INTRAOPERATIVE ASSESSMENT OF ATRIAL SEPTAL DEFECT MORPHOLOGY USING 3D TRANSESOPHAGEAL ECHOCARDIOGRAPHY Vs 2D TRANSESOPHAGEAL ECHOCARDIOGRAPHY

Dissertation

Submitted for partial fulfilment of the requirement for the degree of DM in Cardiothoracic and Vascular Anaesthesia by

Dr. ANKUR JOSHI

Senior resident

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DIVISION OF CARDIOTHORACIC AND VASCULAR ANAESTHESIOLOGY,

DEPARTMENT OF ANAESTHESIOLOGY,

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

DECLARATION

I, **Dr. ANKUR JOSHI**, Hereby declare that this thesis titled **"INTRAOPERATIVE ASSESSMENT OF ATRIAL SEPTAL DEFECT MORPHOLOGY USING 3D TRANSESOPHAGEAL ECHOCARDIOGRAPHY Vs 2D TRANSESOPHAGEAL ECHOCARDIOGRAPHY"** has been prepared by me under the able supervision and guidance of **Dr. Shrinivas Gadhinglajkar**, Professor, **Dr. Rupa Sreedhar**, Senior Professor, Division of Cardiothoracic and Vascular Anaesthesiology, Department of Anaesthesiology, and **Dr. Jayakumar. K**, Senior Professor, **Dr. Bineesh. KR**, Assistant Professor, Department of Cardiovascular and Thoracic Surgery, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram.

Dr Ankur Joshi
Senior Resident,
Division of Cardiothoracic and
Vascular Anaesthesiology,
Department of
Anaesthesiology,
SCTIMST,
Thiruvananthapuram

Thiruvananthapuram
30-07-2019

CERTIFICATE

We hereby certify that this thesis titled "INTRAOPERATIVE ASSESSMENT OF ATRIAL SEPTAL DEFECT MORPHOLOGY USING 3D TRANSESOPHAGEAL ECHOCARDIOGRAPHY Vs 2D TRANSESOPHAGEAL ECHOCARDIOGRAPHY" is the bonafide work of **Dr. Ankur Joshi,** done under our guidance at Division of Cardiothoracic and Vascular Anaesthesiology, Department of Anaesthesiology at Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram. She has shown keen interest in preparing this project.

Prof. Shrinivas Gadhinglajkar (Co-guide)
Professor
Division of Cardiothoracic and Vascular Anaesthesiology,
Department of Anaesthesiology, SCTIMST, Thiruvananthapuram

Prof. Rupa Sreedhar (Co-guide)
Professor (Senior Grade)
Division of Cardiothoracic and Vascular Anaesthesiology,
Department of Anaesthesiology, SCTIMST, Thiruvananthapuram

Prof. Jayakumar .K (Co-guide)
Professor (Senior Grade),
Department of Cardiovascular and Thoracic surgery, SCTIMST, Thiruvananthapuram

Dr Bineesh KR (Co-guide)
Assistant Professor,
Department of Cardiovascular and Thoracic surgery, SCTIMST, Thiruvananthapuram

CERTIFICATE

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Prof. Thomas Koshy

Senior Professor and Head,
Division of Cardiothoracic and Vascular Anaesthesiology,
Department of Anaesthesiology,
SCTIMST, Thiruvananthapuram

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30-07-2019
Thiruvananthapuram

Dr. Ankur Joshi

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ABBREVIATIONS AND EXPANSIONS	
CHD	CONGENITAL HEART DISEASE
ASD	ATRIAL SEPTAL DEFECT
PDA	PATENT DUCTUS ARTERIOSUS
2D-TEE	2-DIMENSIONAL TRANSESOPHAGEAL ECHOCARDIOGRAPHY
3D-TEE	3-DIMENSIONAL TRANSESOPHAGEAL ECHOCARDIOGRAPHY
2D	2-DIMENSIONAL
3D	3-DIMENSIONAL
OT	OPERATION THEATRE
TEE	TRANESOPHAGEAL ECHOCARDIOGRAPHY
TTE	TRANSTHORACIC ECHOCARDIOGRAPHY
MV	MITRAL VALVE
RUPV	RIGHT UPPER PULMONARY VEIN
TR	TRICUSPID REGURGITATION
PAH	PULMONARY ARTERIAL HYPERTENSION
AVSD	ATRIO VENTRICULAR SEPTAL DEFECT
AOC	AMPLATZER OCCLUSIVE DEVICE
CMRI	CARDIAC MAGNETIC RESONANCE IMAGING
IAS	INTER ATRIAL SEPTUM
INJ	INJECTION
I.V.	INTRAVENOUS
AoV	AORTIC VALVE
SD	STANDARD DEVIATION
BPM	BEATS PER MINUTE

TITLE

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INTRODUCTION

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Advances in perioperative care for children with congenital heart diseases (CHD) over the past few decades have resulted in an increasing number of these children reaching adulthood. Also the present day advanced and non invasive imaging techniques have started diagnosing CHDs in adults, who were earlier missed. Although surgical cure is the goal – a true universal cure, without any residua, is uncommon on a population wide cover. Exceptions however include closure of Atrial Septal Defects (ASD) and non-pulmonary hypertensive Patent Ductus Arteriosus (PDA). Atrial Septal Defects are one of the most common congenital defects encountered in adult population, accounting for 30-40% of the total intracardiac shunts in adults.[1, 2] They account for 6-10% of the congenital heart effects (CHD), with an incidence of 1in 1500 live births.[3] The patent foramen ovale though, is more common and is present in 20-25% of adults. [4]

Accurate preoperative determination of an atrial septal defect location and size is important, not only for a successful transcatheter closure but also to ascertain the feasibility and choice between a device closure and open repair of the ASD. A successful transcatheter closure of the defect requires reliable preoperative imaging of the location and size of the defects as well as the information on the relationship of the rim length to the neighboring cardiac structures.[5, 6]

Although 2D Transesophageal echocardiography (2D-TEE) has been widely used for the preoperative assessment of ASD, it does not always provide reliable information on the maximal defect size and the minimal rim length due to imaging of the defect in a single cross section at a time. [7, 8] 3D echocardiography provides an enface view of the ASD and the relationship with adjacent structures, thus eliminating some of the drawbacks of 2D imaging. [9,10] Earlier 3D studies have also described the dynamic nature of the ASD size during the phases of the cardiac cycle. [11,12]

We hypothesized that 3D-TEE is more accurate in evaluating the location, size and the Atrial septal margins of a secundum ASD compared to 2D-TEE, when correlated on the operation theatre (OT) table with measurements performed by the surgeon.

OBJECTIVES

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The objectives of this study were as follows:

Primary:

a) To compare 3D TEE and standard 2D TEE examination for assessment of morphology of interatrial septum & atrial septal defect, such as the size, shape, orientation, location and number of defects.

b) To compare the observations on 2D & 3D TEE with the surgeons' observations.

Secondary:

To assess the rim margins around the ASD.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Role of echocardiographic evaluation in decision making…

Silvestry et al in their 2015 guidelines on echocardiographic assessment of ASD & PFO have mentioned clearly the areas to assess in a case of ASD. A complete evaluation of the ASD includes the detection and quantification of the size, shape of the defect, the rims surrounding the defect, the degree & direction of shunting, the extent of remodeling and the changes in size & functioning of the chambers and pulmonary circulation. [13]

Transesophageal echocardiography (TEE) has an integral role before percutaneous device deployment. It helps in establishing the initial diagnosis of an ASD, determining its size, and whether single or multiple. The sizing of the ASD is a very important step to decide the size of the device required for the closure. TEE provides further anatomic detail including the presence of other associated lesions such as mitral valve prolapse and anomalous pulmonary venous drainage.

The relation of the secundum ASD to adjacent cardiac structures is an important information to be assessed before the device deployment.[14] Specifically, the distance of the defect from the mitral valve and right upper pulmonary vein should be at least 7 mm from the margin of the ASD, for insertion of the ASO device. Defects exceeding 40 mm cannot be closed with current Amplatzer devices.[14]

ASO device deployment can be fully performed under echocardiographic guidance only, without the need for fluoroscopy.[15] A multi-planar view of the defect makes it feasible to guide the proceduralists during guide wire placement across the ASD and into the left atrium and confirm its position there.[14] The delivery catheter is passed over the guide wire and into the left atrium, as confirmed on TEE. It is ensured that the catheter tip is free in the body of the left atrium before releasing the left atrial disk so as not to entrap it in the left atrial appendage, the mitral valve, or its apparatus. Another important hazard which can be assessed on TEE is the entanglement of the catheter in a Chiari network, before device deployment.[16] A successful device positioning involves opening of the left atrial disk and waist, positioning against the inter-atrial septum before release of the right atrial disk. If the left atrial disk is pulled back against a large defect before the waist is expanded, part of the disk edge may prolapse into the right atrium. Incorrect device position therefore occurs during deployment.[14] TEE helps confirm that the disks lay to either side of the ASD/septum and have assumed the desired profile. Any residual trivial shunt is assessed for after device deployment because device retrieval and its exchange with an adequately sized device is still possible at this stage.

Post-deployment, the TEE helps in checking the device position, structural integrity, residual shunt and monitor changes in right heart chambers. Also helps check relation to other structures mitral valve (MV), right upper pulmonary veins (RUPV),etc. and look for complications like thrombus, infection, etc.[14]

With the current emphasis on less invasive approaches for all cardiac surgical procedures, modifications of the traditional surgical approaches such as median sternotomy and right anterior lateral thoracotomy have been evaluated.[17] Options for surgical closure are simply, a patch closure or a primary closure of the defect. As part of the general evolution of techniques, emphasis has been placed on shorter incisions and other surgical methods proposed as "less" or as "minimally" invasive techniques, including minimal access, port access, robotics, video-assisted, etc.[18][17] Echocardiography, like in a transcatheter percutaneous closure, aids preoperatively to assess the site, size and deficient rims in an ASD planned for surgical closure. This way a surgeon can anticipate as to what to expect on cardiotomy and the element of surprises is negated.

Also the assessment of the right sided chambers and the presence of any tricuspid regurgitation (TR) with or without an associated pulmonary arterial hypertension (PAH) is also assessed. It is mandatory to review the patch closure efficacy in the post operative period. A residual ASD may have to be followed up for aggravation or patch dehiscence and symptom reappearance.[17] This post operative echocardiography helps in the post operative decision making of key critical issues of these individuals.

Percutaneous transcatheter ASD closure

Percutaneous transcatheter closure of ASD has become the preferred management strategy instead of open heart surgery.[19] In 1976, King and Mills performed the first successful percutaneous ASD closure. The procedure has been improved with user friendly delivery systems and devices. The use of new percutaneous closure devices is associated with a low rate of complications and good long term outcomes.[19] In a prospective study spanning 4years from 2000-2004 by Butera et al, it was concluded that approximately 80% of secundum defects are suitable for device closure.[20]

Decision-making about whether closure is required, typically relates to patient symptoms and evidence of right ventricular volume loading due to a significant left to right shunt. Other factors such as associated arrhythmias and evidence of pulmonary hypertension also have an impact on whether to opt for closure of the defect. Echocardiographic imaging of the atrial septum is essential to assess if the defect is suitable for device closure.

At a bare minimum, the atrial septum can be evaluated fully using a transthoracic echocardiography (TTE). Multiple views to evaluate the size, shape, and location of an atrial communication and the relationship of the defect to its surrounding structures are recommended. In adolescence and adulthood, the sub-xiphoid TTE window is often inadequate because of the distance from the probe to the atrial septum. Thus, other views such as the parasternal windows should be used to assess the atrial septum. Occasionally, a full assessment of the atrial septum might not be possible with TTE. Hence, the need for transoesophageal echocardiography (TEE).[13]

A comprehensive, multiplanar, systematic and sequential TEE examination should able to evaluate the IAS - size, shape, and location of any atrial communication present, and the relationship of the defect to its surrounding structure. A TEE is usually easy to perform intra-operatively compared to a TTE in a cardiac surgery operation theatre where the chest is draped for a sterile cardiac surgical procedure.(21) Capturing 3D volumes with and without color Doppler of the IAS, allows for even greater data acquisition without the need for sequential multi-plane interrogation. In some units, intracardiac echocardiography is used as an alternative modality.(13)

Atrial septal defects not suitable for device closure

Several types of defects are generally regarded as unsuitable for device closure depending upon their rims. The **'rims'** refer to the tissue between the defect and key adjacent anatomic structures. Some prefer to name the rims according to the closest adjacent anatomic structure, namely the **inferior vena cava (IVC), superior vena cava (SVC), coronary sinus, mitral valve, right pulmonary veins and the aortic valve rims**. Device closure requires 'rims' of tissue surrounding the defects, to which the closure device can grip to attain a stable, permanent position within the atrial septum.(21)

A complete absence of the IVC rim is viewed as a contraindication by most operators. A small, or even absent rim to the aorta is common in around 30–40% of secundum defects. Most operators do not regard absence of an aortic rim as a contraindication to device closure.(21) Most view it as acceptable for devices to splay over the aorta provided the aorta is not indented by the device, thus negating the need for a tissue rim.

Atrio ventricular septal defect (AVSD) is a type of ASD which has one of the borders of the atrial communication made up of the inferior and superior bridging leaflets themselves, without any rim.[21]

The superior sinus venosus ASD is located at the junction between the SVC and atrial septum with the SVC typically 'overriding' the upper margin of the atrial septum. There is no tissue rim between the SVC and the atrial septum, thus being unsuitable for device closure. It has the added complication of being associated with anomalous drainage of the right pulmonary veins (most commonly the right upper pulmonary vein).[21]

The inferior sinus venosus ASD is located at the junction between the IVC and atrial septum. There is no IVC tissue rim for the device to grip onto, which would therefore seriously affect the stability of a device if it was deployed.[21]

Pre operative TEE assessment of Ostium secundum ASDs

Echocardiography in patients undergoing surgical closure helps in appropriate patient selection, assessment of complications. Transthoracic echocardiography (TTE) has the advantage of offering unlimited multiple planes to evaluate the atrial septum. But has limitations evaluating the lower rim of atrial septal tissue which is just above the IVC, after device placement because of the device shadowing.[13] Also, because the septum is relatively far from the transducer, the imaging is often suboptimal in larger pediatric and adult patients. If ASD closure is attempted, a detailed assessment of the IAS anatomy and surrounding structures using TEE is typically indicated for patient selection and procedural guidance. [13]

Using a structured, systematic approach the defect can be fully evaluated with 2D, 3D and color Doppler with respect to the:

- Size and position of the defect
- Size and quality of the tissue rims
- Presence of additional defects and their position within the septum
- Presence of any additional lesions, which may affect the course of the surgery.

The 2015 echocardiography guidelines by Silvestry et al describe the specific transducer angles for the standard TOE views, to visualize the relationship between the ASD and the surrounding cardiac structures. However, these angles may vary slightly between patients to obtain the optimal images.[21]

Transthoracic echocardiography vs Transesophageal echocardiography for assessment of ASD

TTE & TEE both have been time tested over decades now for the successful assessment, therapeutic decision making and following up cases of ASD. However, both the modalities of echocardiography are fraught with advantages and disadvantages.

TTE offers a low cost, portability, noninvasive method of cardiac assessment not requiring any sedation/ anaesthesia for the examination. It offers excellent image quality in children but may result in sub optimal images in adults. Also the visualization of the inferior rim of the IAS is poor after device deployment due to the shadowing in all possible views.[22] There are no contraindications on performing a TTE as it is a non invasive examination requiring minimal cooperation by the patient.

TEE on the other hand offers better quality images than the TTE as the probe in the oesophagus is in close proximity to the IAS. And a 3D TEE assessment offers an en face view of the ASD which might be more intuitively be understood to nonimagers.[23] But the examination needs anaesthesia or heavy sedation with some pharyngeal anaesthesia. This increases chances of aspiration and patient discomfort. Also being an invasive investigation, chances of a pharyngo-oesophageal trauma cannot be ruled out.[13] Certain medical conditions are regarded as contraindications for the placement of a TEE probe, like oesophageal varices/ strictures/ upper GI bleeds, laryngeal diverticuli, etc.

A TTE examination is not possible intra operatively, which makes a TEE examination a mandatory examination intra-operatively by the anaesthesiologists. Hence, we as anaesthesiologists should know the characteristics of an ASD on the echocardiography.

Advantages of 3D over 2D echocardiography in assessing ASDs

The 3D imaging of ASDs has been under development for more than 15 years. Early technology was dependent on 3D images reconstructed from 2D echocardiograms. In 1995, Marx et al [24] first reported some of the unique and useful 3D images of ASDs, which were successfully reconstructed from transthoracic 2D images in 13 of their 16 patients. Although this was groundbreaking work, the technology was labor-intensive and resulted in images of somewhat limited resolution. One year later, Magni et al [12] validated the accuracy of the 3D reconstruction method to measure ASD major and minor axes, size, and location in 10 explanted porcine cadaver.

It goes without doubt that 3D echocardiography in its earlier days of inception, was a labour intensive and time consuming modality to gather information on the IAS. And this delay in the processing of these images to get decisive information, nullified the entire exercise of using 3D echocardiography imaging intra-operatively in the operation theatre. The present day 3D echo software offer virtual cropping, image rotations, display of anatomical orientations and post processing of the acquired high quality images. The development of matrix ultrasound probes allowed the visualization of a real-time 3D cardiac image within a user defined volume.[25] The miniaturization of the 3D transducer allowed its incorporation into transoesophageal ultrasound probes.[26] The unique region-oriented views obtained from the 3D data set can be acquired quickly and have the potential to enhance understanding of complex cardiac anatomy.[27] All these features aid in faster and more user friendly interface for processing images. These advances in 3D technology have brought the 3D echocardiography at par or at certain comparisons even better than the 2D echocardiography.

