

**EVALUATION OF DIMENSIONS OF LEFT
MAIN CORONARY ARTERY, OSTIO-
PROXIMAL LEFT ANTERIOR DESCENDING
ARTERY, AND OSTIO-PROXIMAL LEFT
CIRCUMFLEX ARTERY BY INTRAVASCULAR
ULTRASOUND IN INDIAN POPULATION.**

Dr Dayanand Kamanakeri

DM THESIS

Jan 2020- Dec 2022



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

An Institution of National Importance established by an Act of the Indian Parliament
(Act No.52 of 1980)

Dept. of Science and Technology, Govt. of India

www.sctimst.ac.in

TITLE OF THESIS

**EVALUATION OF DIMENSIONS OF LEFT
MAIN CORONARY ARTERY, OSTIO-
PROXIMAL LEFT ANTERIOR DESCENDING
ARTERY, AND OSTIO-PROXIMAL LEFT
CIRCUMFLEX ARTERY BY INTRAVASCULAR
ULTRASOUND IN INDIAN POPULATION**

A THESIS SUBMITTED

BY

Dr Dayanand Kamanakeri

TO

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND
TECHNOLOGY, TRIVANDRUM

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE AWARD OF

DM cardiology

Jan 2020 - Dec 2022



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

DECLARATION BY THE STUDENT

CERTIFICATE

I, **Dr Dayanand Kamanakeri**, hereby certify that I had personally carried out the work depicted in the thesis titled " **Evaluation of dimensions of left main coronary artery, ostio-proximal left anterior descending artery, and ostio-proximal left circumflex artery by intravascular ultrasound in Indian population**".

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

Date: 12.08.2022

Dr. Dayanand Kamanakeri



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

CERTIFICATE BY THE RESEARCH GUIDE

Name of the Guide : Dr. V K Ajit Kumar

Division/ Department : Cardiology

This is to certify that **Dr Dayanand Kamanakeri**, department / division of Cardiology of this institute has fulfilled the requirements prescribed for the DM degree of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, " **Evaluation of dimensions of left main coronary artery, ostio-proximal left anterior descending artery, and ostio-proximal left circumflex artery by intravascular ultrasound in Indian population**" was carried out under my direct supervision. No part of this thesis has been submitted for the award of any other degree or diploma prior to this date.

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

Date: 12.08.2022

Dr. V K Ajit Kumar



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

CERTIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide : Dr. G Sanjay

Division/Department : Cardiology

This is to certify that **Dr Dayanand Kamanakeri**, department/division of Cardiology of this institute has fulfilled the requirements prescribed for the DM degree of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, " **Evaluation of dimensions of left main coronary artery, ostio-proximal left anterior descending artery, and ostio-proximal left circumflex artery by intravascular ultrasound in Indian population**" was carried out under my direct supervision. No part of this thesis has been submitted for the award of any other degree or diploma prior to this date.

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

Date:

12/8/22

Dr. G Sanjay

APPROVAL OF THE THESIS

DM programme affiliated to the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum

The thesis entitled

EVALUATION OF DIMENSIONS OF LEFT MAIN CORONARY ARTERY, OSTIO-PROXIMAL LEFT ANTERIOR DESCENDING ARTERY, AND OSTIO-PROXIMAL LEFT CIRCUMFLEX ARTERY BY INTRAVASCULAR ULTRASOUND IN INDIAN POPULATION

Submitted by

Dr Dayanand Kamanakeri

for the degree of DM **CARDIOLOGY**

of

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

is evaluated and approved by

.....


(Dr. VK Ajit Kumar)

.....
(Name & Signature of thesis examiner)

ACKNOWLEDGEMENTS

It is with deep sense of gratitude, satisfaction and with the divine blessings of God that I submit this dissertation. I take this opportunity with much pleasure to thank all who contributed in many ways for the success of this study.

I would like to express my deep sense of thanks and gratitude to **Dr. Ajit Kumar V.K**, professor senior grade, for his contributions and suggestions during the entire work.

I am greatly indebted to my co-guide and supervisor **Dr. Sanjay G**, professor for the continued support and advice he has extended to me throughout my work towards this thesis.

I am grateful to **Dr. Anoop A**, associate professor, Department of Imaging Sciences and Intervention Radiology, SCTIMST for providing valuable suggestions that helped me to make the study better.

I would also like to sincerely thank **Dr Basavaraj N Biradar**, Senior resident Department of Imaging Sciences and Intervention Radiology for his help in acquiring and measurement of data; my colleague **Dr Deepanjan Bhattacharya**, Senior resident Cardiology for his immense help in statistical analysis and all the faculty members of the Department of Cardiology, SCTIMST for academic support. I have no words to express my heartfelt gratitude and love to my family, who provided the most precious support. I want to thank the technical staff and the nursing staff of SCTIMST for their friendly support and helping hands. Finally, my sincere thanks to all my patients who consented to participate in this study.

Dr. Dayanand Kamanakeri

TABLE OF CONTENTS

List of figures	ix
List of tables	xi
List of abbreviations	xiii
Abstract	xv
1. Introduction	1
2. Literature review	3
3. Materials and methods	11
4. Results	20
5. Discussion	42
6. Summary and conclusion	47
7. References	48
8. Annexure	59

LIST OF FIGURES

Figure No	Figure Caption	Page No
Fig 1	CT CAG: The images and method of measurement of LMCA.	13
Fig 2	CT CAG: The images and method of measurement of LMCA.	13
Fig 3	CT CAG: The images and method of measurement of LMCA.	14
Fig 4	CT CAG: The images and method of measurement of LMCA.	14
Fig 5	QCA analysis: calibration of contrast filled catheter (panel a), measurement LMCA in RAO caudal view (panel b), LAD in RAO caudal view (panel c), and LCX in RAO caudal view (panel d).	16
Fig 6	The depiction of IVUS measured dimensions	18

Fig 7.	Coronary artery diameter by CT CAG (mm) without indexing to body surface area.	23
Fig 8	Coronary artery diameter by CT CAG (mm/m²) indexed to body surface area.	23
Fig 9	Bland-Altman plot for CTCAG analysis of correlation of measured diameter of LMCA with calculated diameter of LMCA using Murray's law (9 a), Finet's law (9 b) and Huo-Kassab's law (9 c).	32,33,34
Fig 10	Bland-Altman plot for QCA analysis of correlation of measured diameter of LMCA with calculated diameter of LMCA using Murray's law (10 a), Finet's law (10 b) and Huo-Kassab's law (10 c).	36,37,38

LIST OF TABLES

Table No	Table Caption	Page No
Table 1	Baseline demographic characters of CT CAG group and IVUS/QCA group.	21
Table 2	Axial diameter of coronary vessels by CT CAG.	22
Table 3	Multiple linear regression models predicting axial CSA indexed for BSA.	24
Table 4	Comparison of axial vessel cross sectional area by CT CAG.	25
Table 5	MLD of coronary vessel by IVUS.	26
Table 6	Vessel (EEM) diameters of coronary vessel by IVUS.	26
Table 7	Comparison of Lumen and EEM Cross sectional area by IVUS.	27
Table 8	MLD of coronary vessel by QCA.	28
Table 9	Comparison of Lumen CSA by QCA	28
Table 10	Comparison of MLD by IVUS and QCA.	29
Table 11	Comparison of EEM diameter by IVUS and axial vessel diameter by CT CAG.	30
Table 12	CT CAG comparison and correlation of calculated and measured LMCA diameters. QCA comparison and correlation of calculated and measured LMCA diameters.	31
Table 13	QCA comparison and correlation of calculated and measured LMCA diameters.	35
Table 14	CTCAG study comparison with Indian studies.	39
Table 15	CTCAG study comparison with western studies.	39
Table 16	IVUS study comparison with other Indian studies.	40
Table 17	IVUS study comparison with western studies.	40

Table 18	QCA study comparison with Indian studies.	41
Table 19	QCA study comparison with western studies.	41



LIST OF ABBREVIATIONS

S No	Abbreviation	Full Form
1	AP	Antero-posterior
2	ACC	American college of cardiology
3	BSA	Body surface area
4	BMI	Body mass index
5	CAD	Coronary artery disease
6	CAG	Coronary angiography
7	CVD	Cardiovascular diseases
8	CABG	Coronary artery bypass graft
9	CSA	Cross sectional area
10	CT CAG	Computed tomography coronary angiography
11	DICOM	Digital imaging and communication in medicine
12	DVD ROM	Digital video disc read only memory
13	ECG	Electrocardiogram
14	EEM	External elastic membrane
15	iCT	Intraoperative Computed tomography
16	ISIR	Imaging Sciences and Intervention Radiology
17	LAD	Left anterior descending artery

18	LAO	Left anterior oblique
19	LCX	Left circumflex artery
20	LMCA	Left main coronary artery
21	LVEF	Left ventricular ejection fraction
22	MLD	Mean lumen diameter
23	MV	Main vessel
24	OM	Obtuse marginal
25	PCI	Percutaneous transluminal coronary intervention
26	PDA	Posterior descending artery
27	PLB	Posterolateral branch
28	POC	Polygon of confluence
29	P+M	Plaque +media
30	QCA	Quantitative coronary angiogram
31	RAO	Right anterior oblique
32	RCA	Right coronary artery
33	RWMA	Regional wall motion abnormality
34	SCTIMST	Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum
35	SD	Standard deviation
36	SPSS	Statistical package for social sciences

ABSTRACT

**EVALUATION OF DIMENSION OF LEFT MAIN CORONARY ARTERY,
OSTIO-PROXIMAL LEFT ANTERIOR DESCENDING ARTERY AND
OSTIO-PROXIMAL LEFT CIRCUMFLEX ARTERY BY INTRAVASCULAR
ULTRASOUND IN INDIAN POPULATION**

BY

Dr Dayanand Kamanakeri

for DM Degree

of CARDIOLOGY

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

ABSTRACT

Introduction: It is essential to know the coronary dimensions which has diagnostic and therapeutic implications in management, especially during interventions such as selection of the appropriate size of the balloon, stent, and the need for stenting etc. As under or oversized, under or over expanded stents are well documented risk factors for stent thrombosis, re-stenosis and procedure related complications. So, the awareness of normative data can serve to mitigate the same. There is paucity of normative data on the dimension of coronary arteries in Indians as measured by intravascular ultrasound (IVUS).

Aim: This study is designed to (a) generate normative data for dimensions of the coronary arteries of non-diseased left main(LMCA), ostio-proximal left anterior descending(LAD), and ostio-proximal left circumflex artery(LCX) in patients by using IVUS and Quantitative coronary angiography(QCA) in same patients and correlate between the IVUS and QCA; (b) to generate normative data for dimension of normal coronary artery from computed tomographic coronary angiography(CT CAG) and its co-relation with IVUS and QCA; and (c) to compare and correlate the measured LMCA diameter by IVUS, QCA and CT CAG with calculated LMCA diameter from Murray's law, Finet's law and Huo-Kassab's law.

Methods: This is an observational study conducted at SCTIMST, Trivandrum after Institutional Ethics Committee clearance included studies from May 2009-July 2022;

enrolled total of 31 patients who underwent IVUS guided PCI of the left coronary system including complete pullbacks of a LMCA, LAD and LCX for their clinical indications along with QCA; and also enrolled 36 patients in CT CAG group with low pretest probability for coronary artery disease (CAD) who found to have no proximal coronary artery disease in all vessels.

Results: In IVUS group mean age was 55.75 ± 10.9 years, mean BSA $1.71 \pm 0.11 \text{m}^2$ and males 80.65%. In CT CAG group patient mean age of 53.83 ± 9.6 years, mean BSA $1.72 \pm 0.14 \text{m}^2$ and males 41.67%. Analysis of baseline characteristics revealed, BMI was higher in CT CAG group compared to IVUS group with statistically significant difference ($27.08 \pm 5.34 \text{kg/m}^2$ vs $24.63 \pm 2.54 \text{kg/m}^2$, $p= 0.009$). IVUS group had statistically significant higher prevalence of hypertension (58.1% vs 19.4%, $p < 0.001$), smoking (58.1% vs 5.6%, $p < 0.001$), and dyslipidemia (61.3% vs 36.1%, $p < 0.001$), compared to CT CAG group. Males had higher mean height ($p < 0.001$ vs 0.004) and BSA ($p = 0.011$ vs 0.017) compared to females in CT CAG group and IVUS/QCA group with statistical significance. Males had higher smoking percentage (72%) in IVUS/QCA group with statistically significant difference ($p = 0.001$). CT CAG group revealed that females had statistically significant more ST-T changes as compared to males (57.1% vs 13.3%, $p = 0.008$). The IVUS measured mean vessel (EEM) diameter of LMCA $4.35 \pm 0.67 \text{mm}$, ostio-proximal LAD $3.60 \pm 0.69 \text{mm}$ and ostio-proximal LCX $3.21 \pm 0.74 \text{mm}$; when indexed to BSA

are 2.57 ± 0.48 mm/m², 2.17 ± 0.54 mm/m², and 1.84 ± 0.47 mm/m² respectively. The QCA measured mean

lumen diameter of LMCA 4.18 ± 0.70 mm, LAD 3.44 ± 0.38 mm, LCX 3.20 ± 0.55 mm, and when indexed to BSA are 2.45 ± 0.47 mm/m², 2.03 ± 0.45 mm/m², and 1.89 ± 0.38 mm/m² respectively. The CT CAG measured mean axial diameter of LMCA is 4.34 ± 0.75 mm, ostio-proximal LAD 3.65 ± 0.54 mm, ostio-proximal LCX 3.3 ± 0.69 mm, and ostio-proximal RCA 3.62 ± 0.77 mm and when indexed to BSA are 2.53 ± 0.42 mm/m², 2.13 ± 0.35 mm/m², 1.92 ± 0.41 mm/m² and 2.11 ± 0.42 mm/m² respectively. The family history of CAD in IVUS study and gender in CT CAG are independent predictor for artery size and area for LMCA. However no independent predictors identified for artery size and area in QCA study. The IVUS and QCA analysis showed no difference in coronary artery diameters between males and females even after indexing to BSA; and showed moderate linear correlation between IVUS and QCA. In CT CAG analysis males had statistically significant larger coronary artery diameter as compared to females, but when the coronary artery size was indexed to the BSA, there was no statistically significant difference except in LMCA. CTCAG study and QCA study analysis showed higher calculated LMCA diameter using Murray's, Finet's and Huo- Kassab's Law, with excellent linear correlation with CT CAG and moderate linear correlation with QCA for measured and calculated LMCA diameter. The Bland-Altman plot showed LMCA size calculation by Murray's methods had good agreement with measured values,

whereas Finet's law and Huo-Kassab's Law calculated LMCA size had no good agreement with measured value in both CT CAG and QCA group. However, these laws could not be tested in IVUS group as only one patient had pullback study from both LAD and LCX. The coronary artery dimensions are smaller compared to western population in our study population.

Conclusion: The IVUS and QCA measured coronary artery dimensions are similar between males and females, even after indexing to BSA. CT CAG showed males had statistically significant larger coronary artery sizes; however, when indexed to the BSA, there was no statistically significant difference for LAD and LCX except for LMCA. The gender and family history of CAD are independent predictor of coronary artery size and area for LMCA in CT CAG and IVUS study respectively. The CTCAG and QCA comparison showed higher calculated LMCA diameter by Murray's, Finet's and Huo-Kassab's Law, with excellent linear correlation for CT CAG and moderate linear correlation for QCA, for measured and calculated LMCA diameter. The coronary artery dimensions are smaller in our study population compared to western population.

Keywords: Intravascular ultrasound, quantitative coronary angiogram, computed tomographic coronary angiography, left main coronary artery, left anterior descending artery, left circumflex Artery, and right Coronary Artery.

1 INTRODUCTION

Ischemic heart disease is the dominant cause accounting for around one quarter of deaths attributable to the cardiovascular diseases (CVD) which are the leading causes of mortality in India (1). In general population, coronary vessel size is variable with numerous factors playing important role such age, gender, habitus, genetics and environmental (2,3). The outcome after the coronary revascularization i.e., percutaneous transluminal coronary intervention (PCI) and coronary artery bypass graft (CABG) are mainly determined by the coronary artery size. Coronary luminal angiography is the most widely employed for determining the coronary artery sizes, However, the derived two-dimensional lumenogram cannot characterize the arterial wall, and thus evaluate vessel sizes and plaque characteristics, nor directly assess the stent implantation results. Three major anatomic factors impair angiographic left main evaluation. being aortic cusp opacification or “streaming” of contrast, which may obscure the ostium, the short length of the vessel that may leave no normal segment for comparison, and concealment of the distal left main artery by bifurcation or trifurcation. Intravascular ultrasound (IVUS) can aid in overcoming these confounding factors and is the most widely used intracoronary imaging tool for the quantitative assessment of coronary artery disease (CAD), which yields more accurate measurement of vessel geometry and lesion severity than conventional quantitative coronary angiogram (QCA) (4,5,6,7). Assessment of lumen dimensions affects many therapeutic decisions and represents an important application for IVUS.

Intracoronary imaging provides valuable incremental information that can be used clinically to

optimize stent implantation and minimize stent-related problems. Pre-procedural measurement of lumen and vessel dimensions and lesion characterization can facilitate accurate stent sizing and guidance of the stenting strategy. Post-procedural imaging provides strut-level evaluation of the stent result and guides optimization measures. There is mounting evidence from observational studies, randomized controlled trials, and meta-analyses that intravascular imaging guidance by IVUS not only enhances the acute procedural result, but also improves clinical outcomes. The knowledge of normal dimensions of coronary artery can aid interventional cardiologist in stent size selection especially when diffusely diseased coronaries are encountered. As under or oversized, under or over expanded stents are well documented risk factors for stent thrombosis, re-stenosis and procedure related complications. So, the awareness of normative data can serve to mitigate the same. There is paucity of data on normal diameter of coronary artery in Indian population as measured by IVUS.

2 LITERATURE REVIEW

Ischemic heart disease is the leading cause of mortality due to cardiovascular diseases. It is recognized that coronary artery stenosis can manifest as chest pain. The CASS study has shown the risk of myocardial infarction (MI) is 2% over 3 years with a coronary artery stenosis of less than 50%, 7% for a stenosis of 50%-70%, 8% for a stenosis of 70%-90%, and 15% for a stenosis of greater than 90% (8). Whereas, as per other studies 80% of all MIs reported in lesions with stenosis less than 50% (9,10). This discrepancy may be because many have a large number of angiographically "insignificant" lesions, but only a few "significant" stenoses. It is possible that the culprit lesion might have started out as "insignificant" even though the more significant stenosis is more likely to lead to an ACS. Second, IVUS and physiologic lesion assessment studies have questioned the ability of angiography to define the critical stenosis (11).

Quantitative coronary analysis (QCA):

Coronary angiography (CAG) has traditionally been the gold standard for invasive assessment of coronary artery disease (CAD) (12). However, CAG is essentially a luminogram which provides only a two-dimensional image of the vessel with significant inter and intra-observer variability depending upon the angulation of the

frame frozen for analysis. Visual interpretation of CAG most widely used for clinical diagnosis and treatment of CAD. However, the need for an accurate, unbiased, objective assessment of severity of stenosis and coronary size led to the development of QCA. It is well known that visual interpretation of angiography overestimates lesion severity prior to percutaneous transluminal coronary angioplasty and underestimates lesion severity after the procedure as compared to QCA (13,14). QCA is a reproducible technique that can be used during or, after the procedure, or at a core laboratory. as a result, these techniques have been used in most

Limitations of QCA:

QCA is a lumenogram and has numerous limitations. Angiography usually underestimates lesion severity, especially with a 51- 75% histopathologic cross-sectional area narrowing (15, 16) and with multivessel involvement (17). An explanation for the discrepancy between pathologic and angiographic findings is compensatory dilation of the arterial wall as a result of accumulation of atherosclerotic plaque (the Glagov phenomenon). An absolute interpolated by the system. The contrast filled catheter, used as a scaling device, allows absolute measurements. It measures vessel dimensions independent of contour and luminal shape and requires homogeneous complete opacification of the lumen. It is less reliable in calcified vessels.

