RADIATION EXPOSURE IN CARDIAC ELECTROPHYSIOLOGY: A PROSPECTIVE OBSERVATIONAL STUDY IN A TERTIARY CARE CENTRE

Dr. SUNDARAM C

DM CARDIOLOGY THESIS

Year 2022

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

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A THESIS SUBMITTED BY

Dr. SUNDARAM C

TO

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

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE AWARD OF

DM CARDIOLOGY

YEAR 2022

DECLARATION BY THE STUDENT

CERTIFICATE

I, Dr. Sundaram C hereby certify that I had personally carried out the work depicted in the thesis titled, “RADIATION EXPOSURE IN CARDIAC ELECTROPHYSIOLOGY: A PROSPECTIVE OBSERVATIONAL STUDY IN A TERTIARY CARE CENTRE”.

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

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Date: 11-08-2022

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*Clearance was obtained from the Institutional Ethics Committee / Institutional Animal Ethics / Institutional Committee for Stem Cell Research / Other appropriate committees (if any, specify) for carrying out the study.

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ACKNOWLEDGEMENTS

It is with a 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 to the success of this study.

I am greatly indebted to my guide and supervisor **Dr. Krishnamoorthy K.M** for the idea of conducting such research, the continued support and advice he has extended to me throughout my work towards this thesis.

I would like to express my deep sense of thanks and gratitude to my co-guide **Dr. K.K. Narayanan Namboodiri** for providing valuable contributions and constant encouragement that helped me to make my study better.

I would also like to sincerely thank all the faculty members of the Department of Cardiology, SCTIMST for all the support. I have no words to express my heartfelt gratitude and love to my parents, Mr. S. Chandrasekar and Mrs. C. Alangaramu who provided the most precious support.

I would like to thank **Dr. Reshma Rajan** for guidance in statistical analysis and for constantly supporting me all the time in my work.

Finally, I would like to thank the technical staff of the cardiac catheterization laboratory of SCTIMST for their friendly support and helping hands.

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LIST OF ABBREVIATIONS

S No	Abbreviation	Full Form
	AVNRT	Atrioventricular nodal reentry tachycardia
	AVRT	Atrioventricular reciprocating tachycardia
	AT	Atrial tachycardia
	AFL	Atrial flutter
	AFIB	Atrial fibrillation
	VT	Ventricular tachycardia
	EPS	Electrophysiological Study
	RFA	Radiofrequency ablation
	CIED	Cardiac implantable electronic device
	PPI/ICD	Permanent Pacemaker Implantation/Implantable Cardioverter Defibrillator
	PVI	Pulmonary Vein Isolation
	BMI	Body mass index
	FT	Fluoroscopy time
	DAP	Dose area product
	AK	Air kerma
	LAR	Lifetime Attributable Risk
	PG	Pulse generator
	CRT	Cardiac Resynchronization Therapy

SYNOPSIS

RADIATION EXPOSURE IN CARDIAC ELECTROPHYSIOLOGY: A PROSPECTIVE OBSERVATIONAL STUDY IN A TERTIARY CARE CENTRE

SYNOPSIS

BY

Dr. SUNDARAM C

for DM CARDIOLOGY

of

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

SYNOPSIS

Background:

There has been a significant increase in the number of electrophysiological (EP) procedures and device implantations over the last two decades, which has raised concerns regarding radiation-related risks to the patient. Children are particularly more sensitive to ionizing radiation than adults which puts them at an increased risk of malignancy. There is, however, a paucity of comprehensive fluoroscopy exposure data on electrophysiological and device implantation procedures, and none so far from India.

Aim:

i) To quantify ionizing radiation exposure to the patient during all electrophysiological (EP) procedures and device implantations.

ii) To measure and compare radiation exposure during different types of EP procedures.

iii) To evaluate the association between patient body mass index and radiation dose during ablations and device implantations.

iv) To compare the radiation exposure between pediatric and adult EP procedures.

Methods:

This is a prospective observational study, including 606 patients who underwent EP procedures in our Cath lab between November 2020 to June 2022. Demographic and

relevant clinical data were obtained from the patient. Patient BMI was categorized as normal weight (BMI<25), overweight (BMI: 25-29.9), and obesity (BMI ≥30). Patients aged <18 years were included in the pediatric age group. Radiation dose parameters that were recorded in the machine during the procedure including fluoroscopy time (FT), cumulative air kerma (AK), and dose area product (DAP) were collected at the end of the procedure. Effective dose and lifetime attributable risk of cancer incidence and mortality were calculated from DAP.

Results:

Among 606 patients who underwent cardiac electrophysiological procedures in our Cath lab, there were 37 EP studies, 299 radiofrequency (RF) ablations, and 267 cardiac device implantation procedures, which were analyzed for radiation exposure. The majority of the EP procedures were done in adults (95%). Ablations represent almost 50% of total EP procedures. The calculated median effective dose (ED) was 0.28 mSv (0.16-0.43) for EP study, 0.89 mSv (0.47-2) for RF ablation, and 0.32 mSv (0.14-0.81) for device implantations. Among RF ablations, the median overall ED of overweight patients was 42% (p=0.03) higher and obese patients was 109% (p=0.02) higher than normal-weight patients. Among device implantations, the median overall ED of obese patients was 61.5% higher than normal-weight patients (p=0.05). There was no significant increase in the fluoroscopy time with an increase in body mass index (p=0.5). An increase in fluoroscopy time is significantly associated with an increase in mean ED (p<0.001). There was no gender difference in radiation exposure (p=0.12). Among RF ablations, the highest radiation was observed in atrial fibrillation (AF) ablation (median ED-5.72 mSv), followed by atrial tachycardia (AT) (median ED-1.96

mSv), Atrial flutter (median ED-1.94 mSv), ventricular tachycardia (VT) (median ED-1 mSv), and atrioventricular reciprocating tachycardia (AVRT) ablation (median ED-1.92 mSv). Among device implantations, the highest radiation was observed with cardiac resynchronization therapy (median ED-4.34 mSv), followed by conduction system pacing (median ED-2.3 mSv), and conventional pacemaker implantation/ implantable cardioverter defibrillator (PPI/ICD) (median ED-0.38 mSv). There was no significant difference in mean ED between children and adults for EP procedures (EP study-1.02 ± 2.2 vs 1.09 ± 0.97, p=0.47; RF ablation-2.06 ± 4.25 vs 2.5 ± 3.69, p=0.5; PPI/ICD-0.73 ± 0.98 vs 0.33 ± 0.18, p=0.37).

