is the subendocardial layer which contributes to the longitudinal motion of the heart. Therefore assessment of global longitudinal strain is a sensitive tool to the alterations in coronary blood flow. To our knowledge, this the only study that has attempted to collect LV strain measurements during the performance of OPCABG

We confined our study to the assessment of the LV strain during cardiac displacement for LAD grafting as the least displacement of heart is with positioning for the LAD graft.
During the positioning of the heart for lateral and inferior grafts, the displacement is extreme leading to suboptimal views which are not suitable for speckle tracking study. Besides the use of stabilizer itself can alter the chamber size and cause decrease in segmental wall motion even in the absence of ischemia. According to criteria defined by previous studies, greater than 14 segments should be visible on TEE to adequately and reliably monitor LV function. We were able to collect good quality images with all 17 segments visible in 25 patients, 16 segments in 2 and 15 segments in 2 patients enrolled into our study. The visibility of all the segmental walls were excellent making the images suitable for study of global longitudinal strain.

Our surgical unit has a low threshold for initiating atrial pacing, though our defined criteria is fall in heart rate below 60. We believe that the early initiation of atrial pacing is in the best interests of patient safety. Once intraoperative atrial pacing had been deemed necessary by the operating team, we did not attempt to disconnect the pacing to obtain the images required for the speckle tracking study. 13 patients required atrial pacing during the procedure and the pacing was initiated in all cases during the performance of the inferior graft. Use of atrial pacing confuses the software (QLAB9) used for speckle tracking. The pacemaker spikes are interpreted by the software as R waves and the software performs the analysis incorrectly from one pace maker spike to another rather than from R wave to R wave. Since the peak of R wave corresponds to end diastole and the point of maximum LV dimension, this is taken as the starting point of assessment of speckle tracking. The LV dimension at all other times in the cardiac cycle is less than the LV dimension at the peak of R wave, leading to the normal, negative strain value. Therefore, misjudging the R wave by QLAB9 in atrially paced patients is a grave error and leads to misinterpretation of the cardiac cycle, notably dissociation of electrical and mechanical cardiac events (Fig 9). The end result is a global strain value that is either abnormally positive or too much negative (Fig 10).