Intravascular Ultrasound (IVUS):

IVUS yields in vivo tomographic transmural images of coronary vessels. A catheter incorporating a miniature transducer which emits high frequency ultrasound (usually in the range of 20 to 50 MHz) and the ultrasonic reflections are electronically

converted to cross sectional images as the transducer is moved through the artery.

The

unique ability is it provide direct visualization of the atherosclerotic plaque on the vessel wall (18,19,20). The echo reflectivity may be used as a surrogate to characterize its underlying histology and hence pathophysiological mechanism, causing coronary narrowing. It provides precise measurements of both lumen and total vessel CSA, representing a major breakthrough in understanding of coronary artery disease. The pathologic observations that atherosclerosis is commonly present in angiographic, apparently normal, reference segments is confirmed from IVUS studies (19). Von Birgelen et al. has demonstrated that plaque progression was associated with a significantly increased risk of clinical events as predicted by established risk-scoring systems (21). In addition, IVUS had shown that stents are often insufficiently deployed despite an apparently satisfying angiographic result, necessitating high-pressure balloon to achieve complete stent expansion (22). IVUS, is the current standard for the evaluation of optimum stent deployment. Qualitative and quantitative IVUS analyses are usually performed according to the American College of Cardiology Clinical Expert Consensus Document on Standards for Acquisition, Measurement and Reporting of Intravascular Ultrasound Studies (23). Planimetry of the leading edge of the blood-intima acoustic interface quantifies Lumen CSA. The outer external elastic membrane [EEM] CSA is identified as the interface between media and adventitia. Atheroma-CSA is obtained as the difference

between EEM-CSA and lumen-CSA. However, IVUS is expensive, time consuming, requires exchange of the balloon for the IVUS catheter (24).

Comparison of IVUS versus QCA:

Multiple studies comparing coronary angiography and IVUS have consistently shown disparities between the presence, location, distribution, composition, and severity of coronary artery atherosclerosis (18-19,25-28). There are systematic differences between IVUS and QCA in the measurement of reference and lesion lumen dimensions. In patients with intermediate lesions QCA correlates poorly with IVUS. Alfonso et al found a moderate correlation between both techniques at sites which were angiographically normal, but contained plaque on IVUS. However, the correlation deteriorated in complex lesions or following intervention (18). De Scheerder compared IVUS and QCA for luminal diameters in normal and moderately diseased coronary vessels; the correlation was excellent ($r= 0.92$, $p < 0.0001$) in normal coronary vessels by CAG, but only moderate for mild stenosis ($r=0.467$, $p < 0.001$) (27). Abizaid et al noted that, IVUS reference segment are consistently larger than QCA with an average difference of 0.5 mm though not predictable (29). Hoffmann et al concluded that IVUS measured reference lumen dimensions were consistently larger than those measured by QCA (30). Fernandes et al study in Intermediate Coronary Lesions showed a significant underestimation of the reference segment luminal diameter by QCA as compared to IVUS. Linear regression analysis showed a weak correlation between the two methods for the assessment of reference segment luminal diameter ($r = 0.4$; $p < 0.001$) (31). The explanation for observed

discordance between IVUS and QCA measurement may be because of elliptical angulation of the IVUS catheter within the vessel may have led to overestimation of reference luminal dimensions by IVUS; and introduction of the ultrasound catheter itself may have resulted in tracking back of dissection flaps, with a resultant larger lumen during IVUS examinations postintervention compared with contrast angiography. Sometimes QCA may yield larger dimension than IVUS which may be caused by extraluminal contrast within fissures, cracks, and dissection as seen around the true lumen (32).

Many studies have shown that angiographic normal left main (LM) may harbor significant atheroma burden with or without luminal stenosis. QCA assessment of left main may underestimate LM reference diameter and stenosis. Hermiller et al, Yamagishi and Gerber showed that, IVUS detected plaque in angiographically normal LM arteries (33-35). Yamagishi and Gerber showed that there was no correlation between QCA and IVUS percent area stenosis, in patients with angiographic disease. Similarly, Riccardi et al in 107 patients with angiographically normal LM found 30% area stenosis by IVUS. They concluded that angiographically silent, LM disease detected by IVUS is an independent predictor of cardiac events and may serve as a marker for future events (36). Abizaid et al correlated IVUS and QCA in normal and intermediate LM lesion (<50%). The QCA reference diameter 3.91 ± 0.76 mm, correlated moderately with IVUS diameter of 4.25 ± 0.78 mm, $r = 0.492$, $p = 0.0001$. The lesion site MLD by QCA correlated less well with IVUS (37). Sano et al evaluated patients with angiographically intermediate LM by IVUS. MLA by IVUS <6.0 mm² was applied as the criterion for a significant LM stenosis because it correlates with a fractional flow reserve <0.75 (38). The discrepancy

between angiography and necropsy or IVUS appear to be because of diffuse atherosclerotic involvement resulting in lack of a normal reference segment; a short LMCA makes identification

of a normal reference segment difficult; and positive remodeling to preserve lumen size as shown by Glagov et al (39).

Computed tomographic coronary angiography:

Coronary artery disease is the leading cause of mortality and morbidity. There is a large amount of evidence yielded by invasive and non-invasive modalities on diseased coronary arteries, but few reports on normal coronary arteries. Invasive intracoronary imaging offers superior resolution compared to computed tomography coronary angiography (CT CAG), but are rarely performed in subjects with normal coronary angiography. Moreover, there are good correlations between measurements provided by intravascular ultrasound and CT CAG (40-44). Not only does CT CAG yields excellent coronary vessel images with high accuracy for detecting CAD (45), and better outcomes for stable chest pain patients than stress testing (46), also identify plaque components and high-risk plaque features (47). Low attenuation plaque on CCTA correlates closely with the necrotic core on IVUS, positive remodeling and spotty calcification to a lesser degree, are associated with the development of ACS (48). CT CAG is indicated as a first line in low-intermediate risk acute chest pain patients, and a majority of stable chest pain evaluations by New AHA/ACC, United Kingdom and European guidelines. As CT CAG can evaluate

both the coronary wall and lumen, seems better tool to evaluate the dimensions in truly normal coronary artery.

The normal caliber of major coronary artery is 4.5 ± 0.5 for Left main coronary artery (LMCA), 3.7 ± 0.4 mm for left anterior descending artery (LAD), 3.4 ± 0.6 mm for a non-dominant vs 4.2 ± 0.6 mm for a dominant left circumflex artery (LCX), 3.9 ± 0.6 mm for a dominant vs 2.8 ± 0.5 mm for a nondominant right coronary artery (RCA) (49). Lip GY et al, found that Indo-Asians as a whole have generally smaller coronary arteries than Caucasians by coronary angiogram study (50). Imad Ghanem Shukri et al, reported the diameter of the coronary arteries were larger in males than females for LMCA, proximal LAD, LCX and RCA. Proximal RCA also was larger among male but statistically was nonsignificant. The diameter of the coronary arteries in Kurdish population were similar to Caucasians and white but greater than that of Indians (51). Raut BK et al, found out males had statistically significant larger coronary artery diameters by QCA as compared to females but there was no difference after indexing to body surface area (BSA) (52). Cheemalpati Sai Krishna et al, revealed the dimensions of branches in the left coronary system by QCA were less and those of the distal circumflex, and the proximal and distal LAD coronary arteries were significantly greater than those of Indo-Asians living in the United Kingdom and the native Caucasians but the dimensions of the RCA were significantly greater in Indians (53). Manjappa Mahadevappa et al shown normal

proximal coronary artery diameters in adults from India as assessed by computed tomography angiography (CT CAG) indexed to BSA are similar to that reported in western population (54). Elangovan C et al, found small coronary size in females after correction for BSA (55). Dhall et al,

reported that the autopsy series data in humans found smaller coronary artery sizes in female (56). Venkateshwaran S et al, found out that left main reference segment-lumen and external elastic membrane (EEM) diameter in Indians is lesser than that of western population (57). The coronary artery dimensions have important diagnostic and therapeutic implications in management of CAD. Assessment of lumen dimensions affects many therapeutic decisions and represents an important application for IVUS. There is paucity of data on normal diameter of coronary artery in Indian population as measured by IVUS. With this background we designed this study with hypothesis that the coronary artery dimensions are same as with western population if indexed to BSA and the calculated diameter of LMCA using Murray's law, Finet's law and Huo-Kassab's law correlates with measured LMCA diameter. In this study our primary aim is to generate data for dimensions of the coronary artery segments of non-diseased LMCA, ostio-proximal LAD, and ostio-proximal LCX in patients with CAD by using IVUS and QCA in same patient and co-relate the findings between the IVUS and QCA; and also to document the normal coronary artery diameters of LMCA, ostio-proximal LAD, and ostio-proximal LCX in patients with low pre-test probability for CAD referred for CT CAG, to evaluate for the

presence of CAD and its co-relation with IVUS and QCA. We also attempt to co-relate the measured LMCA diameter by IVUS, QCA and CT CAG with calculated LMCA diameter from Murray's law, Finet's law And Huo-Kassab's law (box 1).

Box 1: Aim of the study:

- (a) To generate normative data for dimensions of the coronary arteries of non-diseased left main (LMCA), ostio-proximal left anterior descending (LAD), and ostio-proximal left circumflex artery (LCX) in patients by using IVUS and Quantitative coronary angiography (QCA) in same patients and correlate between the IVUS and QCA
- (b) To generate normative data for dimension of normal coronary artery from computed tomographic coronary angiography (CT CAG) and its co-relation with IVUS and QCA.
- (c) To compare and correlate the measured LMCA diameter by IVUS, QCA and CT CAG with calculated LMCA diameter from Murray's law, Finet's law And Huo-Kassab's law.

3 METHODOLOGY

This is an observational study conducted at SCTIMST, Trivandrum, after Institutional Ethics Committee clearance included studies from May 2009-July 2022. All the consecutive cohort of patients who underwent IVUS guided PCI of the left coronary system including complete pullbacks of a LMCA, LAD and LCX for their clinical indications fulfilling inclusion criteria i.e., patients with CAD, who underwent CAG followed by PCI under IVUS guidance and had proximal disease-free coronary artery segments or minimal atheroma (<20% cross-sectional narrowing to nullify the remodeling effect), included if IVUS images from the LMCA, LAD and LCX available. Both CAG and IVUS study were used to identify normal segments of coronary artery. A sample size of 30 for IVUS study group and 30 for CTCAG group was determined. The exclusion criteria were those with disease in LMCA, proximal LAD as well as proximal LCX; non visibility of transition from aorta to LMCA ostium in IVUS; tortuous coronary vessels precluding IVUS examination; and past history of PCI or CABG of study vessels. IVUS examinations confined to RCA or graft vessels were also excluded.

Computed tomographic coronary angiography (CT CAG):

The patients aged above 18 years who had all proximal coronaries normal, in CT CAG done at SCTIMST, ISIR department during Apr 2012 to Jul 2022 were enrolled as CT CAG group. The collection of baseline data was done from hospital records and electronic medical records using consecutive sampling method. CT CAG was done

under supervision of radiologist using 256 slice helical scanner Brilliance iCT with retrospective ECG gating as per protocol. Two ml per kg of non-ionic, water-soluble Iohexol (350mg/ml) injection, at 5-6ml/sec followed by saline 50cc, 5ml per second administered. No adverse reactions to contrast were noted in any of the subjects. ECG gated CT CAG was done at a resting heart rate of 60 to 70bpm as per the guidelines (84-87). If the heart rate was more than 80bpm, it was pharmacologically controlled using 50mg of oral Metoprolol 1 hour before/ Ivabradine 15mg by mouth 1 hour before the scanning. In patients who had a history of reactive airway disease or known sensitivity to Metoprolol, 5-10mg of intravenous Diltiazem was used to control the rate. The images were acquired as per the standard guidelines. The measurements for LMCA caliber were taken at the mid segment in three-dimensional multiplanar reformat images to obtain true axial vessel. Similarly for LAD, LCX, and RCA the measurements were taken at 5mm from their origin using the same methodology. The dominance of the coronary circulation was noted by the origin of Posterior Descending

Artery (PDA), posterolateral branch (PLB)) and the vessel crossing crux. Any anomalies in origin, ectasia, spontaneous dissection was noted and such patients were excluded from the study. None of the CT CAG patients underwent IVUS study. All the measurements for epicardial coronary arteries from wall to wall were taken at the end diastole with magnified source image in axial plane using standard DICOM viewer software provided with the machine. The three-dimensional multiplanar reformat

images were used to obtain true axial vessel diameters. Maximal diameters of the vessel and diameter of vessel perpendicular to maximal diameter of vessel were taken and averaged to obtain respective vessel diameter. Thirty-six patients aged above 18

years who had all the proximal coronaries normal in CT CAG done at SCTIMST ISIR department were included in CT CAG group. The coronary artery images of CT CAG with methods of measurement are depicted in Figure 1, 2, 3, and 4 for LMCA, LAD, LCX and RCA respectively.

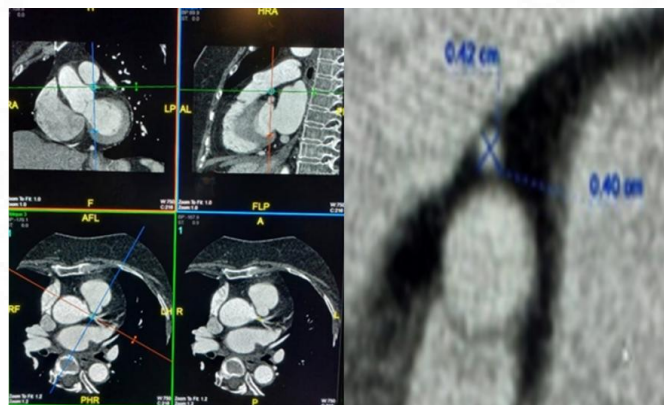


Figure 1. CT CAG: The images and method of measurement of LMCA

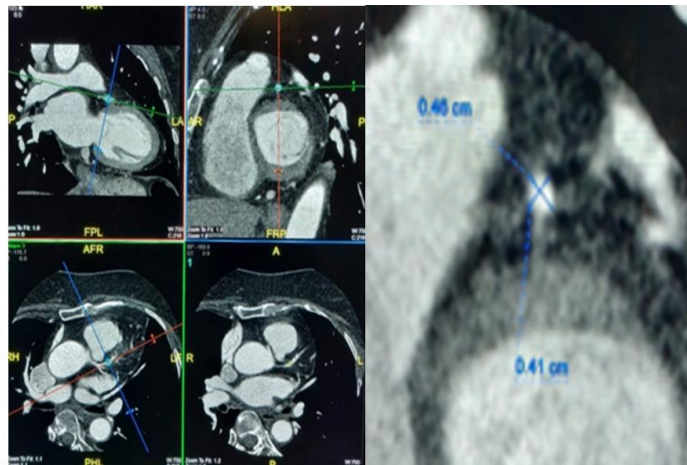


Figure 2. CT CAG: The images and method of measurement of LAD

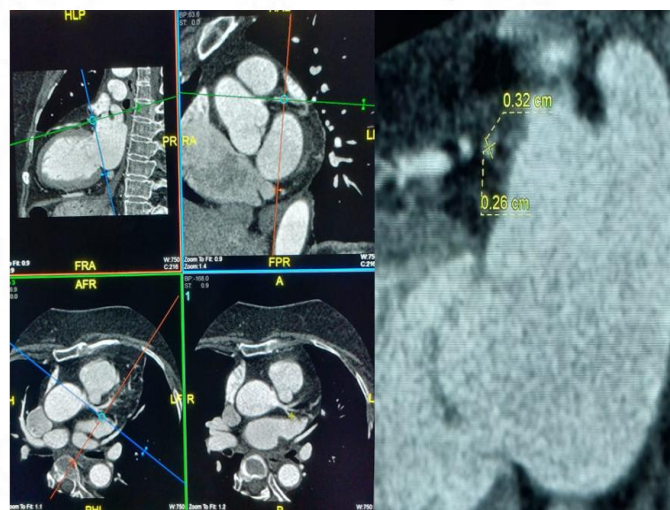


Figure 3. CT CAG: The images and method of measurement of LCX

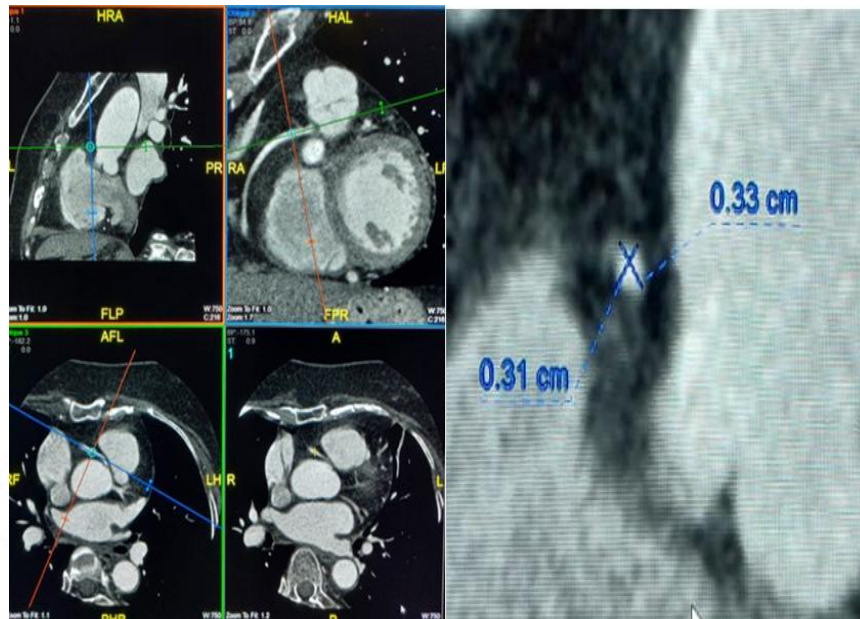


Figure 4. CT CAG: The images and method of measurement of RCA

Coronary Angiography, QCA, and IVUS:

A total 31 patients who underwent both angiography and IVUS examinations during PCI were enrolled in this study. Detailed retrospective review of medical records, coronary angiogram and IVUS study was made with standardized forms. Angiographic images were recorded at 15 frames/sec. IVUS pullback scans were performed at operator discretion, by manual pullback with a 20 MHz transducer catheter and 2.2 F imaging sheath (Volcano s5, Volcano Corporation, USA). Standard angiographic views (the right anterior oblique (RAO) 30-degree projection or antero-posterior (AP) caudal view or the left anterior oblique (LAO) caudal view whichever demarcated the left main bifurcation for LMCA LAD, and LCX the best)

were obtained. The proximal coronary artery segments evaluated are (a) proximal LAD segment before the first septal, (b) the proximal LCX segment before the first obtuse marginal (OM). The decision to intervene on a lesion is frequently made in the coronary catheterization laboratory based on the visual estimation of the lesion's severity. CAD with 70% stenotic lesion on visual quantification are considered to be hemodynamically significant and advised intervention. The IVUS examination starting 15 mm distal to the lesion till the aorto-ostial junction using a manual pull back was done before any balloon dilatation. PCI, if necessary, was performed as per standard procedure after IVUS. The normal vessel segments of interest were identified and measured on QCA and IVUS images and all images analyzed offline as discussed below.