Importance of knowing the ASD shape

An atrial septal defect has measurable dimensions which give it a shape. Both ASD and PFO exist in a wide variety of heterogeneous sizes, shapes, and configurations.[13] Most commonly, the ASDs are oval in shape and occasionally may be round too. Using an 'en face' view, the recently introduced 3D-TEE technology allows accurate visualization of the number, the shape and the rims.[28] Multi-planar reconstruction (MPR) also allows ASD diameters and area to be measured.[26]

Sizing of the ASD

Two- dimensional TEE relies on the integration of multiple image planes for the operator to mentally reconstruct the true 3D anatomy of an ASD, and this limitation can lead to a failure to appreciate the true dimensions and shape of the defect. Visualization of ASDs by real-time 3D-TEE overcomes these limitations and allows for more accurate assessment of the shape and size of the defects.[28] Complex shaped defects, hence prove difficult to accurately be defined by 2D-TEE.

Johri et al in their study (2011) comparing real time 3D-TEE imagery with 2D-TEE assessment of ASD sizing found that 2D-TEE significantly underestimated the sizes of ASDs compared with 3D imaging in patients with evidence of residual shunting.

Patients without residual shunting had similar measures of ASD size by 2D and 3D TEE. These findings suggested the underestimation of true ASD size by 2D-TEE adversely affected the success of transcatheter ASD closure, because of under sizing of the device.[28] They concluded that real-time 3D-TEE had advantages over 2D-TEE for accurately measuring ASD size and defining defect shape.

Location of the ASD

There are several ways to know if the device is in a sub- optimal position and will need to be recaptured and redeployed. It is important to confirm the position of the device early with the interventionalist. Once in position against the septum, the device should appear linear and sit flat to the septum. The discs of the device should not appear bulky or appear to stand some distance from the septum nor should they move excessively within the heart. The position of the device with respect to the mitral valve - anterior leaflet needs to be carefully assessed. If the device appears to impinge upon the anterior leaflet of the mitral valve and there is an increase in the amount of mitral regurgitation from the initial imaging, this may be an indication to not deploy or to redeploy the device. Lastly, a residual leak seen between the device and the septal tissue with colour Doppler may indicate that the device is not well seated or is not the correct size to occlude the defect.[21]

Similarly, it is imperative to examine the surgical patch closure of the ASD, postoperatively. A surgical suture may run through vital structures like the IVC, SVC, mitral valve – anterior leaflet or the roof of the coronary sinus. Occasionally, a residual ASD may be observed in the post operative scan which should be communicated to the surgeon for a revision of the patch.

Especially, certain differently located ASDs like sinus venosus – svc type ASDs can only be corrected by surgical closure and involve the risk of the right upper pulmonary vein ligation in the suture bite, by the surgeons. Such instances are vital for a post operative scan and reinforce the importance of communication between the echocardiographer and the surgeons.

RIMS of ASD

When an ASD or PFO is present, attention is given to determining the relationship of the defect to the venae cavae, pulmonary veins, mitral and tricuspid valves, and coronary sinus. An assessment of the amount of the surrounding rims of tissue is important to decide the candidacy for percutaneous transcatheter closure.

A deficient rim *is defined as less than 5 mm in multiple sequential views, and this should be evaluated in at least three sequential related multi-plane views in 15 degree increments*. A rim less than 3mm is acceptable in case of antero-septal or aortic rim device placement since the device splays around the aorta. A 3D echo assessment is more useful for conforming this.[13]

Number of ASDs/ Fenestrated ASDs

Device closure has become first choice for secundum defect closure when feasible from morphology (which includes stretched diameter < 38 mm and sufficient rim of 5 mm except towards the aorta). Larger ASDs of > 40mm diameter are not recommended for a device closure strategy due to non availability such a large ASD closure device.[29][14] Fenestrated or multiple ASDs are also a contraindication for device closure. The fenestrations pose a hindrance to the adequate and effective deployment of a device to close the ASD.

A 3D-TEE views such ASDs en face and eases the decision making for the treating cardiologist/ surgeons to have a plan ready to tackle such a complicated ASD morphology effectively.

Validation of 2DE and 3DE with CMR for the evaluation of ASD

There is an increasingly important role played by CMRI in the diagnosis and management of ASDs, especially sinus venosus type in adults. This pathology can easily be 'missed' on TTE.[30] CMR agrees closely with TOE assessment of atrial septal defects for closure. In addition, it is able to assess the septal margins such as the posterior inferior margin, which is known to be difficult to assess with TOE.[31]

CMRI is noninvasive, has high spatial resolution with large fields of view, and does not involve exposure to ionizing radiation like the CT scan. This allows for serial studies and documentation of normalization of the ventricular volumes, in ASDs and other cardiac lesions, etc.(30)

As a non-invasive procedure with higher patient comfort, MRI allows both pre-intervention planning and post-interventional control after AOC implantation with high accuracy. In a study on 20 patients in 2002, Weber et al (Germany) pointed out a high correlation of the ASD diameters measured in vivo in the MRI with those measured using a TEE examination.

The correlation between MR Volumetry and MR flow vs TEE measurement was also high. TEE has been used in routine clinical practice as the gold standard method of shunt quantification. It should, however, be borne in mind that even the TEE can ultimately only be classified as a semi-quantitative process. The high correlation coefficient of Qp / Qs -Ratio compared to TEE allows the positioning of quantitative MRI as an equivalent measurement procedure.(32)

It is for these above mentioned reasons that cardiac MRI has been considered a gold standard in the assessment of ASD, pre operatively and post operatively. It has been recommended by the American Society of Echocardiography as a gold standard evaluation tool for ASD.(13)

Cardiac MRI is the gold standard to compare the morphological findings and functional status of an ASD and to validate a 2DE/ 3DE examination. But logistic issues like cost, time and sedation for uncooperative claustrophobic patients make it a unsuitable for a study like ours to include it in.

Surgeons' assessment of ASD on Operation Table

Surgical assessment of the size of an atrial septal defect has never been validated as a comparative tool for reasons very logical. A patient put to the complex procedure of an open surgical patch repair of the ASD, has never ever undergone an abandonment of the surgical procedure midway, for a change in the therapeutic plan of closing the ASD non invasively. In brief, a person planned for an invasive surgical closure of ASD (for indications on echocardiography / cardiac MR) always does undergo a surgical closure even if the intra operative findings point towards a possible transcatheter closure of that ASD, retrospectively.

Hence, there is a paucity of literature which validates or even compares the sizing of the ASD after a cardiotomy, to the gold standards of sizing an ASD (namely echocardiography & cardiac MR). We however in this study, wanted a reference standard to compare our echocardiography evaluations of 2D/ 3D. And cardiac MR as a reference standard would lead to a financial loss and expenditure for our patients, especially in a developing country like ours.

A surgical measurement has the advantage of direct visualization of the defect with a naked eye. Also, measurement using a silk thread and a scale intra-operatively, takes relatively a few minutes compared to the time and resource consuming CMRI.

Measurements of the size of the ASD, shape and rim sizes can all be carried out without much difficulty. Additionally, ASD dimension measurements can fit in as a part of the surgical steps towards closure of the defect. And hence avoids any inconvenience to the surgical team without affecting the Cardio-pulmonary bypass times for the patients.

However, the surgical method offers a few disadvantages too. For the surgical measurement, the right atrial free wall is incised open in a collapsed heart and then the ASD is located and measured. The defect is thereby prone to stretching in random directions – depending on the tissue handling by the surgeon in charge. This may result in altering the shape of the ASD or even the dimensional measurements of the defect as compared to what would be there in a beating functional heart.

Also the accuracy of measuring an ASD using a silk thread and a scale has its own drawbacks though. Firstly, it gives us an adynamic measurement of the septal defect, which has been proven to be a dynamic defect whose dimensions change with every systole & diastole. Because the IAS is a complex, dynamic, and 3D anatomic structure, limitations exist in its evaluation using any single form of 2D echocardiography. Secondly, the IAS (and associated abnormalities such as ASD or PFO) does not exist in a true flat plane that can be easily aligned or interrogated using 2D imaging.(13) Nonetheless, we have mentioned this mode of surgical measurement of ASD as our reference standard for comparison with the 2DE and 3DE assessments.

Surgical closure of atrial septal defects

Since the early reports of surgical atrial septal defect (ASD) closure in 1948 (without direct visualization) and in 1952 (with hypothermia and inflow occlusion), over 50 years of surgical experience has resulted in an operation with minimal mortality or morbidity.[33,34]Today ASDs are closed using cardiopulmonary bypass (CPB) with direct vision of the lesion. The classic approach is by median sternotomy, however, other approaches are used as well in an effort to reduce morbidity.[35]The long- term results of surgical repair of secundum defects are excellent, especially when patients are operated on under 25 years of age with an actuarial survival curve identical to the general population .[36]

ASD closure is indicated in the presence of any hemodynamically significant shunt causing enlargement of right heart structures, irrespective of the presence of symptoms.[37][29] A hemodynamically significant shunt is classically defined as any shunt that causes right-sided volume overload and pulmonary over-circulation. This typically occurs when the Qp : Qs ratio is greater than 1.5 to 1. Other indications for ASD closure include the rare cases of documented orthodeoxia-platypnea—regardless of shunt size, and confirmed paradoxical embolism[29]. Small defects without evidence of right heart volume overload may be followed without surgery; however, increased shunt may occur later in life and closure become necessary.

Secundum defects can be closed surgically or percutaneous using a catheter delivered device. Limitations to transcatheter closure generally relate to the size of defects (too large) or the size of infants (too small).[37] Relative contraindications to device closure of secundum defects include very large size (diameter greater than 36–40 mm), inadequate margins for device anchorage, potential device interference with atrio-ventricular valve function, and potential obstruction of systemic or pulmonary venous drainage.[38][37] Sinus venosus, ostium primum, and coronary sinus septal defects almost always require surgical repair.

TEE is preferred in patients who are intubated for the procedure, which includes all children aged <13 years. Standard 2D trans- esophageal echocardiographic images as well as a series of deep trans-gastric 2D images are applied in all cases. Three-dimensional TEE is generally added in all patients who weight >20 kg and are intubated for the procedure. Three-dimensional transoesophageal echo- cardiographic images of en face right atrial and left atrial views from short-axis and long-axis images and trans-gastric bicaval sagittal views acquired with the 3D zoom and live 3D modes are used routinely in all cases. These views provide real-time imaging of most of the important ASD features in a single view and are easily and rapidly obtained after the learning curve.[39]

2DE is adequate in detecting these defects, but the images obtained can lack the detail necessary in accurately measuring their size, shape, and location, specifically with respect to the Swiss cheese pattern or multiple hole pattern, in which these limitations become more pronounced. 3D transthoracic echocardiography (TTE) performed via the apical, para-apical, right parasternal and subcostal views provide good visualization of the defect in the majority of patients. [40] Furthermore, 3D TTE has been shown to better approximate the location and dimensions of ASDs as well as the surrounding anatomy and rim size when compared to 2D images.[24]

In one study, Morgan et al. compared results obtained from 2D transoesophageal echocardiography (TEE) to 3D-TTE. Though the differences in precisely measuring the defect's diameter, area, and circumference was not statistically significant when comparing the two imaging modalities, it was clinically significant, in that 3D TTE was just as accurate in its ability to recognize appropriate candidates for percutaneous closure of ASDs, thus diminishing the need for the more invasive TEE procedure and circumventing its major complications such as GI bleeding, esophageal hematoma formation, and perforation.[41] A real-time transthoracic 3D echocardiographic measurements of maximum dimension, maximum circumference, and maximum area of atrial septal defect (ASD) agreed well with the sizing balloon in the catheterization laboratory.[10] 3D TEE has showed greater values of the maximal ASD size than 2D echo because 3D echo can visualize the entire shape of ASD clearly while 2D echo could not, however these pilot studies had too miniscule a sample size to arrive at a significant conclusion. The comparison of 3D echocardiography vs 2D echocardiography for assessment of ASDs is still unaddressed, especially using a trans esophageal echocardiography.

Traditionally, the assessments of ASD size, geometry and atrial septal margins have been obtained by 2D transoesophageal echocardiography (TOE) prior to the percutaneous closure.[14] This is a semi-invasive technique and all of the information could potentially be obtained by non-invasive cardiovascular magnetic resonance (CMR). Furthermore, 2D TOE is imperfect at assessing all atrial septal margins. A large atrial septal defect that is located infero-posteriorly is difficult to both assess and close [14] and relates to the limited assessment of the posterior inferior margin by TOE.(42)Measurements of the ASD can only be obtained from the 4-chamber, short axis and bicaval views on 2D TOE due to the plane on TOE that generally projects the ASD in a relatively fixed direction.(42) CMR has been shown to visualize secundum ASDs. Studies comparing CMR with TOE to assess ASD and suitability for percutaneous closure have mainly been done in paediatric populations.(42) In the assessment of atrial septal margins, CMR agrees closely with 2D TOE for percutaneous closure. Additionally, it can assess the posterior inferior margins also.[31]

3D echocardiography provides good visualization of the defect in the majority of patients. 3D echo also shows better location and dimensions of ASDs as well as the surrounding anatomy and rim size when compared to 2D images.[40] The ability of 3D TTE to estimate measurements correctly not only helps when planning the transcatheter approach to the procedure, but also provides important data needed to select the appropriate size of the occluder device which is imperative to avoid procedure related complications, including breakdown of the device, persistence of the shunt, device embolization, and even perforation of the heart.(43) The American Society of Echocardiography currently recommends 2D TEE during percutaneous closure and repair of ASDs; however, this is contingent on the observer's ability to mentally recreate these images in 3D space, which can be difficult. 3D TEE allows the observer to evade this problem and can offer a clearer view of the defect, leading to more accurate measurements, increased repair rates, and better identification of patients at higher risk of complications, prompting closer follow up.[40] Specifically, 3D TEE allows the user to measure defect size, rim size, left and right atrial occluder disc dimensions, and the distance between the left atrium and aorta which can help recognize appropriate candidates with secundum type ASDs for percutaneous closure.(44)

Surgeons assessment of ASD as a Reference parameter

Surgical measurements could be performed using approximations of a naked eye examination. But more accurate assessments would be using maximum measurements in 2 dimensions (length & breadth). This could be achieved using a silk thread in situ and cutting it to the size of the measurement. And thereafter measuring it using a measuring scale.

Also, the dimensions of an ASD change in a collapsed heart as compared to fully functional beating heart. Post sternotomy and pericadiotomy, the heart is cannulated and put on the cardio pulmonary bypass (CPB) machine. Once on the CPB the cardiac chambers tend to collapse, and the collapsed heart offers a change in the dimensions of the ASD. A surgical dissection to access the ASD intra operatively would mean to perform a right atrium incision and that in itself would change the working dimensions of the Atrialseptal defect as would be visualized using an echjocardiography. We must also not forget the surgeon would be invariably and unknowingly, stretching the defect rims in order to measure the defect size using a silk thread and a scale. This would again negate the surgical technique of sizing the ASD as a standard and accurate technique. Hence, the surgical technique would rather serve as just a reference standard to compare the accuracy or non accuracy of the echocardiographic measurements.

Intra operative measurements of the rims of the atrial septal defect however are expected to relate well with the echocardiographic assessments as the rims extend from the relatively fixed wall of the atrium (namely aortic, mitral, superior vena cava, inferior vena cava and the posterior wall of the septum). Likewise for reasons mentioned above, no validated studies have been conducted to assess the accuracy of the rim sizing as compared to an echocardiographic/ cardiac MR sizing. But sizing the Aortic and the pulmonary vein rims of the ASD are impossible surgically due to the inaccessibility of these rim locations though the RA surgical incision (approach for ASD closure).

Justification of our study

Traditionally, ASD and IAS morphology is being assessed on a 2D echocardiography. Introduction of the 3D echocardiography may offer a better info than 2D echo TEE because of its proximity to the IAS and a better profiling of the septum compared to the TTE.

In our opinion, an intra-operative surgical evaluation will be considered one of the best parameters to compare between 2D & 3D echo findings which will obviate the necessity for a cardiac MR. The findings of our study will help prepare the interventionalist or the surgeon before the therapeutic intervention of the defect is carried out.

MATERIALS AND METHODS

Materials & Methods

Study Design

Our study was a prospective, observational, non randomised and non blinded study, which was performed in a tertiary reference centre, a university level hospital, annually performing 1500 cardiac surgeries (SCTIMST). This study was conducted over a period of 12 months from Jul 2018 to Jul 2019.

This study was approved by the Institute Ethics Committee letter no. SCT/IEC/1261/AUGUST-2018 dated 19 Sep 2018.

No extramural or intramural funding was required for the study.

Informed Consent

After obtaining the approval of IEC, patients were selected on previous day during our pre anaesthetic check-up. Patients were educated on the study in the presence of a witness. The witness was allowed to counter question the patient whether he/ she has really understood the proposed study, of which he/ she would be a part. An informed consent form was signed by patient or relative of the patient as per the institute protocol.

Participants included adult patients coming for an elective closure of ASD under Cardio pulmonary bypass (CPB).

Inclusion criteria were as follows:

- All Adult patients scheduled for elective ASD closure under CPB.
- We will include ostium secundum ASD, superior sinus venosus ASD and coronary sinus ASD
- Age group b/w 18 – 70 years.
- Normal sinus rhythm.