Conclusion:

Overall radiation exposure to patients during various electrophysiological procedures and device implantations was less in our study which could be due to the low frame rate used in fluoroscopy and cine acquisition. Other contributing factors could be the use of an advanced X-ray imaging system and appropriate use of radiation safety measures in the Cath lab. There was no significant difference in mean ED between children and adults for EP procedures. Obesity is associated with significantly increased radiation exposure to the patient during RF ablation and device implantations.

1 INTRODUCTION

There has been tremendous growth in the field of electrophysiology, including ablations and device implantations, over the last 20 years which also led to growing concerns over potential risks of radiation exposure (1). Knowledge about radiation exposure for an individual cardiac interventional procedure is vital as the laboratory staff gets the majority of the scattered radiation from the patient, which over time becomes significant. An experienced interventional cardiologist receives an average of 5 mSv per year, which is almost three times higher compared to radiologists and nuclear physicians (2). Radiation in the electrophysiology (EP) lab is not just determined by fluoroscopy and cine acquisition, also by the type of X-ray imaging system used, appropriate use of collimation, angle of projection, use of lead aprons and proper education of the operator and the staff (3). Radiation hazards can be divided into either deterministic or stochastic effects. These radiation health hazards apply to both the patients and the laboratory personnel as they are susceptible to the stray radiation from the Cath lab, mainly due to scattering from the patient (4). Children are particularly more sensitive to radiation-related health hazards mostly due to the stochastic effects, primarily due to their hypersensitivity to radiation and prolonged life span, also contributed by the number of procedures and their complexity (5) (6). Obesity is increasingly seen among the general population due to the sedentary lifestyle and unhealthy food habits. According to National Family Health Survey (NFHS-5), obesity has increased by at least 4% in both men and women in the last five years with the current prevalence of 22.9% in men and 24% in women (7). Also, obesity is frequently seen among patients who undergo cardiac catheterization procedures. Obesity is associated with significantly increased radiation exposure compared to normal-weight patients. This is primarily related to the increased requirement of radiation to produce an appropriate quality of images (8). We have adequate data regarding radiation exposure during coronary interventional procedures. However, there is a paucity of data, especially from our country, regarding the fluoroscopy time, radiation dose parameters like dose area product (DAP), radiation-associated risk measured by effective dose (ED) and lifetime attributable risk of malignancy incidence in patients undergoing EP and device implantation procedures. Also, we tried to compare the difference in radiation between adult and pediatric procedures and the impact of obesity on radiation exposure to the patient.

AIM:

i) To quantify ionizing radiation exposure to the patient during all electrophysiological (EP) procedures and device implantations.

ii) To measure and compare radiation exposure during different types of EP procedures.

iii) To evaluate the association between patient body mass index and radiation dose during ablations and device implantations.

iv) To compare the radiation exposure between paediatric and adult EP procedures.

2 LITERATURE REVIEW

There has been significant growth in the field of Cardiology, both in diagnostic and therapeutic aspects. The number of interventional procedures has increased enormously in both coronary and electrophysiological interventions as well as device implantations. The majority of these interventions are done under fluoroscopic guidance. This leads to higher radiation exposure to both the patient, operator and other laboratory staff. The patients are prone to develop acute radiation injury with prolonged procedure times, also they are at risk of increased lifetime malignancy. The operators are exposed to scattered radiation and its associated risks, from cataracts to cancers. There have been reports of incidence of brain tumours among interventional cardiologists (9) and breast malignancy (left-sided) among female cardiologists (10).

RADIATION EXPOSURE AND PROJECTED CANCER RISK IN PATIENTS:

The effective dose of radiation received by the patients during commonly performed cardiological procedures ranges from 1 to 60 mSv. An average of 15 mSv is received by the patient during atrial fibrillation radiofrequency ablation (AFIB-RFA), percutaneous coronary intervention (PCI), myocardial perfusion imaging scintigraphy, and multi-detector coronary angiography. The effective dose (ED) is variable for the same procedure by a factor of 10. For every 10 mSv of radiation exposure, the absolute lifetime attributable risk of fatal malignancy for an adult increases by 0.05% (11). For men aged 50 years, increased cancer risk of 1 in 750 is observed with accumulated ED of 15 mSv. In other words, 1 in 100 is exposed to additional cancer risk (50% of them being fatal) with every 100 mSv exposure. The radiation risks are not uniform across all age groups. It is 3-4 times higher in children (1 in 200), 38% more in females (1 in 500), and ½ the risk in the elderly (1 in 1500 in an octogenarian).

STOCHASTIC AND DETERMINISTIC EFFECTS

Ionizing radiation can lead to two kinds of biological effects: stochastic and deterministic. Stochastic effect (cancers, genetic mutations) was explained by the 'Linear Non-Threshold' model, which tells that every little amount of radiation received is associated with an excess cancer risk with no threshold limit, and there is a linear risk correlation with an increase in radiation dose (12). Whereas the deterministic effect (like skin injury, cataract) has a threshold dose below which it will not occur, and there is a linear correlation with dose. The standard dose limit for skin is 2-3 Gy, and 500 mGy for eyes, above which skin injuries and radiation-induced opacity of eye lens can occur (13). A new dose threshold of 500 mGy to the heart for the non-cancer effects of radiation was given by ICRP (13).

DETERMINANTS OF RADIATION EXPOSURE IN EP LAB

There are two major sources of radiation in the Cath lab: fluoroscopy and cine angiography. Fluoroscopy is commonly used for the placement of catheters and this amounts to a majority (95%) of the X-ray usage time in EP. But it leads to only 40% of the overall radiation exposure to the patients and the laboratory personnel. Cine angiography is used to acquire fluoroscopic images which require a higher frame rate. Though it constitutes 5% of the X-ray time, it amounts to around 60% of the overall radiation dose to the patients and the staff (14). Radiation exposure is not just determined by fluoroscopy time and cine acquisition. Other determinants of radiation exposure include proper collimation, angle of projections during fluoroscopy, operation position in the low-dose scatter area, appropriate usage of a protective lead apron, and adequate training of the operator and the laboratory staff (15). The ED of laboratory staff varies by a factor of 40 attributed to positional changes in fluoroscopy and by a factor of 11 with the usage of protective shielding (3). Hence, all these above-mentioned factors indicate that the amount of radiation exposure in the EP lab is not negligible, and may even be comparable to the dose received during coronary interventions.

RADIATION DOSE DURING COMMON ELECTROPHYSIOLOGICAL PROCEDURES

Interventional EP procedures:

The amount of radiation dose varies with each procedure, depending on the duration and its complexity, also contributed by the experience of the operator. Radiofrequency ablation leads to relatively higher radiation exposure with a median ED of 15.2 mSv compared to an electrophysiological study with a median ED of 3.2 mSv (16). The ED for a cardiac ablation procedure as given by the UK Health Protection Agency was 3-21 mSv (17), but a wide range of ED has been reported by other authors, ranging from 1.6 to 59.6 mSv (5,16,18). The ED of the operator varies from 40-65 mSv, as measured from the dosimeters (16), but varies widely in other case reports.