(a) Quantitative coronary angiography (QCA):

The QCA analysis was performed offline using standard commercial software on workstation. All analyses were performed during the ECG-gated end-diastolic frame. A computer-assisted automatic contour detection using software was performed. The outer diameter of the contrast filled catheter served as the calibration standard. Angiographic views with the least foreshortening and yielding the best depiction were used. The edge detection correction was performed if required manually. Figure 5 shows QCA analysis which included calibration of contrast filled catheter, measurement LMCA, LAD, and LCX dimensions with display of maximum diameter, minimum diameter, mean diameter and length of assessed artery segment.

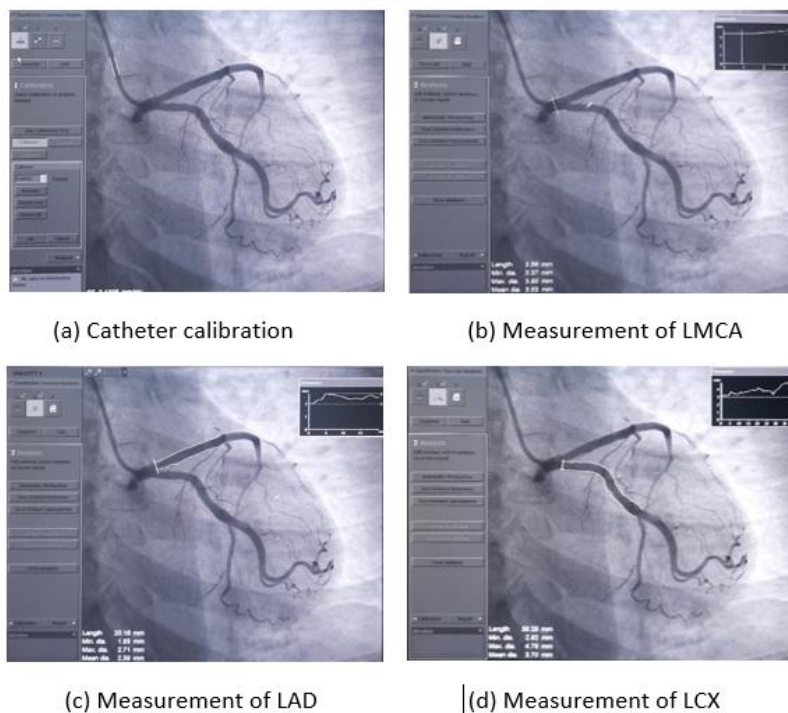


Figure 5. QCA analysis: calibration of contrast filled catheter (panel a), measurement LMCA in RAO caudal view (panel b), LAD in RAO caudal view (panel c), and LCX in RAO caudal view (panel d).

(b) Intravascular ultrasound:

A coronary segment was considered as diseased if the plaque burden by IVUS was $\geq 40\%$. Left main Ostium was defined as the first frame of proximal border of coronary vessel which contained a 360° luminal border. Distal LMCA was defined as the frame immediately proximal to the carina in which vessel has circular or oval shape. Distal LMCA was defined as the frame immediately proximal to the carina in which

vessel had circular or oval shape (that imaged the full circumference of LMCA before an

asymmetric lumen indicating the start of the bifurcation). Shaft of LMCA was defined as the segment between ostium and distal LMCA. The proximal LAD was defined as segment from ostium till before the first septal and the proximal LCX was segment from ostium till before the first obtuse marginal (OM). Lumen cross sections were measured in the disease-free or minimal atheroma segments from the ostium before any side branch. The edge detection correction was performed if required manually. The IVUS images were recorded and stored on a DVD-ROM for offline analysis. Quantitative analysis was performed in accordance with the ACC Clinical Expert Consensus Document on Standards for Acquisition, Measurement and Reporting of IVUS Studies (5). IVUS analysis was done using a validated and computerized software. After automatic border detection for the lumen and media-adventitia interface by the software, manually correction and confirmation were done, to obtain the results measured and displayed automatically. Validation of cross-sectional measurements of EEM, stent, lumen and plaque plus media (P+M) CSAs by IVUS have been previously reported (5). The term EEM i.e., media-adventitia border, which is a reproducible measure of the total arterial CSA. Since

media thickness cannot be measured accurately, percentage Plaque + Media (P+M) was used as a measure of atherosclerotic plaque burden. The following dimensions were assessed in coronary artery segments of disease free left main coronary artery, ostio-proximal LAD, and ostio-proximal LCX in patients; 1) MLD (mm); 2) EEM diameter (mm); 3) lumen

CSA (mm²); 4) EEM CSA (mm²); 5) P+M CSA (mm²) and 6) plaque burden (%).

The IVUS measured dimensions as shown in the figure 6.

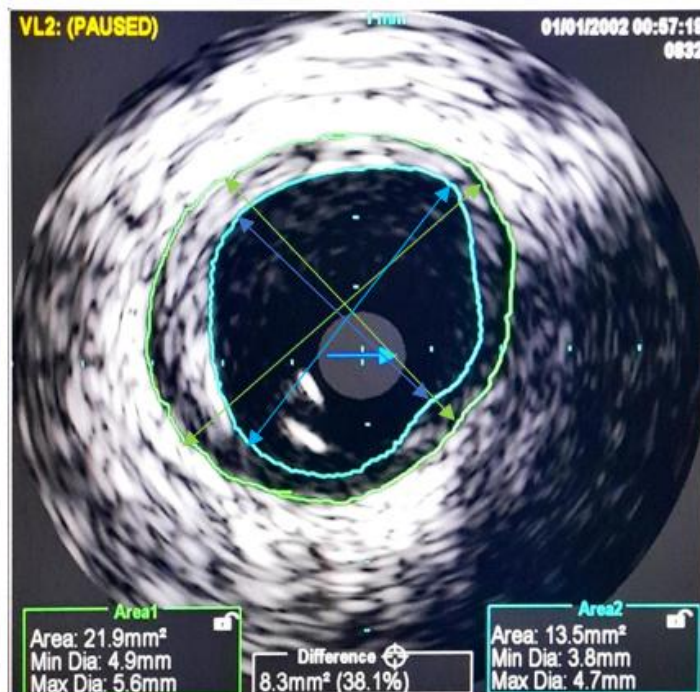


Figure 6. The depiction of IVUS measured dimensions. Mean luminal diameter;

MLD = 4.3mm, lumen cross sectional area = 13.5mm², plaque burden = 38%

Statistical analysis:

Data was analyzed using IBM SPSS statistics version 28.0 software. The continuous variables expressed were expressed in mean or median or range, with standard deviation as appropriate and categorical data was expressed in percentages. The vessel diameter (EEM to EEM) by IVUS was compared to CT CAG axial vessel diameters and mean luminal diameter by IVUS was compared to reference lumen diameter by

QCA using student 't' test. The relations between IVUS and QCA, IVUS and CT-CAG dimensions were analyzed with use of the Pearson's correlation and linear regression analysis. Multiple linear regression analysis was done to determine whether age, BSA, sex, diabetes, hypertension, smoking and family history of CAD was independently associated with coronary dimension. Body size being a confounding variable for coronary size, multiple regression analysis was again performed with the dependent variables in each model indexed for BSA. A value of $p < 0.05$ is considered to be statistically significant.

4 RESULTS

A total of 31 patients in IVUS /QCA group were eligible for analysis, of which 25 males and 6 were females. The proximal coronary segments analyzed includes, 31 LMCA, 15 proximal LAD, and 5 proximal LCX. A total of 36 patients in CT CAG group were eligible for analysis, of which 21 females and 15 were males. The proximal coronary segments analyzed includes, 31 LMCA, 31 proximal LAD, and 31 proximal LCX and 31 proximal RCA. The baseline demographic characters are as shown in Table1 for CT CAG group and IVUS group.

Baseline characteristics:

The IVUS group had mean age of 55.75 ± 10.9 years, mean height of 163.74 ± 7.9 kg, mean weight of 65.84 ± 6.28 kg, mean body mass index of 24.63 ± 2.54 kg/m², mean BSA of 1.71 ± 0.11 m² and males were 80.65%. The CT CAG group had mean age of 53.83 ± 9.6 years, mean height of 160.5 ± 8.79 kg, mean weight of 69.38 ± 10.94 kg,

mean body mass index of $27.08 \pm 5.34 \text{ kg/m}^2$, mean BSA of $1.72 \pm 0.14 \text{ m}^2$ and males were 41.67%. The baseline demographic characters of CT CAG group and for IVUS/QCA group shown in Table 1. The CT CAG group had hypertension in 44.4%, Diabetes in 19.4%, dyslipidemia in 36.1%, smoking in 5.6% and family history of CAD in 22.2%. IVUS/QCA group had hypertension in 58.1%, Diabetes in 41.9%, dyslipidemia in 61.3%, smoking in 58.1% and family history of CAD in 19.4%. Males had higher mean height ($p < 0.001$ vs 0.004) and BSA ($p = 0.011$ vs 0.017) compared to females

in CT CAG group and IVUS/QCA group with statistical significance. Males had higher smoking percentage (72%) in IVUS/QCA group with statistically significant difference ($p = 0.001$). Chronic stable angina (32.25%) was the predominant presentation in IVUS/QCA group. Anginal equivalents (36.1%) was the predominant presentation in CT CAG group. The ST-T changes on ECG were noted in 71% and 38.9% of patients in IVUS/QCA and CT CAG group respectively. The mean LVEF was $65 \pm 9\%$ and $61 \pm 12\%$ in CT CAG and IVUS/QCA group respectively. Regional wall motion abnormality was present in 38.7% in IVUS group and 5.6% of CT CAG group. There was no statistically significant difference observed for mode of presentation, LVEF, RWMA and on ECG changes between male and female in IVUS/QCA group. CT CAG group showed similar results except ECG changes where female had statistically significant more ST-T changes as compared to males (57.1% vs 13.3%, $p = 0.008$).

Table 1. Baseline demographic characters of CT CAG group and IVUS group

Parameter	CT CAG group Mean \pm SD	IVUS group Mean \pm SD	P value
Total number	36	31	
Age (years)	53.83 \pm 9.6	55.75 \pm 10.9	0.21
Height (cm)	160.50 \pm 8.79	163.74 \pm 7.9	0.059
Weight (kg)	69.38 \pm 10.94	65.84 \pm 6.28	0.051
BMI (kg/m ²)	27.08 \pm 5.34	24.63 \pm 2.54	0.009
BSA (m ²)	1.72 \pm 0.14	1.71 \pm 0.11	0.396
Diabetes, n (%)	16 (44.4%)	13 (41.9%)	0.418
Hypertension, n (%)	7 (19.4%)	18 (58.1%)	<0.001
Smokers, n (%)	2 (5.6 %)	18 (58.1%)	<0.001
Dyslipidemia (%)	13 (36.1%)	19 (61.3%)	0.002
Family history of CAD, n (%)	8 (22.2%)	6 (19.4%)	0.389

Analysis of baseline characteristics revealed, BMI was higher in CT CAG group compared to IVUS group with statistical significance (27.08 \pm 5.34kg/m² vs 24.63 \pm 2.54 kg/m², p= 0.009). IVUS group had statistically significant higher prevalence of hypertension (58.1% vs 19.4%, p=<0.001), smoking (58.1% vs 5.6 %, p=<0.001), and dyslipidemia (61.3% vs 36.1%, p=<0.001), compared to CT CAG group.

CT CAG analysis:

The CT CAG measured mean axial diameter of LMCA was 4.34 \pm 0.75mm, ostio-proximal LAD 3.65 \pm 0.54mm, ostio-proximal LCX 3.3 \pm 0.69mm, and ostio-proximal RCA 3.62 \pm 0.78mm and when adjusted to BSA values were 2.53 \pm 0.42mm/m², 2.13 \pm 0.35mm/m², 1.92 \pm 0.41mm/m² and 2.11 \pm 0.42mm/m² respectively (Table 2).

Table 2. Axial diameter of coronary vessels by CT CAG.

CT CAG	Axial diameters (mm)	Axial diameters (indexed to BSA) (mm/m²)
LMCA	4.34±0.75	2.53±0.42
Ostio-proximal LAD	3.65±0.54	2.13±0.35
Ostio-proximal LCX	3.3±0.69	1.92±0.41
Ostio-proximal RCA	3.62±0.78	2.11±0.42

CT CAG showed males had larger coronary artery diameter as compared to females (Fig 7). In females, the mean diameters were smaller than males in LMCA by 0.87mm, in ostio-proximal LAD by 0.38mm, in ostio-proximal LCX by 0.53mm, and in ostio-proximal RCA by 0.53 mm with statistical significance. When the coronary artery size was indexed to the BSA, there was no statistically significant difference except in LMCA (Fig 8).

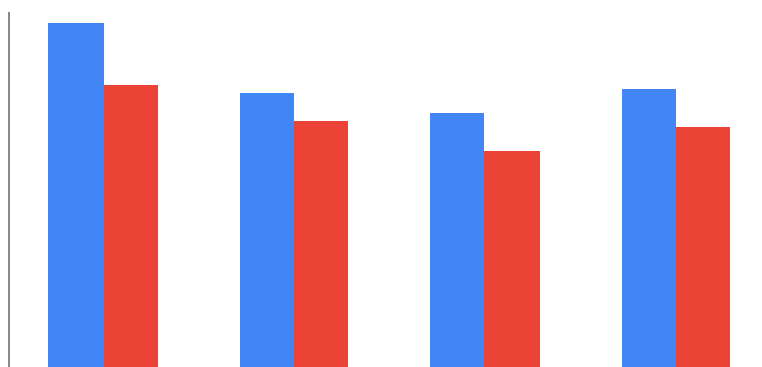


Figure 7. Coronary artery diameter by CT CAG (mm) without indexing to body surface area.

Figure 8. Coronary artery diameter by CT CAG (mm/m^2) indexed to body surface area.

On multiple linear regression analysis revealed gender was independent predictor for axial diameter ($\beta=-0.671$, $p=0.012$) and axial CSA ($\beta= -4.575$, $p=0.016$), when analysis was performed for indexed axial CSA ($\beta=-2.084$, $p=0.049$) gender remained independent predictor for LMCA model in CT CAG group (Table 3). For ostio-proximal LAD, ostio-proximal LCX and ostio-proximal RCA, no independent predictor was found for axial diameter, indexed axial diameters, axial CSA and indexed axial CSA. Neither age, diabetes, hypertension, dyslipidemia, smoking, nor

family history of CAD are independently correlated with any of the arterial measured dimensions.

Table 3. Multiple linear regression predicting axial CSA, indexed for BSA.

Characteristics	β	p-value
LMCA model		
Age	-0.016	0.809
Gender	-2.084	0.049
Hypertension	1	0.402
Diabetes	-1.073	0.368
Dyslipidemia	-1.001	0.357
Smoking	3.381	0.155
Family history of CAD	0.831	0.504
LAD model		
Age	-0.06	0.223
Gender	-0.383	0.615
Hypertension	0.588	0.507
Diabetes	-0.551	0.533
Dyslipidemia	-0.036	0.964
Smoking	0.337	0.847
Family history of CAD	0.608	0.512
LCX model		
Age	-0.017	0.75
Gender	-0.714	0.389
Hypertension	0.091	0.924
Diabetes	-0.753	0.432
Dyslipidemia	0.631	0.469
Smoking	1.928	0.31
Family history of CAD	0.283	0.777
RCA model		
Age	-0.017	0.75
Gender	-0.714	0.389
Hypertension	0.091	0.924
Diabetes	-0.753	0.432
Dyslipidemia	0.631	0.469
Smoking	1.928	0.31
Family history of CAD	0.283	0.777

Gender based comparison of axial vessel CSA in CT CAG group showed males had statistically significant larger axial CSA compared to females and when indexed CSA to BSA only LMCA showed larger diameter with statistical significance (Table 4)

Table 4. Comparison of axial vessel cross sectional area by CT CAG.

Dimensions: CT CAG	Males(N=15)	Females(N=21)	P Value
<i>Unindexed axial vessel CSA (mm²)</i>			
LMCA	18.87 ± 5.6	12.67 ± 3.71	<0.001
Ostio-proximal LAD	12.07 ± 3.87	9.71 ± 2.4	0.030
Ostio-proximal LCX	10.55 ± 3.62	7.74 ± 3.17	0.019
Ostio-proximal RCA	12.9 ± 7.77	9.19 ± 2.3	0.046
<i>Indexed to BSA, axial vessel CSA (mm²/m²)</i>			
LMCA	10.63 ± 3.31	7.56 ± 2.04	0.002
Ostio-proximal LAD	6.81 ± 2.32	5.84 ± 1.48	0.136
Ostio-proximal LCX	5.95 ± 2.16	4.64 ± 1.91	0.063
Ostio-proximal RCA	7.17 ± 4.17	5.52 ± 1.38	0.098

The prevalence of dominance of the epicardial coronary system pattern revealed 77.8% right dominance, 16.7% left dominance and 5.6% codominance pattern in CT CAG group. The mean LMCA length was 11.88±4.53mm, LMCA length more than 10mm seen in 61.1% and less than 10 mm in 38.9% of the CT CAG group.

IVUS analysis:

The IVUS measured mean lumen diameter (MLD) of LMCA 4.08±0.67mm, ostio-proximal LAD 3.31±0.70mm and ostio-proximal LCX 3.04±0.96mm and when

indexed to BSA are $2.40\pm 0.45\text{mm/m}^2$, $1.99\pm 0.53\text{mm/m}^2$, and $1.77\pm 0.58\text{mm/m}^2$ respectively (Table 5).

Table 5. MLD of coronary vessels by IVUS.

IVUS	MLD (mm)	MLD (indexed to BSA) (mm/m^2)
LMCA	4.08 ± 0.67	2.40 ± 0.45
Ostio-proximal LAD	3.31 ± 0.70	1.99 ± 0.53
Ostio-proximal LCX	3.04 ± 0.96	1.77 ± 0.58

The IVUS measured mean vessel (EEM) diameter of LMCA $4.35\pm 0.67\text{mm}$, ostio-proximal LAD $3.60\pm 0.69\text{mm}$ and ostio-proximal LCX $3.21\pm 0.74\text{mm}$; when indexed to BSA values are $2.57\pm 0.48\text{mm/m}^2$, $2.17\pm 0.54\text{mm/m}^2$, and $1.84\pm 0.47\text{mm/m}^2$ respectively (Table 6).

Table 6. Vessel (EEM) diameters of coronary vessel by IVUS.

IVUS	Vessel (EEM) diameters (mm)	Vessel (EEM) diameters (indexed to BSA) (mm/m^2)
LMCA	4.35 ± 0.67	2.57 ± 0.48
Ostio-proximal LAD	3.60 ± 0.69	2.17 ± 0.54
Ostio-proximal LCX	3.21 ± 0.74	1.84 ± 0.47

The mean lumen diameter and vessel diameter as assessed by IVUS was largest in LMCA, followed by ostio-proximal LAD, and ostio-proximal LCX. Both lumen CSA and EEM CSA showed no statistically significant difference between male and female for LMCA, ostio-proximal LAD, ostio-proximal LCX by IVUS (Table 7).

Table 7. Comparison of Lumen and EEM Cross sectional area by IVUS.