Exclusion criteria were as follows:

- Ostium primum ASD and Inferior type of sinus venosus ASD will be excluded from the study because of complexity of the anatomy and difficulty in echocardiographic evaluation.
- Multiple ASDs, fenestrated ASDs and large ASD > 40mm
- Patients with Severe MR.
- Patients with other associated complex congenital anomalies.
- Contraindication to TEE probe placement like oesophageal strictures, oesophageal varices, oesophageal 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, postradiation therapy

- Patient refusing to participate in the project
- Poor 2D & 3D image quality
- Emergency and Redo surgeries.
- Patient with moderate or severe LV dysfunction (LVEF < 40%)

Study methodology

All patients were pre-medicated with diazepam @ 0.2mg/kg orally. None of the patients were receiving any cardiac medications, before their ASD closure procedures. On the day of the surgery, after having been transferred to the Operation theatre, they were made to lie comfortably on the operation theatre table. Standard ASA monitoring in the form of a 5-lead ST analysis Electrocardiogram, pulse oximeter, non invasive blood pressure monitoring cuff were attached to the patient and readings confirmed on the monitors. Thereafter a broad gauge intravenous access was secured using adequate local anaesthetic infiltration. Also, an invasive arterial line for invasive arterial blood pressure (IBP) was placed in the left or right radial artery (whichever better palpable) under local anaesthetic infiltration and was well secured.

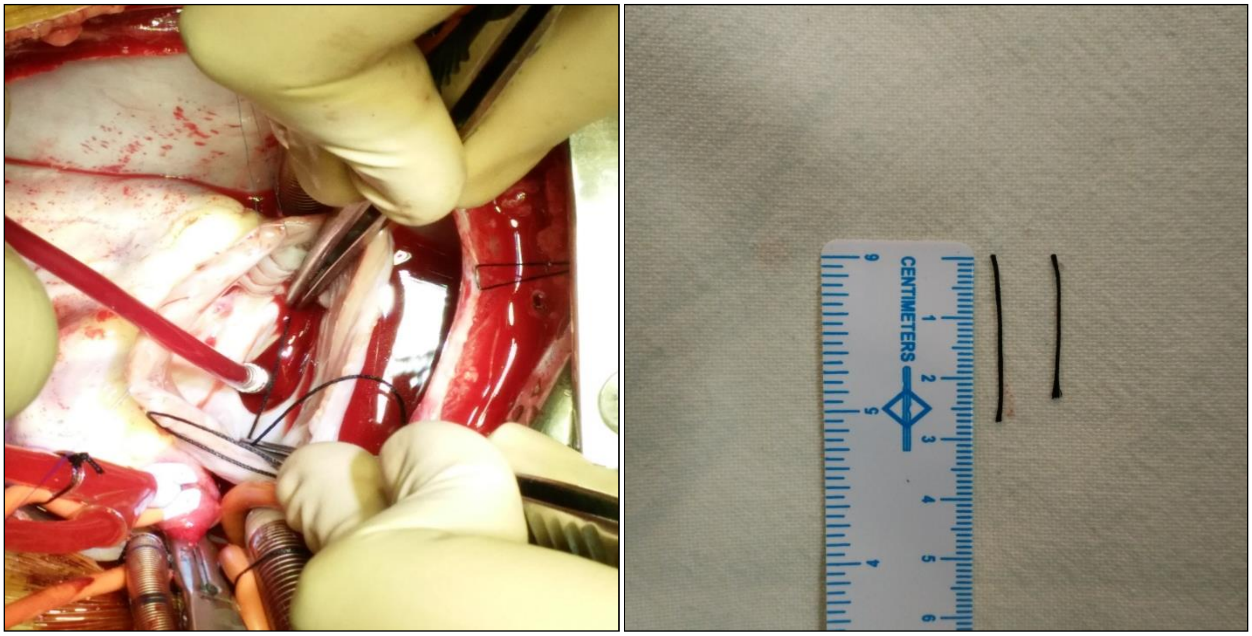
Pre induction medications in the form of Inj Midazolam @ 50µg/ kg i.v, Inj Fentanyl @ 3µg/ kg i.v, Inj Propofol @ a sleep dose (1-1.5mg/ kg) i.v was given till the patient induced into a sleep with apnoea. After which a non depolarising muscle relaxant in the form of Inj Pancuronium @ 100µg/ kg i.v was given only after confirming the ability to mask ventilate the patient. Once the adequate time for full muscle relaxation was allowed (nearly 3min), the trachea was intubated using an adequate sized laryngoscope and endotracheal tube – under strict aseptic conditions with ideal positioning of the patient for an unobstructed laryngoscopic view of the laryngeal inlet. After confirming the ETT tube placement in the trachea by confirming the end tidal carbon dioxide trace on the monitor, the ETT was secured and connected to the mechanical ventilator on the anaesthesia work station. Patient was ventilated with PRVC mode of ventilation bearing a tidal volume of 6-8ml/ kg, at an inspired fractional oxygen concentration (FiO2) of 40-50% to avoid an increase in the Qp/ Qs ratio. A peep of 4-5 cm of water was adjusted keeping stable haemodynamics in view. Respiratory rate of 16-20 per minute was adjusted to keep the end tidal volume of carbon dioxide between 30 – 36mmHg.

A deeper plane of surgical anaesthesia was maintained using inhalational anaesthetic agents like Sevoflurane/ Isoflurane to target MAC values of 0.8 – 1 MAC. Also intermittent top ups of Inj Fentanyl & Inj Pancuronium were given to maintain intraoperative haemodynamic stability all throughout. A triple lumen central venous catheter was introduced in the right internal jugular vein (landmark or USG guided) for want of infusing cardiotropic drugs/ monitoring the central venous pressure and sampling venous blood on required bases. A left sided jugular cannulation was preferred over the right side in sinus venosus - SVC type of atrial septal defects.

An adult-size RT-3D-TEE probe was inserted after induction of anaesthesia and heart was inspected using an ultrasound system (IE 33, Philips Ultrasound, Bothel WA, USA). All echocardiographic examinations were performed before the institution of Cardiopulmonary bypass (CPB). Initially in the 2D mode followed by acquiring images in the 3D mode. The 3D images were processed offline.

After the CPB was initiated, aortic cross clamp was applied and an electromechanical quiescence was achieved with the administration of cardioplegia. Cardiotomy was performed and the surgeon had a visual assessment of the morphology of the IAS & ASD.

- All the margins/ rims of ASD were noted and measured using a silk thread and a measuring scale. (Photograph - 1)
- The long and short diameters of the ASD were measured using a silk thread and a measuring scale. A note of the shape and the orientation of the ASD were made.



Photograph 1: showing the ‘Thread & Scale method of intraoperative measurement of the ASD morphology. Cut threads being measured up using a measuring scale.

ECHOCARDIOGRAPHIC PROTOCOL

All echocardiographic measurements were performed in the pre CPB period at stable haemodynamic parameters. The baseline 2D echocardiographic measurements were performed as mentioned in the observation chart. Full volume 3D loops were acquired in the pre-decided views.

2D views for assessment of IAS [13]

While using TEE, five base views were used to assess the IAS and surrounding structures, which included

a) Mid-esophageal four-chamber view (Image1)

b) Mid-esophageal aortic valve (AoV) short-axis view (Image 2)

c) Mid-esophageal bicaval view (Image 3)

d) Mid-esophageal Extended bicaval view (Image 4)

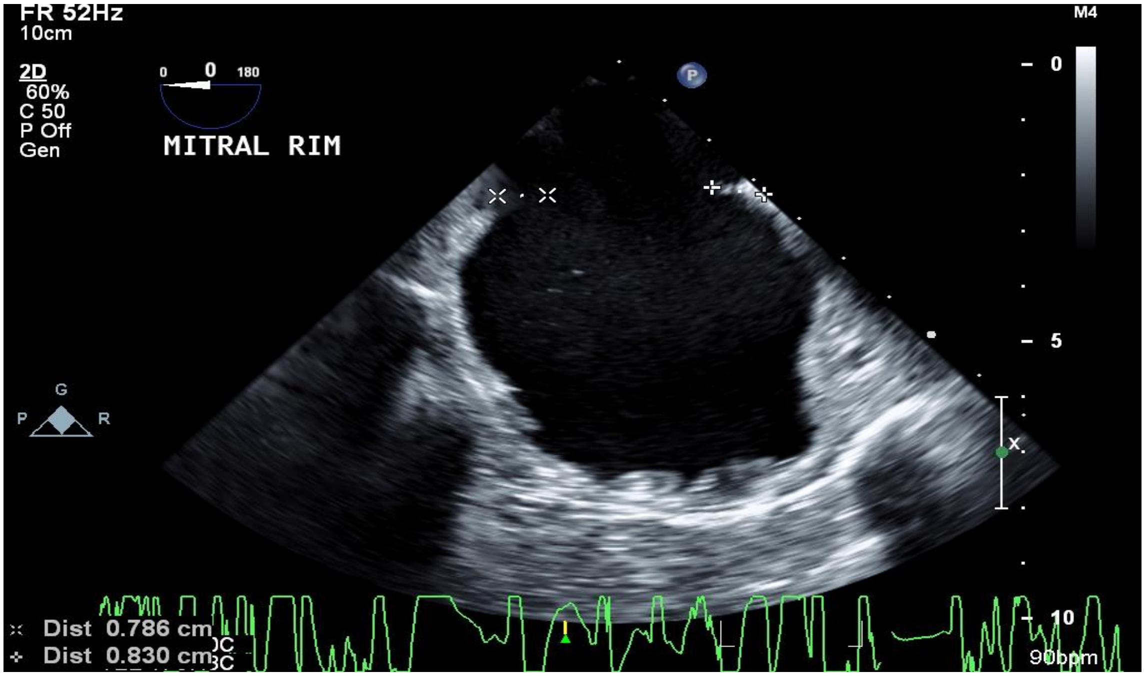


Image 1: shows a 2D-TEE mid-esophageal 4 chamber view focused to see the Mitral and the posterior wall rims and measure the ASD size

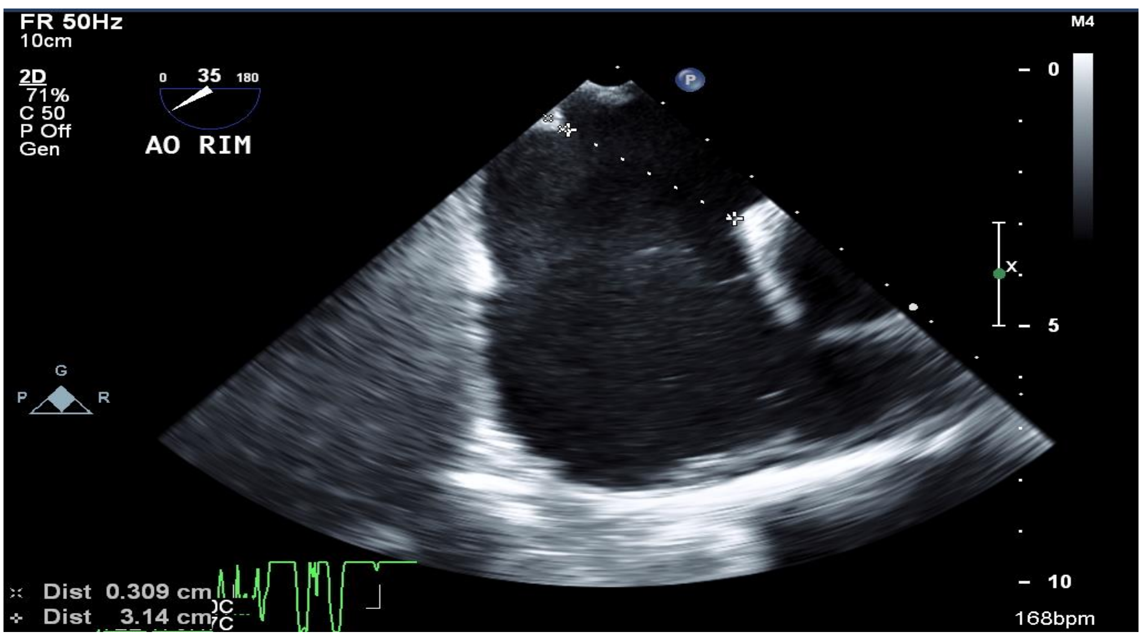


Image 2: shows a 2D-TEE mid-esophageal aortic valve short axis view to measure the aortic valve and the posterior wall rims and measure the ASD size.

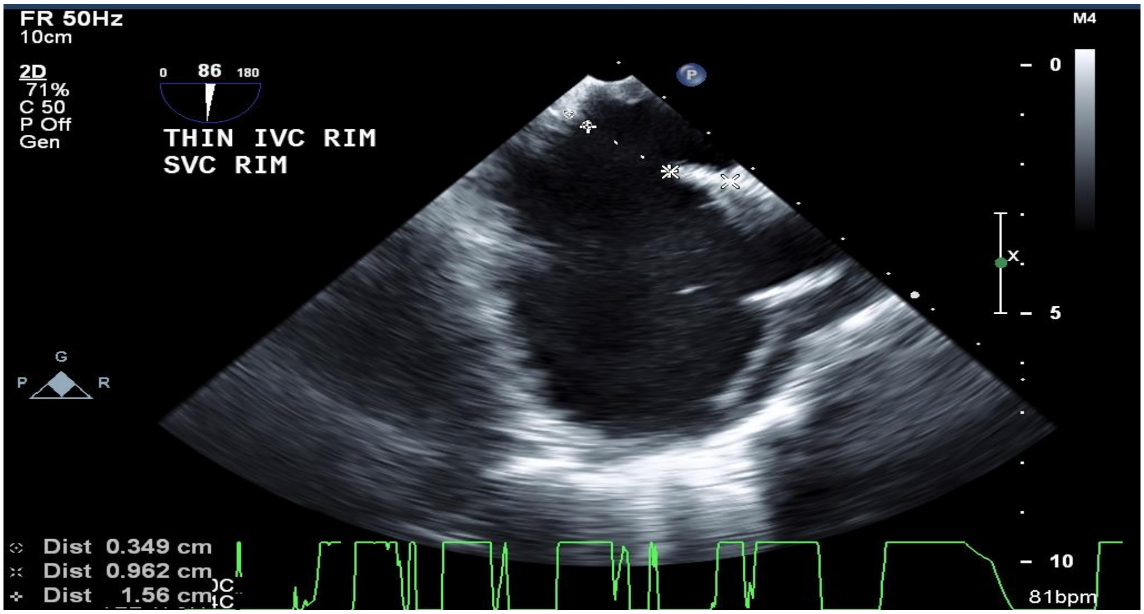


Image 3: shows a 2D-TEE midesophageal bicaval view to measure the IVC and SVC rims and measure the ASD size.

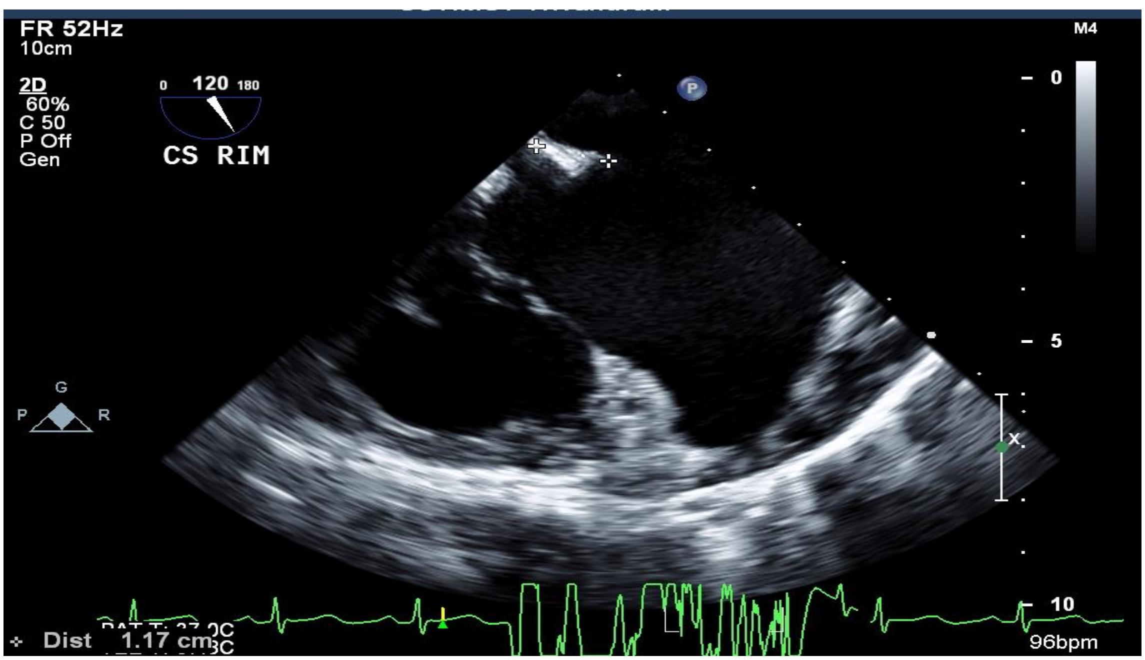


Image 4: shows a 2D-TEE midesophageal extended bicaval view to measure the coronary sinus rim length.