Cardiac implantable electronic device procedures:

The quantum of radiation received during conventional pacemaker implantation (single chamber or dual chamber) ranges from 1.4 to 1.7 mSv (18–20). Compared to ablations, shielding is difficult to use at the time of device implantations, leading to excess scatter radiation to the operator. Coronary sinus angiogram for left ventricular lead placement often requires more radiation because of cine acquisition, and usage of multiple views for acquisition. Overall radiation exposure is determined by the type of procedure, location of leads, baseline anatomy, and the operator experience (21–23). Hence, among all the device implantation procedures, the highest radiation is observed with CRT implantation, both for the patient (2.2-95 mSv) (18) and the operator (24).

DIAGNOSTIC REFERENCE LEVELS FOR PATIENTS AND DOSE LIMITS FOR OPERATORS

An average dose limit for a laboratory staff per year is 20 mSv. For the eye lens, the annual dose limit for staff is 20 mSv/year (13). Strict dose limits are not applicable for the patients undergoing the procedures as clinical benefit becomes their priority and radiation is a secondary parameter. But it is vital to know about the radiation dose for each patient. If the benefit of a procedure is more than the radiation-related risks, then the procedure can be continued with adequate radiation protection measures. 'Diagnostic reference levels' (DRL) as recommended by the ICRP helps in a better way of managing radiation exposure during EP procedures. These reference levels are created for a particular procedure and it helps as a tool to aid in optimal practice. If the patient radiation dose values are persistently high, around the 75th percentile of DRL, the X-ray imaging system and other parameters have to be reviewed. The threshold recommended for total skin dose is 2-3 Gy above which skin injuries can occur, whereas the threshold is 500 mGy for radiation-induced cataracts (13).

OBESITY AND RADIATION EXPOSURE

With the increase in the prevalence of overweight and obesity in the general population, the overall prevalence of obesity in patients undergoing interventional procedures is increasing. An increase in patient body mass index (BMI) is independently associated with a larger radiation dose to the patient as well as the operators and other laboratory staff (25). Also, Shah et al noted that patients with obesity (BMI >30 kg/m^2) had 2.5 times additional radiation for coronary angiogram in comparison to patients with normal weight (25). Ector et al observed a strong correlation between patient BMI and DAP among patients undergoing atrial fibrillation (AF) ablation procedures (8).

Madder et al did a study to find a correlation between patient BMI and physician radiation dose during a coronary angiogram and observed that increase in BMI was independently associated with significantly higher radiation dose to the physician (26).

METHODS TO CONTROL RADIATION EXPOSURE

Optimization of fluoroscopy settings:

Multiple variables are available in the X-ray imaging system to regulate the radiation dose and image quality, like tube voltage, tube current, pulse duration, and copper filtration which reduces most of the ineffective low-energy radiation. All these variables can be adjusted as appropriate for the patient. The frame rate settings range from as low as 1 frame per second (fps) to nominal settings of 25-30 fps. Reduction of frame rate from 25 fps to 3 fps drastically reduces radiation dose by a factor of 8 (1).

Workflow adaptations:

Angle of Projection:

The left anterior oblique (LAO) projection amounts to a higher radiation dose rate compared to the right anterior oblique (RAO) projection during RF ablation procedures (18). The entrance site of the beam, which is the origin of maximum scatter radiation, is very close to the operator with the LAO compared to RAO or the AP projection. There is also poor shielding of the entrance site by the patient with LAO projection, which leads to at least six times excess radiation dose to the operator with LAO compared to RAO. Hence, reducing the usage of LAO projection reduces the overall exposure to the patient and the operator. Whereas, during left-sided device implantations, RAO amounts to higher dose exposure than LAO (1).

Cine acquisition:

Cine angiography leads to a higher amount of radiation exposure by a factor of 10 compared to fluoroscopy. Hence, its usage should be minimized. When cine is used, duration should be less, with a low framerate and optimal collimation (1).

Detector position:

The image intensifier should be lowered down onto the patient all through the procedure as the output from the X-ray tube is directly proportional to the tube-detector distance. Once table adjustments are done, the detector has to be brought back to the patient before the use of fluoroscopy.

Collimation:

At the start of the procedure, a larger field of view is required. Later, it can be focused on our area of interest using appropriate collimation. This reduces the radiation dose by 4-fold. With the use of 3D imaging during ablations, more informed collimation is possible, due to a better anatomic visualization by 3D imaging (27).

Auto-exposure settings:

The auto-exposure settings have to be monitored throughout the procedure as it controls the detector target dose rate. With bigger electrodes, low-dose imaging would suffice. However, smaller electrode visualization requires higher dose settings. Higher BMI would require a higher dose.

Considering all the above factors, fluoroscopy time is not the only determinant of radiation dose, but the frame rate, use of collimation and the dose rate determines the overall radiation exposure. Hence, DAP and calculated ED gives a more accurate measurement of radiation dose compared to fluoroscopy time alone (1).

3 MATERIALS AND METHODS

Study design:

Single-centre prospective observational study.

Selection of patients:

All patients who underwent electrophysiological (EP) and device implantation procedures in our cardiac catheterization laboratory at the Department of Cardiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology from November 2020 to June 2022 were included in the study. The protocol was approved by the Institutional Ethics Committee (SCT/IEC/1568).

Inclusion criteria:

1. Diagnostic and therapeutic electrophysiological procedures include EP study and cardiac ablations.
2. Cardiac electrical device implantation procedures.

Exclusion criteria:

1. Patients with incomplete clinical and fluoroscopic data.
2. Those who do not wish to give consent.
3. Pregnant patients were excluded.

Data collection:

The demographic and relevant clinical and procedural data, including age, gender, height, weight, and type of electrophysiological procedure was obtained from the patient and electronic medical records. The study population was categorized into 3 groups based on WHO classification of weight status: Normal weight (body mass index

(BMI <25), overweight (BMI 25-29.9) and obesity (BMI $\geq$ 30). Radiation dose parameters including fluoroscopy time, cumulative dose area product and cumulative air kerma recorded in the Philips X-ray system were collected at the end of each procedure. All the procedures were done in a single cardiac catheterization lab dedicated to electrophysiological procedures. The X-ray imaging system used was Allura Clarity (Philips) Flat panel. The screening fluoroscopy for ablations was routinely performed at 3.75 frames per second with a field of view of 25cm, source to image distance of 90-100cm, and energy per frame of 70-80 kV with collimation. Angiography was done with 15 frames per second whenever required. For pacemaker and implantable cardioverter defibrillator (ICD) implantation, screening fluoroscopy and venogram were done at 3.75 frames per second.