Dimensions: IVUS	Males(N=25)	Females(N=6)	P Value
<i>Unadjusted Lumen CSA (mm²)</i>			
LMCA	13.56 ± 4.18	12.99 ± 5.45	0.284
Ostio-proximal LAD	8.55 ± 3.09	9.76 ± 5	0.588
Ostio-proximal LCX	4.86 ± 0.48	13.5	14.671
<i>Adjusted to BSA, Lumen CSA (mm²/m²)</i>			
LMCA	7.96 ± 2.72	8.42 ± 3.6	0.346
Ostio-proximal LAD	4.98 ± 1.83	6.5 ± 3.53	1.118
Ostio-proximal LCX	2.82 ± 0.4	7.94	10.382
<i>Unadjusted EEM CSA (mm²)</i>			
LMCA	15.3 ± 4.76	14.87 ± 4.94	0.198
Ostio-proximal LAD	10.01 ± 3.43	11.53 ± 5.27	0.679
Ostio-proximal LCX	6.65 ± 1.31	15.54	6.058
<i>Adjusted to BSA, EEM CSA (mm²/m²)</i>			
LMCA	8.86 ± 2.83	9.46 ± 3.67	0.443
Ostio-Proximal LAD	5.84 ± 2.07	7.46 ± 3.94	1.061
Ostio-proximal LCX	3.76 ± 0.76	9.14	6.357

Multiple linear regression analysis in IVUS study group showed family history of CAD was independently associated with lumen diameter ($\beta = -0.419$, $p = 0.033$) and lumen CSA ($\beta = -0.44$, $p = 0.022$), and lumen area indexed to BSA ($\beta = -0.44$, $p = 0.025$) for LMCA model. The average plaque burden (%) detected in IVUS group was 12.08 ± 7.4 in LMCA, 15.77 ± 6.0 in Ostio-Proximal LAD and 18.15 ± 7.2 in ostio-proximal LCX. LMCA length could not be measured as all the IVUS procedure was done by manual pullback.

QCA analysis:

QCA measured mean lumen diameter of LMCA 4.18 ± 0.70 mm, LAD 3.44 ± 0.38 mm, LCX 3.20 ± 0.55 mm, and when indexed to BSA are 2.45 ± 0.47 mm/m², 2.03 ± 0.45 mm/m², and 1.89 ± 0.38 mm/m² respectively (Table 8).

Table 8. MLD of coronary vessel by QCA.

QCA	MLD (mm)	MLD (indexed to BSA) (mm/m ²)
LMCA	4.18 ± 0.70	2.45 ± 0.47
Ostio-proximal LAD	3.44 ± 0.38	2.03 ± 0.45
Ostio-proximal LCX	3.20 ± 0.55	1.89 ± 0.38

The mean diameter as assessed by QCA was largest in LMCA, followed by ostio-proximal LAD, and ostio-proximal LCX. Lumen CSA showed no statistically significant difference between male and female for LMCA, ostio-proximal LAD, ostio-proximal LCX by QCA (Table 9).

Table 9. Comparison of Lumen CSA by QCA

Dimensions: QCA	Males(N=25)	Females(N=6)	P Value
Unadjusted Lumen CSA (mm ²)			
LMCA	13.81 ± 4.7	15.12 ± 4.32	0.545
Ostio-proximal LAD	9.24 ± 3.35	10.79 ± 2.09	0.295
Ostio-proximal LCX	8.36 ± 3.19	7.93 ± 1.46	0.748
Adjusted to BSA, Lumen CSA (mm ² /m ²)			
LMCA	8.09 ± 2.88	9.08 ± 2.80	0.454
Ostio-proximal LAD	5.48 ± 2.27	6.44 ± 1.28	0.335
Ostio-proximal LCX	4.93 ± 2.06	4.69 ± 0.58	0.782

Multiple linear regression analysis in QCA group could not identify any independent predictors for measured dimensions for LMCA, ostio-proximal LAD, and ostio-proximal LCX. The prevalence of dominance of the epicardial coronary pattern revealed 64.86% right dominance and 22.58% left dominance pattern in QCA/IVUS

group. The mean LMCA length was 11.85 ± 3.19 mm, LMCA length more than 10 mm seen in 80.65% and less than 10 mm in 19.35% by QCA.

Comparison between studies:

IVUS versus QCA comparison: mean lumen diameter

There is no statistically significant difference between MLD measured by IVUS and QCA for both unindexed and indexed to BSA diameters. However, there was an excellent linear correlation between IVUS and QCA for mean lumen diameter for LMCA, Ostio-Proximal LAD, and Ostio-Proximal LCX (Table 10).

Table 10. Comparison of MLD by IVUS and QCA.

Dimensions	MLD by IVUS	MLD by QCA	R -Value	P -Value
<i>Unindexed MLD (mm)</i>				
LMCA	4.08 ± 0.67	4.18 ± 0.70	0.95	0.55
Ostio-proximal LAD	3.31 ± 0.70	3.44 ± 0.38	0.99	0.34
Ostio-proximal LCX	3.04 ± 0.96	3.20 ± 0.55	0.99	0.39
<i>Indexed to BSA, MLD (mm/m²)</i>				
LMCA	2.40 ± 0.45	2.45 ± 0.47	0.95	0.64
Ostio-proximal LAD	1.99 ± 0.53	2.03 ± 0.45	0.99	0.71
Ostio-proximal LCX	1.77 ± 0.58	1.89 ± 0.38	0.99	0.31

IVUS versus CT CAG comparison: mean vessel diameter

There is no statistically significant difference between vessel diameter measured by IVUS and by CT CAG for both unindexed and indexed to BSA diameters. However,

there was an excellent correlation between IVUS and CT CAG for vessel diameter for LMCA, Ostio-Proximal LAD, and Ostio-Proximal LCX (Table 11).

Table 11. Comparison of EEM diameter by IVUS and axial vessel diameter by CT CAG.

Dimensions	EEM diameter IVUS	Axial diameter QCA	T -Value	P -Value
<i>Unindexed diameters (mm)</i>				
LMCA	4.35±0.67	4.34± 0.75	0.019	0.985
Ostio-proximal LAD	3.60±0.69	3.65± 0.54	0.276	0.784
Ostio-proximal LCX	3.21±0.74	3.3± 0.69	0.260	0.796
<i>Indexed to BSA, diameters (mm/m²)</i>				
LMCA	2.57±0.48	2.53 ±0.42	0.407	0.686
Ostio-proximal LAD	2.17±0.54	2.13 ± 0.35	0.262	0.795
Ostio-proximal LCX	1.84± 0.47	1.92 ± 0.41	0.441	0.662

Analysis of correlation of measured diameter of LMCA with calculated diameter of LMCA using Murray's law, Finet's law and Huo-Kassab's law:

CT CAG showed higher calculated LMCA diameter by Murray's, Finet's law and Huo-Kassab's Law when correlated to measured LMCA diameter, however linear strong correlation between measured and calculated LMCA diameter was noted (Table 12).

Table 12. CT CAG comparison and correlation of calculated and measured LMCA diameters.

CT CAG	Calculated axial LMCA diameter (mm)	Measured axial LMCA diameter (mm)	R- value	P- value
Murray's law	4.43±0.67	4.34± 0.75	0.763	<0.001
Finet's law	4.71±0.73	4.34± 0.75	0.752	<0.001
Huo-Kassab's law	4.74±0.72	4.34± 0.75	0.761	<0.001

The Bland-Altman plot for CT CAG showed the mean bias ±SD between Measured LMCA and the LMCA assessed by Murray's law in **Figure 9 (a)** as -0.085 ± 0.50 mm, and the limits of agreement were -1.07 and 0.90 mm. The average of the differences is -0.085 mm. The data suggest that on average LMCA assessed by Murray's law

measures 0.085 units more than the actual measurements as mean difference is nonzero. However, the differences were very close to zero the Murray's methods has good agreement with measured values.

Bland-Altman Plot LMCA calculated by Murray's law with Measured LMCA

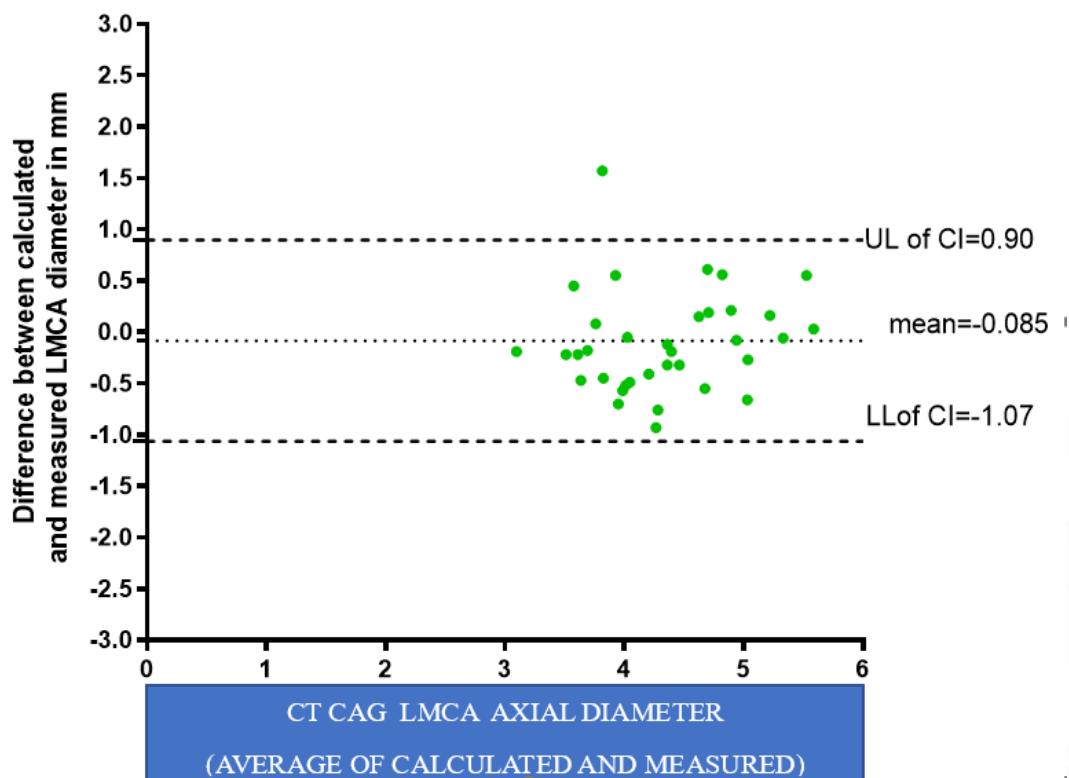


Figure 9(a) Bland-Altman plot for CT CAG analysis of correlation of measured diameter of LMCA with calculated diameter of LMCA using Murray's law,

The Bland-Altman plot for CT CAG showed the mean bias \pm SD between Measured LMCA and the LMCA assessed by Finet's law in **Figure 9 (b)** as -0.367 ± 0.524 , and the limits of agreement were -1.40 and 0.66 . The average of the differences is -0.367 units. The data suggest that on average LMCA assessed by Finet's law

measures 0.367 units more than the actual measurements as mean difference is nonzero. However, the differences were not close to zero. The Finet's methods had no good agreement with measured values.

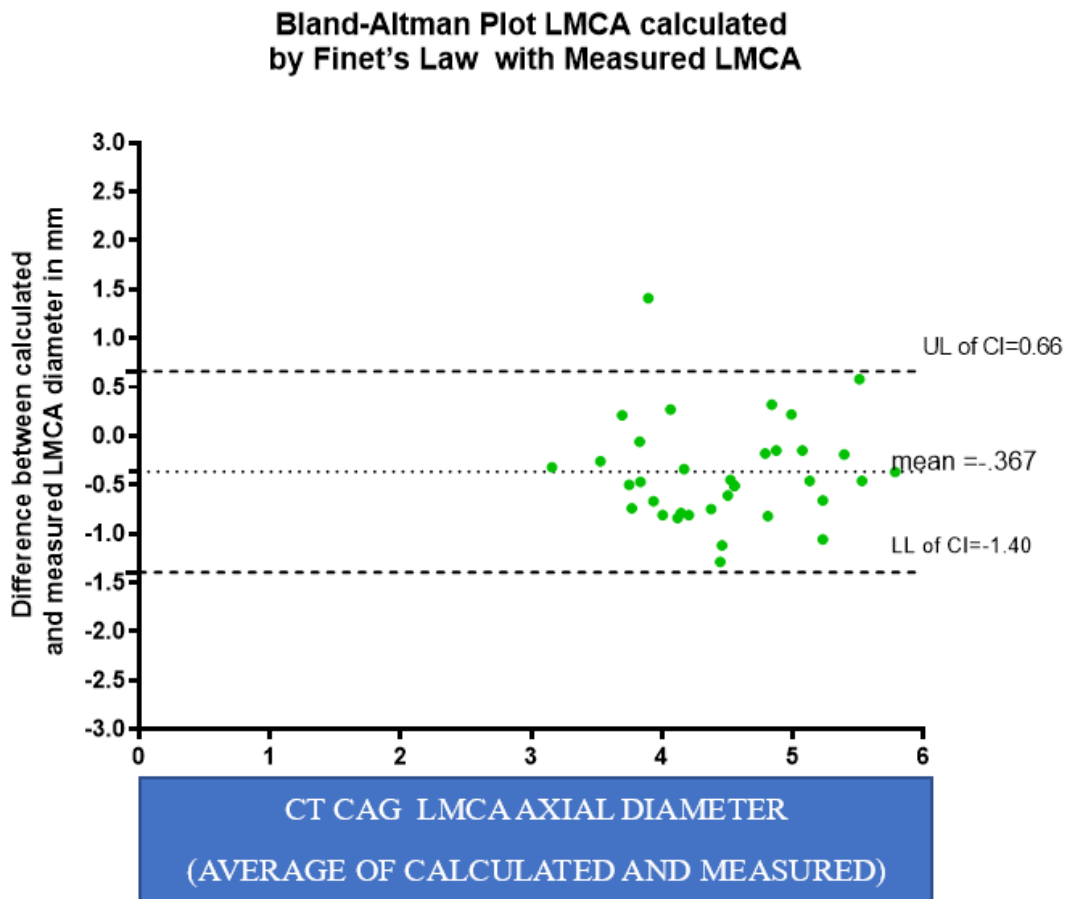


Figure 9(b) Bland-Altman plot for CT CAG analysis of correlation of measured diameter of LMCA with calculated diameter of LMCA using Finet's law,

The Bland-Altman plot for CT CAG showed the mean bias \pm SD between Measured LMCA and the LMCA assessed by Huo-Kassab's law in **Figure 9 (c)** as -0.392 ± 0.513 , and the limits of agreement were -1.40 and 0.61 . The average of the differences is -0.392 units. The data suggest that on average LMCA assessed by

Huo-Kassab's law measures 0.392 units more than the actual measurements as mean difference is nonzero. However, the differences were not close to zero. Huo-Kassab's law had no good agreement with measured values.

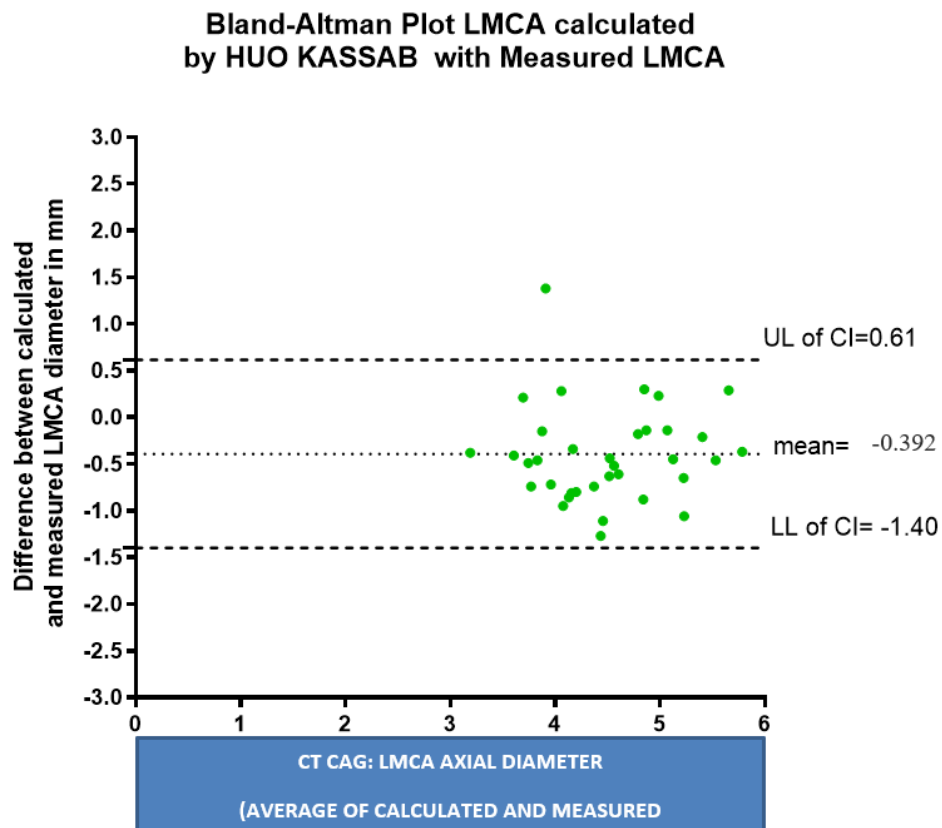


Figure 9(c) Bland-Altman plot for CT CAG analysis of correlation of measured diameter of LMCA with calculated diameter of LMCA using Huo-Kassab's law,

The IVUS measured LMCA correlation to Murray's law, Finet's law and Huo-Kassab's Law could not be done because study had only one sample having pullback of both LAD and LCX into LMCA.

The QCA analysis showed higher calculated LMCA diameter by three above laws with moderate linear correlation for Murray's Law and Finet's and Huo-Kassab's law for measured and calculated LMCA diameter (Table 13).

Table 13. QCA comparison and correlation of calculated and measured LMCA diameters.

QCA	Calculated axial LMCA diameter (mm)	Measured axial LMCA diameter (mm)	R-value	P-value
Murray's law	4.15± 0.7	4.18±0.70	0.578	0.001
Finet's law	4.45 ± 0.7	4.18±0.70	0.576	0.001
Huo-Kassab's law	4.43 ± 0.7	4.18±0.70	0.579	0.001

The Bland-Altman plot for QCA showed the mean bias ±SD between Measured LMCA and the LMCA assessed by Murray's law in **Figure 10(a)** as -0.034 ± 0.61 , and the limits of agreement were -1.24 and 1.17 . The average of the differences is

-0.034 units. The data suggest that on average LMCA assessed by Murray's law measures 0.034 units more than the actual measurements as mean difference is nonzero. However, the differences were very close to zero. The Murray's methods had good agreement with measured values.