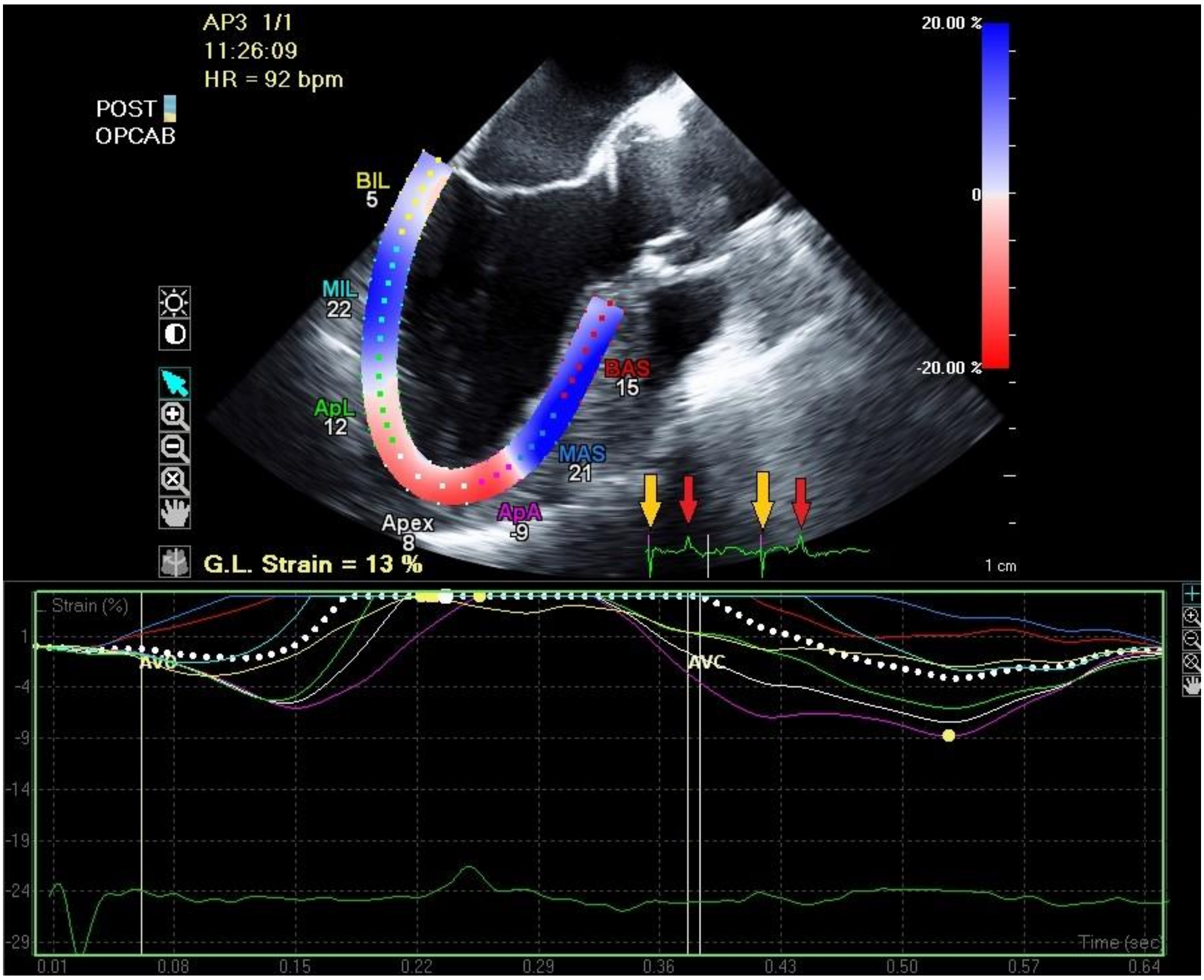

Figure 9: Shows longitudinal strain measured post OPCABG in a patient with pacing. Yellow arrows on the ECG point to the pacing spikes which are detected by the software as R waves. Red arrows point to the actual R waves.

The values of global strain in atrially paced patients did not correspond with regional wall movements patterns at the time of data collection, further confirming the erroneous interpretation by the QLAB9 software. We attempted to reset the R wave on the software during offline analysis but we found that R wave reset is unavailable. No references could be found in literature to overcome this shortcoming in speckle tracking analysis. Therefore 13 patients had to be excluded from the analysis of speckle tracking.

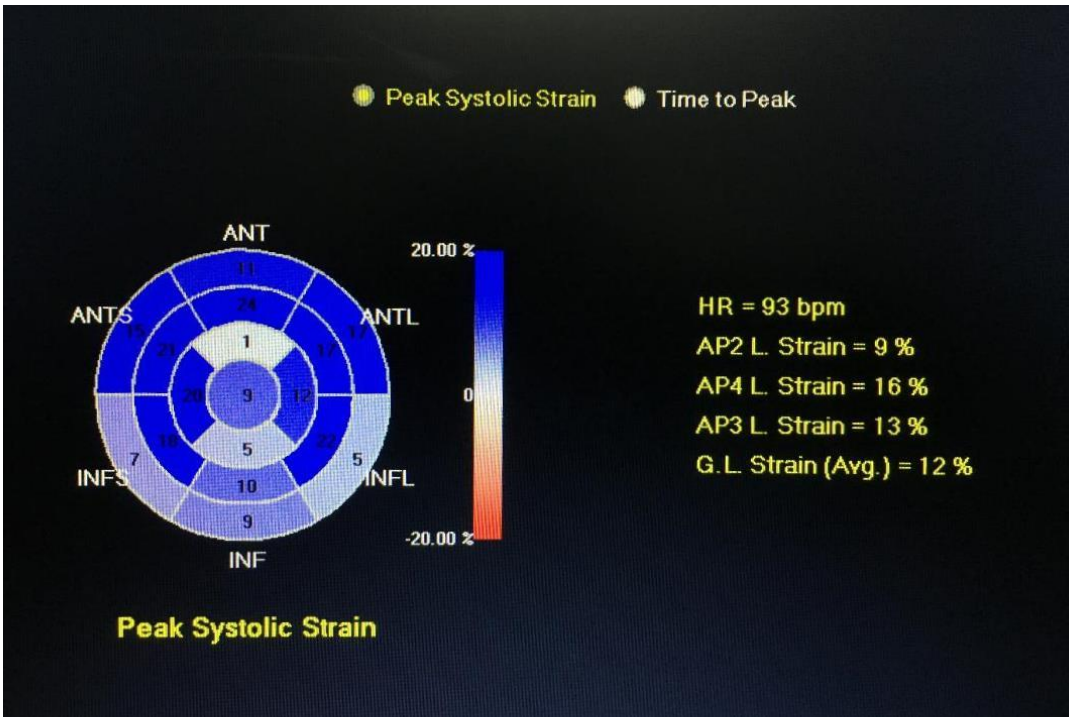

Figure 10: Bulls eye image of the patient in figure 1 who required pacing shows regional and global longitudinal strain were all positive.

Global longitudinal strain measured in all our patients prior OPCABG were normal with a mean score of -15.8±3.46 which declined to a mean of -13.8±2.73. The change in global longitudinal strain between the pre-grafting and the grafting period was found to be statistically significant with a p value 0.013. The change in the global longitudinal strain could be the result of either myocardial ischemia or due to the restriction in myocardial movement due to the epicardial stabiliser device. Since there were no changes in wall motion scoring index at this time, the decline in global longitudinal strain could possibly be attributed to epicardial immobilisation required for placement of LIMA graft to LAD. The change in the mean global longitudinal strain between the pre-grafting and the grafting phase does not seem significant in absolute terms as the mean range for normal global longitudinal strain is between -15.9% to -22.1% (mean, -19.7%; 95% CI, -20.4% to -18.9%). Besides the global longitudinal strain varies with differences in systolic pressure[37]. Since we targeted the mean arterial pressures to remain greater than 70 mm Hg and maintained nearly identical blood pressures during data collection, we are confident of excluding the influence of systolic pressures on the change in global longitudinal strain values. In the post grafting phase, the global longitudinal strain values had recovered to -14.8±3.25. When the global longitudinal strain values between the pre-grafting phase and the post-graft phase were compared, we found that there was no statistical difference between the two with a p value of 0.282. We postulate that the decline in the global longitudinal strain during grafting recovers in the immediate post graft phase when the cause of fall in strain value is due to epicardial stabilisation rather than due to myocardial ischemia. This is in accordance with the findings of Biswas et al[3] who found that wall motion score index returns to baseline after the grafting when the alteration in wall motion is due to epicardial immobilisation.