Electrophysiological procedures included EP study, radiofrequency catheter ablation of atrioventricular nodal re-entry tachycardia, atrioventricular reciprocating tachycardia, atrial tachycardia, atrial fibrillation, and ventricular tachycardia and cryoablation.

Device implantation procedures included conventional permanent pacemaker, implantable cardioverter defibrillator, pacemaker pulse generator change, cardiac resynchronization therapy, and left bundle branch pacing.

Radiation measures:

Radiation quantity	Unit	Comment
Fluoroscopy time (FT)	min	X-ray exposure time for a particular procedure.
Dose area product (DAP)	cGy. cm^2	Measured or calculated by the X-ray imaging system: the integral of air kerma across the whole X-ray beam emitted from the X-ray tube (can be used for the crude estimation of effective dose)
Effective dose (ED)	mSv	It's the tissue-weighted sum total of the equivalent doses in all specified body organs and tissues. It gives a rough estimation of global biological risk to a patient or medical worker.

Cumulative air kerma (AK)	mGy	The air kerma that is accumulated at the patient entrance reference point. It's measured or calculated by the X-ray imaging system, and gives a rough estimate of the cumulative skin dose.

The dose area product (DAP) was measured automatically by the inbuilt DAP meter in the X-ray imaging system by Philips, and the value was mentioned in centigray x cm^2 (cGy x cm^2).

The mean effective dose (ED) gives the malignancy risk related to the radiation exposure during the EP procedures. It was calculated by the following formula: mSv=DAP (Gy x cm^2)x 0.2 for men; mSv=DAP (Gy x cm^2)x 0.2 x 1.38 for women; for children less than 15 years of age, 0.4 was used instead of 0.2 (28).

The lifetime attributable risk for malignancy incidence and mortality was calculated by multiplying the ED received during each procedure by the patient with the standardized Biological Effects of Ionizing Radiation VII conversion factor of 0.0001/mSv (29).

STATISTICAL ANALYSIS:

The data analysis was performed using the SPSS Statistics software for Windows Version 28. Normally distributed continuous variables were expressed as mean ± standard deviation (SD). Non-normally distributed continuous variables were shown as median (25^{th}-75^{th} percentile). Categorical variables were shown as numbers and percentages. Nonparametric tools were used as all outcome measures were skewed by continuous variables. Differences in measures of radiation exposure across groups were compared using the Kruskal-Wallis H test (nonparametric analog of ANOVA). For comparing two groups with non-parametric distribution, the Mann-Whitney U test was used. Pearson correlation coefficient was used to measure the linear correlation between two quantitative variables. A p value of <0.05 was considered statistically significant. The data will be stored in the personal computer of the principal investigator for three years, maintaining confidentiality.

4 RESULTS

We conducted a prospective observational study in our institution, which included a total of 606 patients including 37 EP studies, 299 RF ablations and 267 device implantations in our Cath lab from November 2020 to June 2022. We analyzed all the radiation parameters obtained from the Allura Clarity X-ray imaging system used for the procedures in our Cath lab. Also, we calculated the effective radiation dose for all the procedures using the baseline radiation data as described in the methodology section and analyzed the difference in dose between various procedures.

BASELINE CHARACTERISTICS:

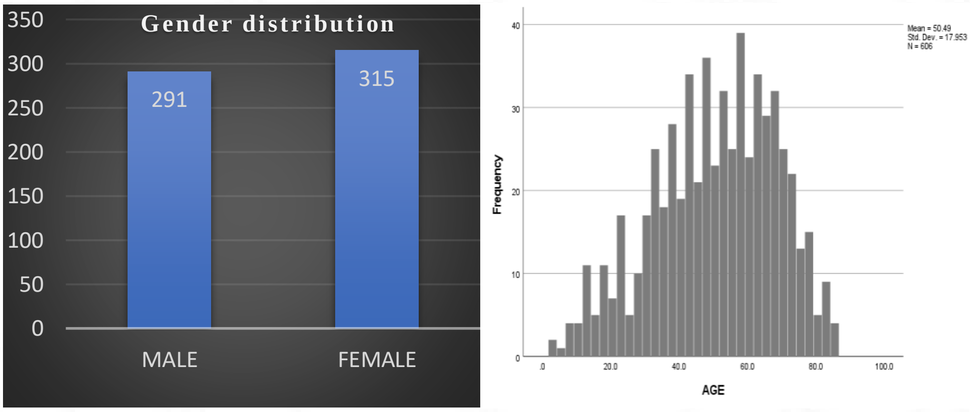

Fig 1: a) Gender distribution of total population b) Histogram shows the age-wise distribution of patients.

The gender distribution of patients in the total population is shown in Fig 1. Out of the total 606 patients, 48% (n=291) were males and 52% (n=315) were females. The mean age of the patients in our study was 50.5 ± 18 years, ranging from 3 years to 86 years. The mean age and gender distribution of individual study groups are as follows: electrophysiological study (EPS) (mean age 40±16; 43% male); atrioventricular reentry tachycardia (AVNRT) (mean age 49±15; 31.5% male); atrioventricular reciprocating tachycardia (AVRT) (mean age 35±15; 55% male); atrial tachycardia (AT) (mean age 40±17; 12.5% male); atrial flutter (AFL) (mean age 52±14; 65% male); atrial fibrillation radiofrequency ablation (AF-RFA) (mean age 40±10; 80% male); AF-Cryoablation (mean age 58±6; 100% male); ventricular tachycardia (VT) (mean age 42±14; 55% male); cardiac implantable electronic device (CIED) (mean age 59±17; 53.5% male); cardiac resynchronization therapy (CRT) (55±14; 65% male).

Table 1: Baseline data and procedural characteristics of all EP procedures and Device implantations.