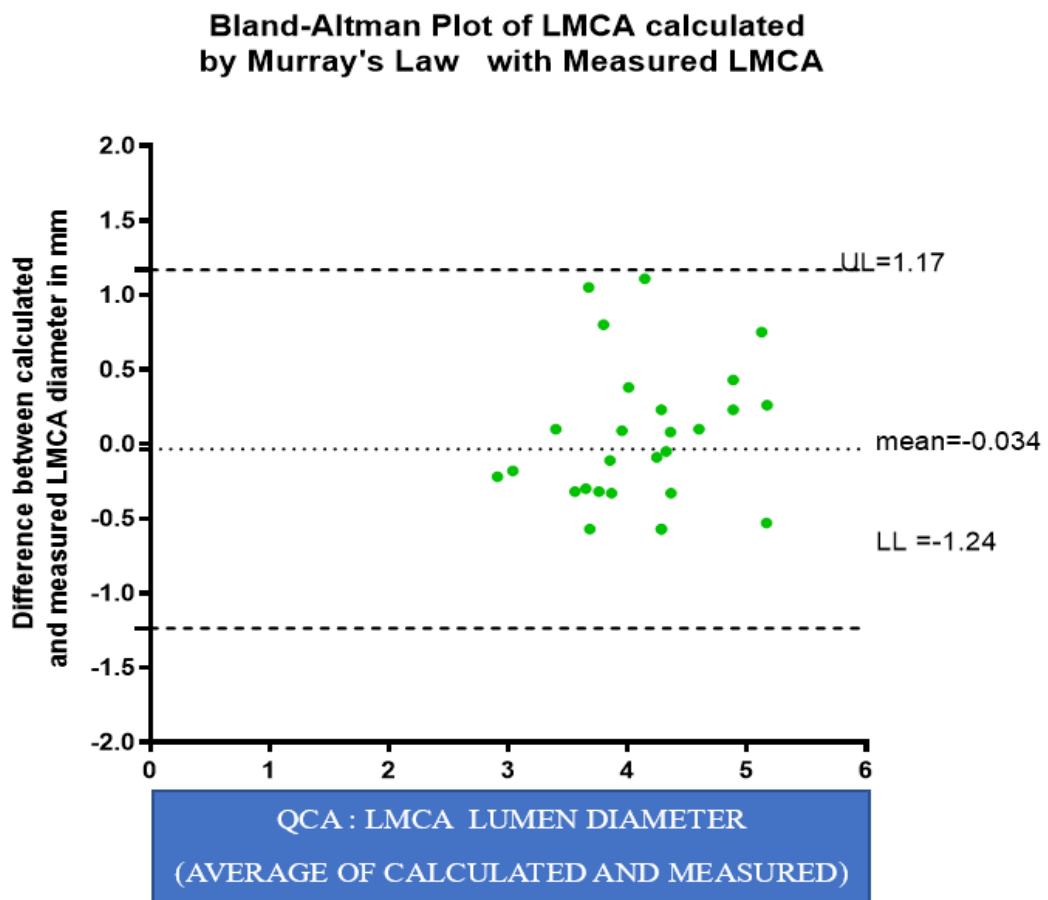


Figure 10(a): Bland-Altman plot for QCA analysis of correlation of measured diameter of LMCA with calculated diameter of LMCA using Murray's law

The Bland-Altman plot for QCA showed the mean bias \pm SD between Measured LMCA and the LMCA assessed by Finet's law **Figure10(b)** as -0.334 ± 0.636 , and

the limits of agreement were -1.58 and 0.913 . The average of the differences is -0.334 units. The data suggest that on average LMCA assessed by Murray's law measures 0.334 units more than the actual measurements as mean difference is nonzero. However, the differences were not close to zero. The Finet's methods had no good agreement with measured values.

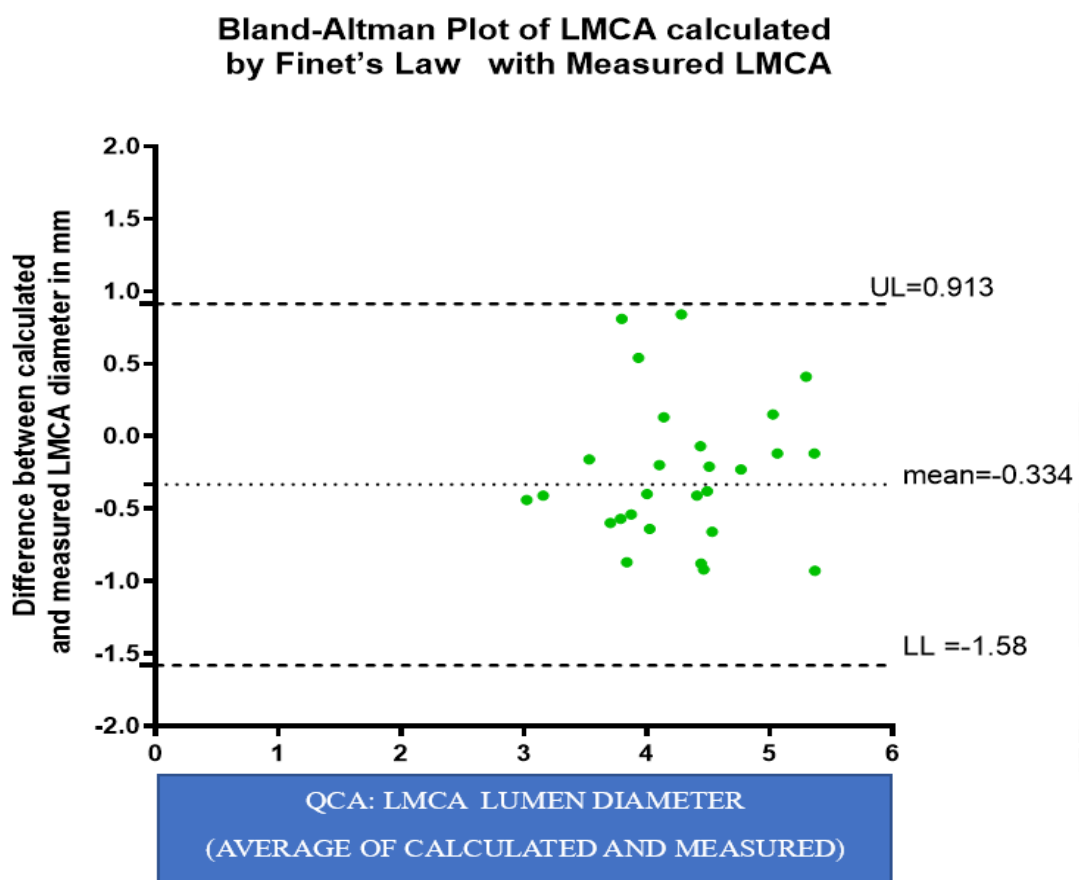


Figure 10(b): Bland-Altman plot for QCA analysis of correlation of measured diameter of LMCA with calculated diameter of LMCA using Finet's law

The Bland-Altman plot for QCA showed the mean bias \pm SD between Measured LMCA and the LMCA assessed by Huo-Kassab's law **Figure 10(c)** as -0.332 ± 0.636 , and the limits of agreement were -1.578 and 0.914 . The average of the differences is

-0.332 units. The data suggest that on average LMCA assessed by Huo-Kassab's law measures 0.332 units more than the actual measurements as mean difference is nonzero. However, the differences were not close to zero. Huo-Kassab's law had no good agreement with measured values.

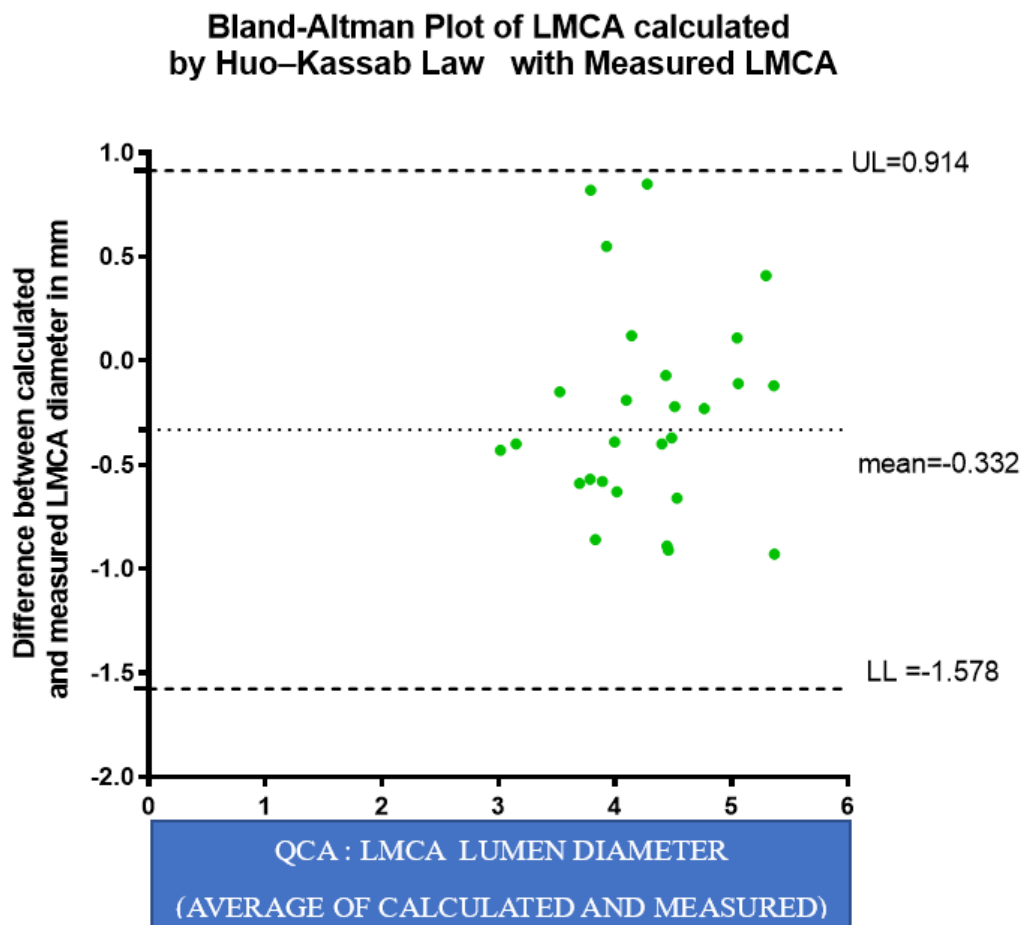


Figure 10(c) Bland-Altman plot for QCA analysis of correlation of measured diameter of LMCA with calculated diameter of LMCA using Huo-Kassab's law

CTCAG study comparison with Indian and western studies:

The CT CAG results comparison of our study with a study by Mahadevappa M et al, showed larger diameters for LMCA, LAD and LCX both unindexed and indexed to BSA diameters and P K Goel et al study shown similar results comparable with our study with minor variations (Table 14). The comparison with western data by Jaroslaw Skowronski et al, a Poland study showed for unadjusted diameters Indians has smaller size coronary arteries compared to western population (Table 15).

Table 14. CTCAG study comparison with Indian studies.

Parameters	Jayadeva institute data(n=168)		Our data (N=36)		p- value	
	Unindexed (mm)	Indexed (mm/m ²)	Unindexed (mm)	Indexed (mm/m ²)	Unindexed	Indexed
LMCA	4.08±0.29	2.32±0.13	4.34±0.75	2.53±0.42	<0.01	<0.01
LAD	3.39±0.27	1.94±0.16	3.65±0.54	2.13±0.35	<0.01	<0.01
LCX	3.05±0.37	1.74±0.21	3.3±0.69	1.92±0.41	<0.01	<0.01
RCA	3.17±0.34	1.82±0.21	3.62±0.78	2.11±0.42	<0.01	<0.01

Table 15. CTCAG study comparison with western studies.

Parameters	Poland study Skowronski J et al (n=201) Unindexed(mm)	Our data (N=36) Unindexed(mm)	P -value
LMCA	5.1±0.7	4.34±0.75	<0.01
LAD	3.9±0.5	3.65±0.54	<0.01
LCX	3.6±0.7	3.3±0.69	<0.01
RCA	4.1±0.6	3.62±0.78	<0.01

IVUS study comparison with other Indian and western studies:

The comparison with study by Reddy et al, our study population had smaller LMCA and LCX diameters but LAD diameters were similar. P K Goel et al, SGPGI study shown similar results comparable with our study with minor variations (Table 16). The comparison with western data by Junbe Ge et al showed Indians has smaller size coronary arteries compared to western population (Table 17).

Table 16. IVUS study comparison with other Indian studies.

	PGI data (n=303)		SGPGI data (n=220)		Our data(n=31)		p- value	
	Unindexed (mm)	Indexed (mm/m ²)	Unindexed (mm)	Indexed (mm/m ²)	Unindexed (mm)	Indexed (mm/m ²)	Unindexed	Indexed
LMCA	4.66±0.69	2.64±0.40	4.33± 0.32	2.30	4.35±0.67	2.57±0.48	0.019	<0.001
LAD	3.71±0.60	2.15±0.35	3.61±0.21	2.13	3.60±0.69	2.17±0.54	0.346	0.061
LCX	3.55± 0.56	2.05±0.30	3.31±0.16	1.95	3.21±0.74	1.84±0.47	0.002	<0.001

Table 17. IVUS study comparison with western studies.

Parameters	Junbe Jo et al Germany study (n=55), Unindexed (mm)	Our data (n=31) Unindexed (mm)
LMCA	4.76	4.35±0.67
LAD	4.14	3.60±0.69
LCX	-	3.21±0.74

QCA study comparison with other Indian and western studies:

The comparison of our study with other Indian studies showed similar coronary artery diameters with minor variation for LCX between the studies (Table 18). The comparison with western data by J T Dodge et al showed our study population has smaller size coronary arteries compared to western population for LMCA and LAD, but LCX size remained similar to western population (Table 19).

Table 18. QCA study comparison with Indian studies.

Parameters	PGI (N=303) Unindexed (mm)	SGPGI data (N=220) Unindexed (mm)	Narayan Hrudayalaya (n=229) Unindexed (mm)	Our data (N=36) Unindexed (mm)	p- value
LMCA	4.5±0.79	3.89± 0.25	4.08 ± 0.44	4.18±0.70	0.999
LAD	3.7+0.4	3.36± 0.28	3.27 ± 0.23	3.44±0.38	0.063
LCX	3.4±0.5	2.85± 0.27	2.97 ± 0.37	3.20±0.55	0.001

Table 19. QCA study comparison with western studies.

Parameters	Washington study. J. T Dodge et al (n=83), Unindexed (mm)	Our data (N=36), unindexed (mm)	p-value
LMCA	4.5±0.5	4.18±0.70	0.006
LAD	3.7+0.4	3.44±0.38	0.001
LCX	3.4±0.5	3.20±0.55	0.054

5 DISCUSSION

The salient findings of this study are as follows: (a) IVUS and QCA measured coronary artery dimensions were similar between males and females even after indexing to BSA; (b) CT CAG showed statistically significant smaller coronary artery sizes in females; when indexed to the BSA, there was no statistically significant difference for LAD and LCX except for LMCA; (c) the gender and family history of CAD were independent predictors of coronary artery size and area in LMCA in CT CAG and IVUS study respectively; (d) comparison of CTCAG and QCA showed the higher calculated LMCA diameter by Murray's, Finet's law and Huo- Kassab's Law, with excellent linear correlation by CT CAG and moderate linear correlation by QCA for measured and calculated LMCA diameter; and (e) the coronary artery dimensions were smaller in our study population compared to western population.

The knowledge of actual size of coronary artery has prime importance during interventional or surgical procedures. It is well known that bulk of the lesions in acute coronary syndromes involve the ostio-proximal segments of the epicardial coronary arteries and put significant amount of myocardium at risk (58-60). The awareness of the dimensions aid in selection of balloons, devices and stents before planning and during the coronary interventions. Epicardial arteries with smaller size tend to decrease the atheroma burden required for significant obstructive coronary lesions to develop and further augments technical challenges during intervention or surgical procedures (61). Luminal angiogram is a well-established method for assessment of the extent and severity of lesion but has its own several limitations

(62). A considerable variability in the visual interpretation of cine-angiograms has been established by multiple studies (63-65). Computer analysis of digital images and automatic edge detection algorithms are used in QCA, but the validity of quantification by this method is also questionable (64-66). Various discrepancies have been noted between coronary angiogram and autopsy findings (67). In this context, IVUS imaging has advantage of precisely defining the vessel size and areas. Various studies have shown coronary dimensions are highly variable in normal population (2,3). Age, gender, weight, BSA, mass of heart, genetic factors, race, ethnic background, and environmental factors, have all been correlated with the coronary artery size (3,49,68-72). Studies have reported smaller coronary artery dimensions in Indians compared to the western population, (50, 73) which has been attributed to the body size and relatively smaller BSA (35). Raut et al., observed similar results, where in coronary artery sizes were larger in Caucasians as compared to Indians, but no difference after indexing for BSA (52).

Our QCA study population had smaller size coronary arteries compared to western population for LMCA and LAD, but LCX size remained similar to western population. The diameter as measured by IVUS were significantly smaller than diameters measured by QCA. There was an excellent linear correlation between IVUS and QCA for measured mean lumen diameter for LMCA, ostio-proximal LAD, and ostio-proximal LCX. These results are contrary to previous studies by S Reddy et al (74) and P K Goel et al (75) both of which showed coronary artery diameters when assessed by IVUS were significantly larger than the QCA. Previously published studies from India, that assessed QCA showed that males had statistically larger coronary

dimension in comparison with females, but there was no difference after indexing to BSA (50,52). However, Elangovan et al noted small coronary size in females after correction for BSA (55). Postmortem examination study data in human revealed smaller coronary vessel size in females (56). A CABG study, found that females had smaller coronary vessel dimension and was associated with increased mortality (76). The association of gender with coronary vessel diameter is consistent with prior pathologic and angiographic studies. But our present study by IVUS and QCA showed no difference in coronary artery diameters between males and females even after indexing to BSA. This finding is probably due to smaller sample size of LCX in females. Kornowski et al (77) also found no difference in vessel diameters between the genders after indexing for BSA in his IVUS study, but this study was limited by the selection of several different vessel locations that may not be completely free of disease always. Our study negates the general belief that women have smaller coronary size. The BSA and gender were reported to be independent predictors of left main coronary artery size (78). Sheifer et al. observed gender difference in coronary size in LMCA and LAD (79). Our study identified gender and family history of CAD as independent predictors of coronary artery size in CT CAG and IVUS study group respectively for LMCA, but body surface area and age were not independent predictors of coronary artery size and area. Our study did not identify, age, body surface area, hypertension, diabetes mellitus, smoking, and dyslipidemia as independent predictors of coronary artery size and area.

The size of coronary arteries are smaller in our study population compared to western population (78,80). Abizaid et al study on western population showed Mean EEM diameter at left main 5.44mm, as compared to 4.35mm in our study (37). Venkateshwaran S et al, also found out that left main reference segment- lumen and EEM diameter in Indians was lesser than that of western population (57). The absolute diameter is lesser than the previously published studies in western population, probably due to low BSA (50, 68).

The important concept to understand a bifurcation lesion is the relationship between the sizes of these vessels. There are three formulas from which we can calculate size of main vessel i.e., Murrey's law ($D_{\text{Proximal main vessel}}^3 = D_{\text{Distal main vessel}}^3 + D_{\text{Side branch vessel}}^3$), Finet's Law ($D_{\text{Proximal Vessel}} = 0.678 \times (D_{\text{Main Branch}} + D_{\text{Side Branch}})$) and Huo-Kassab's Law ($D_{\text{Proximal Vessel}}^{7/3} = D_{\text{Main Branch}}^{7/3} + D_{\text{Side Branch}}^{7/3}$). Murrey's law is applicable in normal and diseased bifurcations, which was proved by the IVUS study (81) But this law is not applicable in calcific lesions and in situations like acute coronary syndrome (ACS). In these two conditions, the size of the vessel is to be assessed by IVUS. Finet's law is derived from the angiograms of normal bifurcation by quantitative analysis (82). In this study we attempted to compare and correlate calculated LMCA diameter by Murray's, Finet's and Huo-Kassab's Law, versus measured LMCA diameter by IVUS, QCA and CT CAG. CTCAG study and QCA study analysis showed higher calculated LMCA diameter using these three laws with excellent linear correlation by CT CAG and moderate linear correlation by QCA for measured and calculated LMCA diameter. However, these laws could not be tested in IVUS study as only one patient had pullback study from both LAD and LCX. The Bland-Altman plot showed LMCA size calculation by Murray's method has good

agreement with measured values, whereas Finet's law and Huo-Kassab's Law calculated LMCA size had no good agreement with measured LMCA size value in both CT CAG and QCA group. When implementing this law in kissing balloon technique, the cross-sectional area of both balloons together is larger than the cross-sectional area of the proximal main vessel (MV). So, to prevent injury to the proximal MV, moderate pressure inflation of two balloons is better as observed by Niemela M et al (83). Our study supports these findings of Niemela M et al. So, it is better to assess the size of the vessels by IVUS, than derive the value from these laws.