Regional longitudinal strain was assessed from the data sets acquired during the grafting of LIMA to LAD. The regional strain values increased (became less negative) in five segments during the grafting. Among the basal segments the anterolateral, inferolateral, inferior septal walls and in mid segments, the anterolateral and inferior wall strains increased significantly (p value <0.05) during LAD grafting. But when comparison was made between the pre-graft and the post-graft values for regional strain in the identical segments, there was no statistical difference in the regional strain. Once again, the cause for alteration in regional strain can be attributable to one of two causes, myocardial ischemia or epicardial immobilisation. The basal anterolateral, basal inferolateral and mid anterolateral are attributable partially or completely to the left circumflex coronary and the basal inferoseptal and mid inferior segments are attributable to the right coronary artery. Therefore the segments exhibiting regional strain do not belong to any one coronary artery territory. Besides these territories are not revascularized yet, though their distal anastomosis have already been performed. But the random involvement of disconnected segments speaks in favour of the alteration of regional strain being the result of epicardial immobilisation. In order to facilitate grafting of LAD, the surgeon usually keeps a sponge pad under the heart and octopus stabilization system which consists of two paddles with suction domes, is used to provide a less mobile field. The two paddles of the octopus are kept on either side of the grafting vessel. As the octopus uses negative suction it does not cause much compression of the heart. Sponge pads are kept under the heart directed towards the base, while leaving the apex free. This may cause mechanical restriction of the inferior and lateral walls more in the basal and less in the mid segments, while not affecting the apical segments. This could probably be the reason for increased strain in inferior and lateral segments of the heart, more in the basal region as observed in our study. The recovery of regional strain to pre-graft values after completion of grafting confirms that the alteration in regional strain is not due to myocardial ischemia.

There were no occurrence of hemodynamic instability or myocardial ischemia necessitating the abandoning of the OPCAB technique in favor of CPB support. There were no occasions of myocardial ischemia as evidenced by ECG changes or by the occurrence of SWMAs. There are three reasons for the hemodynamic stability in our patients. First, our surgical team had strict criteria for choosing patients to undergo OPCAB. Only patients requiring less number of grafts (generally ≤ 3), without severe LV dysfunction and LMCA disease are chosen for OPCABG. Second, the order of distal graft placement was different than usually recommended. The surgeon performed the distal anastomosis of the OM first, the PDA second, the Diagonal third and the LAD last. LIMA was grafted to LAD and venous grafts were used for other targets. One favored practice is to provide distal anastomosis in the order of increasing cardiac displacement. This means that LAD anastomosis is done first, followed by inferior wall and the lateral wall. Anastomosing the LAD first allows the critical mass of myocardium to be perfused early, namely the anterior wall and the apex. This has the advantage of providing hemodynamic stability as the heart is progressively revascularized, and the revascularized heart is able to withstand displacement more. Another favored method is to begin anastomosis with the most stenotic or occluded vessel. We posit that the order in which grafts were performed in our cases makes the occurrence of ischemia during LAD grafting unlikely. The anterior and lateral wall have the greatest excursion during systole and diastole. Compression of these walls have the greatest hemodynamic consequence. Therefore, the most profound hemodynamic instability occurs with exposure of the OM because the heart is displaced more extensively for exposure of the lateral wall[32]. In our patients, the heart has already withstood the maximal displacement for the placement of the lateral and inferior grafts without ischemic event and hence, even though not revascularized, the heart is now unlikely to develop ischemia during the relatively minimal displacement required for the LAD graft. Third, the use of intracoronary shunts has been proven to be protective against ischemia but has the risk of causing endothelial damage. The routine use of flexible intracoronary shunts in all our patients may have provided protection against the occurrence of myocardial ischemia in our patients [38,39] The small number of patients studied could also be a reason for the absence of intraoperative myocardial ischemia.