3D views for assessment of IAS [13]***:***

We acquired zoomed and wide-angled 3D data from several key views as under mentioned

a) Mid esophageal short-axis view: acquired from the mid-esophagus starting at a multiplanar angle of 0. The probe was rotated toward the IAS.

b) Basal short-axis view: acquired from the mid-esophagus starting at 30 to 60 multiplanar angles. Processing the 3D images from this view facilitated the demonstration of an ASD en face and demonstrated the relationship to the surrounding structures (e.g., the aorta and aortic rim)

c) Bicaval view: acquired from the mid-esophageal level with the transducer starting at the 90 to 120 multi-plane orientations. This view was also used to measure the size and shape of the ASD in systole and diastole.

d) Sagital bicaval view: obtained from the deep trans-gastric position with a transducer orientation of 100 to 120. The settings and processing were identical to the mid-esophageal bicaval view.

e) Four-chamber view: acquired from the mid-esophageal level starting at 0 to 20 transducer orientations.

Patients with inadequate 2D or 3D imaging quality were excluded from the study at this stage. The 3D echocardiographic images were processed & assessed using offline Q-lab Philips software. The acquired images were retrieved using portable storage devices.

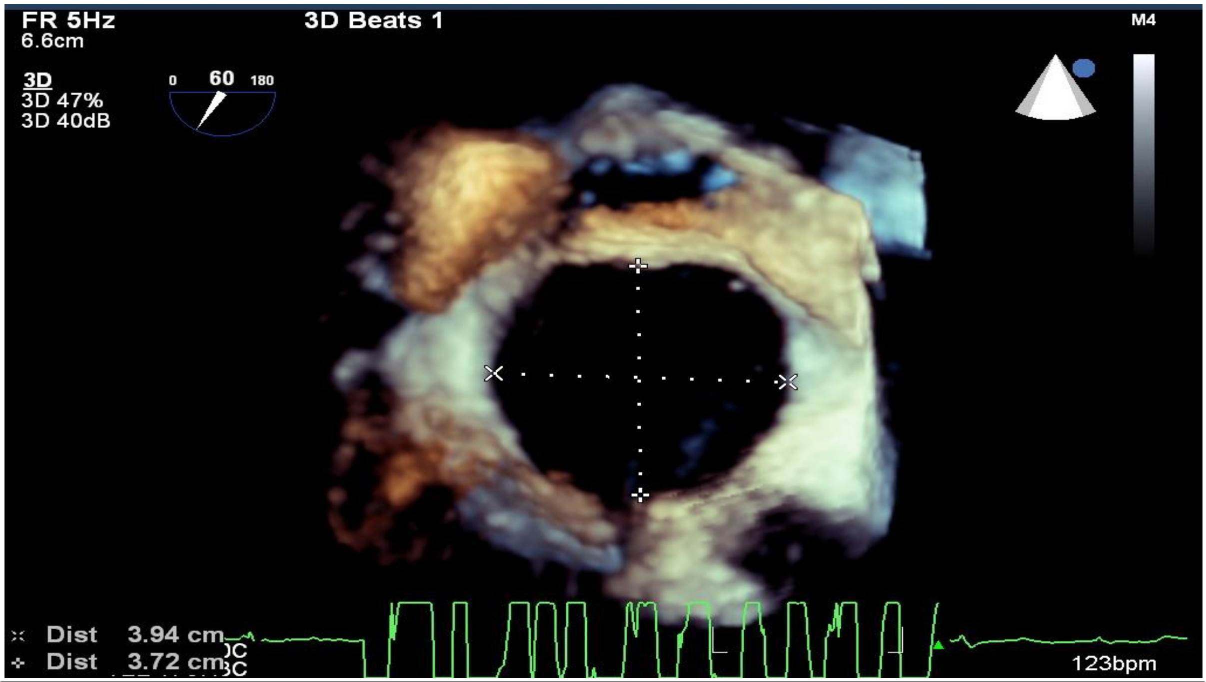


Image 5: shows an en face view of the ASD after cropping the right atrium on the Qlab software. IVC and SVC are appreciable at 12'oclock and 6'oclock positions. Sizing of the ASD is also shown.

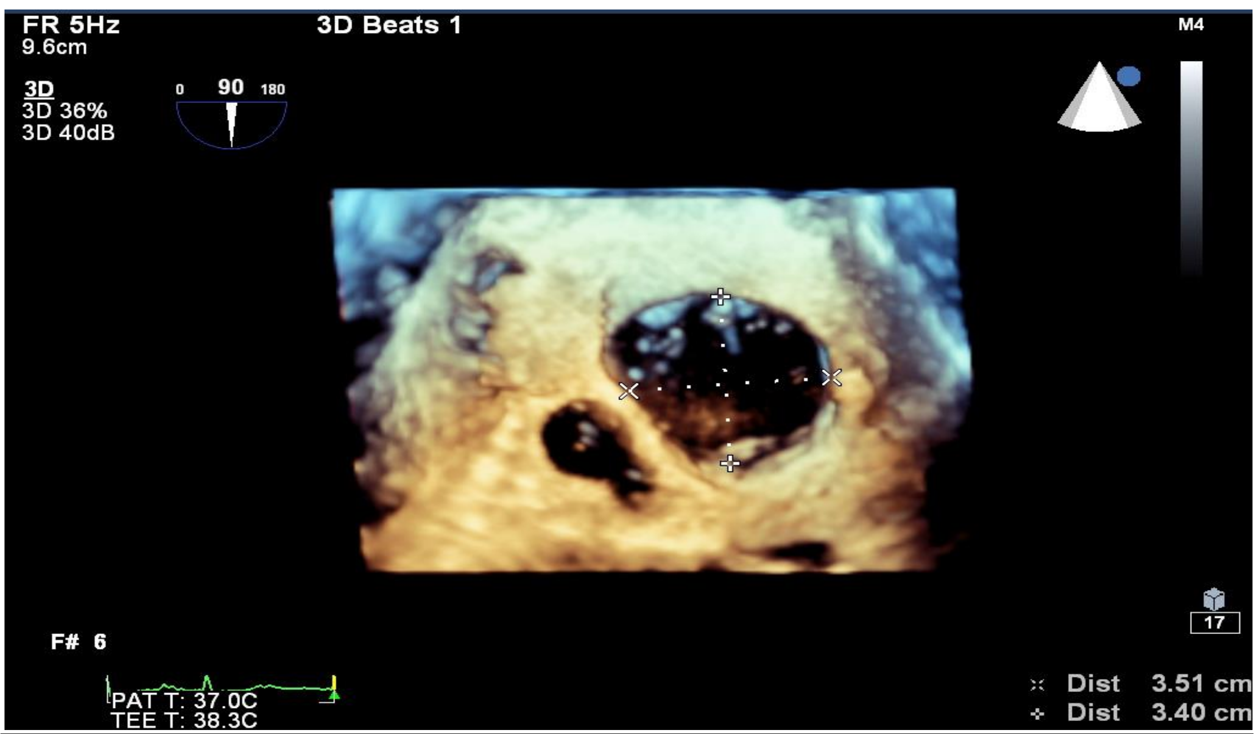


Image 6: shows an en face view of the ASD after cropping the left atrium on the Qlab software. Aorta, right upper pulmonary veins and the mitral valve are seen in the vicinity. Sizing of the ASD is also shown.

Statistical Method

Data analysis performed by using STATA 15:0 Statistical Software. Qualitative data variables expressed by using Frequency and Percentage (%). Quantitative data variables expressed by using Mean, SD etc.

For the comparison of maximum size on 2D, 3D and Intraoperative measurements we have used ANOVA test followed by Tukey's test for pair-wise comparisons. Mean Rim size of AO, Mitral, SVC, IVC and Posterior by using 2D and Intra operative we have used unpaired t-test.

To find the correlation between rim size on 2D-TEE and Intraoperative measurements, we have used correlation coefficient and Bland Altmann Plot to compare the agreement between 2 diagnostic modalities. A p-value < 0.05 is considered as significant.

RESULTS

Results

We included a total of 39 patients in our study, based on a pilot study by Kohyama et al to achieve a power of 80%, to detect a small difference with an effect size of 0.50 and an alpha error of 0.025 (to correct for multiple comparisons) in our study.[9] Examinations of 3 patients posed difficulty in assessing the ASD dimensions, using 3D echocardiography. One patient had a tri-radiated atrial septal defect which could be confirmed only on a 3D echocardiography and not on the 2D echocardiography. But being a tri-radiate ASD had to be excluded from our analysis. Hence, we analyzed 35 patients in our study. 11 of our 35 patients were males, 24 were females (Fig 1).

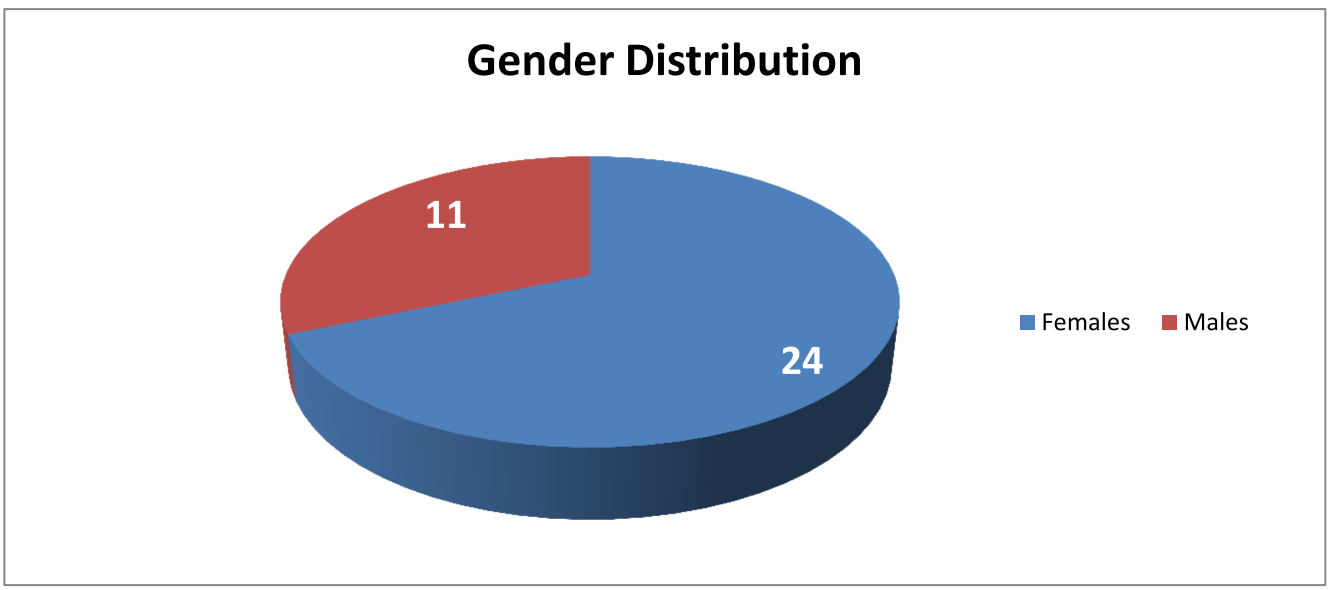


Fig 1 – shows gender distribution of the study sample, with female predominance

The demographic details of the 35 participants (Table 1) show an average age of 35 $\pm$ 10years with an average weight of 45.51 $\pm$ 15.42kg and an average height of 165.88 $\pm$ 10.36 cm. The average body surface area ranged 1.65 $\pm$ 0.22.

A tabulation of the average values of the heart rates (bpm) and the mean arterial pressures is shown in Table 2, with near normal values at the various intraoperative timelines.

Parameters	**Average values (n=35)**
Age (years)	35± 10
Weight (kg)	45.51 ± 15.42
Height (cm)	165.88 ± 10.36
Body surface area (kg/m^2)	1.65 ± 0.22

Table 1: Mean values of Age, Weight, Height and body surface area among the study sample.

Intra operative timeline	**n = 35 (Mean ± SD)**	
	Heart rate (bpm)	**Mean arterial pressures (mmHg)**
Baseline	75 ± 16	74.1 ± 9.85
At skin incision	85 ± 15	78.2 ± 13.55
At sternotomy	74.5 ± 11.7	74.6 ± 10.59
During sternal closure	67 ± 13	72.5 ± 7.74

Table 2: Average values of Heart rate (bpm) and Mean arterial pressures (mmHg) at various timelines during the intraoperative period.

Abbreviations: - SD: standard deviation; bpm: beats per minute; mmHg: mm of mercury

ASD numbers, shape, location and orientation

All 35 of our patients had a single, oval shaped ASD (long axis diameter at least more than 1mm of short axis diameter). Majority of the atrial septal defects were large in size and centrally located with the ASD margin almost encroaching the supporting rims of the aortic valve, IVC, SVC and the coronary sinus. A total of 23 patients out of 35 (nearly 65%) had their ASD located centrally. Of the remaining 12 patients, 7 had their ASD located antero-superiorly (nearly 20%) with the balance 5 having the defect located postero-inferiorly (nearly 15%). 30 patients out of a total of 35 (85%) had their atrial septal defects aligned in the IVC-SVC axis of the right atrium. This was a vertical orientation of the defect. The remaining 5 patients had their defects oriented in an antero-oblique axis (remaining 15%). All the above mentioned 3D-TEE parameters of the ASD, were confirmed by the surgeons.

ASD size (maximum dimension)

Our echocardiographic protocol successfully recorded and measured the ASD sizes in 2D TEE and 3D TEE for all the chosen 35 patients (Table – 3). The maximum dimension of the septal defect ranged from 42mm to a least of 10mm, with a mean value of 25.2mm $\pm$ 7mm on a 2D TEE measurement. On a 3D measurement, the maximum dimension of the septal defect ranged from 52mm to 10mm with a mean value of 31mm

± 9.7mm. Intraoperative surgical measurements showed the maximal septal defect range from 48mm to a min of 15mm with a mean of 29.7±8.3mm.

Comparison of maximum ASD dimensions using the three modalities of ASD evaluation (Table 4), showed 2D TEE vs 3D TEE, a trend of larger maximum diameters measured with 3D TEE, with a statistically significant difference (*p*-value of 0.012). A similar comparison between the ASD measurements using 2D TEE vs intraoperative surgical assessment, showed a trend of larger maximum diameters measured by the surgeons, although the difference was statistically not significant (*p*–value of 0.072). The average sizes of maximum ASD diameter were slightly higher with 3D TEE compared to those obtained by surgical measurements, although it was statistically insignificant (*p*–value of 0.763).

ASD Rim lengths

Comparison of different ASD rims measured on 2DE and by direct surgical method is shown in Table 5. Surgeons could not measure the Aortic and coronary sinus rims because of technical limitations. Among the remaining rims, the 2DE was found to underestimate the Mitral and SVC rims whereas; the IVC and the Posterior rims were not significantly different between the methods.

Modality	Number of patients (n)	Maximum Size in mm		p-value
		Mean	±SD	
2D	35	25.24	±7.18	0.012
3D	35	31.16	±9.70	
Intra operative	35	29.74	±8.37	

Table 3: showing the Mean values of 2D, 3D and Intra-operative ASD measurements in 35 patients

p-value < 0.05 (ANOVA test used) is significant

Pair wise comparison By using Tukey's test used	p-value
2D vs 3D	0.012*
3D vs Intra operative	0.763
2D vs Intra operative	0.072

Table 4: showing comparison of maximum ASD diameters using the three evaluation techniques using the Tukey's test

Rims	Number of patients (n)	Rim Size on 2DE in mm		Number of patients (n)	Rim Size on Intra operative Measurement in mm		*p*-value
		Mean	SD		Mean	SD	
AO Rim	24	6.2	3.6				
Mitral Rim	34	10.1	4.8	34	14.0	7.5	0.012*
IVC Rim	33	6.3	6.1	34	9.1	8.3	0.116
SVC Rim	34	10.1	4.3	34	15.0	7.8	0.002*
Post Rim	34	7.0	4.2	34	7.7	4.7	0.506
CS Rim	3	8.2	5.1				

Table 5: Comparison of different ASD rims measured on 2DE and by direct surgical method. Surgeons could not measure the Aortic and coronary sinus rims because of technical limitations. Among the remaining rims, the 2DE was found to underestimate the Mitral and SVC rims whereas; the IVC and the Posterior rims were not significantly different between the methods.

*Significant (p-value < 0.05) Unpaired t-test used

Abbreviations: - AO: Aortic rim; IVC: Inferior vena cava rim; SVC: Superior vena cava rim; Post: Posterior rim; CS: Coronary sinus rim; SD: standard deviation; 2DE: 2 dimensional echocardiography

Comparing the rim lengths measured using 2D TEE vs Intraoperative surgical measurements, inaccuracy in measurements of the (Fig-2) Mitral rim [Pearson's coeff (r) is 0.193 & p-value 0.270] were noticed. Similarly, the SVC rim (Fig-3) did not correlate in 2D TEE vs surgical measurements [Pearson's coeff (r) is 0.234 & p-value 0.181].

The Bland- Altman plot analysis of surgically measured mitral rim and 2D TEE measured mitral rim showed a difference in the paired values of rims plotted on the ordinate (y axis) against the mean difference on the abscissa (x axis). The observed mean difference displayed as a continuous blue line and the limits of agreement displayed as a dashed blue line. The scattered plot shows poor agreement between the methods (Fig 4)

Similarly, Fig 5 shows that the two ways of measuring the SVC rims of an ASD (2D TEE vs Intraoperative measurements) have a poor correlation as well.