Limitations of the study:

This was a single tertiary center study with smaller sample size. Females were proportionately less in IVUS/QCA group. All coronary artery segments were not analyzed in a single individual. The coronary sites compared by IVUS and QCA may not have been exactly identical as IVUS analysis was done with manual pull-back. Though it will not affect the area analysis, it would have guided us measuring the length of vessel/lesion and aided in acquiring dimension at identical region. Landmarks such as side branches were used to identify the measurement region. Only one sample included both LAD and LCX pull back which was insufficient to calculate the correlation and statistical significance between measured LMCA diameter and calculated LMCA based on Murray's law, Finet's law and Huo-Kassab's law for IVUS study group. Eccentricity of the vessel could also affect the mean diameter assessment, when only orthogonal values are obtained.

6 SUMMARY AND CONCLUSIONS

- The LMCA diameter as measured by IVUS is 4.35 ± 0.67 mm, QCA is 4.18 ± 0.70 mm and by CT CAG is 4.34 ± 0.75 mm.
- The LAD diameter as measured by IVUS is 3.60 ± 0.69 mm, QCA is 3.44 ± 0.38 mm and by CT CAG is 3.65 ± 0.54 mm.
- The LCX diameter as measured by IVUS is 3.21 ± 0.74 mm, QCA is LCX 3.20 ± 0.55 mm and by CT CAG is LCX 3.3 ± 0.69 mm.
- RCA diameter as measured by CT CAG is 3.62 ± 0.77 mm.
- The IVUS and QCA measured coronary artery dimensions are similar between males and females, even after indexing to BSA. Females had smaller indexed LMCA diameters than males by CTCAG.
- Sex and family history of CAD are independent predictors of coronary artery size and area for LMCA in CT CAG and IVUS study respectively.
- The calculated diameters for LMCA using the various formulae were higher than the actually measured diameters.
- The coronary artery dimensions are smaller in our study population compared to western population.

7 REFERENCES

1. Prabhakaran D et al (2016). Cardiovascular diseases in India: current epidemiology and future directions. *Circulation* 133:1605-1620.
2. Hermiller JB et al (1992). Quantitative and qualitative coronary angiographic analysis: review of methods, utility, and limitations. *Cathet Cardiovasc Diagn* 25:110-131.
3. Restrepo C et al (1973). Postmortem dimensions of the coronary arteries in different geographic locations. *Lab Investig* 28: 244-251.
4. Takayama T and Hodgson JM (2001). Prediction of the physiologic severity of coronary lesions using 3D IVUS: validation by direct coronary pressure measurements. *Cathet Cardiovasc Interv.* 53:48-55).
5. Mintz GS et al (2001). American College of Cardiology Clinical Expert Consensus Document on Standards for Acquisition, Measurement and Reporting of Intravascular Ultrasound Studies (IVUS). *J Am Coll Cardiol* 37: 1478-1492.
6. Laurens J. C. et al (2019). References for left main stem dimensions: A cross sectional intravascular Ultrasound analysis. *Catheter Cardiovasc Interv* 92:233–238.
7. Junbo Ge et al (1994). Intravascular ultrasound imaging of angiographically normal coronary arteries: a prospective study in vivo. *BrHeart* 3(71): 572-578.

8. Ellis S et al (1988). Prediction of risk of anterior myocardial infarction by lesion severity and measurement method of stenoses in the left anterior descending coronary distribution: a CASS Registry study. *J Am Coll Cardiol* 11: 908-916.
9. Little WC et al (1988). Can coronary angiography predict the site of a subsequent myocardial infarction in patients with mild-to-moderate coronary artery disease? *Circulation* 78: 1157-1166.
10. Vogel, RA. et al (1988). Assessing stenosis significance by coronary arteriography: are the best variables good enough? *J Am Coll Cardiol* 12. 692-693.
11. Luis Gruberg et al (1999). Intravascular Imaging and Physiologic Lesion assessment to Define Critical Coronary Stenoses. *Ann Thorac Surg* 68. 1547-1551.
12. DeRouen TA et al (1977). Variability in the analysis of coronary arteriograms. *Circulation* 1: 324-328.
13. Bertrand ME et al (1993). Discordant results of visual and quantitative estimates of stenosis severity before and after coronary angioplasty. *Cathet Cardiovasc Diagn* 28: 1-6.
14. Flemming RM et al (1991). Patterns in visual interpretation of coronary arteriograms as detected by quantitative coronary arteriography. *J Am Coll Cardiol* 18: 945-51.
15. Waters D, et al (1991). Regression of coronary atherosclerosis: an achievable goal? Review of results from recent clinical trials. *Am J Med* 91: 10-17.

16. Ornish D et al (1998). Intensive lifestyle changes for reversal of coronary heart disease. *JAMA* 280: 2001-2200
17. Marcus ML et al (1988). Visual estimates of percent diameter coronary stenosis: "a battered gold standard. *J Am Coll Cardiol* Vol. 11: 882-5.
18. Alfonso F et al (1994). Intravascular ultrasound imaging of angiographically normal coronary segments in patients with coronary artery disease. *Am Heart J* 127: 536-44.
19. Mintz GS et al (1995). Atherosclerosis in angiographically "normal" coronary artery reference segments: an intravascular ultrasound study with clinical correlations. *J Am Coll Cardiol* 25: 1479-85.
20. Nissen SE et (1991). Intravascular ultrasound assessment of lumen size and wall morphology in normal subjects and patients with coronary artery disease. *Circulation* 84: 1087-1099.
21. von Birgelen C al (2004). Relationship between cardiovascular risk as predicted by established risk scores versus plaque progression as measured by serial intravascular ultrasound in left main coronary arteries. *Circulation* 110: 1579-85.
22. Colombo A et al (1995). Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance. *Circulation* 91: 1676-1688.
23. Mintz GS et al (2001). American College of Cardiology clinical expert consensus document on standards for acquisition, measurement and reporting of intravascular ultrasound studies (IVUS). *J Am Coll Cardiol* 37: 1478-92.

24. Clara E.E. et al (1999). Comparison of Quantitative Coronary Angiography, Intravascular Ultrasound, and Coronary Pressure Measurement to Assess Optimum Stent Deployment. *Circulation*, 99: 1015-1021.
25. Pirolo JS et al (1997). Intracoronary ultrasound-guided CABG in patients with angiographically noncritical lesions. *Ann Thorac Surg* 64: 375-9.
26. Porter T et al (1993): Intravascular ultrasound study of angiographically mildly diseased coronary arteries. *J Am Coll Cardiol* 22: 1858-65.
27. De Scheerder et al (1994). Intravascular ultrasound versus angiography for measurement of luminal diameters in normal and diseased coronary-arteries. *Am Heart J* 27: 243-251.
28. Nissen SE et al (1991). Intravascular ultrasound assessment of lumen size and wall morphology in normal subjects and patients with coronary artery disease. *Circulation* 84: 1087-1099.
29. Abizaid et al (1997). Is intravascular ultrasound clinically useful or is it just a research tool? *Heart* 78 (2). 27-30.
30. Hoffmann R et al (1997): Overestimation of acute lumen gain and late lumen loss by quantitative coronary angiography (compared with intravascular ultrasound) in stented lesions. *Am J Cardiol* 80: 1277-1281.
31. Fernandes MR et al (2007). Assessing intermediate coronary lesions: Angiographic prediction of lesion severity on intravascular ultrasound. *J Invasive Cardiol* 19: 412-416.

32. Ozaki Yet al (1999). Comparison of coronary luminal quantification obtained from intracoronary ultrasound and both geometric and videodenstometric quantitative angiography before and after balloon angioplasty and directional atherectomy. *Circulation*, 96. 491-499.
33. Hermiller JB (1993). Unrecognized left main coronary artery disease in patients undergoing interventional procedures. *Am J Cardio* 71: 173-176.
34. Yamagishi M et al (1996). Intravascular ultrasound evidence of angiographically undetected left main coronary artery disease and associated trauma during interventional procedures. *Heart Vessels* 11: 262-268.
35. Gerber TC et al (1994). Extent of atherosclerosis and remodeling of the left main coronary artery determined by intravascular ultrasound. *Am J Cardiol* 73. 666-671.
36. Ricciardi MJ et al (2003). Angiographically silent left main disease detected by intravascular ultrasound: a marker for future adverse cardiac events. *Am Heart J* 146: 507-512.
37. Abizaid AS et al (1999). One-year follow-up after intravascular ultrasound assessment of moderate left main coronary artery disease in patients with ambiguous angiograms. *J Am Coll Cardiol* 34: 707-715.
38. Sano K et al (2007). Assessing intermediate left main coronary lesions using intravascular ultrasound. *Am Heart J*: 983-988.
39. Glagov S et al (1987). Compensatory enlargement of human atherosclerotic coronary arteries. *N Engl J Med* 316: 1371-1375.

40. Dragu Ret al (2008). Angiographically uncertain left main coronary artery narrowings: correlation with multidetector computed tomography and intravascular ultrasound. *Int J Cardiovasc Imaging* 24: 557–563.
41. Leber AW et al (2005). Quantification of obstructive and nonobstructive coronary lesions by 64-slice computed tomography: a comparative study with quantitative coronary angiography and intravascular ultrasound. *J Am Coll Cardiol* 46: 147–154.
42. Moselewski F et al (2004). Comparison of measurement of cross-sectional coronary atherosclerotic plaque and vessel areas by 16-slice multidetector computed tomography versus intravascular ultrasound. *Am J Cardiol* 94: 1294–1297.
43. Okabe Tet al (2008). Comparison of intravascular ultrasound to contrast-enhanced 64-slice computed tomography to assess the significance of angiographically ambiguous coronary narrowings. *Am J Cardiol* 15: 994–1001.
44. Kass M et al (2010). Lesion characteristics and coronary stent selection with computed tomographic coronary angiography: a pilot investigation comparing CTA, QCA and IVUS. *J Invasive Cardiol* 22: 328–334.
45. Budoff MJ et al (2008). Diagnostic performance of 64-multidetector row coronary computed tomographic angiography for evaluation of coronary artery stenosis in individuals without known coronary artery disease: results from the prospective multicentre ACCURACY (Assessment by Coronary Computed Tomographic Angiography of Individuals Undergoing Invasive Coronary Angiography) trial. *J Am Coll Cardiol* 52:1724–32.

46. Newby DE et al (2018). Coronary CT angiography and 5-Year risk of myocardial infarction. *N Engl J Med* 379: 924–33.
47. Motoyama S et al (2015). Plaque characterization by coronary computed tomography angiography and the likelihood of acute coronary events in Mid-Term Follow-Up. *J. Am. Coll. Cardiol* 66:337–46.
48. Narula J et al (2021). SCCT 2021 expert consensus document on coronary computed tomographic angiography: a report of the society of cardiovascular Computed Tomography. *J Cardiovasc Comput Tomogr* 15(3): 192–217. doi: 10.1016/j.jcct.2020.11.001
49. Dodge J Tet al (1992). Lumen diameter of normal human coronary arteries- influence of age, sex, anatomic variation, and left ventricular hypertrophy or dilation. *Circulation* 86: 232.
50. Lip G Y H et al (1999). Do Indo-Asians have smaller coronary arteries? *Postgrad Med J* 75: 463–466.
51. Imad Ghanem Shukri et al (2014). Angiographic study of the normal coronary artery in patients attending Ulaimani center for heart diseases. *European scientific journal* 10(24): 384-415.
52. Raut BK et al (2017). Coronary artery dimensions in normal Indians. *Indian Heart J* 69: 512-514.
53. Saikrishna C et al (2006). Normal coronary artery dimensions in Indians. *Indian J Thorac Cardiovasc Surg* 22:159-164.

54. Manjappa Mahadevappa et al (2016). Normal Proximal Coronary Artery Diameters in Adults from India as Assessed by Computed Tomography Angiography. *Journal of Clinical and Diagnostic Research* 10(5): 10-13.
55. Elangovan C et al (2005). Clinical and anthropometric correlation of normal Coronary artery dimensions. *Indian Heart J* 57: 381-425
56. Dhall U et al (2003) Histomorphometric analysis of Coronary arteries: sexual dimorphism. *J Anat Soc India* 52(2):144-146.
57. Venkateshwaran S (2010). Comparison between Intravascular ultrasound (IVUS), Three-Dimensional Quantitative Coronary Angiogram (3D QCA) and Quantitative Coronary Angiogram (QCA) for the measurement of luminal dimensions- *a research project*, SCTIMST, Trivandrum, India;1-41
58. Fox B et al (1982). Distribution of fatty and fibrous plaques in young human coronary arteries. *Atherosclerosis* 41:337-347.
59. Hochman JS et al (1988). The distribution of atherosclerotic lesions in the coronary arterial tree: relation to cardiac risk factors. *Am Heart J* 116: 1217-1222.
60. Vieweg WV et al (1979) Distribution and severity of coronary artery disease in 500 patients with angina pectoris. *Cathet Cardiovasc Diagn* 5: 319-330.
61. Makaryus AN et al (2005). Coronary artery diameter as a risk factor for acute coronary syndromes in Asian-Indians. *Am J Cardiol* 96:778-780.

62. Fisher LD et al (1982). Reproducibility of coronary arteriographic reading in the coronary artery surgery study (CASS). *Cathet Cardiovasc Diagn* 8: 565-575.
63. Blankenhorn DH and Curry PJ (1982). The accuracy of arteriography and ultrasound imaging for atherosclerosis measurement: a review. *Arch Pathol Lab Med* 106:483-490.
64. Galbraith JE et al (1981). Coronary angiogram interpretation: interobserver variability. *J Am Med Assoc* 240: 2053-2056.
65. Zir LM et al (1976). Interobserver variability in coronary angiography. *Circulation* 53: 627-632.
66. Arnett EN et al (1979). Coronary artery narrowing in coronary heart disease: comparison of cineangiographic and necropsy findings. *Ann Intern Med* 91: 350-356.
67. Grondin CM et al (1974). Discrepancies between cineangiographic and post-mortem findings in patients with coronary artery disease and recent myocardial revascularization. *Circulation* 49: 703-708
68. Dhawan J and Bray CL (1995). Are Asian coronary arteries smaller than Caucasian? A study on angiographic coronary artery size estimation during life. *Int J Cardiol* 49: 267-269.
69. Hutchins GM et al (1977). Correlation of age and heart weight with tortuosity and caliber of normal human coronary arteries. *Am Heart J* 94: 196-202.

70. Wilsens SL et al (1966). Size of the major epicardial coronary arteries at necropsy: relation to age, weight and myocardial infarction. *J Am Med Assoc* 198: 1325-1329.
71. Leung WH et al (1991). Determinants of normal coronary artery dimensions in humans. *Circulation* 84: 2294-2305.
72. Dhawan J and Bray CL (1994). Angiographic comparison of coronary artery disease between Asians and Caucasians. *Postgrad Med J* 70: 625-630.
73. Dhawan J and Bray CL (1994). Angiographic comparison of coronary artery disease between Asians and Caucasians. *Postgrad Med J* 70: 625-630.
74. Reddy S et al (2019). Coronary artery size in North Indian population e Intravascular ultrasound-based study. *Indian Heart Journal* 71: 412-417.
75. Goel PK et al (2021). Left main coronary artery diameter- A correlation between intravascular ultrasound and quantitative coronary angiography. *Indian Heart Journal* 73: 660-663.
76. O'Connor NJ et al (1996). Effect of coronary artery diameter in patients undergoing coronary bypass surgery: northern New England Cardiovascular Disease Study Group. *Circulation* 93(4): 652-655.
77. Kornowski R et al (1997). Comparison of men versus women in cross-sectional area luminal narrowing, quantity of plaque, presence of calcium in plaque, and lumen location in coronary arteries by intravascular ultrasound in patients with stable angina pectoris. *Am J Cardiol* 79: 1601-1605

78. Kim SG et al (2004). The importance of gender on coronary artery size: in-vivo assessment by intravascular ultrasound. *Clin Cardiol* 27: 291-294.
79. Sheifer SE et al (2000). Sex differences in coronary artery size assessed by intravascular ultrasound. *Am Heart J* 139:649-653.
80. Ge J et al (1994). Intravascular ultrasound imaging of angiographically normal coronary arteries: a prospective study in vivo. *Heart* 71:572-578.
81. Foin N et al (2011). Final proximal post-dilatation is necessary after kissing balloon in bifurcation stenting. *EuroIntervention* 7(5): 597–604.
82. Song YB et al (2012). Randomized comparison of conservative versus aggressive strategy for provisional side branch intervention in coronary bifurcation lesions: results from the SMART-STRATEGY (Smart Angioplasty Research Team-Optimal Strategy for Side Branch Intervention in Coronary Bifurcation Lesions) randomized trial. *JACC Cardiovasc Interv* 5(11):1133–1140
83. Niemela M et al (2011). Nordic-Baltic PCI Study Group. Randomized comparison of final kissing balloon dilatation versus no final kissing balloon dilatation in patients with coronary bifurcation lesions treated with main vessel stenting: the Nordic-Baltic Bifurcation Study III. *Circulation* 123(1): 79–86
84. Jacobs JE et al (2006). ACR practice guideline for the performance and interpretation of cardiac computed tomography (CT). *J Am Coll Radiol* 3:677-685.
85. Stillman AE et al (2007). Use of multidetector computed tomography for the assessment of acute chest pain: a consensus statement of the North American Society

of Cardiac Imaging and the European Society of Cardiac Radiology. *Int J Cardiovasc Imaging* 23: 415-427.

86. Hendel RC et al (2006). ACCF/ACR/SCCT/SCMR/ASNC/ NASCI/SCAI/SIR 2006 appropriateness criteria for cardiac computed tomography and cardiac magnetic resonance imaging: a report of the American College of Cardiology Foundation Quality Strategic Directions Committee Appropriateness Criteria Working Group, American College of Radiology, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, American Society of Nuclear Cardiology, North American Society for Cardiac Imaging, Society for Cardiovascular Angiography and Interventions, and Society of Interventional Radiology. *J Am Coll Cardiol* 48:1475-1497.

87. Schroeder S et al (2008). Cardiac computed tomography: indications, applications, limitations, and training requirements- report of a Writing Group deployed by the Working Group Nuclear Cardiology and Cardiac CT of the European Society of Cardiology and the European Council of Nuclear Cardiology. *Eur Heart J* 29(4): 531-556.