There are several limitations to our study. The science of speckle tracking echocardiography is performed offline whereas in the dynamic environment of OPCABG online evaluation is required to provide clinical inputs. The assessment of global and regional longitudinal strain involves collection of three different midesophageal views and applying the cardiac motion quantification and analysis. The shortest time period this requires is at least 4 minutes even with experience. Therefore this tool is unlikely to be of benefit for immediate clinical use. The purpose of our study was to assess the feasibility of speckle tracking echocardiography during OPCABG when there is cardiac displacement and compression. Our findings suggest that the tool is useful and can provide meaningful data during OPCABG which is well in line with the findings of other studies that used regional wall motion scoring. Only global longitudinal strain can be assessed during OPCABG, radial and circumferential strain cannot be measured as the transgastric views required for their assessment cannot be obtained when the heart is displaced for distal anastomosis. Another limitation of the study is that it is yet to be established whether LV strain assessment can provide advance warning of myocardial ischemia before the occurrence of regional wall motion abnormality. Since none of our patients developed myocardial ischemia, and from the small study population, we are unable to comment whether GLS or regional strain provides prediction of myocardial ischemia. Another interesting factor that needs to be studied in patients who do develop myocardial ischemia during the OPCABG is whether the decrease in longitudinal strain during the ischemic period persists in the post-operative period even when the regional wall movement abnormality returns to the baseline. The time period for which the strain changes persist following the occurrence of intraoperative myocardial ischemia would also be of great scientific interest. The problems experienced with atrial pacing during the analysis phase reduced the number of patients available for analysis. This is an inherent limitation of the software and future software updates may be able to overcome this issue. We studied the strain values only during the anastomosis of LIMA to LAD and not during the grafting of circumflex and RCA territories where the cardiac displacement is more.

CONCLUSION

Conclusion

We were able to prove that speckle tracking is feasible during the intraoperative period of OPCABG and that in the absence of perioperative myocardial ischemia, the global and regional strain values are reduced during the cardiac displacement phase of OPCABG and return to the baseline after the placement of the graft

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ABBREVIATIONS

Abbrevations

LV – Left ventricle

FS – Fractional shortening

FAC – Fractional area change

EF – Ejection fraction

CO – Cardiac output

LVEF – Left ventricular ejection fraction

CABG - Coronary artery bypass grafting

OPCABG – Off pump coronary artery bypass grafting

CPB – Cardio pulmonary bypass

STE – Speckle tracking echocardiography

GLS – Global longitudinal strain

RWMA – Regional wall motion abnormality

CAD – Coronary artery disease

SR – Strain rate

SV – Stroke volume

TDI – Tissue Doppler imaging

STI – Speckle tracking imaging

2-D – Two dimensional

3-D – Three dimensional

TTE – Transthoracic echocardiography

TEE – Transesophageal echocardiography

LS – Longitudinal strain

ANNEXURES

Technical Advisory Committee (Clinical Studies)
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM – 695011, INDIA

TAC Registration No: SCT-/S/2017/586 **Date:04.04.2017**

Project title: ASSESSMENT OF MYOCARDIAL DEFORMATION DURING OFF PUMP CABG (OPCABG) USING SPECKLE TRACKING ECHOCARDIOGRAPHY

Principal Investigator:
Dr. Garre Sandeep Degree: M.D. (Anaesthesiology), M.B.B.S. Address: Senior Resident, Department of Cardiothoracic Anaesthesia, SCTIMST
Co-Principal Investigator(s)
Dr. Suneel P.R, Professor, Department of Anesthesiology SCTIMST Degree: Post-Doctoral Certificate Course: Cardiothoracic and Vascular Anaesthesia. M.D. (Anesthesiology), M.B.B.S. ,
Dr. Unni Krishnan KP, Professor, Department of Anesthesiology, SCTIMST Degree: Fellowship in Cardiac Anaesthesia and Perioperative TEE.. M.D. (Anesthesiology), D.A. (Anesthesiology), M.B.B.S
Dr. Vivek V Pillali, Additional Professor, Department of Cardiothoracic and vascular Surgery, SCTIMST Degree: Mch Cardiothoracic and vascular Surgery, M.S (Surgery), M.B.B.S

Members who participated in the TAC meeting on 14/03/2017

Dr. Rupa Sreedhar (Chairperson)
Dr. Sankara Sarma. P
Dr. Prasantakumar Dash
Dr. Sylaja P.N
Dr. Krishna Kumar K
Dr. Syam. K
Dr. Bijulal S
Dr. Jayadevan E.R.
Dr. K. Shivakumar (Member Secretary)

Dr. Prasanta Kumar Dash, Dr. Rupa Sreedhar, Dr. Sankara Sarma and Dr. P.N. Sylaja stayed away from the proceedings when the projects in which they are involved as investigators were discussed (# 572, 573,575).

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
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)
Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

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

SCT/IEC/1059/JUNE-2017

19.09.2017

Dr. Garre Sandeep
Senior Resident
Department of Anaesthesiology
SCTIMST, Thiruvananthapuram

Dear Dr. Garre Sandeep,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "ASSESSMENT OF MYOCARDIAL DEFORMATION DURING OFF PUMP CABG (OPCABG) USING SPECKLE TRACKING ECHOCARDIOGRAPHY (IEC/1059)" on 17th June, 2017.