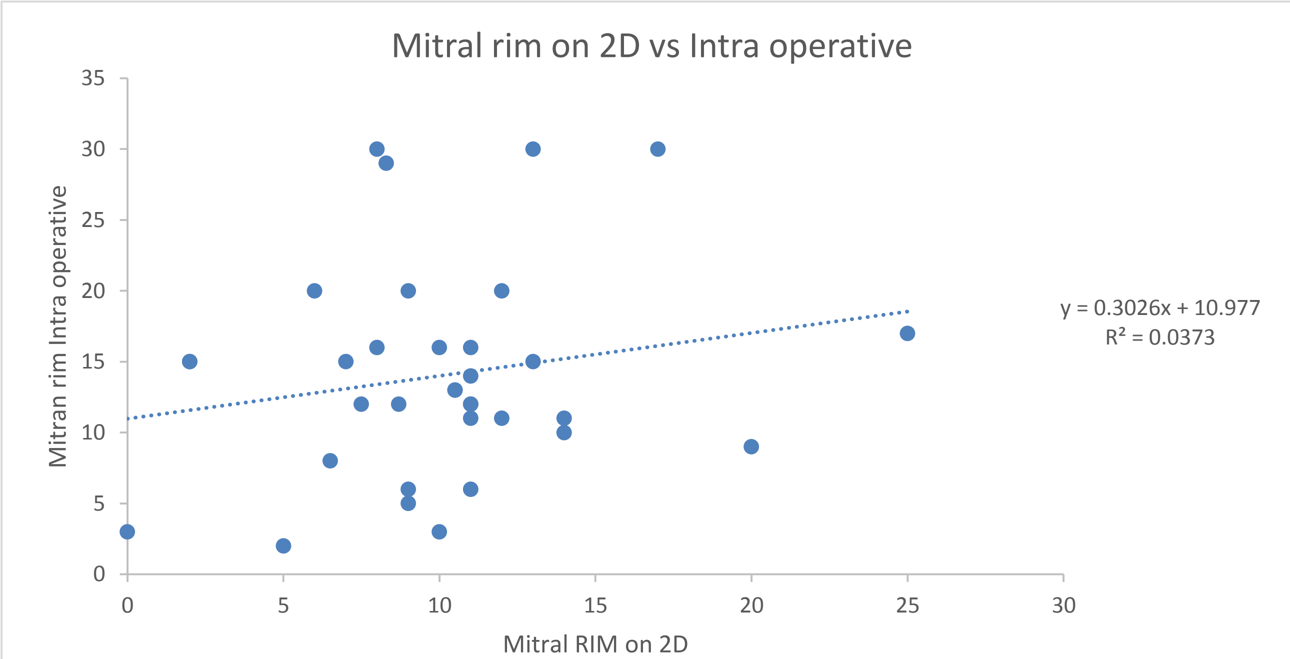


Fig 2 - shows a Pearson's correlation coefficient (r) is 0.193, p-value is 0.270.
(0 to 0.35 – Poor/weak correlation; 0.36 to 0.55 – good correlation; >0.55 – significant correlation)
No Significant correlation between 2D Mitral rim measurements with Intraoperative Mitral rim.

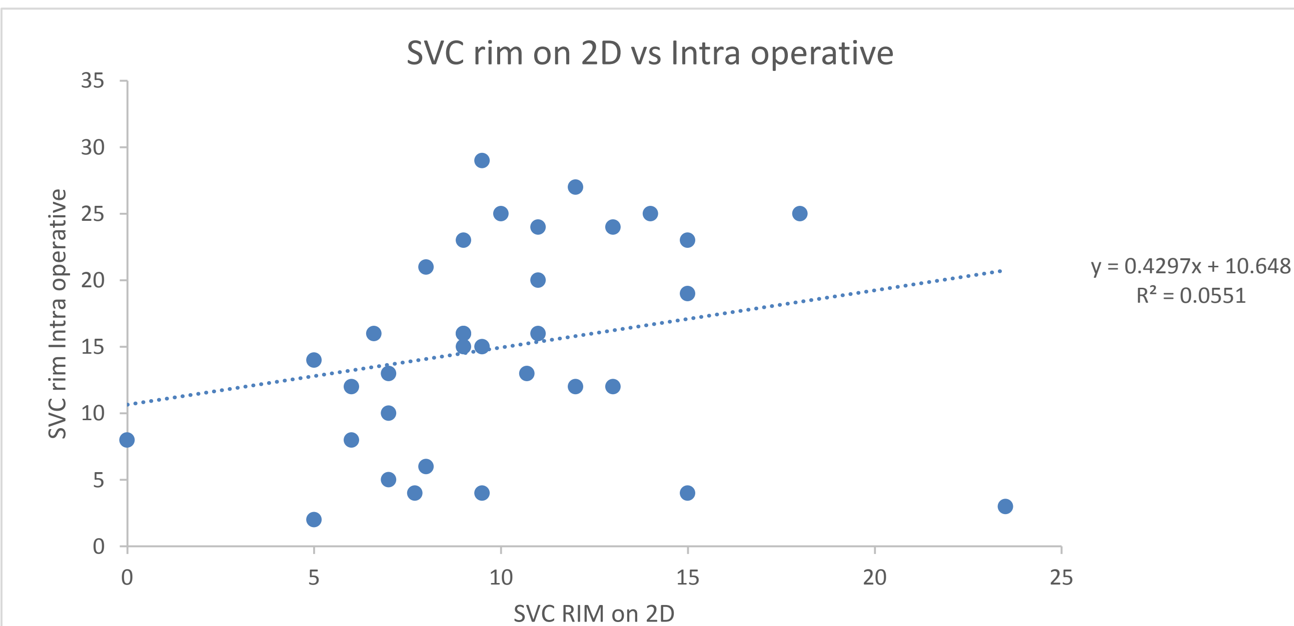


Fig 3 - shows Pearson's correlation coefficient (r) is 0.234, p-value is 0.181
No Significant correlation between 2D SVC rim with Intraoperative SVC rim

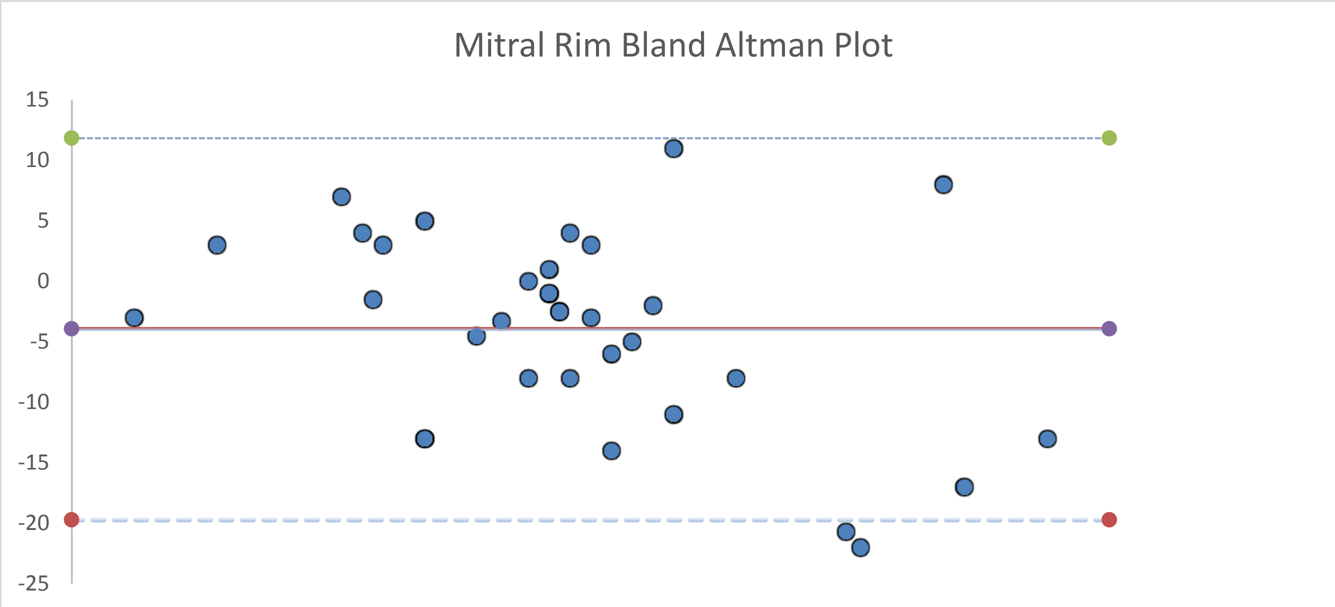


Fig 4; The Bland- Altman plot analysis of surgically measured mitral rim and 2D TEE measured mitral rim. The difference in the paired values of rims is plotted on the ordinate (y axis) against the mean difference on the abscissa (x axis). The observed mean difference is displayed as a continuous blue line and the limits of agreement are displayed as a dashed blue line. The scattered plot shows poor agreement between the methods

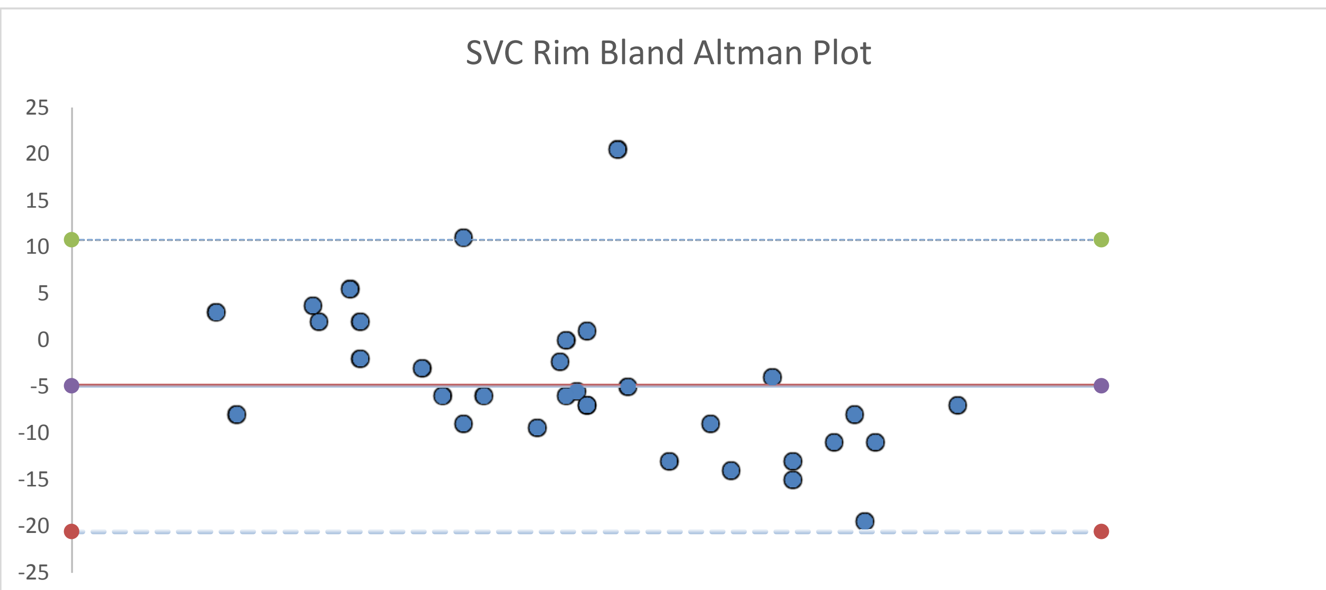


Fig 5: shows that the two ways of measuring the SVC rims of an ASD (2D TEE vs Intraoperative measurements) have a poor correlation.

We used the oldest version of Q lab (8.4) for the 3D quantification. This version of Q lab does not permit on screen measurement of length or area after virtually cropping the 3D volume. For 3D measurements of the ASD rims, we had to render the 3D volume using 3DQ MPR view. We found significant limitations in identifying the ASD rims using this particular view. Hence, we could not reliably measure the ASD rims using the 3D TEE method. However, this limitation may be overcome by directly measuring the rims on screen, which is feasible with the newer versions of Qlab and newer platforms.

But the 2D TEE and Intraoperative surgical measurements of the IVC & the Posterior rim lengths correlated well with each other, with p–values being 0.484 & 0.326, respectively (Fig 6 & 7).

The Bland- Altman plots analysis shows (Fig 8 & 9) that there exists a good agreement between the surgically measured and 2DTEE measured IVC rim and posterior rim.

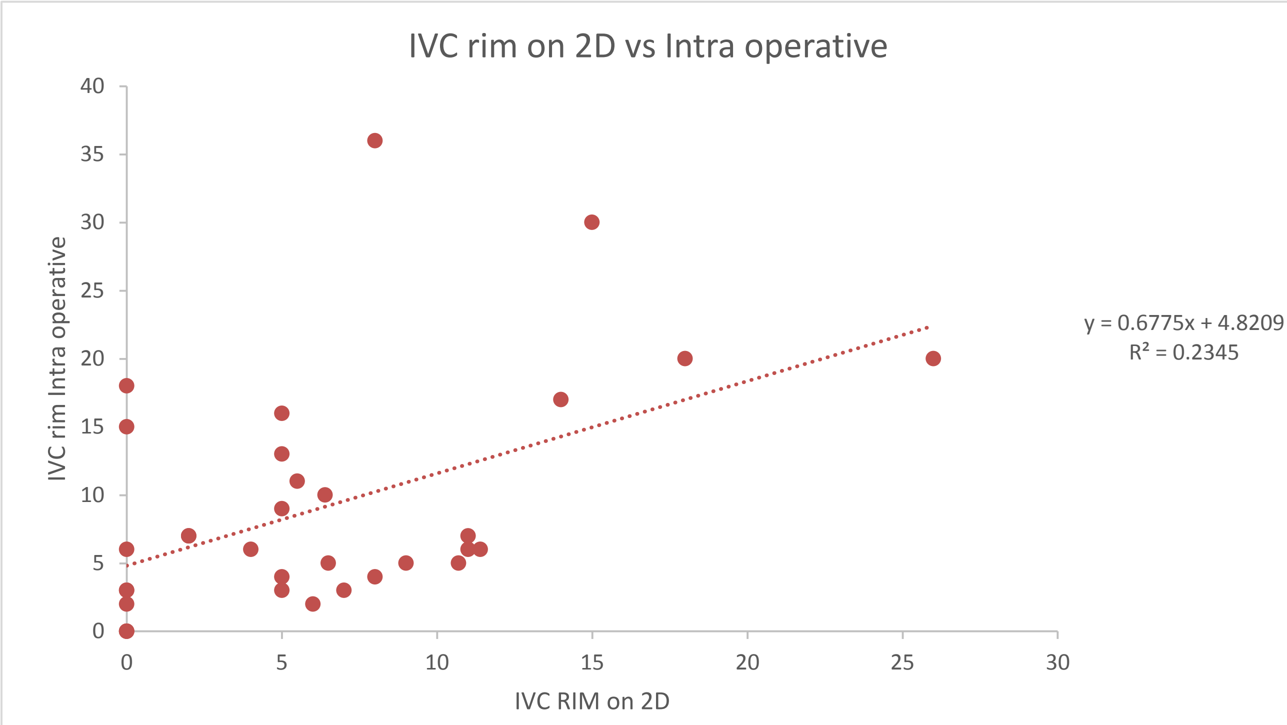


Fig 6 - Pearson's correlation coefficient (r) is 0.484, p-value is 0.004.
Significant correlation between 2D IVC rim with Intraoperative IVC rim

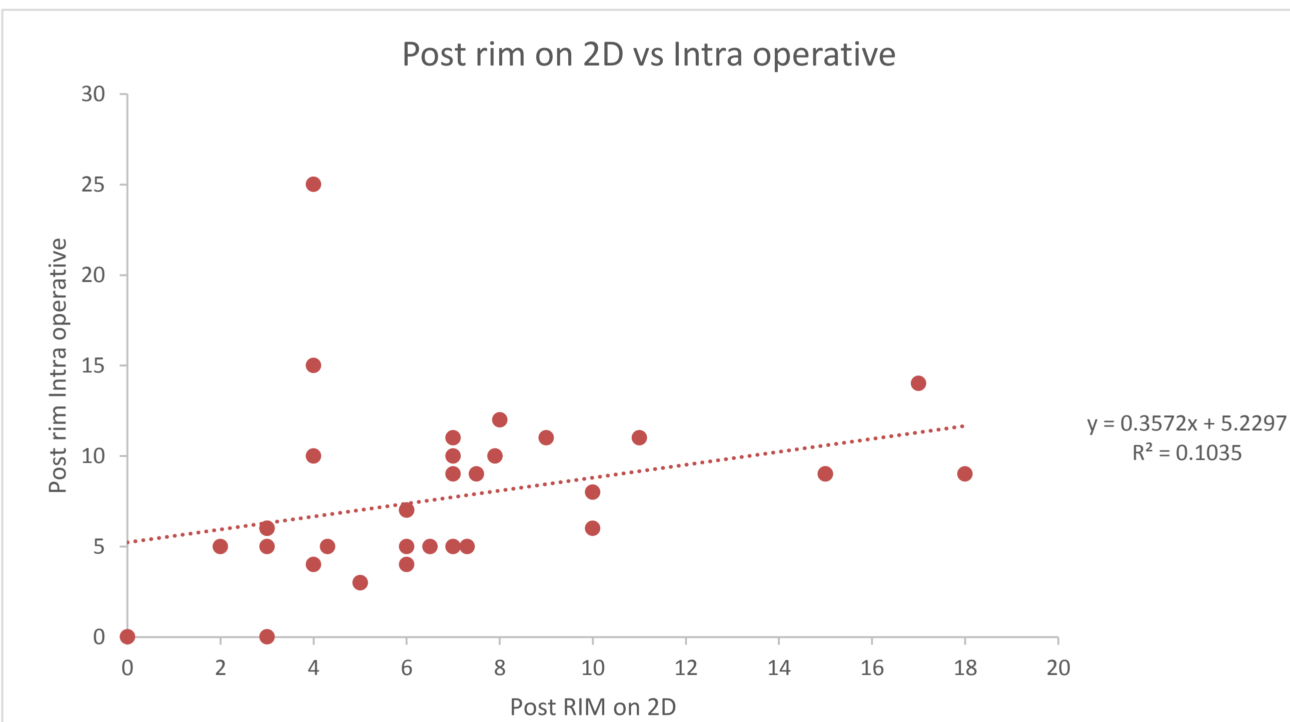


Fig 7 - Pearson's correlation coefficient (r) is 0.326, p-value is 0.063
Significant correlation between 2D posterior rim with Intraoperative posterior rim