Parameters	Number (%)
Total, n	606
Males, n %	291(48)
Paediatric, n %	29 (5)
EPS, n %	37 (6)
RFA, n %	299 (49)
- AVNRT, n %	146 (24)
- AVRT, n %	65 (11)
- AT, n %	8 (1)
- AFL, n %	20 (3)
- AF, n %	5 (0.8)
- VT, n %	51 (8)
- DUAL TACHY, n %	4 (0.6)
CIED, n %	267 (44)
- PPI/ICD, n %	167 (27.5)
- PG change, n %	69 (11)
- LBBP, n %	14 (2)
- CRT, n %	17 (3)
Cryoablation, n %	3 (0.5)

(Abbreviations: EPS-electrophysiological study, RFA-radiofrequency ablation, AVNRT-atrioventricular nodal re-entry tachycardia, AVRT-atrioventricular reciprocating tachycardia, AT-atrial tachycardia, AFL-atrial flutter, AF-atrial fibrillation, VT-ventricular tachycardia, CIED-cardiovascular implantable electronic devices, PPI-permanent pacemaker implantation, ICD-implantable cardioverter defibrillator, PG-pulse generator, LBBP-left bundle branch pacing, CRT-cardiac resynchronization therapy)

Baseline data and procedural characteristics of all EP and device implantations are shown in Table 1. The majority of the procedures were done in adults (95%) and pediatric procedures constitute 5% of the overall study population. EP study was done in 37 patients (6%), RFA in 299 patients (49%), CIED in 267 patients (44%) and Cryoablation in 3 patients (0.5%). Among the RF ablations, most commonly performed were AVNRT (24%), followed by AVRT (11%), VT (8%) and other ablations which include AT, AFL, and AF. Among the CIED, the most commonly done was permanent pacemaker implantation/ implantable cardiac defibrillator (PPI/ICD) (27.5%), followed by pulse generator (PG) change (11%), CRT and left bundle branch pacing (LBBP). Cryoablation was done in only 3 patients. Due to the lesser number of patients in the cryoablation group and dual tachycardia, they were excluded from the analysis of radiation data.

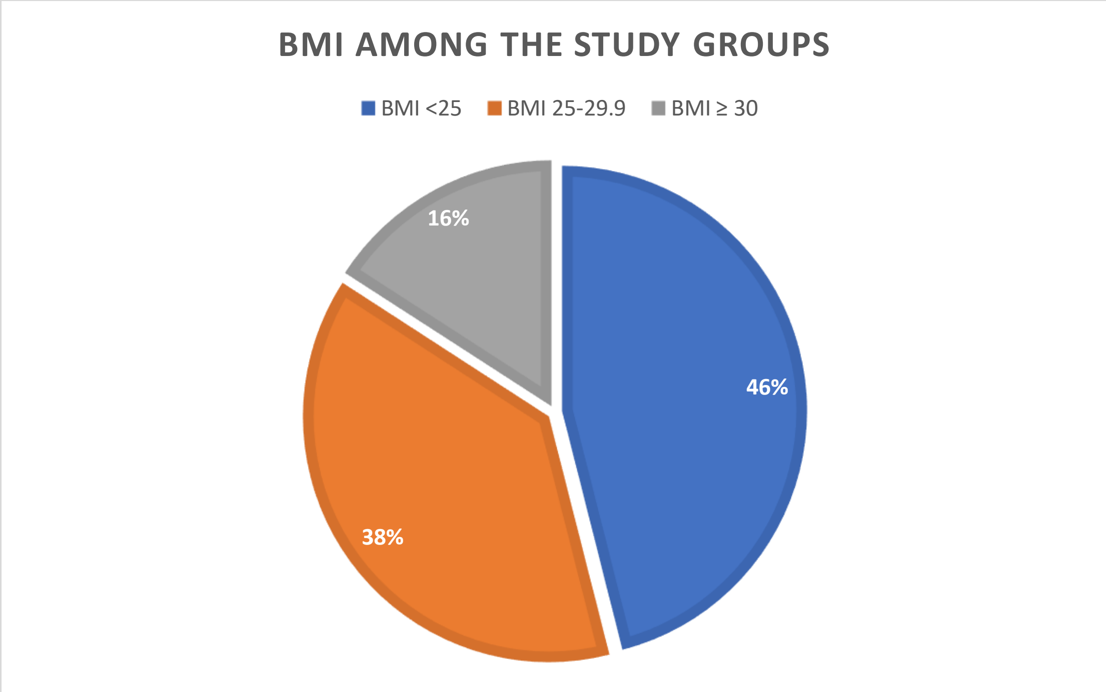

Fig 2: BMI distribution of the study population.

(BMI-body mass index)

The study population was categorized into 3 groups according to their body mass index (BMI) based on WHO classification of weight status (Fig 2): Normal weight (BMI <25), overweight (BMI 25-29.9) and obesity (BMI ≥ 30). 46% of the patients were normal weight, 38% were overweight, and 16% were obese.

Table 2: BMI distribution among individual study groups. (BMI-body mass index)

Division	N	Age	Weight (kg)	Height (cm)	Body mass index (kg/m^2)
Electrophysiology study	37	40 ± 16	61 ± 16	158 ± 13.7	24 ± 4.7
Radiofrequency catheter ablation	299	44 ± 16	66 ± 14	160.2 ± 10.5	25.5 ± 4.6
Cardiac device implantation procedures	267	59 ± 17	66 ± 13	157.5 ± 11	26.5 ± 4.1

Table 2 shows BMI distribution among major study groups; EPS, RFA and CIED. The mean age of the patients who underwent EPS was 40±16 years, RFA: 44±16 years and CIED: 59±17 years. The mean BMI of patients who underwent EPS was 24±4.7 kg/m^{2,} RFA: 25.5±4.6 kg/m^2, CIED: 26.5±4.1 kg/m^2.

ANALYSIS OF BMI AND RADIATION DOSE:

Table 3: Fluoroscopy exposure data of RF ablations among various BMI groups. (BMI-body mass index, FT-fluoroscopy time, DAP-dose area product, AK-air kerma, ED-effective dose)

Parameters	BMI <25 kg/m^2 (n=133)	BMI 25-29.9 kg/m^2 (n=118)	BMI ≥30 kg/m^2 (n=48)
FT, min	14.5 (9.3-25.2)	15.3 (9.2-22.3)	18.5 (22.2-30.1)
DAP, cGy x cm^2	259 (161-667)	439 (206-888)	523 (300-1620)
AK, mGy	27 (17-80.6)	48.6 (22.2-99.5)	63.1 (32-165.9)
ED, mSv	0.67 (0.4-1.7)	0.95 (0.48-2)	1.4 (0.78-3.4)

Fluoroscopy exposure data of RF ablations among various BMI groups are summarized in Table 3. The median effective dose received by patients with normal weight, overweight and obese are respectively 0.67 mSv (0.4-1.7), 0.95 mSv (0.48-2) and 1.4 mSv (0.78-3.4). A comparison of patient BMI with median effective dose received and dose area product is shown in Fig 3. For obese patients, the median total effective dose for RF ablations was 1.4 mSv (1st quartile-0.78, 3rd quartile-3.4), compared to 0.67 mSv (1st quartile-0.4, 3rd quartile-1.7) for patients with a normal BMI (p=0.003). Analysis of fluoroscopy time between normal weight and obese patients showed no significant difference (14.5 min vs 18.5 min, p=0.5).