The following documents were reviewed:

Original submission

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

Revised submission

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

The following members of the Ethics Committee were present at the meeting held on 17th June, 2017 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.Lekha Pandit	MD.DM Neurology, PhD (Bioscience)	Female	Clinician	No
3.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
4.	Dr. Rema M. N	MD	Female	Basic Medical Scientist	No
5.	Dr. S S Giri Sankar	LL.M. Ph.D.	Male	Legal Expert	No
6.	Dr. Aneesh V Pillai	BA. LLB (Hons.), LLM, Ph. D, SET (Law)	Male	Legal Expert	No
7.	Mr. Satheesh Chandran	MSW, PGDPM	Male	Lay person/ NGO/ Social Scientist	No
8.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
9.	Dr. P. Manickam	BSMS, MSc (Epid).,PhD	Male	Health Science Expert/ Social Scientist	No
10.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
11.	Dr. V. Raman Kutty	M D, M Phil, M P H	Male	Health Sciences Expert/Clinician	Yes
12.	Dr. K R S Krishnan	M.E., Ph.D.	Male	Medical Technology	Yes
13.	Dr. Harikrishna Varma PR	Ph.D(Materials Science)	Male	Medical Technology	Yes
14	Dr. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
15.	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

Patient Information Sheet

TITLE OF THE STUDY: ASSESSMENT OF MYOCARDIAL DEFORMATION DURING OFF PUMP CABG (OPCABG)

Study number:

We request you to give consent to use data collected during the surgery. Transesophageal echocardiography (TEE) probe is mandatory during your surgery to assess the function of your heart before, during and after surgery. This study will be conducted in 30 patients undergoing elective off pump CABG.

What is the rationale of the study?

The left ventricular (LV) myocardium undergoes a complex multi-dimensional deformation during the cardiac cycle. Ejection fraction (EF), the most commonly used measure of myocardial function is too simplistic measure of LV function and has many limitations. Strain using speckle tracking overcomes many of the limitations of EF. In this study we aim to assess the complex myocardial deformation using speckle tracking for off pump CABG.

Does this procedure have any side effects?

Transesophageal probe is a requirement for you optimal care during surgery and therefore is routinely inserted during cardiac surgery at our institution. We will use the images acquired and saved with transesophageal probe during your surgery for further analysis. There is no invasive procedure or any experimental drug given for the sake of the study so this procedure will not have any side effects.

If you take part what will you have to do?

If you agree to take part in this study, no additional procedure/ intervention/follow up is required. During the TEE examination, images will be saved, which will be processed offline later on for calculating strain and strain rate.

Can you withdraw from this study after it starts?

Your consent to use the data in this study is entirely voluntary. If you don't give this consent, this will not affect your usual treatment at this hospital in any way. You can withdraw from the study at any time.

What will happen if you develop any study related injury?

TEE is mandatory for your care during surgery , the study involves analysis of the images saved during the conduct of the surgery We do not expect any injury to happen to you as a result of the study.

Will you have to pay for the investigations?

No.

What happens after the study is over?

As we are not performing any additional/new intervention, this study will not alter the course of surgery intraoperatively and postoperatively.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission.

If you have any further questions, please ask the Principle Investigator - Dr Garre Sandeep (Senior resident, department of cardiac anaesthesia), Telephone no. 9989421851, email id-drsandeep189@gmail.com

Dr. Suneel PR(Professor, department of cardiac anaesthesia)

Telephone no. 9847280218, email – suneelpr@gmail.com

For any clarifications regarding the study's ethics clearance you may contact the Member Secretary of the SCTIMST-IEC – Dr Mala Ramanathan. The phone number is: 0471- 2524234 and the email id is iec.mem.sec@sctimst.ac.in

Informed Consent Form

Participant's name:

Date of Birth / Age (in years):

I____ ___________,

son/daughter/mother/father of ____________________________________ (Please tick boxes)

declare that I have read the above information provide to me regarding

the study: **: ASSESSMENT OF MYOCARDIAL DEFORMATION DURING OFF PUMP CABG (OPCABG)** and have clarified any doubts that I had.

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

• I also understand that Transesophageal echocardiography probe will be routinely inserted during my surgery. [ ]

• I also understand that the study is not posing any additional risk. [ ]

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

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

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

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

Name:

Signature:

Date:

Name of witness:

Relation to participant:

Date:

Signature:

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

________________________________ ____________________

Name and Signature of Person Obtaining Consent

(For Principal Investigator)

Witness:

DATA COLLECTION FORM

The following information will be recorded.

Pre-operative information

Hospital number: Date:

Age: Weight: Gender:

Diagnosis and surgery:

Pre-operative medications:

Pre-operative TTE findings:

Co-morbidities:

Intra-operative data

1. Hemodynamics data:

Time (hrs)	HR	SBP	DBP	MAP	CVP
0.5					
1.0					
1.5					
2.0					
2.5					
3.0					
3.5					
4.0					
4.5					
5.0					
5.5					
6.0					

2. Pre – CABG echocardiographic data

End systolic volume (ml)	
End diastolic volume (ml)	
Stroke volume (ml)	
Ejection fraction (%)	
Cardiac output (L/min)	
Global longitudinal strain (%)	
Radial Strain	
Strain rate	

3. Surgical data

No. of bypass grafts	
Global longitudinal strain (%)	

4. After OPCABG echocardiographic data

End systolic volume (ml)	
End diastolic volume (ml)	
Stroke volume (ml)	
Ejection fraction (%)	
Cardiac output (L/min)	
Global longitudinal strain (%)	
Strain rate	
Radial strain	

5. Post-operative data

Ionotrope 1	Dose	Duration
Ionotrope 2	Dose	Duration
Ionotrope 3	Dose	Duration
Duration of mechanical ventilation (hrs)		
Duration of ICU stay (hrs)		

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Left ventricular dysfunction (LVD) raises the risk of cardiovascular complication and death after cardiac1 and non cardiac surgery2. Echocardiography is the most versatile and accessible imaging modality for assessing of cardiac function. Estimation of LV systolic function is a prime goal of echocardiography, performed for almost any indication.