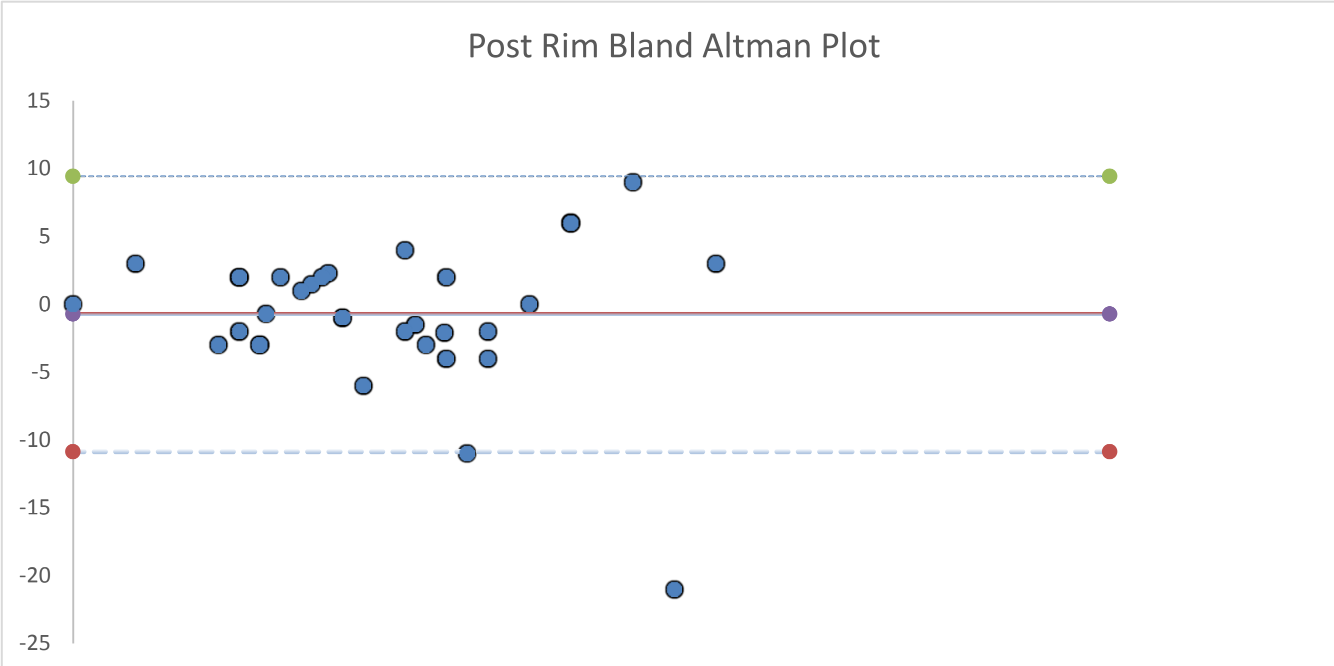


Fig 8 - shows clustering together of points above and below the reference line for Posterior Rim 2D vs Intraoperative measurements

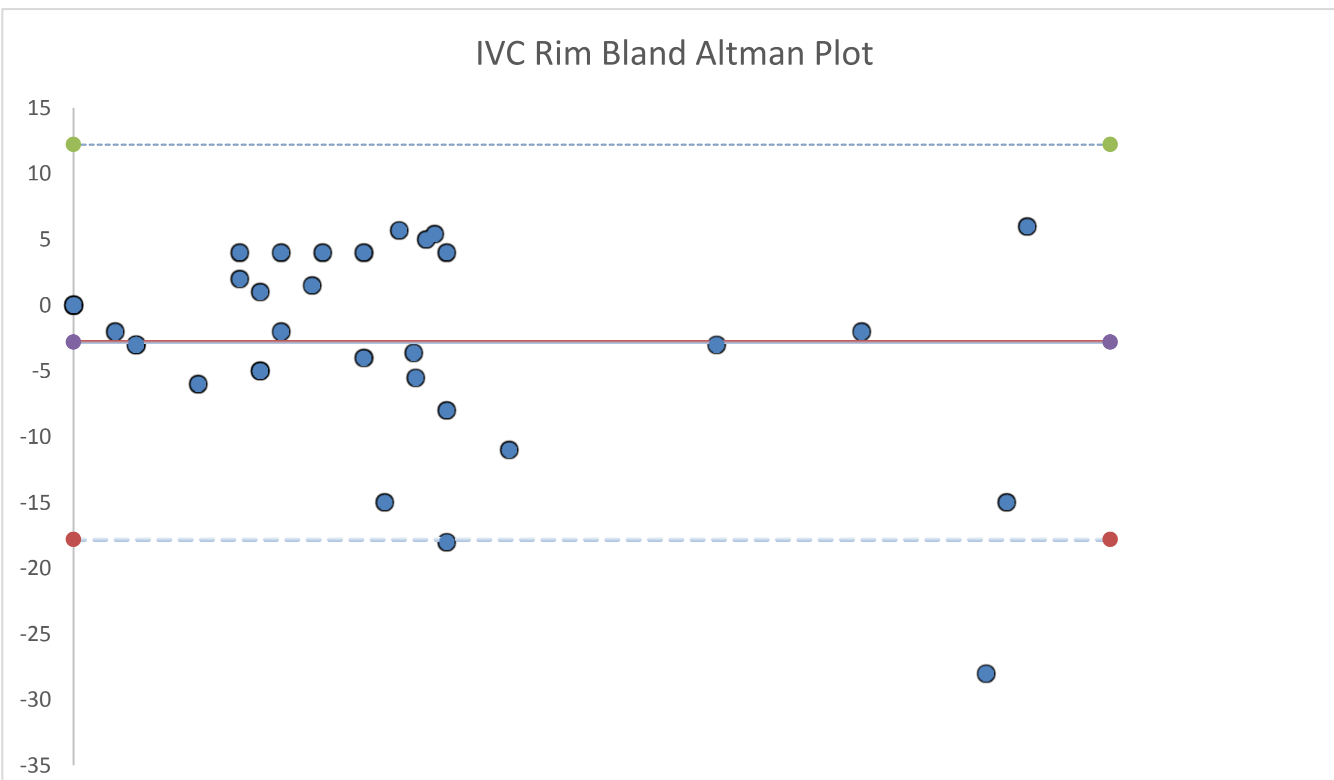


Fig 9 - shows clustering together of points above and below the reference line for IVC Rim 2D vs Intraoperative measurements

DISCUSSION

Discussion

A complete echocardiographic evaluation of the ASD, as described by the ASE includes the assessment of the size, shape of the defect, the rims surrounding the defect and the degree & direction of shunting. (13)

The morphology of IAS and features of ASD are commonly assessed on 2D transthoracic echocardiography. TEE may offer a better info than 2D-TTE because of its proximity to the IAS and a better profiling of the septum compared to the TTE. Two-dimensional TEE relies on the integration of multiple image planes for the operator to mentally reconstruct the true 3D anatomy of an ASD, and this limitation can lead to a failure to appreciate the true dimensions and shape of the defect. Visualization of ASDs by real-time 3D TEE overcomes these limitations and allows for more accurate assessment of the shape and size of the defects.(28) Complex shaped defects hence prove difficult to accurately be defined by 2D TEE.

The modern 3D echocardiography offers virtual cropping, image rotations, display of anatomical orientations and post processing of the acquired high quality images.(25) The unique region-oriented views obtained from the 3D data set can be acquired quickly and have the potential to enhance understanding of complex cardiac anatomy.(27) They also aid in a faster and more user friendly interface for processing images. These features have made the RT-3D-TEE an ideal tool for the intraoperative evaluation of an ASD.

The 3D-TEE en face view permits evaluation of the atrial septum, both from the left and the right atrial perspectives. The proximity of the ASD to the SVC – IVC and the coronary sinus can be visualized real time with virtual cropping of the right atrium. The relations of the aortic valve and the pulmonary veins with the ASD can be best appreciated by cropping the left atrium. This potential of a detailed evaluation of the septal morphology and surrounding structures gives an edge to the 3D-TEE over the 2D-TEE.

We inspected the IAS & the ASD from both atrial aspects using 3D-TEE in our study patients. As most of the patients referred for surgical closure had either large ASDs or deficient or floppy rims, we had to inspect the ASD in multiple views. The ASD margins however were not clearly visualized in some of the patients even on 3D-TEE.

We found that 3D TEE gave us a better and more accurate evaluation of the ASD. Viewing the defect en face helped us to easily confirm the orientation of the defect – horizontal/ vertical/ oblique in relation to the IVC-SVC axis; and thereafter, helped us note the maximum and minimum dimensions of the defect and measure them accurately. 3D TEE makes it easy to decide on the number of defects also, especially in the presence of a fenestrated ASD. We could easily identify and exclude from our study sample, a tri-radiated ASD which resembled the Mercedes Benz sign, on a 3D TEE evaluation. 2D TEE evaluation of this patient showed us multiple septae and made it difficult to arrive at a visual confirmation on the shape of the ASD. We recommend assessing such defects using 3D TEE, if possible, for the diagnostic interpretation. Alexander Savis et al in a recent review (2018) mentioned these advantages and we comply with his observations on the subject.[21]

Measuring an accurate maximal diameter is essential for selecting the size of the ASD device. An ASD having a maximum diameter more than 40mm is generally considered unsuitable for device closure.[14] Larger the maximum ASD diameter, more are chances of the rim being deficient in that axis. This deficiency may be a matter of concern for the deployment of an ASD device. This also matters if the coronary sinus rim remains deficient, which creates difficulty to stabilize the surgical patch in the region of coronary sinus.

Our results indicate that 3D-TEE estimations of the ASD size (maximum diameter) has better agreement with the ASD sizes as measured by the surgeons, than that measured by 2D-TEE. Johri et al in their study (2011) comparing real-time 3D- TEE imagery with 2D-TEE assessment of ASD sizing found that 2D TEE significantly underestimated the sizes of ASDs compared with 3D imaging in patients with evidence of residual shunting. Patients without residual shunting had similar measures of ASD size by 2D and 3D TEE. These findings are similar to those in our study.[45]

The shape of the ASD is also a matter of significance as some area of the ASD may remain uncovered by the deployed device, which may permit shunting across the residual area. All our patients had oval-shaped defects and these were well-corresponding with the shapes assessed and documented by the operating surgeons. We were able to accurately delineate the shape of the defect on a 3D-TEE enface visualization and it was correlating well with the surgical observations.

Kohyama et al in their study in 2002[9], which is the closest any study has related to ours, concluded a correlation between the 3D-TEE assessments of the ASD size with the surgical measurements. They included just 17 patients and measured the en face – maximum and minimum axis lengths of the ASD on 3D-TEE. They reported a significant correlation of the maximum and minimum axis lengths of the ASD, to that measured in the intraoperative period. Our findings are in agreement with this pilot study.

Determining the relationship of the defect to the surrounding structures such as venae cavae, pulmonary veins, mitral and tricuspid valves, and coronary sinus is necessary during the deployment of the device. ***A deficient rim** is defined as less than 5 mm in multiple sequential views.* A rim less than 3mm is acceptable in case of antero-septal or aortic rim device placement since the device splays around the aorta. A 3D echo assessment is more useful for conforming this morphology.[13] Measurement of the ASD rims was not the primary objective of our study as majority of the patients referred for surgery has deficient rims and the operating surgeon will have direct visualizations of the rims after cardiotomy. We could not measure the rims on 3D-TEE because of our old version of Qlab software which does not support onscreen measurement of the structures and necessitates measurements only through 3DQ software. Since the defects were large in size and margins were deficient in a large number of patients, we did not perform any 3D measurements of the rims. On 2D-TEE, we noticed that the mitral and SVC rim lengths were not matching when compared with the intraoperative surgical measurements. The 2D-TEE measurements of the IVC & posterior rim lengths matched up with the intraoperative measurements. To the best of our knowledge, we did not find any study correlating the 2D-TEE rim lengths with surgical measurements.

Surgical assessment of the size of an atrial septal defect has never been validated as a comparative tool. Hence, we did not find in the literature, to the best of our knowledge, any publication, which compares the sizing of the ASD after a cardiotomy, with echocardiography. We may claim that ours is the only study which advocates intraoperative measurements related to an ASD, using silk threads and measuring scale. We considered the thread and scale method as a reference standard against which the echocardiographic measurements were compared, as a substitute for CMR.

The thread and scale method has the advantage of direct manual measurement of the defect. It is also a less time-consuming and resource-intensive modality feasible in the intraoperative period compared to the CMRI. ASD measurements can be performed with ease and assist the surgeon in sizing of the ASD patch.

However, the surgical method is associated with certain limitations. All measurements are performed on a flaccid heart. The defect is prone to stretching errors in random directions – depending on the tissue handling by the surgeon. This may result in altering the shape of the ASD or even the dimensional measurements of the defect as compared to what would be there in a beating functional heart.

Cardiac MRI has been considered a gold standard in the assessment of ASD, pre operatively and post operatively. It has been recommended by the American Society of Echocardiography as a gold standard evaluation tool for ASD.(13) CMRI offers certain advantages over 2D-TEE in the evaluation of an ASD. The anatomy of the pulmonary veins in a high ASD is better appreciated on CMRI. The ASD size can be measured more accurately on the CMR. The CMR delineates morphology of the postero-inferior rim of the defect, which usually drops out on 2D-TEE.(31) Intraoperative use of 3D-TEE overcomes these limitations of 2D-TEE and functions as a substitute for the CMR in the intraoperative period.

Limitations

1. Although the sample size was adequate for our study, with a study power of 80%, larger studies may be required to support our conclusions.

2. Most of the patients referred for a surgical closure have a large ASD or deficient rims which makes it unsuitable for the device closure. The features on 3D-TEE may not be extrapolated for the patients subjected to device closure.

3. The surgical measurements were performed on a flaccid heart which was arrested in diastole. As the dynamic component of the atrial septum was lost due to cardioplegic arrest, the echocardiographic measurements may differ from the measurements performed during the surgery.

4. We used the oldest version of Qlab software for the assessment of ASD morphology. As this software does not support on-screen measurements and necessitates rendering the 3D volume through the MPR view, we could not measure the ASD rims in all cases. Also, we had limitations in determining the intra-observer and inter-observer variability.

CONCLUSION

Conclusion

A total of 39 patients were evaluated during the study period; although, 4 were excluded from the study under different exclusion criteria. A total of 35 patients were included for the final analysis.

1. Comparison of maximum ASD dimensions using 2D TEE vs 3D TEE, showed a trend of larger maximum diameters measured with 3D TEE, with a statistically significant difference (*p*-value of 0.012).

2. Comparison between the ASD measurements using 2D TEE vs intraoperative surgical assessment, showed a trend of larger maximum diameters measured by the surgeons, although the difference was statistically not significant (*p*–value of 0.072).

3. The average sizes of maximum ASD diameter were slightly higher with 3D TEE compared to those obtained by surgical measurements, although it was statistically insignificant (*p*–value of 0.763).

4. All 35 of our patients had a single, oval shaped ASD (long axis diameter at least more than 1mm of short axis diameter).

5. Majority of the atrial septal defects being very large in size occupied a central location. About 15% of the total had an antero-superior location. An even lesser

12% were located postero-inferiorly. These 3D findings were confirmed by the surgeons.

6. Nearly 15% of the defects were oriented in an antero-oblique axis while the remaining majority was aligned in the vertical IVC-SVC axis, as seen on 3D-TEE. This 3D orientation of the ASD was difficult on the 2D-TEE to confirm, as it required making a mental picture of the ASD based on multiple views on 2D-TEE. However, these 3D-TEE orientations were confirmed by the surgeons.

7. The ASD rims measured on 2D-TEE were compared with that obtained on thread and scale method of surgical measurement. Surgeons could not measure the Aortic and coronary sinus rims because of technical limitations. Among the remaining rims, the 2DE was found to underestimate the Mitral and SVC rims (*p*-value: 0.012 and 0.002 respectively), whereas the IVC and the Posterior rims were not significantly different between the methods (p-value: 0.116 and 0.506 respectively).