6 ANNEXURES

List of publications from Thesis: NIL

Curriculum Vitae:

Kamanakeri	Dayanand	
Last Name	First Name	Middle Name
Date of Birth - 05/07/1980		Sex- Male
Professional Mailing Address (Include Institution name)		Study Site Address (Include Institution name)
Dr. Dayanand Kamanakeri, Sowparnika sandal wood tower. Flat number 11B, Near Pharmacy College Kattela, Althara, Thiruvananthapuram-695017, State Kerala, India		Department of Cardiology, SCTIMST, Trivandrum 695011
Telephone (Office): NIL		Mobile Number: 8277418242
Telephone (Residence): NIL		Email: majdayanand81@sctimst.ac.in majdayanand81@gmail.com
Academic Qualifications (Most recent qualification first)		
Degree/Certificate	Year	Institution, Country
MD (General Medicine)	2013	Armed Forces Medical College, Pune, India
MBBS	2005	Vijayanagar Institute of Medical Sciences, Ballari, Karnataka, India
Details of professional registration: (MCI/State Registration/Bar Council/DCI/etc including Registration Number and Year of Registration:		

Karnataka Medical Council, Registration number- 72454; The Travancore -Cochin Council of Modern Medicine, Registration number- 74525,		
Current and previous positions (most recent position first)		
Month and Year	Title	Institution/Company, Country
1/1/2020 till date	Senior Resident, Dept. of cardiology	Department of Cardiology, SCTIMST, Trivandrum 695011 India
2/7/2013-31/12/2019	Graded Specialist (Medicine)	Armed Forces Medical Services, Ministry of Defence, Government of India
1/7/2013 -25/04/2013	Medical Officer (Medicine)	Armed Forces Medical Services, Ministry of Defence, Government of India
25/04/2010- 24/04/2013	Junior Resident	Armed Forces Medical College Pune India
20/01/2006-25/04/2010	Regimental Medical Officer	Armed Forces Medical Services, Ministry of Defence, Government of India
21/11/2004-20/11/2005	Internship	Vijayanagar Institute of Medical Sciences, Ballari, Karnataka, India
Brief summary of relevant research experience:		
<ol style="list-style-type: none"> Dayanand Kamanakeri (2013). Ultrasound change in small joints of hands in rheumatoid arthritis patients in clinical remission, MD thesis project. <i>AFMC Pune; India</i> 		
Publications:		
<ol style="list-style-type: none"> D Kamanakeri et al (2022). Ascending aortic aneurysm with rupture into the right atrium associated with COVID 19. <i>J Postgrad Med Case Snippet</i> 68(2):117-119. DOI: 10.4103/jpgm.jpgm_903_21. 		



APPENDICES

APPENDIX A – TECHNICAL ADVISORY COMMITTEE APPROVAL



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

TAC Registration No: SCT-/S/2020/1121

Date: 23.09.2020

Project title: EVALUATION OF DIMENSIONS OF LEFT MAIN CORONARY ARTERY, OSTIO-PROXIMAL LEFT ANTERIOR DESCENDING ARTERY, AND OSTIO-PROXIMAL LEFT CIRCUMFLEX ARTERY BY INTRAVASCULAR ULTRASOUND IN INDIAN POPULATION

Principal Investigator:	
Dr. Dayanand Kamanakeri, Department of Cardiology, SCTIMST	Degree: MBBS, MD (General Medicine)
Co-Principal Investigator(s)	
Dr. Ajit Kumar V.K., Department of Cardiology, SCTIMST	Degree: MBBS, MD, DM
Dr. Sanjay. G. Department of Cardiology, SCTIMST	Degree: MBBS, MD, DM

Members who participated in the TAC meeting on 20/06/2020

Dr Harikrishnan S (Chairman)
Dr Manikandan S
Dr Narayanan Namboodiri
Dr Jayadevan E R
Dr Sylaja P N
Dr Ramshekhar N Menon
Dr Unnikrishnan K P
Dr Syam K
Dr Sanjay G
Dr Deepti A N
Dr Sabarinath Menon
Dr Jayanand Sudhir E
Dr Srinivas G (Member Secretary)

Dr Sabarinath Menon, Dr Ramshekhar N Menon, Dr Sylaja P N, Dr Deepti A N, Dr Manikandan S, Dr Narayanan Namboodiri, Dr Srinivas G, Dr Sanjay G, Dr Harikrishnan S, Dr Unnikrishnan K P, Dr Syam K and Dr Jayadevan E R stayed away from the proceedings when the projects in which they are involved as investigator were discussed (#1072, 1037, 1089, 1092, 1093, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1103, 1107, 1108, 1111, 1113, 1114, 1116, 1118, 1119, 1120, 1121, 1122, 1123, 1127, 1129, 1130)

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.

Dr Srinivas G

MEMBER SECRETARY
TAC (Clinical Studies)
SCTIMST

Note for IEC

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

APPENDIX B – INSTITUTIONAL ETHICS COMMITTEE 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-21)

SCT/IEC/1731/SEPTEMBER/ 2021

13.12.2021

Dr. Dayanand Kamanakeri
Senior Resident
Department of Cardiology
SCTIMST, Thiruvananthapuram

Dear Dr. Dayanand Kamanakeri,

The Institutional Ethics Committee held on 24th September, 2021, reviewed and discussed your application to conduct the study titled "EVALUATION OF DIMENSIONS OF LEFT MAIN CORONARY ARTERY, OSTIO-PROXIMAL LEFT ANTERIOR DESCENDING ARTERY, AND OSTIO-PROXIMAL LEFT CIRCUMFLEX ARTERY BY INTRAVASCULAR ULTRASOUND IN INDIAN POPULATION (IEC/1731)".

The following members of the Ethics Committee were present at the meeting held on 24th September, 2021 at Residences and Offices of IEC Members via Video Conference

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Prof. C.C. Kartha	MBBS,MD	Male	Basic Medical Scientist (Chairman)	No
2.	Dr. Kala Kesavan P	MBBS,MD	Female	Basic Medical Scientist	No
3.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
4.	Dr. Pradeep S	MBBS, MD	Male	Basic Medical Scientist	No
5.	Adv. N Anand	BAL, L.LB	Male	Legal Expert	No
6.	Adv. Priya Kaimal	LLM, MBL	Female	Legal Expert	No
7.	Dr. Harikrishna Varma P. R	Ph.D (Materials Sciences)	Male	Medical Technology	Yes
8.	Dr. Narayanan Namboodiri. K K	MBBS,MD,DM	Male	Clinician	Yes
9.	Dr. Ashalatha R	MBBS, MD,DM	Female	Clinician	Yes
10.	Dr. Biju Soman	MBBS,MD, DPH, MSc, DLSHTM	Male	Basic Medical Scientist	Yes
11.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

Page 1 of 2

The following documents were reviewed:Original submission

1. Checklist
2. Project Proposal
3. IEC Application Form
4. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 19.7.2021
5. Proforma
6. TAC Approval Letter
7. Patient Information sheet in English and Malayalam
8. Study Consent Form in English and Malayalam
9. CV of PI and Co-PIs
10. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 19.07.2021
11. Declaration Form

Revised submission

1. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 06.11.2021
2. Checklist
3. Project Proposal
4. IEC Application Form
5. Forwarding Letter dated 14.09.2021
6. Proforma
7. TAC Approval Letter
8. Patient Information sheet in English and Malayalam
9. Study Consent Form in English and Malayalam
10. CV of PI and Co-PIs
11. Covering letter addressed to the Chairperson, IEC, SCTIMST
12. Declaration Form
13. Copy of IEC Recommendation Letter dated 21.10.2021

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,



G. Srinivas
Member Secretary, IEC



MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST, TRIVANDRUMPURAM

APPENDIX C – PUBLICATIONS

1. D Kamanakeri et al (2022). Ascending aortic aneurysm with rupture into the right atrium associated with COVID 19. *J Postgrad Med Case Snippet* 68(2):117-119. DOI: 10.4103/jpgm.jpgm_903_21.

APPENDIX D: PATIENT INFORMATION SHEET (IN ENGLISH)

SREE CHITRA THIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM: PATIENT INFORMATION SHEET

TITLE: EVALUATION OF DIMENSIONS OF LEFT MAIN CORONARY ARTERY, OSTIO-PROXIMAL LEFT ANTERIOR DESCENDING ARTERY, AND OSTIO-PROXIMAL LEFT CIRCUMFLEX ARTERY BY INTRAVASCULAR ULTRASOUND IN INDIAN POPULATION

Name of Investigators:

DR DAYANAND KAMANAKERI, DR AJIT KUMAR V K, DR SANGAY G.

Dear Patient/Parent

We welcome you and thank you for your interest in this research project titled "EVALUATION OF DIMENSIONS OF LEFT MAIN CORONARY ARTERY, OSTIO-PROXIMAL LEFT ANTERIOR DESCENDING ARTERY, AND OSTIO-PROXIMAL LEFT CIRCUMFLEX ARTERY BY INTRAVASCULAR ULTRASOUND IN INDIAN POPULATION". Before you participate in this study, it is important for you to understand why this research is being carried out. This form will provide you all the relevant details of this research. It will explain the nature, the purpose, the benefits, the risks, the discomforts, the precautions and the information about how this project will be carried out. It is important that you read and understand the contents of the form carefully. This form may contain certain scientific terms and hence, if you have any doubts or if you want more information, you are free to ask the study personnel or the contact person mentioned below before you give your consent and also at any time during the entire course of the project.

WHAT IS INTRAVASCULAR ULTRASOUND?

Intravascular ultrasound (IVUS) is a medical imaging methodology using a specially designed catheter with a miniaturized ultrasound probe attached to the lower end of the catheter. The upper end of the catheter is attached to computerized ultrasound equipment. It allows the application of ultrasound technology to see from inside blood vessels out through the surrounding blood column, visualizing the inner wall of blood vessels in living individuals. The arteries of the heart are the most frequent imaging target for IVUS. IVUS is used in the coronary arteries to determine the amount of fatty plaque built up at any particular point in the arteries of the heart. Intravascular ultrasound provides a unique method to study the regression or progression of atherosclerotic lesions inside. The progressive accumulation of fatty plaque within the artery wall over decades is the setup for vulnerable plaque which, in turn, leads to heart attack and narrowing of the arteries of the heart. IVUS is of use to determine both plaque volume within the wall of the artery and/or the degree of stenosis of the artery lumen. It can be especially useful in situations in which angiographic imaging is considered unreliable where angiographic images do not visualize lumen segments adequately, such as regions with multiple overlapping arterial segments. It is also used to assess the effects of treatments of stenosis with or without stents, and the results of medical therapy over time.

WHAT DOES THE PRESENT STUDY INVOLVE?

It involves collection of clinical and demographic data as per structured proforma, recorded CD of angiography and IVUS.

HOW LONG DOES IT TAKE?

The IVUS study done will be after hospitalization as per clinical indication according to standard guidelines. This may take up to 1 hours.

WHAT ARE THE RESPONSIBILITIES OF PARTICIPANTS?

Your decision to participate in this study is voluntary, your own personal choice. You may choose not to continue at any time, for any reason, without notice.

WHAT ARE THE EXPECTED RISKS FOR THE PARTICIPANTS?

The study involves collection of data from case records, pre and post procedure. There will be no risks for the participants because of participation in the study. They will be managed according to the hospital protocol. No specific intervention will be done.

24

WHAT ARE THE EXPECTED BENEFITS OF THE RESEARCH TO THE PARTICIPANTS?

The participants are evaluated in detail for any cardiac cause for functional impairment. A follow up examination and evaluation may be helpful in identification of any risk factors for poor outcomes or functional deterioration. It may be helpful in detecting patients who require early intervention or addition of medical therapy. The data derived from the study may be helpful in planning appropriate timing and surgical strategies for patients with similar conditions in the future.

WILL PARTICIPANTS BE COMPENSATED FOR PARTICIPATION IN THIS TRIAL?

You will not be paid for participation in the study.

WILL MY PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?

All records of your study will be kept confidential. Your identity will not be revealed in any publication or release of results. Study records will be kept indefinitely for analysis and follow-up.

CAN I WITHDRAW FROM THE STUDY AT ANY TIME DURING THE STUDY PERIOD?

Yes, you can. Your decision will not affect your regular medical care.

IF THERE ARE ANY NEW FINDINGS / INFORMATION, WOULD I BE INFORMED?

Yes.

WHAT HAPPENS IN CASE OF A STUDY RELATED INJURY?

There will be no study related injury.

IS THERE ANY ALTERNATIVE TO THE TREATMENT MENTIONED?

Not applicable.

If you have any further questions, please ask: Dr. Dayanand Kamanakeri (Principal investigator), Senior Resident, Department of Cardiology (Email: majdayanand81@sctimst.ac.in Ph No: 8277418242)

For any technical clarifications, please contact Dr Srinivas G, Member Secretary, IEC, SCTIMST (Email: iec.mem.sec@sctimst.ac.in, Phone no. 0471-2524-689)

=====
Participant's name ----- Age: ----- Y ----- M; Sex: M / F
I (Name of Participant/ Parent / Guardian) ----- aged
(in years) ----- son/daughter of -----(Please tick
boxes).

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

"EVALUATION OF DIMENSIONS OF LEFT MAIN CORONARY ARTERY, OSTIO-PROXIMAL LEFT ANTERIOR DESCENDING ARTERY, AND OSTIO-PROXIMAL LEFT CIRCUMFLEX ARTERY BY INTRAVASCULAR ULTRASOUND IN INDIAN POPULATION" 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 may 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 may 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 & Signature of witness:
Relation to participant
Date:

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 benefits and risk that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

Name and Signature of Person obtaining consent:

Date:

Dr. Dayanand Kamanakeri,
Senior resident, Dept. of Cardiology, SCTIMST.

APPENDIX E: STUDY CONSENT FORM (IN ENGLISH)

IEC/Ver3/09

STUDY CONSENT FORM

TITLE OF THE STUDY: EVALUATION OF DIMENSIONS OF LEFT MAIN CORONARY ARTERY, OSTIO-PROXIMAL LEFT ANTERIOR DESCENDING ARTERY, AND OSTIO-PROXIMAL LEFT CIRCUMFLEX ARTERY BY INTRAVASCULAR ULTRASOUND IN INDIAN POPULATION

Study number: all patients who undergo/underwent intravascular ultrasound guided percutaneous intervention of the left coronary system including complete pullback of a LMCA, LAD and LCX for their clinical indications will be included in the study.

Participant's name: Date of Birth / Age (in years):

I _____, son/ daughter of _____
(Please tick boxes).

I declare that I have read the above information provided to me regarding the study: "*evaluation of dimensions of left main coronary artery, ostio-proximal left anterior descending artery, and ostio-proximal left circumflex artery by intravascular ultrasound in Indian population*" 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 may 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 may not be revealed in any information released to third parties or published.

I voluntarily agree to take part in this study.

I received a copy of this signed consent form.

Name:

Signature:

Date:

Name of witness:

Relation to participant

Date:

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

Name and Signature of Person Obtaining Consent

Dr Dayanand Kamanakeri

Senior resident, Dept. of Cardiology SCTIMST

For any technical clarifications, please contact Dr Srinivas G, Member Secretary, IEC, SCTIMST & Additional Professor, AMCHSS, SCTIMST (Email: iec.mem.sec@sctimst.ac.in, Phone no.0471-2524-689)

APPENDIX E: PATIENT INFORMATION SHEET (IN MALAYALAM)

ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസ് ആന്റ് ടെക്നോളജി

രോഗികളുടെ കാര്യവിവരണ പത്രം

ശീർഷകം: ഇൻഡ്യയിലെ ജനസാമാന്യത്തിന്റെ ഇടതുവശത്തെ പ്രധാന കൊറോണറി ആർട്ടറി, ഓസ്റ്റിയോ-പ്രോക്സിമൽ ഇടത് വശത്ത് താഴെയുള്ള അവരോഹണം നടത്തുന്ന ആർട്ടറി, ഓസ്റ്റിയോ-പ്രോക്സിമൽ ലെഫ്റ്റ് സർക്കോഫ്ളക്സ് ആർട്ടറി എന്നിവയുടെ പരിമാണത്തിന്റെ ഇൻട്രാവെൻഡുലാർ അൾട്രാസൗണ്ട് ഉപയോഗിച്ചുള്ള അപഗ്രഥനം.

ഗവേഷകരുടെ പേര്

ഡോ. ദയാനന്ദ് കാമനകേരി, ഡോ. അജിത്കുമാർ വി കെ, ഡോ. സൺജയ് ജി

പ്രിയ സുഹൃത്തേ,

ഇൻഡ്യയിലെ ജനസാമാന്യത്തിന്റെ ഇടതുവശത്തെ പ്രധാന കൊറോണറി ആർട്ടറി, ഓസ്റ്റിയോ-പ്രോക്സിമൽ ഇടത് വശത്ത് താഴെയുള്ള അവരോഹണം നടത്തുന്ന ആർട്ടറി, ഓസ്റ്റിയോ-പ്രോക്സിമൽ ലെഫ്റ്റ് സർക്കോഫ്ളക്സ് ആർട്ടറി എന്നിവയുടെ പരിമാണത്തിന്റെ ഇൻട്രാവെൻഡുലാർ അൾട്രാസൗണ്ട് ഉപയോഗിച്ചുള്ള അപഗ്രഥനം എന്ന ഗവേഷണ പദ്ധതിയിലെ താങ്കളുടെ താല്പര്യം ഞങ്ങൾ സാഗതം ചെയ്യുകയും നന്ദി പറയുകയും ചെയ്യുന്നു. താങ്കൾ ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതിനു മുമ്പ് എന്തിനാണ് ഈ ഗവേഷണ പദ്ധതി നടപ്പാക്കുന്നത് എന്നു മനസ്സിലാക്കേണ്ടത് പ്രധാനമാണ്.

ഈ പത്രിക ഈ ഗവേഷണപദ്ധതിയുടെ പ്രസക്തമായ വിശദാംശങ്ങൾ താങ്കൾക്ക് നൽകും. എങ്ങനെയാണ് ഈ പദ്ധതി നടപ്പാക്കുന്നത് എന്നതിന്റെ വിവരങ്ങൾ, അതിന്റെ സ്വഭാവം, ഉദ്ദേശം, നേട്ടങ്ങൾ, അപായങ്ങൾ, അസ്വസ്ഥതകൾ, മുൻകരുതലുകൾ എന്നിവ ഈ പത്രിക വിശദീകരിക്കും. താങ്കൾ ഈ പത്രികയുടെ ഉള്ളടക്കം ശ്രദ്ധയോടെ വായിക്കുകയും മനസ്സിലാക്കുകയും ചെയ്യേണ്ടത് പ്രധാനമാണ്. ഈ പത്രികയിൽ ചില ശാസ്ത്രീയ പദങ്ങൾ ഉണ്ടായേക്കാം ആകയാൽ, താങ്കളുടെ സമ്മതം തരുന്നതിനുമുമ്പോ, പദ്ധതിയുടെ മൊത്തം കാലയളവിലോ, താങ്കൾക്കെന്തെങ്കിലും സംശയങ്ങളോ അല്ലെങ്കിൽ താങ്കൾക്ക് കൂടുതൽ വിവരങ്ങളാവശ്യമുണ്ടെങ്കിലോ, താങ്കൾക്ക് പഠനം നടത്തുന്ന വ്യക്തിയോടോ താഴെ പ്രതിപാദിച്ചിരിക്കുന്ന ബന്ധപ്പെടാനുള്ള ആളോടോ ചോദിക്കാൻ സാധിക്കുമുണ്ട്.

എന്താണ് ഇൻട്രാവെൻഡുലാർ അൾട്രാസൗണ്ട്?