A number of parameters such as fractional area change (FAC), fractional shortening (FS),ejection fraction (EF) cardiac output (CO) have been developed to assess global LV function. Of them left ventricular ejection fraction (LVEF) is robust, clinically the most relevant and widely used parameter. Despite their utility all of them have several limitations and are indirect measures of myocardial contractile function.

Most of them are calculated making certain geometrical assumptions and all of them are influenced by.LV loading conditions and heart rate. None of them are enough sensitive to detect subtle changes in the contractile function and therefore not suitable for detecting subclinical myocardial damage which may have major therapeutic and prognostic implications3.

Off pump coronary artery bypass grafting (OPCABG) is popular as it avoids the complications associated with cardiopulmonary bypass (CPB). During OPCABG the heart is subjected to a lot of distortion due to positioning and the application of stabilization devices such as octopus, and star fish, may cause alterations in the loco-regional myocardial blood flow, impairing myocardial function.

These changes may be too subtle to be picked up by the routine measures of myocardial function such as EF. Speckle tracking echocardiography (STE) is a developing technique for the characterization and quantification of myocardial deformation. It is a grey-scale based technique, angle-independent and permits a better assessment of myocardial deformation.

Conclusion We were able to prove that speckle tracking is feasible during the intraoperative period of OPCABG and that in the absence of perioperative myocardial ischemia, the global and regional strain values are reduced during the cardiac displacement phase of OPCABG and return to the baseline after the placement of the

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SL.NO	Age	Wt(Kg)	Gender	H/O ACS	HTN	DM	Pre op EF (%	eop CO(L/M	Preop GLS	BAW	BAL	BIL	BIW	BIS	BAS
1	52	53	1	0	1	1	67	2.2	-19	-19		-12	-21	-7	-12
2	54	63	1	0	0	1	55	2.8	-17	-13	-12	-9	-19	-12	-10
3	67	60	1	0	1	0	55	4	-15	-11	-10	-13	-5	-5	-19
4	57	82	1	1	1	0	45	2.1	-14	-7	-11	-10	-8	-15	-7
5	68	44	0	0	0	1	65	5.1	-16	-26	-16	-19	-31	-14	-9
6	63	48	1	0	1	1	48	4.4	-13	-14	-17	-10	-9	-9	-5
7	55	70	1	0	0	0	65	3.4	-19	-19	-28	-13	-21	-8	-16
8	59	62	1	1	1	0	50	4.4	-13	-9	-20	-10	-14	-8	-16
9	70	68	1	0	0	0	45	2.4	-8	-7	-4	-5	-10	-2	-11
10	49	74	1	0	0	0	55	2.8	-19	-18	-21	-16	-14	-9	-13
11	58	90	1	1	0	1	55	2.7	-20	-8	-20	-15	-17	-11	-11
12	54	51	1	0	1	0	67	3	-19	-18	-21	-16	-14	-9	-13
13	59	68	1	0	1	0	50	3.3	-14	-23	-14	-17	-5	-10	-20
14	67	51	0	0	1	0	64	3.2	-19	-12	-12	-14	-19	-20	-14
15	51	70	1	0	1	1	38	3.3	-12	-11	-16		-7	-8	8
16	45	84	1	0	0	0	44	3.4	-11	-13	-14	-7	-10	-6	-5
17	65	76	1	0	1	1	60	4.7	-14	-23	-14	-17	-5	-10	-20
18	58	78	1	0	1	0	60	4.1	-18	-21	-21	-8	-29	-15	-7
19	60	60	0	0	0	1	45	1.7	-13	-4	-8	-5	-6	-12	-9
20	60	62	1	0	0	1	54	4.2	-16	-15	-13	-14	-21	-10	-10
21	62	68	1	0	1	1	67	3.4	-17	-10	-23	-22	-13	-13	-10
22	64	58	1	0	0	0	65	3	-20	-8	-20	-15	-17	-11	-11
23	61	65	1	1	1	1	42	3	-13	-12	-14	-7	-11	-14	-10
24	60	65	1	0	1	1	68	3.2	-16	-9	-14	-18	-17	-6	-9
25	48	94	1	1	1	0	48	5.9	-15	-7	-23	-7	-7	-6	-16
26	64	55	1	0	1	1	66	3.2	-19	-15	-20	-13	-17	-10	-17
27	68	57	0	0	1	1	73	3.5	-13	-12	-14	-7	-11	-14	-10
28	62	68	1	0	1	1	48	3.1	-13	-7	-19	-5	9	-4	-9