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ANNEXURES

TAC Approval

30

Technical Advisory Committee (Clinical Studies)

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

TAC Registration No: SCT-/S/2018/736 **Date:10.07.2018**

Project title: ASSESSMENT OF ATRIAL SEPTAL DEFECT SIZE AND RIMS USING 3D Vs 2D TRANSESOPHAGEAL EHOCARDIOGRAPHY

Principal Investigator:
Dr. (Lt Col) Ankur Joshi, Senior Resident, Department of Anaesthesiology, SCTIMST Degree: DM Course: Cardiothoracic And Vascular Anaesthesiology. M.D. (Anaesthesiology), M.B.B.S.
Co-Principal Investigator(s)
Dr. Shrinivas Gadhinglajkar, Professor, Department of Anesthesiology, SCTIMST Degree: Post-Doctoral Certificate Course: Cardiothoracic Vascular And Neurosurgical Anesthesiology. M.D. (Anesthesiology), M.B.B.S.
Principal Investigator(S)
Dr. Rupa Sreedhar, Professor and Head of Department of Anesthesiology, SCTIMST Degree: Post-Doctoral Certificate Course: Cardiothoracic Vascular And Neurosurgical Anesthesiology. D.N.B. (Anesthesiology), M.D. (Anesthesiology), D.A. (Anesthesiology), M.B.B.S.
Dr. Jayakumar.K, Professor and Head of Department of Cardiovascular & Thoracic Surgery, SCTIMST Degree: Mch (Cardiovascular And Thoracic Surgery), M.S (General Surgery), M.B.B.S
Dr Bineesh Radhakrishnan, Assistant Professor, Department of Cardiovascular & Thoracic Surgery, SCTIMST Degree : Mch (Cardiovascular And Thoracic Surgery), M.S (General Surgery), M.B.B.S

Members who participated in the TAC meeting on 19/05/2018
Dr. Rupa Sreedhar (Chairperson)
Dr. Prasantakumar Dash
Dr. Sanjay G
Dr. Krishna Kumar K
Dr. Sankara Sarma P
Dr. Sylaja PN
Dr. Ashalatha. R
Dr. Bijulal S
Dr. Jayadevan ER
Dr. Syam K
Dr. Varghese T. Panicker
Dr. K. Shivakumar (Member Secretary)

Dr. Rupa Sreedhar, Dr. Syam K, Dr. Sylaja PN, Dr. Prasantakumar Dash, Dr. Varghese T. Panicker and Dr. Ashalatha. R stayed away from the proceedings when the projects in which they are involved as investigator were discussed (#736,737, 738, 740, 741,743,744, 746, 749, 752).

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).

(31)

Appendix-1

1. Investigators mention that surgical measurement of ASD as the gold standard. Surgeons measure the stretched diameter of the ASD in a collapsed heart. How physiological is this? How exact is this?

   Answer: We have now changed it from "Gold standard" to "Reference standard" as it'll be a reference for all the subjects in the study and act as a control

2. Investigators have not mentioned how surgical measurements will be done? Please mention the procedure of surgical measurements

   Answer: The measurements will be made by the surgeon using a silk thread and a scale.

3. Since surgical measurements are not physiological and only approximate, is it useful to compare this with 2D and 3D measurements, where the difference between these modalities will be 1-2 mm only. Please clarify these points.

   Answer: That is the aim of the study to find out by how much the echo measurements differ from the surgical findings. (since there is no study to have carried such a correlation)

IEC Approval

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/RR-16)

SCT/IEC/1261/AUGUST-2018 19.09.2018

Dr. (Lt Col) Ankur Joshi
Senior Resident
Department of Anaesthesiology,
SCTIMST, Thiruvananthapuram

Dear Dr. (Lt Col) Ankur Joshi,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "ASSESSMENT OF ATRIAL SEPTAL DEFECT SIZE AND RIMS USING 3D Vs 2D TRANSESOPHAGEAL EHOCARDIOGRAPHY (IEC/1261)" on 31st August, 2018.

The following documents were reviewed:

Original submission

1. *Covering letter addressed to the Secretary, IEC, SCTIMST dated 21.07.2018 with check list*
2. *TAC Approval Letter*
3. *IEC Application Form*
4. *List of Abbreviations*
5. *Project Proposal*
6. *Observation Chart*
7. *Patient Information Sheet and Informed Consent Form in English and Malayalam*
8. *CV of Principal Investigator and Co-Principal Investigators*

Revised submission

1. *Covering letter addressed to the Secretary, IEC, SCTIMST dated 18.09.2018 with check list*
2. *TAC Approval Letter*
3. *IEC Application Form*
4. *Project Proposal*
5. *Patient Information Sheet and Informed Consent Form in English and Malayalam*
6. *CV of Principal Investigator and Co-Principal Investigators*

Page 1 of 2

The following members of the Ethics Committee were present at the meeting held on 31st August, 2018 at G. Parthasarathi Board Room, AMCHSS, SCTIMST

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

IEC Decision

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

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

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

Sincerely,

Mala Ramanathan
Member Secretary, IEC

Observation Chart

Study title: Same as title

Preoperative information:

Name Age Weight

Gender Hospital number BSA

Date of surgery

Diagnosis & Surgery

Preoperative C/F: H/O MI:

Preoperative medications

Preoperative TTE findings:

Location of ASD	
Size of ASD (in mm)	
Atrial septal rims	
Adequate/ not adequate	
Any deficient rim	
ASD device closure attempted or not	
LVEF (%)	
Pulmonary hypertension (RVSP)	
Catheter report (if any)	
Severity of MR	

Intraoperative observations:

Hemodynamic data:

Baseline recording: HR: BP: CVP:

2DTEE observations

Parameter	Observations
ASD size (max in mm end-diastole)	
ASD size (min in mm end-diastole)	
ASD size (max in mm end-systole)	
ASD size (min in mm end-systole)	
ASD area (in mm sq end-diastole)	
ASD area (in mm sq end systole)	
ASD shape	Round/oval/irregular
ASD location	Secundum/ High SV/ CS
ASD rim (in mm)	
Aortic rim	
Mitral rim	
SVC rim	
IVC rim	
Posterior rim	
CS rim	
Atrial septal aneurysm	Present/ absent
Any other	
LVEF (in %)	
MR grade	Mild/ Moderate.
Direction of ASD shunt	L→R, Bidirectional
PAH (RVSP in mmHg)	

3DTEE Observations

Parameter	Observations
ASD size (max in mm end-diastole)	
ASD size (min in mm end-diastole)	
ASD size (max in mm end-systole)	
ASD size (min in mm end-systole)	
ASD area (in mm sq end-diastole)	
ASD area (in mm sq end systole)	
ASD shape	Round/oval/irregular
ASD location	Secundum/ High SV/ CS

ASD rim (in mm)	
Aortic rim	
Mitral rim	
SVC rim	
IVC rim	
Posterior rim	
CS rim	
Atrial septal aneurysm	Present/ absent
Any other	
LVEF (in %)	
MR grade	Mild/ Moderate.
Direction of ASD shunt	L→R, Bidirectional
PAH (RVSP in mmHg)	

Surgical findings:

Parameter	Observations
ASD size (max in mm end-diastole)	
ASD size (min in mm end-diastole)	
ASD area (in mm sq end-diastole)	
ASD shape	Round/oval/irregular
ASD location	Secundum/ High SV/ CS
ASD rim (in mm)	
Aortic rim	
Mitral rim	
SVC rim	
IVC rim	
Posterior rim	
CS rim	
Atrial septal aneurysm	Present/ absent
Any other	

<u>English Consent Form</u>

Patient Information Sheet

Title of the study:

<u>INTRAOPERATIVE ASSESSMENT OF ATRIAL SEPTAL DEFECT MORPHOLOGY USING3D TRANSESOPHAGEAL ECHOCARDIOGRAPHY VS2D TRANSESOPHAGEAL ECHOCARDIOGRAPHY</u>

Study numbers: We request you to participate in the study wherein we are planning to evaluate intraoperative echocardiographic assessment of Atrial Septal Defect size and rims using 3-dimensional vs 2-dimensional Trans-esophageal echocardiography. We hope to include 50 people from this hospital in this study.

What is the Atrial Septal Defect ?

Heart works as a pump in the body to pump out blood effectively to the various organs of the body. A normal heart comprises of 4 compartments (2 on the Right side & 2 on the left side of the heart). The left chambers are namely the Left Atrium & Left Ventricle. The LV receives oxygen rich blood from the lungs and pumps this blood to the various vital & non vital organs of the body. Hence for the heart to function very effectively, the left sided chambers of the heart are naturally separated from the right sided chambers. This prevents mixing of oxygenated blood (left side) with the de-oxygenated blood (right side). A defect in the membrane separating the left atrium from the right atrium is called the Atrial Septum. A discontinuity in this septum is called an Atrial Septal defect. It is thereby very important to assess the Atrial septal defect anatomy and physiology before an effective surgical closure of the same.

What is Trans-esophageal echocardiography?

Trans-esophageal echocardiography or TEE is a test that uses sound waves to create high-quality moving pictures of the heart and its blood vessels. This can pin point the problematic areas of the heart and helpful in assessing function of heart valves before and after valve replacement surgery. Usually echocardiography is performed via chest (transthoracic echocardiography). However, under anesthesia, transthoracic echocardiography cannot be performed during cardiac surgery as the surgeon will be operating in that area. Hence echocardiography probe is inserted via esophagus (food pipe). TEE involves a flexible tube (probe) with a transducer at its tip. The Anesthesiologist will guide the probe down your throat and into your esophagus (the passage leading from your mouth to your stomach). This will be done when you will be unconscious under anesthesia and it will not cause any discomfort to you. This approach allows your doctor to get more detailed pictures of your heart because the esophagus is directly behind the heart.

What is the 3D vs 2D Trans-esophageal echocardiography?

A 3dimensional echocardiography helps us visualize the heart structure in a 3 dimensional format giving a more accurate view of the defects in terms of size, shape and functional problems. A 2 dimensional echocardiography on the other hand restricts our image interpretations and leaves a lot to imagination. Hence the interobserver differences in 2D are more, depending on the proficiency & experience of the echo operator. Not much research has compared the advantages of a 3D vs 2D echocardiographic interpretation of an ASD with the surgical findings. Hence, we intend to carry out this study.

How is Transesophageal echocardiography performed?

This will be done when you are under anesthesia and will not cause any discomfort to you. Your Anesthesiologist will insert the lubricated probe into your mouth. He or she will then gently guide it down your throat into your esophagus. Your esophagus lies directly behind your heart. During this process, Anesthesiologist will take care to protect your teeth and mouth from injury.

What are the risks and side-effects?

We do not expect that our study will cause any injury to you because our study protocol is a part of routine intraoperative TEE examination. You will be under the effect of anesthesia while the test is being performed, thus you are unlikely to experience any discomfort.

Why are we doing this study?

The purpose of this study is to assess the role of 2d/ 3d echocardiography in assessment of Atrial Septal Defect (size, shape, location and rims) and compare with the surgical findings on the OT table. It will also help to explore further its utility during cardiac surgery.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you because of our study as it is a part of routine examination during the surgery.

Will you have to pay for the study?

No.

Will your personal details be kept confidential?

Your personal details will be kept confidential. The result 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.

Dr. (Lt Col) Ankur Joshi ,

Senior Resident, CVTA,

SCTIMST.

(Ph No: 9765755537)

(E Mail – jo5007@yahoo.com) Date :

If you have any further questions, please ask:

Dr. (Lt Col) Ankur Joshi, Senior Resident, Department of Anaesthesia (Ph No: 9765755537)

Dr.Rupa Sreedhar, Professor and Head of Department of Anaesthesia. (Ph no : 9446314043)

Dr. Shrinivas Gadhinglajkar, Professor, Department of Anaesthesia. (Ph no: 9446304043)

Dr. Mala Ramanathan, Professor, Achutha Menon Centre (non study contact person)

(Ph no: 0471-2524243/ 2556026)

CONSENT FORM

I, ____, **(Participant's name)**

Date of Birth / Age (in years) _________________________

Son / daughter of __________________________________ .

Declare that I have read the above information provide to me regarding the study:

TITLE: *Intraoperative assessment of atrial septal defect morphology using3D transesophageal echocardiography vs 2D transesophageal echocardiography*

(Please tick boxes)

- And have clarified any doubts that I had. [ ]
- I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]
- I understand that the study staff and institutional ethics committee members 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:

(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.

________________________________ ____________________

Dr. (Lt Col) Ankur Joshi ,

Senior Resident, CVTA,

SCTIMST.

(Ph No: 9765755537)

(E Mail – jo5007@yahoo.com) Date :

If you have any further questions, please ask:

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രോഗിക്കുള്ള കാര്യവിവരണപത്രം

പഠന ശീർഷകം:

എട്രിയൽ സെപ്റ്റൽ തകരാറിന്റെ വലുപ്പവും അരികുകളും 3ഡി, 2ഡി ട്രാൻസിസോഫേജിയൽ എക്കോകാർഡിയോഗ്രഫികൾ ഉപയോഗിച്ച് വിലയിരുത്തുന്നതിന്റെ മൂല്യനിർണ്ണയം.

പഠന നമ്പർ

ശസ്ത്രക്രിയക്കുമുൻപും സമയത്തും ശേഷവും എട്രിയൽ സെപ്റ്റൽതകരാറിന്റെ വലുപ്പവും അരികുകളും ത്രിമാന, ദ്വിമാന ട്രാൻസ് ഇസോഫേജിയൽ എക്കോകാർഡിയോഗ്രഫികളുപയോഗിച്ച് നടത്തുന്ന വിലയിരുത്തലുകളുടെ മൂല്യനിർണ്ണയം നടത്താൻ ഞങ്ങൾ ആസൂത്രണം ചെയ്യുന്ന പഠനത്തിൽ പങ്കെടുക്കാൻ താങ്കളോട് അഭ്യർത്ഥിക്കുന്നു. ഈ പഠനത്തിൽ ഈ ആശുപത്രിയിലെ 50 പേരെ ഉൾപ്പെടുത്താമെന്ന് ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നു.

എന്താണ് എട്രിയൽ സെപ്റ്റൽ തകരാർ?

ശരീരത്തിലെ വിവിധ അവയവങ്ങളിലേക്ക് രക്തം ഫലപ്രദമായി എത്തിക്കുന്നതിന് ഹൃദയം ഒരു പമ്പുപോലെ പ്രവർത്തിക്കുന്നു. ഒരു സാധാരണഹൃദയത്തിൽ 4 അറകളുണ്ട് (2 എണ്ണം ഹൃദയത്തിന്റെ വലതുവശത്തും 2 എണ്ണം ഇടതുവശത്തും). ഇടതി അറകളെ ഇടത് എട്രിയമെന്നും.ഇടത് വെൻട്രിക്കിളെന്നും പറയുന്നു ഇടതു വെൻട്രിക്കിൾ പ്രണവായു നമ്പന്നമായ രക്തം ശ്വാസകോശത്തിൽനിന്നും സ്വീകരിച്ച് വിവധ മർമ്മപ്രധാനവും അല്ലാത്തതുമായ അവയവങ്ങളിലേക്ക് പ്രവഹിപ്പിക്കുന്നു. ആകയാൽ ഹൃദയം വളരെ ഫലപ്രദമായി പ്രവർത്തിക്കാൻ ഹൃദയത്തിന്റെ ഇടതുവശത്തെ അറകൾ വലതുവശത്തെ അറകളിൽനിന്നും സ്വാഭാവികമായി വേർതിരിക്കപ്പെട്ടിരിക്കുന്നു. ഇടത് എട്രിയത്തെ വലത് എട്രിയത്തിൽ നിന്നുറി വേർതിരിക്കുന്ന സ്തരത്തിന്റെ തകരാറിനെ എട്രിയൽ സെപ്റ്റം എന്നു വിളിക്കുന്നു. ഈ സെപ്റ്റത്തിന്റെ തുടർച്ചയില്ലായ്മയെ എട്രിയൽ സെപ്റ്റൽ തകരാറെന്ന് പറയുന്നു. ആകയാൽ ശസ്ത്രക്രിയയിലൂടെ വിടവ് നികത്താൻ, എട്രിയൽ സെപ്റ്റൽ തകരാറിന്റെ ഘടനയും ശരീരശാസ്ത്രവും വിലയിരുത്തേണ്ടത് വളരെ പ്രധാനമാണ്.

എന്താണ് ട്രാൻസ്– ഇസോഫേജിയൽ എക്കോകാർഡിയോഗ്രഫി?

ഹൃദയത്തിന്റെയും അതിന്റെ രക്തക്കുഴലുകളുടെയും ഉയർന്ന നിലവാരമുള്ള ചലിക്കുന്ന ചിത്രങ്ങൾ ലഭിക്കാൻ ശബ്ദതരങ്കങ്ങളുപയോഗിക്കുന്ന ഒരു പരിശോധനയാണ്(ടാൻസ്– ഇസോഫേജിയൽ എക്കോകാർഡിയോഗ്രഫി അല്ലെങ്കിൽ റ്റിഇഇ. ഇതിന് ഹൃദയത്തിന്റെ പ്രശ്നബാധിതമായ മേഖലകൾ ചൂണ്ടിക്കാണിക്കാനാകും, ഹൃദയവാൽവുകളുടെ പ്രവർത്തനം വാർവ് മാറ്റിവയ്ക്കൽ ശസ്ത്രക്രിയക്കുമുൻപും ശേഷവും വിലയിരുത്തുന്നതിന് അത് സഹായകമാണ്. ഗാധാരണ എക്കോകാർഡിയോഗ്രഫി ചെയ്യുന്നത് നെഞ്ചുവഴിയാണ് (ട്രാൻസ് തൊറാസിക് എക്കോകാർഡിയോഗ്രഫി). എന്നുവരികിലും അതേ ഭാഗമാണ് സർജൻ ശസ്ത്രക്രിയനടത്തുന്നത് എന്നതിനാൽ ഹൃദയശസ്ത്രക്രിയാസമയത്ത് ടാൻസ് തൊറാസിക് എക്കോകാർഡിയോഗ്രഫി ചെയ്യാനാകില്ല. ആകയാൽ എക്കോകാർഡിയോഗ്രഫി പ്രോബ് ഇസോഫാഗസിലൂടെ (അന്നനാളം) കടത്തുന്നു. റ്റിഇഇയിൽ വഴക്കമുള്ളതും അറ്റത്ത് ട്രാൻസ്ഡ്യൂസർ ഘടിപ്പിച്ചതുമായ കുഴലുണ്ട് (പ്രോബ്). അനസ്തീഷ്യോളജിസ്റ്റ് താങ്കളുടെ തൊണ്ടയിലൂടെ താങ്കളുടെ ഇസോാഗസിലേക്ക് (വായിൽനിന്നും ആമാശയത്തിലേക്കുള്ള വഴിയിൽ) പ്രോബ് കടത്തും. താങ്കൾ മയക്കലിന് വ്ധേയമായി

അബോധാവസ്ഥയിലായിരിക്കുമ്പോഴാണ് ഇത് ചെയ്യുന്നത് എന്നതിനാൽ താങ്കൾക്ക് അസ്വസ്ഥതയൊന്നും ഉണ്ടാകില്ല. ഇസോഫാഗസ് ഹൃദയത്തിന് നേരെ അടിയിലാകയാൽ താങ്കളുടെ ഡോക്ടർക്ക് ഈ സമീപനത്തിലൂടെ ഹൃദയത്തിന്റെ കൂടുതൽവിശദമായ ചിത്രങ്ങൾ ലഭിക്കും.