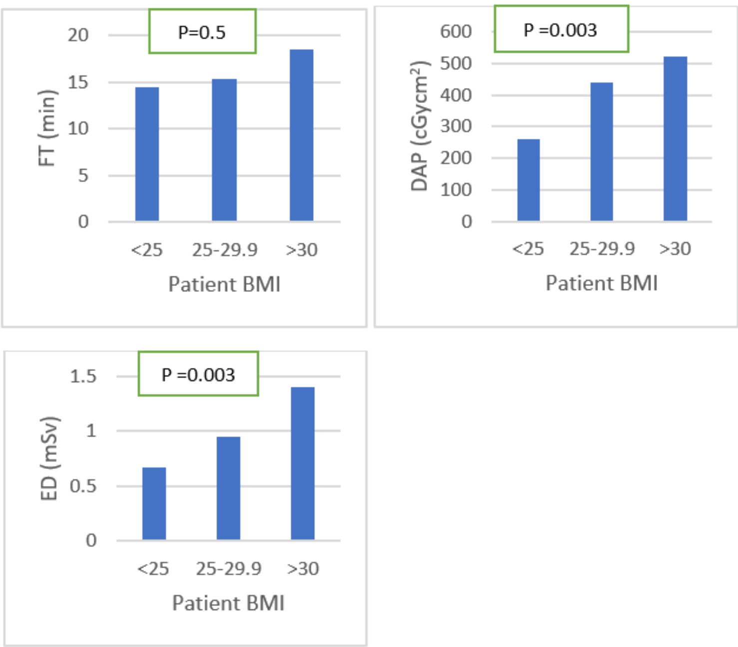

Fig 3: Bar chart showing the comparison of patient BMI with FT, DAP, and median ED. (BMI-body mass index, FT-fluoroscopy time, DAP-dose area product, ED-effective dose)

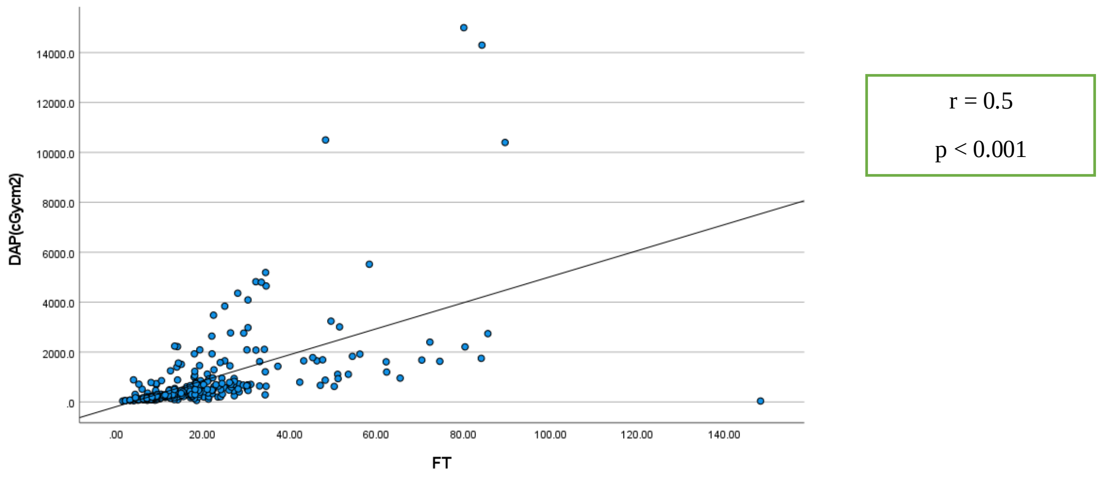

Fig 4: Scatter plot showing the relation between patient radiation dose and total fluoroscopy time. r=0.5, p<0.001 (FT-fluoroscopy time, DAP-dose area product)

The scatter plot shown in Fig 4 shows a stronger correlation between fluoroscopy time and dose area product (r=0.5, p<0.001).

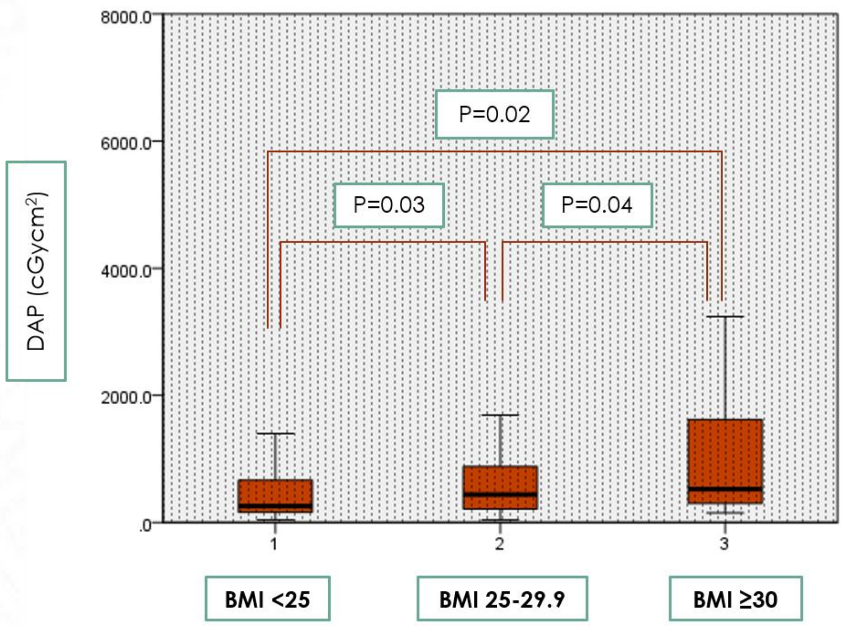

Fig 5: Box and whisker plot showing the distribution of overall DAP among all RF ablations for normal weight (BMI <25 kg/m^2), overweight (BMI 25-29.9 kg/m^2), and obese patients (BMI ≥30 kg/m^2). The boxes indicate the median with the first and third quartiles, and the "whiskers" indicate the upper and lower limits excluding the extreme values. (BMI-body mass index, DAP-dose area product)

From the box and whisker plot shown in Figure 5, among RF ablations, the median DAP of overweight and obese patients was significantly higher than normal weight patients (normal weight vs overweight, p=0.03; normal weight vs obese, p=0.02). There was also a significant difference in radiation dose received between overweight and obese patients (p=0.04).