പ്രത്യേകമായി അവിഷ്കരിച്ച ഒരു കതീറ്ററിനറ്റത്ത് ഒരു ചെറു ക്യാമറ ഘടിപ്പിച്ച് അൾട്രാസൗണ്ട് പ്രോബ് ഉപയോഗിക്കുന്ന ഇന്റർ വെൻഡുലാർ അൾട്രാസൗണ്ട് (ഐയുവിഎസ്) വൈദ്യശാസ്ത്ര ഇമേജിംഗ് സങ്കേതമാണ്. കതീറ്ററിന്റെ മുകളിലത്തെ അറ്റം കമ്പ്യൂട്ടർവൽക്കരിച്ച ഒരു അൾട്രാസൗണ്ട് ഉപകരണവുമായി ഘടിപ്പിച്ചിരിക്കുന്നു. അത് ചുറ്റുമുള്ള രക്തത്തിലൂടെ രക്തക്കുഴലിനകം കാണാൻ അനുവദിക്കുന്നു, ജീവനുള്ള വ്യക്തികളുടെ രക്തക്കുഴലിനുകൾക്കും കാണാൻ കഴിയുന്നു. ഐവിയുഎസ്സിന്റെ മിമിപ്പോഴുമുള്ള പ്രധാന ഇമേജിംഗ് ലക്ഷ്യം

ഹൃദയത്തിന്റെ ആർട്ടിക്ളാണ്. ഹൃദയത്തിന്റെ കൊറോണറി ആർട്ടിക്ളുകളിലെ പ്രത്യേക സ്ഥലത്ത് കൊഴുപ്പിന്റെ പ്ലേക്ക് ഉണ്ടായതിന്റെ അളവ് നിർണ്ണയിക്കാൻ ഐവിയുസ് ഉപയോഗിക്കുന്നു. ഇൻട്രാവസ്കുലാർ അൾട്രാസൗണ്ട് ഉള്ളിലെ അതിറോസ്റ്റീറോസിസ്സിന്റെ മുറിവുകളുടെ നാശമോ വളർച്ചയോ പഠിക്കാൻ ലഭ്യമായ അനന്നമായ സമ്പ്രദായമാണ്. ആർട്ടിക്ളയുടെ ഭിത്തികളിൽ ദശാബ്ദങ്ങളായി സംഭരിക്കപ്പെടുന്ന അപായകരമായ കൊഴുത്ത പ്ലേക്ക്, ഹൃദയാഘാതത്തിലേയ്ക്ക് നയിക്കുകയും ഹൃദയത്തിന്റെ ആർട്ടിക്ളെ ഇടുങ്ങിയതാക്കുകയും ചെയ്യുന്നു. ഐവിയുസ് ആർട്ടിക്ളയുടെ ഭിത്തികളിലെ പ്ലേക്കിന്റെ അളവും/ഒപ്പം അല്ലെങ്കിൽ ആർട്ടിക്ളയുടെ ലുമിനൽ സ്റ്റ്രോംസിസ്സിന്റെ നിലവാരം തീരുമാനിക്കാനും ഉപയോഗിക്കുന്നു. ഒന്നിലേറെ അടുക്കുകളായിരിക്കുന്ന ആർട്ടിക്ളിൽ ഭാഗങ്ങളിൽ ആൻജിയോഗ്രഫിക് ഇമേജിംഗിലൂടെ ലുമിനൽ ഭാഗം വേണ്ടുവിധം കാണാനാവാത്ത ഭാഗങ്ങളിൽ ആൻജിയോഗ്രഫിക് ഇമേജുകൾ അവലംബിക്കാനാവാത്തതായി പരിഗണിക്കപ്പെടുന്ന സാഹചര്യങ്ങളിൽ ഇത് പ്രത്യേകമായും ഉപയോഗപ്രദമാണ്. വൈദ്യചികിത്സയുടെ കാലാനുരൂപതയിലെ ഫലവും, സ്റ്റേജ് ഉപയോഗിച്ചോ ഉപയോഗിക്കാതെയോ ഉള്ള സ്റ്റ്രോംസിസ്സ് ചികിത്സയുടെ പ്രയോജനവും വിലയിരുത്താനും ഇത് ഉപയോഗിക്കുന്നു.

ഇപ്പോഴത്തെ പഠനത്തിലുൾക്കൊള്ളുന്നതെന്ത്?

സുഖലിതമായ ചോദ്യവലിപ്രകാരമുള്ള ക്ലിനിക്കലും സാമൂഹ്യ-വ്യക്തിപരമായ വിവരങ്ങളുടെയും, ആൻജിയോഗ്രഫി രേഖപ്പെടുത്തിയ സിഡികളുടെയും ഐവിയുസ്സിന്റെയും ശേഖരണവും ഇതിൽ അടങ്ങുന്നു.

ഇതിനെത്ര സമയമെടുക്കും?

അംഗീകൃതമായ മാർഗ്ഗനിർദ്ദേശ പ്രകാരം ആശുപത്രിയിൽ പ്രവേശിപ്പിച്ച ശേഷമാണ് ഐവിയുസ് പഠനം നടത്തുന്നത്. ഒരുമണിക്കൂർ സമയം വരെ ഇതിനെടുക്കാം.

പങ്കെടുക്കുന്നവരുടെ ഉത്തരവാദിത്തങ്ങളെന്തെല്ലാം?

താങ്കളുടെ പഠന പങ്കാളിത്തം സ്വയമേവയാണ്, താങ്കളുടെ വ്യക്തിപരമായ തീരുമാനമാണ്. കാരണം കാണിക്കാതെ ഏതുസമയത്തും തുടരേണ്ടതില്ലെന്ന് താങ്കൾക്ക് തീരുമാനിക്കാം.

പങ്കെടുക്കുന്നവർക്ക് പ്രതീക്ഷിക്കപ്പെടുന്ന അപായങ്ങളെന്തെല്ലാം?

പഠനത്തിൽ നടപടിക്കു മുമ്പും ശേഷവുമുള്ള ചികിത്സാ രേഖകളിൽ നിന്ന് വിവരങ്ങൾ ശേഖരിക്കുകയാണ്. പങ്കെടുക്കുന്നതുകൊണ്ട് പങ്കാളികൾക്ക് അപായമൊന്നുമില്ല. അവ ആശുപത്രി നടപടിക്രമമനുസരിച്ച് കൈകാര്യം ചെയ്യും. ഒരു പ്രത്യേക ഇടപെടലും നടത്തില്ല.

പങ്കെടുക്കുന്നവർക്ക് ഗവേഷണത്തിൽ നിന്നും പ്രതീക്ഷിക്കുന്ന ഗുണങ്ങളെന്തെല്ലാം?

പ്രവർത്തനപരമായ കോട്ടങ്ങൾക്ക്, പങ്കാളികളുടെ ഹൃദയസംബന്ധമായ എന്തെങ്കിലും കാരണങ്ങളുണ്ടോയെന്ന് വിശദമായി വിലയിരുത്തും. പ്രവർത്തനപരമായ അധപതനത്തിനോ, മോശം നേട്ടങ്ങൾക്കോ എന്തെങ്കിലും അപായഘടകങ്ങളുണ്ടോയെന്ന് കണ്ടെത്താൻ തുടർചികിത്സയും വിലയിരുത്തലും പ്രയോജനപ്രദമായേക്കാം. നേരത്തെയുള്ള ഇടപെടലും കൂടുതൽ വൈദ്യചികിത്സയും അവശ്യമായ രോഗികളെ കണ്ടെത്താൻ അത് സഹായിച്ചേക്കാം.

ഭാവിയിൽ സമാനമായ അവസ്ഥയുള്ളവരുടെ ശസ്ത്രക്രിയാ തന്ത്രം ആസൂത്രണം ചെയ്യുന്നതിൽ പഠനത്തിൽനിന്നും ലഭ്യമാകുന്ന വിവരങ്ങൾ സഹായകരമായേക്കാം.

ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നവർക്ക് നഷ്ടപരിഹാരം നൽകുമോ?

പഠനത്തിൽ പങ്കെടുക്കുന്നതിന് താങ്കൾക്ക് നഷ്ടപരിഹാരം നൽകില്ല.

എന്റെ ഈ പഠനത്തിലെ പങ്കാളിത്തം രഹസ്യമായിരിക്കുമോ?

താങ്കളുടെ പഠനത്തന്റെ എല്ലാ രേഖകളും രഹസ്യമായി സൂക്ഷിക്കും. താങ്കളുടെ വ്യക്തിവിവരങ്ങൾ ഒരു പ്രസിദ്ധീകരണത്തിലും പഠനഫലങ്ങൾ പ്രസിദ്ധീകരിക്കുമ്പോഴും ഉണ്ടാകില്ല. പഠനരേഖകൾ വിശകലനത്തിനും തുടർ പരിശോധനയ്ക്കുമായി അനന്തമായി സൂക്ഷിക്കും.

പഠനകാലയളവിലെപ്പോഴും എനിക്ക് പിൻമാറ്റാനാകുമോ?

താങ്കൾക്ക് കഴിയും. താങ്കളുടെ തീരുമാനം പതിവ് ചികിത്സയെ ബാധിക്കില്ല.

എന്തെങ്കിലും കണ്ടെത്തലുകൾ വിവരങ്ങൾ ഉണ്ടെങ്കിൽ അറിയിക്കുമോ?

അറിയിക്കും.

പഠനസംബന്ധമായ പര്യടനങ്ങൾക്കായി സൗജന്യമായി സൗകര്യമുണ്ടാകുമോ?

പഠനസംബന്ധമായി ഒരു പര്യടനമുണ്ടാവില്ല.

സൂചിപ്പിച്ച ചികിത്സയ്ക്ക് പകരമെന്തെങ്കിലുമുണ്ടോ?

ബാധകമല്ല.

താങ്കൾക്ക് കൂടുതൽ ചോദ്യങ്ങളുണ്ടെങ്കിൽ ചോദിക്കുക ഡോ. ദയാനന്ദ് കാമനകരി (പ്രധാന ഗവേഷകൻ), സീനിയർ റെസിഡന്റ്, കാർഡിയോളജി ഡിപ്പാർട്ട്മെന്റ്, SCTIMST (ഫോൺ 8277418242) ഇമെയിൽ majdayanand81@sctimst.ac.in

പഠനത്തിന്റെ നൈതിക അംഗീകാരവുമായി ബന്ധപ്പെട്ട വിശദീകരണങ്ങൾക്ക് ബന്ധപ്പെടുക IEC മെമ്പർസെക്രട്ടറി, ഡോ. ശ്രീനിവാസ് ഓ (ഫോൺ. 0471-2524-689) ഇമെയിൽ iec.mem.sec@sctimst.ac.in

APPENDIX F: STUDY CONSENT FORM (IN MALAYALAM)

ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി

രോഗിക്കുള്ള കാര്യവിവരണ പത്രം

ശീർഷകം: ഇൻഡ്യയിലെ ജനസാമാന്യത്തിന്റെ ഇടതുവശത്തെ പ്രധാന കൊറോണറി ആർട്ടറി, ഓസ്റ്റിയോ-പ്രോക്സിമൽ ഇടത് വശത്ത് താഴെയുള്ള അവരോഹണം നടത്തുന്ന ആർട്ടറി, ഓസ്റ്റിയോ-പ്രോക്സിമൽ ലെഫ്റ്റ് സർക്കോഫ്ളക്സ് ആർട്ടറി എന്നിവയുടെ അളവിന്റെ ഇൻട്രാവസ്കുലാർ അൾട്രാസൗണ്ട് ഉപയോഗിച്ചുള്ള അപഗ്രഥനം.

ഗവേഷകരുടെ പേര്

ഡോ. ദയാനന്ദ് കാമനകേരി, ഡോ. അജിത്കുമാർ വി കെ, ഡോ. സൺജയ് ടീ

പഠനനമ്പർ: ഇടത് കൊറോണറിസംവിധാനത്തിൽ ഇൻട്രാവസ്കുലാർ അൾട്രാസൗണ്ട് മാർഗ്ഗനിർദ്ദേശത്തോടെ ഇടപെടൽ നടത്തപ്പെട്ട/നടത്തപ്പെടുന്ന എല്ലാരോഗികളും, പൂർണ്ണമായ എൽഎംസിഎ പൂർബാക്ക്, എൽഎഡി, എൽസിഎക്സ് ഉൾപ്പെടെ അവരുടെ ക്ലിനിക്കൽ സൂചകങ്ങളും പഠനത്തിലുൾപ്പെടുത്തും.

സമ്മതപത്രം

പങ്കെടുക്കുന്നയാളുടെ പേര്.....

ജനനതീയതി/വയസ്സ്(വർഷത്തിൽ).....

ഞാൻമകൻ/മകൾ.....

(ദയവായി കോളങ്ങളിൽ ശരിയടയാളമിടുക)

- ഇൻഡ്യയിലെ ജനസാമാന്യത്തിന്റെ ഇടതുവശത്തെ പ്രധാന കൊറോണറി ആർട്ടറി, ഓസ്റ്റിയോ-പ്രോക്സിമൽ ഇടത് വശത്ത് താഴെയുള്ള അവരോഹണം നടത്തുന്ന ആർട്ടറി, ഓസ്റ്റിയോ-പ്രോക്സിമൽ ലെഫ്റ്റ് സർക്കോഫ്ളക്സ് ആർട്ടറി എന്നിവയുടെ അളവിന്റെ ഇൻട്രാവസ്കുലാർ അൾട്രാസൗണ്ട് ഉപയോഗിച്ചുള്ള അപഗ്രഥനം. എന്ന പഠനസംബന്ധമായി എനിക്ക് തന്ന വിവരങ്ങൾ വായിച്ചതായും എനിക്കുണ്ടായ സംശയങ്ങൾ പരിഹരിച്ചതായും ഞാൻ പ്രഖ്യാപിക്കുന്നു. []
- എന്റെ പങ്കാളിത്തം സ്വമേധയായാണെന്നും, എന്റെ പതിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളോയോ ബാധിക്കാതെ ഏതുസമയത്തും പങ്കെടുക്കുന്നതിനും അതുപോലെ പിൻവാങ്ങുന്നതിനും അനുവാദമുണ്ടെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. []
- പഠനത്തിൽ നിന്നും ഞാൻ പിൻമാറിയാലും ഈ പഠനവുമായി ബന്ധപ്പെട്ട ആരോഗ്യരേഖകൾ പഠനസംഘാഗങ്ങളും ഇൻസ്റ്റിറ്റ്യൂഷണൽ എത്തിക്സ് കമ്മിറ്റി അംഗങ്ങളും എന്റെ അനുവാദംകൂടാതെ പരിശോധിക്കാമെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. അതിന് ഞാൻ സമ്മതിക്കുന്നു.
- എന്റെ വ്യക്തിപരമായ വിവരങ്ങൾ മൂന്നാംകക്ഷികൾക്കോ പ്രസിദ്ധീകരണത്തിനോ നൽകില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. []

- ഞാൻ സ്വമേധയാ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു. []
- സമ്മതപത്രത്തിന്റെഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു. []

പേര്

ഒപ്പ്

തീയതി

സാക്ഷിയുടെ പേര്

രോഗിയുമായുള്ള ബന്ധം

ഒപ്പ്

സമ്മതപത്രംവാങ്ങുന്ന ആൾ

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

സമ്മതപത്രംവാങ്ങുന്ന ആളുടെ പേര് ഒപ്പ്

ഡോ. ദയാനന്ദ് കാമനേരി,

സീനിയർ റെസിഡന്റ്,

കാർഡിയോളജി ഡിപ്പാർട്ട്മെന്റ്, SCTIMST

സാക്ഷി:

നൈതീകാനുവാദം സംബന്ധിച്ച വിശദീകരണങ്ങൾക്ക് ബന്ധപ്പെടുക മെമ്പർസെക്രട്ടറി,
 ഡോ. ശ്രീനിവാസ് ജി, SCTIMST-IEC, ഫോൺ. 0471-2524-689 ഇമെയിൽ iec.mem.sec@sctimst.ac.in

APPENDIX G: PROFORMA FOR IVUS/QCA GROUP

IEC/Ver3/09

EVALUATION OF DIMENSIONS OF LEFT MAIN CORONARY ARTERY, OSTIO-PROXIMAL LEFT ANTERIOR DESCENDING ARTERY, AND OSTIO-PROXIMAL LEFT CIRCUMFLEX ARTERY BY INTRAVASCULAR ULTRASOUND IN INDIAN POPULATION

PROFORMA: PATIENTS

Patient data:

1. Patient code:	2. Age:	3. Gender:
4. Address:	5. Contact no:	6. Date of study:
		Cath no:
7. Weight: kg	8. Height:	9. BMI: kg/m ²
10. BSA: m ²	11. Hypertension: mmHg	12. Diabetes: yes/no
13. Dyslipidemia: YES/NO	14. Smoking(current/Past) YES/NO	15. F/H/O CAD: YES/NO
16. Presentation: CSA, UA, NSTEMI, STEMI	17. Diagnosis:	18. Indications for IVUS:
19. Lipid profile:	20. ECG:	21. Echo findings:

QCA measurements:

Measurements	LMCA	OSTIOPROXIMAL LAD	OSTIOPROXIMAL LCX
MINIMAL LUMEN DIAMETER			
REFERENCE LUMEN DIAMETER			
LENGTH			

IVUS measurements:

Dimensions	LMCA			OSTIO- PROXIMAL LAD	OSTIO- PROXIMAL LCX
	OSTIAL	SHAFT	DISTAL		
Maximum Lumen diameter(mm)					
Minimum Lumen diameter(mm)					
Mean lumen diameter(mm)					
Lumen CSA					
Maximum vessel diameter (EEM diameter) (mm)					
Minimum vessel diameter (EEM diameter) (mm)					
Mean vessel diameter (EEM diameter) (mm)					
EEM CSA (mm ²)					
Plaque and media CSA (EEM CSA-LUMEN CSA). (mm ²)					
Plaque burden: plaque and media CSA / EEM CSA x 100.					

APPENDIX G: PROFORMA FOR CT CAG GROUP

EVALUATION OF DIMENSIONS OF LEFT MAIN CORONARY ARTERY, OSTIO-PROXIMAL LEFT ANTERIOR DESCENDING ARTERY, AND OSTIO-PROXIMAL LEFT CIRCUMFLEX ARTERY BY INTRAVASCULAR ULTRASOUND IN INDIAN POPULATION

PROFORMA: CT CAG

⊕ Patient data:

1. Patient code:	2. Age:	3. Gender:
4. Address:	5. Contact no:	6. Date of study:
7. Weight: kg	8. Height:	9. BMI: kg/m ²
10. BSA: m ²	11. Hypertension: mmHg	12. Diabetes: yes/no
13. Dyslipidemia: YES/NO	14. Smoking(current/Past) YES/NO	15. F/H/O CAD: YES/NO
16. Presentation: CSA, UA, NSTEMI, STEMI	17. Diagnosis:	18. Indications for IVUS:
19. Lipid profile:	20. ECG:	21. Echo findings:

CT CAG measurements:

Measurements	LMCA	OSTIOPROXIMAL LAD	OSTIOPROXIMAL LCX
AXIAL VESSEL DIAMETER			

APPENDIX E – PLAGIARISM CHECK REPORT



Report: Evaluation of dimension of left main coronary artery,ostioproximal left anterior des...

Evaluation of dimension of left main coronary artery,ostioproximal left anterior descending artery,and ostioproximal left circumflex artery by intravascular ultrasound in Indian population

by Nitin Naik

General metrics

45,650	7,171	336	28 min 41 sec	55 min 9 sec
characters	words	sentences	reading time	speaking time

Score



This text scores better than 72% of all texts checked by Grammarly

Writing Issues

493	129	364
Issues left	Critical	Advanced

Plagiarism



18 sources

2% of your text matches 18 sources on the web or in archives of academic publications

Report was generated on Monday, Aug 15, 2022, 10:01 PM

Page 1 of 61