എന്താണ് 3ഡി, 2ഡി ട്രാൻസിസോഫേജിയൽ എക്കോകാർഡിയോഗ്രഫി?

ഒരു ത്രിമാന എക്കോകാർഡിയോഗ്രഫി ഹൃദയഘടനയുടെ ത്രിമാനരീതിയിലുള്ള ചിത്രം കാണുന്നതിന് സഹായിക്കുന്നതിനാൽ തകരാറുകളുടെ വലുപ്പം, ആകൃതി, പ്രവർത്തന പ്രശ്നങ്ങൾ എന്നിവയുടെ കൂടുതൽ കൃത്യതയുള്ള ദർശനം നൽകുന്നു. ഒരു ദ്വിമാന എക്കോകാർഡിയോഗ്രഫി ചിത്രത്തിന്റെ വ്യാഖ്യനത്തെ പരിമിതപ്പെടുത്തുകയും നല്ലൊരളവ് ഊഹത്തിന് വിടുകയും ചെയ്യുന്നു. ആകയാൽ എക്കോ പ്രവർത്തിപ്പിക്കുന്നയാളുകളുടെ ശേഷിയുടെയും പരിജ്ഞാനത്തിന്റെയും അടിസ്ഥാനത്തിൽ നിരീക്ഷണങ്ങൾ തമ്മിലുള്ള വ്യത്യാസങ്ങൾ 2ഡിയിൽ കുടുതലാകാം. കസ്ത്രക്രിയയിലെ കണ്ടെത്തലുകളമായി, എഎസ് ഡിയുടെ വ്യാഖ്യാനത്തിൽ 3ഡിയും 2ഡിയും എക്കോഗ്രാഫികളുടെ മെച്ചം താരതമ്യം ചെയ്യുന്ന അധികം ഗവേഷണങ്ങളൊന്നും ഉണ്ടായിട്ടില്ല. ആകയാൽ ഞങ്ങൾ ഈ പഠനം നടത്താൻ ഉദ്ദേശിക്കുന്നു.

എങ്ങിനെയാണ് ട്രാൻസ്- ഈസോഫോജിയൽ എക്കോകാർഡിയോഗ്രഫി ചെയ്യുന്നത് ?

താങ്കൾ മയക്കത്തിന് വ്ധേയമായിരിക്കുമ്പോഴാണ് ഇത് ചെയ്യുന്നതെന്നതിനാൽ താങ്കൾക്ക് അസ്വസ്ഥതകളൊന്നുമുണ്ടാകില്ല. താങ്കളുടെ അനസ്തീഷ്യോളജിസ്റ്റ് വഴക്കമുണ്ടാക്കിയ പ്രോബ് വായിലൂടെ കടത്തുന്നു. ഡോക്ടർ താങ്കളുടെ തൊണ്ടയിലൂടെ അത് സാവകാശം ഈസോഫാഗസിലേക്ക് നയിക്കുന്നു. താങ്കളുടെ ഈസോഫാഗസ് ഹൃദയത്തിന് നേരെ താഴെയാണ്. ഈ പ്രക്രിയക്കിടയിൽ താങ്കളുടെ പല്ലുകൾക്കും വായയ്ക്കും പരിക്കുണ്ടാകാതെ ഡോക്ടർ സംരക്ഷിക്കും.

അപായങ്ങളും പാർശ്വഫലങ്ങലുമെന്തെല്ലാം?

ഞങ്ങളുടെ പഠന പദ്ധതിയിലെ റ്റിഇഇ എന്നത് പതിവ് ശ്സ്ത്രക്രിയാപരിശോധനകളുടെ ഭാഗമാണെന്നതിനാൽ ഞങ്ങളുടെ പഠനം എന്തെങ്കിലും പരുക്കുകളുണ്ടാക്കും എന്ന് പ്രതീക്ഷിക്കുന്നില്ല. പരിശോധന നടത്തുമ്പോൾ താങ്കൾ മയക്കത്തിന് വിധേയമാണെന്നതിനാൽ താങ്കൾക്ക് എന്തെങ്കിലും അസ്വസ്ഥതയുണ്ടാകാൻ സാദ്ധ്യതയില്ല.

ഞങ്ങളെന്തിന് ഈ പഠനം നടത്തുന്നു ?

ശസ്ത്രക്രിയാടേബിളിലെ ശസ്ത്രക്രിയയിലൂടെയുള്ള കണ്ടെത്തലുകളുമായി താരതമ്യം ചെയ്യുമ്പോൾ എട്രിയൽ സെപ്റ്റൽ തകരാറ് (വലുപ്പം, ആകൃതി, സ്ഥാനം, അരികുകൾ) വിലയിരുത്തുന്നതിൽ 2ഡി, 3ഡി എക്കോകാർഡിയോഗ്രഫിയുടെ പങ്കിന്റെ മൂല്യനിർണ്ണയം ചെയ്യുക എന്നതാണ് ഈ പഠനത്തിന്റെ ഉദ്ദേശം. ഹൃദയ ശസ്ത്രക്രിയാവേളയിൽ കുടുതൽ ഉപയോഗയോഗ്യത പരിശോധിക്കാനും അത് സഹായിക്കും.

പഠനമാരംഭിച്ചശേഷം താങ്കൾക്ക് പിൻമാറാമോ?

താങ്കളുടെ പഠനത്തിലെ പങ്കാളിത്തം തികച്ചും സ്വമേധയാ ഉള്ളതും അനുവാദം പിൻവലിക്കാൻ ഏതുസമയത്തും താങ്കൾക്ക് തീരുമാനിക്കാവുന്നതുമാണ്. അങ്ങിനെചെയ്യുന്നതുകൊണ്ട് താങ്കളുടെ ഈ ആശുപത്രിയിലെ പതിവ് ചികിത്സയെ ഒരുതരത്തിലും ബാധിക്കില്ല.

പഠനസംബന്ധമായ പരിക്കുണ്ടായാലെന്ത് സംഭവിക്കും ?

ഞങ്ങളുടെ പഠനം ശസ്ത്രക്രിയക്കിടയിലെ പതിവ് പരിശോധനകളുടെ ഭാഗമാകയാൽ പഠന സംബന്ധമായി താങ്കൾക്ക് പരിക്കുകളൊന്നും ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നില്ല

പഠനത്തിന് താങ്കൾ പണം ചിലവാക്കണോ?

വേണ്ട

താങ്കളുടെ വ്യക്തിവിവരങ്ങൾ രഹസ്യമായി സൂക്ഷിക്കുമോ ?

താങ്കളുടെ വ്യക്തിവിവരങ്ങൾ രഹസ്യമായി സൂക്ഷിക്കും. പഠനഫലങ്ങൾ ഒരു മെഡിക്കൽ ജർണ്ണലിൽ പ്രസിദ്ധീകരിക്കപ്പെട്ടേക്കാം പക്ഷേ താങ്കളെ പേരുകൊണ്ട് പ്രസിദ്ധീകരണത്തിലോ പഠനഫലങ്ങളുടെ പ്രദർശനത്തിലോ തിരിച്ചറിയാനാവില്ല.

താങ്കൾക്ക് കൂടുതൽ ചോദ്യങ്ങളുണ്ടെങ്കിൽ ദയവായി ചോദിക്കുക.

പ്രധാന ഗവേഷകന്റെ പേര് ഡോ. (ലെഫ്.കേണൽ) അങ്കുർ ജോഷി, സീനിയർ റസിഡന്റ്, അനസ്തീഷ്യ ഡിപ്പാർട്ട്മെന്റ്, ഫോൺ. 9765755537, ഇമെയിൽ. jo5007@yahoo.com

ഡോ രൂപ ശ്രീധർ, പ്രൊഫസർ ആന്റ് ഹെഡ്, അനസ്തീഷ്യ ഡിപ്പാർട്ട്മെന്റ്,

ഡോ. ശ്രീനിവാസ് ഗാധിംഗ്ലജ്കർ, പ്രൊഫസർ, അനസ്തീഷ്യ ഡിപ്പാർട്ട്മെന്റ്,

സമ്മതപത്രം

ഞാൻ................................ (പങ്കാളിയുടെപേര്)

ജനനതീയതി/വയസ്സ് (വർഷത്തിൽ)................................
....ന്റെ പുത്രൻ/പുത്രി

പഠനസംബന്ധിയായി എനിക്കു നൽകിയ വിവരങ്ങൾ വായിച്ചു എന്ന് പ്രസ്താവിക്കുന്നു.

ശീർഷകം. **എടിയൽ സെപ്റ്റൽ തകരാറിന്റെ വലുപ്പവും അരികുകളും 3ഡി, 2ഡി ട്രാൻസിസോഫേജിയൽ എക്കോകാർഡിയോഗ്രഫികൾ ഉപയോഗിച്ച് വിലയിരുത്തുന്നതിന്റെ മൂല്യനിർണ്ണയം**

ദയവായി പ്രസക്തമായ കള്ളികളിൽ ടിക് അടയാളമിടുക

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- എനിക്കുണ്ടായഎല്ലാ സംശയങ്ങളും പരിഹരിച്ചു [ ]
- എന്റെ പഠനത്തിലെ പങ്കാളിത്തം തികച്ചും സ്വമേധയാ ഉള്ളതും ഏതുസമയത്തും അനുവാദം പിൻവലിക്കാൻ തീരുമാനിക്കാൻ എനിക്ക് സ്വാതന്ത്ര്യമുണ്ടെന്നും അങ്ങിനെചെയ്യുന്നതുകൊണ്ട് എന്റെ ഈ ആശുപത്രിയിലെ പതിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളെയോ ഒരുതരത്തിലും ബാധിക്കില്ലെന്നും ഞാൻ മനസ്സിലാക്കുന്നു [ ]
- ഞാൻ പഠനത്തിൽനിന്നും പിൻമാറായാലും എന്റെ ചികിത്സാ വിവരങ്ങൾ പഠിതാക്കൾക്കും സ്ഥാപനത്തിലെ നൈതീകകമ്മിറ്റി അംഗങ്ങൾക്കും പരിശോധിക്കാൻ എന്റെ അനുവാദം ആവശ്യമില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. അതിനോട് ഞാൻ യോജിക്കുന്നു [ ]
- മൂന്നാംകക്ഷിക്ക് വിവരങ്ങൾ കൈമാറുമ്പോഴോ പ്രസീദ്ധീകരിക്കുമ്പോഴോ എന്റെ വ്യക്തിവിവരങ്ങൾ രഹസ്യമായി സൂക്ഷിക്കും എന്നെനിക്ക് മനസ്സിലായിട്ടുണ്ട് [ ]
- ഞാൻ സ്വമേധയാ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു [ ]
- സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് കിട്ടി [ ]

പേര്
ഒപ്പ്
തീയതി
സാക്ഷിയുടെ പേര്
പങ്കാളിയുമായുള്ള ബന്ധം
ഒപ്പ്

(സമ്മതം വാങ്ങുന്നയാൾ)

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

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേര്............................... ഒപ്പ്............................

പ്രധാന ഗവേഷകൻ

____ _______________________

ഡോ (ലഫ്. കേണൽ) അങ്കൂർ ജോഷി
സീനിയർ റസിഡന്റ്, CVTA,
SCTIMST. (9765755537)
jo5007@yahoo.com

Plagiarism Checker X Originality Report

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Date: Tuesday, July 30, 2019
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MASTER CHART

S.no.	Name	Ao rim_2D	Mitral rim_2D	IVC rim_2D	SVC rim_2D	Post rim_2D	CS rim_2D	Max_Size_2D	Max_Size_3D	Max_Size_Intraop	Shape_Intraop	Location_intraop	Ao rim_Intra_op	Mitral rim_Intra_op	IVC rim_Intra_op	SVC rim_Intra_op	Post rim_Intra_op	CS rim_Intra_op
1	APARNA SURESH		7	0	7	5	4.5	26	32	35	OVAL	OSASD		15	2	13	3	
2	LATHA RAJU							26	18	34	OVAL	OSASD						
3	RAHIYANATH	9	0	6	7	6		42	39	28	OVAL	OSASD		3	2	5	4	
4	RESHMA		6.5	5	6	17		32	30	33	OVAL	OSASD		8	4	12	14	
5	AKSHAYA (13/4/18)		11	5	15	0		24	28	31	OVAL	OSASD		16	9	19	0	
6	BINDHU G NAIR	3	8.7	10.7	7.7	8		22	20	24	OVAL	OSASD		12	5	4	12	
7	JAYALEKSHMI		9	5	7	3		40	49	42	OVAL	OSASD		6	3	10	6	
8	JYOTHILEKSHMI		5	0	15	5		21	39	19	OVAL	OSASD		2	0	4	3	
9	REHMATHULLA		7.5	0	8	2		33	39	27	OVAL	OSASD		12	3	6	5	
10	SUDHARMANI		25	0	0	9		20	21	15	OVAL	OSASD		17	6	8	11	
11	ASODA LIMBUS	5	11	0	9.5	7	6	22	35	24	OVAL	OSASD		12	18	4	11	
12	GAYAL	2	14	18	6	10	14	22	24.5	25	OVAL	OSASD		10	20	8	8	
13	HILARIYA	3.4	2	6.4	11	11		27	36	32	OVAL	OSASD		15	10	20	11	
14	ROHINI	3	10	4	9	4.3		23	36	37	OVAL	OSASD		3	6	16	5	
15	JAYAKUMAR	6	6	9	9.5	4		21	52	28	OVAL	OSASD		20	5	15	25	
16	SIVAKUMAR	0	17	0	5	3		15	24	23	OVAL	OSASD		30	0	2	0	
17	SYAM LAL	6.3	9	0	13	7.9		31	23	38	OVAL	OSASD		20	15	24	10	
18	SAVITHRI SURESH	7.4	8.3	11.4	6.6	7.3		34.5	43	37	OVAL	OSASD		29	6	16	5	
19	AISWARYA		8	0	5	10		26	32	33	Oval	OSASD		30	0	14	6	
20	RADHAMANI AMMA		13	0	9	3		31	45	46	Oval	OSASD		30	3	23	6	
21	SANTHIYA	5	9	15	11	3		27	21	20	Oval	OSASD		5	30	24	5	
22	SYLA KUMARI	2	20	8	9.5	6		38	39	24	Oval	OSASD		9	36	29	7	
23	MURUGESHWARI	6.5	11	2	12	15		19	22	18	OVAL	OSASD		6	7	12	9	
24	NASEEMA		12	26	18	18		19	21	18	OVAL	OSASD		20	20	25	9	
25	VSMAYA	13.3	10.5		23.5	4		22	14.5	27	OVAL	OSASD		13	10	3	15	
26	ADHEEN MD	7.5	11	7	9	6.5		10	10	20	Oval	OSASD		14	3	15	5	
27	INDHUJA	5.5	12	5.5	8	6		22	42	29	Oblong	OSASD		11	11	21	7	
28	BIJU V	5	10	5	14	4		27	29	30	Oval	OSASD		16	16	25	10	
29	ANICHANDRAN	16	2	14	15	15		26	36	39	Oval	OSASD		15	17	23	9	
30	DEVI N	10	13	11	10	7		31	30	48	Oval	OSASD		15	7	25	5	
31	ASHNI	6	11	8	11	6		22	34	36	Oval	OSASD		12	4	16	5	
32	PRITHIEV	9	8	2	13	7		14	25	18	OVAL	OSASD		16	7	12	10	
33	SADHIKA	3	11	11	9	7.5		15	33	35	OVAL	OSASD		11	6	16	9	
34	SREECHITHRRA	8.5	10.5	6.5	10.7	7		25	34.5	28	OVAL	OSASD		13	5	13	9	
35	SARATHA	7	14	5	12	4		28	34	40	OVAL	OSASD		11	13	27	4	
	Count	24	34	33	34	34	3	35	35	35			0	34	34	34	34	0
	Min	0	0	0	0	0	4.5	10	10	15			0	2	0	2	0	0
	Max	16	25	26	23.5	18	14	42	52	48			0	30	36	29	25	0
	Mean	6.23	10.09	6.26	10.06	7.01	8.17	25.24	31.16	29.74			#DIV/0!	14.03	9.09	14.97	7.74	#DIV/0!
	SD	3.63	4.77	6.05	4.28	4.20	5.11	7.18	9.70	8.37			#DIV/0!	7.47	8.34	7.84	4.67	#DIV/0!
	Median	6	10	5.25	9.5	6.5	6	24.5	32	28.5			#NUM!	13.00	6.00	15.00	7.00	#NUM!
	p-value													0.010	0.149	0.004	0.502	#DIV/0!

p-value for 2D vs 3D	0.006
p-value for 3D vs Intra op	0.462
p-value for 2D vs Intra op	0.027

Significant

Unpaired t-test used