Table 4: Fluoroscopy exposure data for CIED among various BMI groups. (CIED-cardiac implantable electronic devices, BMI-body mass index, FT-fluoroscopy time, DAP-dose area product, AK-air kerma, ED-effective dose)

Parameters	BMI <25 kg/m^2 (n=125)	BMI 25-29.9 kg/m^2 (n=100)	BMI ≥30 kg/m^2 (n=42)	P value
FT, min	6.37 (3.38-10.57)	7.77 (2.21-12.4)	6.29 (2.27-9.5)	0.8
DAP, cGy x cm^2	108 (67-226)	191 (67.1-533)	172 (81.7-791)	0.05
AK, mGy	10 (5.6-19.4)	20.6 (6.6-53.5)	17 (7.7-81.2)	0.02
ED, mSv	0.26 (0.16-0.5)	0.45 (0.18-1.15)	0.42 (0.2-1.6)	0.05

Fluoroscopy exposure data for all CIED among various BMI groups are summarized in Table 4. The median effective dose received by patients with normal weight, overweight and obese were respectively 0.26 mSv (0.16-0.5), 0.45 mSv (0.18-1.15) and 0.42 mSv (0.2-1.6). There was no significant difference in fluoroscopy time between normal weight and overweight/obese patients (p=0.8). Box and whisker plot (Fig 6) shows the comparison of patient BMI with the median effective dose received. Overweight and obese patients received significantly higher radiation than normal weight patients (normal weight vs overweight, p=0.03; normal weight vs obese, p=0.05), whereas no significant difference in radiation exposure was observed between overweight and obese patients (p=0.79).

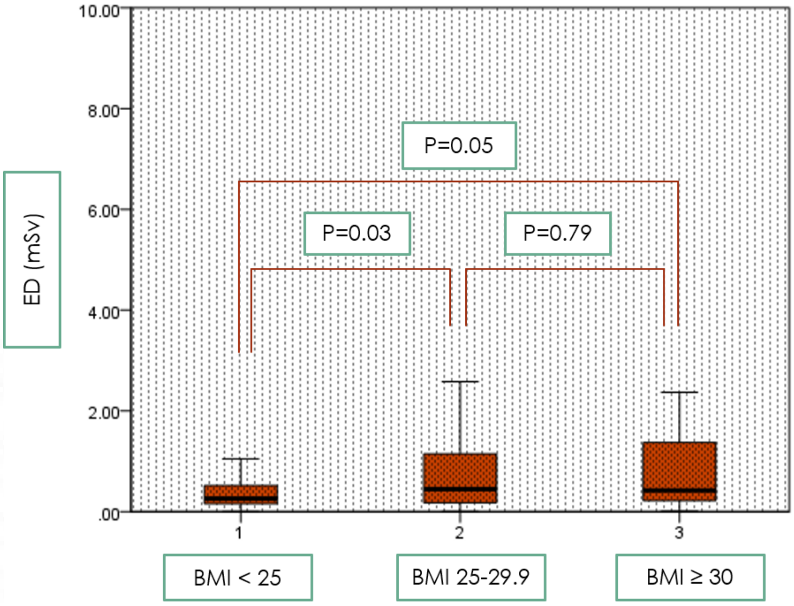

Fig 6: Box and whisker plot showing the distribution of median ED among all CIED for normal weight (BMI <25 kg/m^2), overweight (BMI 25-29.9 kg/m^2), and obese patients (BMI ≥30 kg/m^2). The boxes represent the median with the first and third quartiles, and the "whiskers" represent the upper and lower limits excluding the extreme values. (BMI-body mass index, CIED-cardiac implantable electronic device)

Table 5: Radiation exposure data of major procedure types. (EPS-electrophysiological study, RFA-radiofrequency ablation, CIED-cardiac implantable electronic device, FT-fluoroscopy time, DAP-dose area product, AK-air kerma, ED-effective dose, LAR-lifetime attributable risk)

Parameters	EPS (n=37)	RFA (n=299)	CIED (n=267)	P VALUE
FT, min	5.23 (4-10.5)	16.1 (9.38-26.06)	6.16 (2.27-12)	<0.001
DAP, cGy x cm^2	109 (66.3-219)	336 (198-853)	134 (59-363)	<0.001
AK, mGy	11.14 (6.18-26.29)	38.74 (21.11-95.8)	12.01 (5.56-35.19)	<0.001
ED, mSv	0.28 (0.16-0.43)	0.89 (0.47-2)	0.32 (0.14-0.81)	<0.001
LAR, %	0.002 (0.001-0.004)	0.008 (0.004-0.02)	0.003 (0.001-0.008)	<0.001

Radiation exposure data of major procedure types are shown in Table 5. Here, the major procedure types include EPS, RFA, and CIED. Fluoroscopy time was significantly higher in RFA compared to EPS and CIED (p<0.001), while no significant difference was observed between EPS and CIED (5.23 min vs 6.16 min, p=0.8). All radiation parameters, including median DAP, cumulative median ED, lifetime attributable risk, and total skin dose received as measured by air kerma, were significantly higher in RFA compared to EPS and CIED (p<0.001). There was no significant difference in median ED, DAP, and AK between EPS and CIED (p=0.8).

Table 6: Radiation exposure data of various device implantation procedures.

(PPI-permanent pacemaker implantation, ICD-implantable cardioverter defibrillator, PG-pulse generator, LBBP-left bundle branch pacing, CRT-cardiac resynchronization therapy, DAP-dose area product, LAR-lifetime attributable risk)

Parameters	PPI/ICD (n=167)	PG change (n=69)	LBBP (n=14)	CRT (n=17)	P VALUE
Fluoroscopy time, min	7.5 (4.57-11.59)	1.02 (0.17-1.54)	16.34 (12.4-20.55)	27.29 (21.57-54.03)	<0.001
DAP, cGy x cm^2	171 (89.6-325)	25.6 (8.36-65.7)	961.5 (498-1510)	2000 (715-4880)	<0.001
Air kerma, mGy	15.88 (8.57-30)	2.39 (0.72-5.3)	96.6 (75.69-193.75)	180.37 (64.41-636.24)	<0.001
Effective dose, mSv	0.38 (0.2-0.7)	0.06 (0.01-0.15)	2.3 (1.37-4.16)	4.34 (1.51-9.76)	<0.001
LAR, %	0.003 (0.002-0.007)	0.0005 (0.0001-0.001)	0.02 (0.01-0.04)	0.04 (0.01-0.09)	<0.001

Radiation exposure data of various device implantation procedures are summarized in Table 6. Device implantation procedures included PPI/ICD, PG change, LBBP, and CRT implantation. Overall, there was a significant difference in fluoroscopy time and radiation received between various device implantation procedures ($p<0.001$). Maximum fluoroscopy time was observed in CRT implantation (median- 27.29 min), followed by left bundle branch pacing (median-16.34 min). The highest amount of radiation exposure was observed in CRT implantation among all the device implantation procedures. The lifetime attributable risk of malignancy for each procedure was 40 in 100000 population. Conduction system pacing by LBBP showed significantly higher median dose area product and effective dose of radiation received compared to conventional PPI and ICD implantations (DAP: 961.5 cGycm^2 vs 171 cGycm^2, p<0.001; ED: 2.3 mSv vs 0.38 mSv, p<0.001). Pacemaker PG replacement had negligible radiation at a median ED of 0.06 mSv.