MAW	MAL	MIL	MIW	MIS	MAS	AW	LW	IW	SW	Apex
-24	-12	-22	-25	-16	-17	-20	-22	-24	-25	-22
-17	-14	-20	-18	-8	-22	-30	-17	-31	-8	-21
-14	-16	-24	-12	-14	-21	-22	-18	-10	-27	-19
8	-34	-16	-16	-16	-14	-20	-15	-19	-9	-16
-30	-23	-15	-27	-17	-13	-16	-7	-27	-20	-14
-15	-27	-12	-11	-15	-19	-12	-11	-20	-15	-14
-24	-15	-22	-25	-20	-17	-20	-22	-24	-25	-22
-11	-14	-10	-11	-19	-22	-18	-12	-25	-14	-16
-9	-7	-9	-15	-2	-14	-16	-7	-14	-4	-11
-12	-12	-14	-19	-20	-14	-23	-24	-27	-33	-25
-21	-18	-26	-22	-22	-26	-25	-24	-24	-25	-25
-12	-14	-19	-12	-20	-14	-27	-24	-30	-23	-26
-9	-17	-16	-22	-24	-12	-18	-21	-8	-16	-16
-18	-21	-16	-14	-9	-13	-23	-27	-24	-33	-25
-14	-18	-14	-9	-18	-9	-16	-12	-16	-11	-14
-7	-13	-20	-12	-11	-10	-11	-12	-16	-15	-11
-9	-17	-16	-22	-24	-12	-18	-16	-21	-8	-16
-13	-23	-19	-16	-22	-21	-26	-10	-35	-24	-22
-10	6	-8	-6	-16	-13	-25	-120	-15	-30	-23
-11	-18	-26	-17	-14	-18	-23	-16	-37	-17	-22
-17	-21	10	-8	-16	-21	-20	-19	-25	-23	-21
-21	-18	-26	-22	-22	-26	-25	-24	-24	-23	-25
-17	-18	-18	-14	-18	-22	-10	-25	-11	-9	-13
-14	-16	-23	-19	-16	-19	-20	-19	-24	-13	-19
-21	-20	-21	-22	-17	-10	-17	-17	-25	-21	-19
-27	-17	-20	-19	-20	-20	-18	-23	-26	-23	-21
-17	-18	-14	-18	-18	-22	-11	-9	-10	-25	-13
-11	-10	-8	-16	-14	-7	-30	-22	-22	-21	-24

SL.NO	NO of grafts	uring LAD gr	BAW	BAL	BIL	BIW	BIS	BAS	MAW	MAL	MIL	MIW	MIS
1	1	-18	-26	-16	-15	-17	-20	-12	-10	-9	-16	-15	-9
2	3	-18	-13	-8	5	-12	-13	6	-12	-14	-12	-10	-17
3	3	-11	-14	-11	-3	-4	-12	-17	-18	-11	-7	-9	-10
4	2	-11	-21	-17	-10	10	-10	4	-13	-8	-19	-15	-19
5	3	-12	-13	-10	-17	-14	-16	-17	-19	-22	-8	-11	-8
6	4	-12	-15	-7	-7	-13	-14	-17	-10	-13	-14	-17	-10
7	2	-18	-26	-16	-15	-17	-20	-12	-10	-9	-16	-15	-9
8	4	-10	-9	-16	-9	-8	-13	-10	-12	-7	-13	-10	-10
9	3	-12	-9	-7	-9	-8	-13	-11	-10	-18	-14	-7	-11
10	2	-16	-8	-14	-10	4	-17	-18	-13	-9	-24	-15	-21
11	1	-13	-19	-7	-4	-11	-14	-13	-22	-14	-11	-9	-12
12	3	-16	-8	-14	-10	4	-18	-17	-9	-13	-15	-21	-24
13	3	-13	-11	-18	-10	9	-20	-7	-12	-19	-21	-19	-18
14	2	-14	-20	-13	-16	-17	-13	-9	-19	-11	-17	-17	-10
15	2	-13	-7	-4	-9	12	-10	-13	-12	-11	-9	-7	-11
16	2	10	15	15	7	-12	15	7	-9	25	28	20	26
17	1	-10	-15	-12	-7	-8	-14	5	-5	-6	-22	-12	-7
18	3	14	6	24	15	14	11	7	18	-9	5	9	7
19	2	17	17	5	17	10	17	10	9	25	19	29	23
20	4	17	17	5	17	17	10	10	25	19	29	23	30
21	2	11	17	11	11	-10	-3	17	13	10	-4	27	11
22	3	-11	-14	-17	-6	-7	5	-11	-14	-11	-15	-18	-11
23	3	12	9	13	-6	10	5	7	13	32	24	16	20
24	3	-12	-17	-9	-2	-3	-11	-5	-17	-10	-8	-21	-11
25	3	16	13	13	12	17	-13	25	21	6	24	29	-11
26	2	15	11	11	22	9	9	7	24	17	15	10	13
27	2	-18	-26	-16	-15	-17	-12	-20	-9	-10	-16	-9	-18
28	3	11	7	11	-4	5	16	10	9	8	6	9	7

MAS	AW	LW	IW	SW	Apex
-18	-26	-11	-26	-39	-24
-15	-33	-22	-35	-22	-27
-8	-13	-19	-13	-7	-13
-27	-12	-12	-14	-10	-11
10	-17	-27	-21	-14	-20
-18	-15	-13	-9	-16	-13
-18	-26	1	-26	-39	-24
-16	-16	-10	-16	-16	-14
-11	-19	-16	-16	-23	-18
-18	-20	-24	-13	-23	-21
-13	-17	-16	-14	-31	-17
-18	-24	-13	-20	-23	-21
-15	-12	-14	-19	-14	-13
-19	-20	-15	-16	-18	-15
-15	-21	-16	-34	-22	-21
-8	12	1	-15	9	3
-8	-12	-14	-6	-13	-13
25	10	25	15	28	19
30	16	20	-34	26	8
9	16	-34	20	26	8
7	12	11	26	15	14
-14	-17	-12	-20	-12	-12
25	0	12	-10	26	4
-6	-20	-13	-22	-18	-17
14	27	20	-12	15	19
25	12	22	5	24	17
-15	-26	-11	-16	-35	-24
7	16	22	-6	31	17

SL.NO	Postop Ef (%	top CO(L/M	Postop GLS	BAW	BAL	BIL	BIW	BIS	BAS	MAW	MAL	MIL
1	74	2.6	-16	-19			-21		-9	-24	-8	-20
2	52	3	-14	-12	-22	-15	-8	-12	-9	-7	-15	-16
3	55	5	-14	-19	-19	-8	-8	-14	-19	-24	-19	-11
4	50	3.4	-18	-11	-9	-13	-13	-10	-5	-23	-21	-14
5	64	5.6	-10	-14	-9	-14	-17	-20	-8	-7	-15	-20
6	57	4.2	-20	-13	-14	-20	-7	-10	-26	-18	-25	-24
7	60	2.8	-16	-19			-21		-9	-24	-8	-20
8	48	2.6	-12	-11	-12	-15	-14	-19	-11	-9	-16	-9
9	40	1.8	-11	6	-12	-7	-5	-14	-7	10	-11	-14
10	40	2.8	-18	-21	-17	-13	-8	-7	-18	-9	-12	-32
11	53	3	-15	-18	-8	-17	-10	-10	-26	-15	-30	-17
12	61	3.2	-18	-10	-12	-25	-15	-19	-25	-21	-18	-14
13	55	4	-10	-11	-15	-14	-4	-8	-5	-13	-16	-14
14	58	4	-18	-21	-17	-13	-9	-10	-16	-11	-12	-25
15	45	3.6	-12	-10	-16	-10	-8	-9	-5	-15	-16	-12
16	50	5.4	12	6	28	19	5	-11	-6	9	14	22
17	56	4.6	-15	-10	-10	-26	-18	-8	-17	-11	-16	-15
18	60	7.2	17	9	14	24	24	-7	11	16	18	20
19	50	2.7	17	15	22	14	13	28	11	24	17	12
20	55	5.3	17	15	22	14	13	28	11	24	17	13
21	62	3.6	18	9	20	13	16	18	13	11	-7	9
22	62	3.5	-15	-18	-8	-17	-10	-10	-26	-15	-30	-17
23	50	4.9	12	-4	-7	12	7	11	18	18	20	23
24	70	3.5	-4	-3	-6	-7	-3	5	3	-5	-4	-13
25	55	8.4	13	11	-5	19	19	-13	-9	22	26	18
26	63	5.1	9	-5	17	6	3	7	16	-8	17	22
27	70	3	5	7	13	11	-8	-13	-11	16	32	13
28	55	3.8	-11	-11	-4	-7	-5	-15	-7	-10	-14	-13

MIW	MIS	MAS	AW	LW	IW	SW	Apex
-25	-13	-19	-16	-15	24	-18	-17
-12	-20	-14	-16	-14	-22	-25	-17
-13	-19	-22	-9	-20	-9	-31	-15
-28	-21	-15	-30	-19	-25	-21	-25
-14	10	-14	-13	-21	14	-20	-7
-16	-24	-13	-22	-28	-14	-31	-24
-25	-13	-19	-16	-15	-24	-18	-17
-7	-11	-19	-5	-14	-21	-17	-15
-11	-13	-14	-24	-10	-18	-15	-16
-12	-19	-26	-24	-21	-17	-29	-23
-11	-16	-15	-20	-13	-20	-20	-19
-12	-10	-18	-20	-21	-20	-25	-23
8	-10	-12	-8	-4	-19	-22	-12
-14	-19	-26	-24	-21	-17	-29	-23
-10	-17	-9	-15	-13	-18	-11	-15
16	14	-12	15	10	13	27	14
-15	-30	-17	-20	-20	-20	-13	-19
11	17	27	26	20	23	11	20
16	13	23	10	25	20	20	14
23	12	16	20	20	10	25	14
12	18	6	28	36	25	19	28
-11	-16	-15	-20	-13	-20	-20	-19
25	15	25	15	17	9	11	12
-5	-9	-8	-10	-1	-18	4	-7
16	-16	43	12	-11	28	14	5
-11	18	18	-7	15	2	20	8
23	22	18	1	-2	-9	10	2
-14	-12	-12	-14	-14	-15	-10	-13