Table 7: Radiation exposure data of various RF ablations.

(AVRT-atrioventricular nodal reentrant tachycardia, AVRT-atrioventricular reciprocating tachycardia, AT-atrial tachycardia, AF-atrial fibrillation, VT-ventricular tachycardia, RFA-radiofrequency ablation, DAP-dose area product, AK-air kerma, ED-effective dose, LAR-lifetime attributable risk)

Parameters	AVNRT (n=146)	AVRT (n=65)	AT (n=8)	ATRIAL FLUTTER (n=20)	AF-RFA(n=5)	VT (n=51)	P VALUE
Fluoroscopy time, min	10.46 (8.03-16.12)	24.11 (15.1-34.17)	32.17 (24.97-51.85)	25.66 (17.88-40.82)	56.14 (42.08-80.32)	19.2 (11.4-29.3)	<0.001
DAP, cGy x cm^2	223.5 (136-373)	826 (305-1930)	764 (316-1370)	820.5 (642-1665)	2210 (1920-2860)	478 (210-743)	<0.001
AK, mGy	25 (14.68-46.74)	87.2 (33.5-214.45)	81.29 (41.55-170.8)	85.94 (59.68-155.4)	189.63 (188.4-264.59)	50.46 (22.5-83.8)	<0.001
ED, mSv	0.58 (0.35-0.95)	1.92 (0.84-4.2)	1.96 (0.9-3.5)	1.94 (1.28-3.47)	5.72 (3.84-6.09)	1 (0.5-1.8)	<0.001
LAR, %	0.005 (0.003-0.009)	0.019 (0.008-0.04)	0.019 (0.009-0.035)	0.019 (0.012-0.034)	0.057 (0.038-0.06)	0.01 (0.004-0.018)	<0.001

Radiation exposure data of various RF ablations are described in Table 7. Overall, there was a significant difference in fluoroscopy time and radiation received between various types of ablations (p<0.001). Maximum fluoroscopy time was observed in AF radiofrequency ablation, compared to other ablations (median 56.14 min). Among all the ablations, the highest total radiation dose and peak skin dose was observed in RFA for AF (median DAP-2210 cGycm^2, median ED-5.72 mSv, median AK-189.63 mGy; p<0.001) followed by AT, AFL, and AVRT respectively (median ED- 1.96 mSv in AT, 1.94 mSv in AFL, and 1.92 mSv in AVRT). The median effective dose in VT ablation was 1 mSv (0.5-1.8 mSv), with a median fluoroscopy time of 19.2 min.

Table 8: Gender-wise radiation exposure. (FT-fluoroscopy time, DAP-dose area product, AK-air kerma, ED-effective dose, LAR-lifetime attributable risk)

Parameters	Male (n=291)	Female (n=315)	P value
FT, min	9.38 (4.49-18.48)	11.35 (6.14-19.32)	0.12
DAP, cGy x cm^2	226 (93.7-708)	239 (103-613)	0.57
AK, mGy	23.35 (9.68-68.53)	25.9 (10.74-63.1)	0.8
ED, mSv	0.48 (0.2-1.4)	0.67 (0.28-1.69)	0.12
LAR, %	0.004 (0.002-0.014)	0.006 (0.002-0.016)	0.12

Analysis of fluoroscopy time and radiation exposure for electrophysiological procedures and device implantations between men and women (Table 8) did not show any statistically significant difference (median ED for men-0.48 mSv, for women-0.67 mSv; p=0.12), though slightly higher fluoroscopy time and median ED was observed in females.

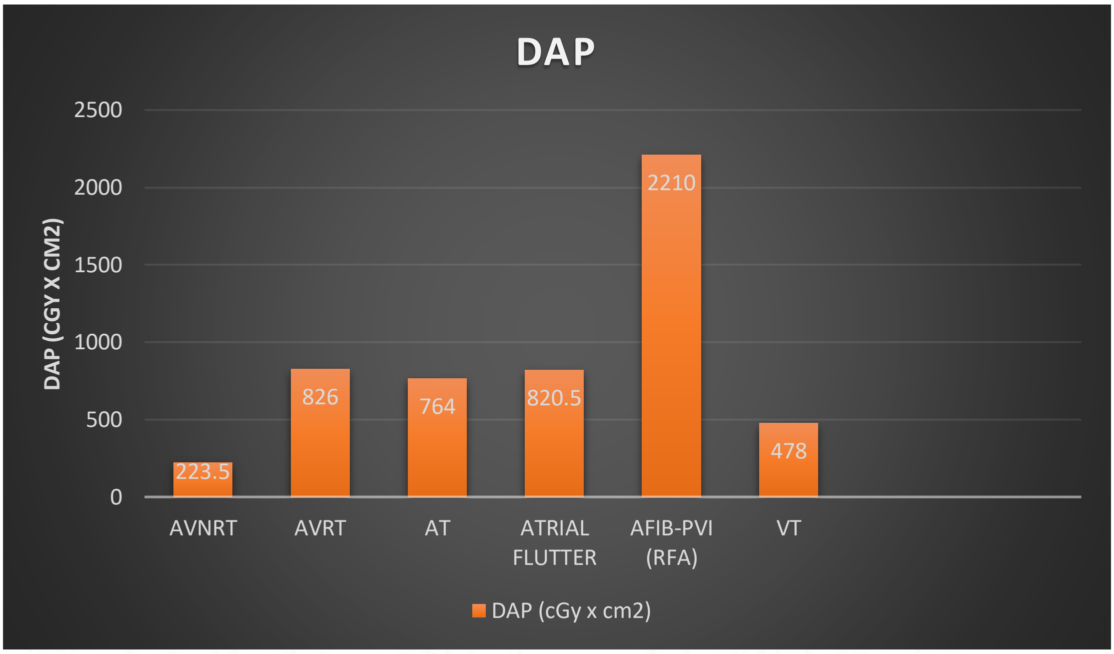

Fig 7: Bar chart showing DAP among various RF ablations. (DAP-dose area product, RF-radiofrequency, AVNRT-atrioventricular nodal reentry tachycardia, AVRT-atrioventricular reciprocating, AT-atrial tachycardia, AFIB-atrial fibrillation, PVI-pulmonary vein isolation, VT-ventricular tachycardia)

The bar chart (Fig 7) shows the median dose area product in various ablation procedures. Pulmonary vein isolation for AF (AF RFA) was associated with maximum radiation dose received compared to other procedures. Also, AVNRT ablation was found to have the least radiation among all the other ablations.

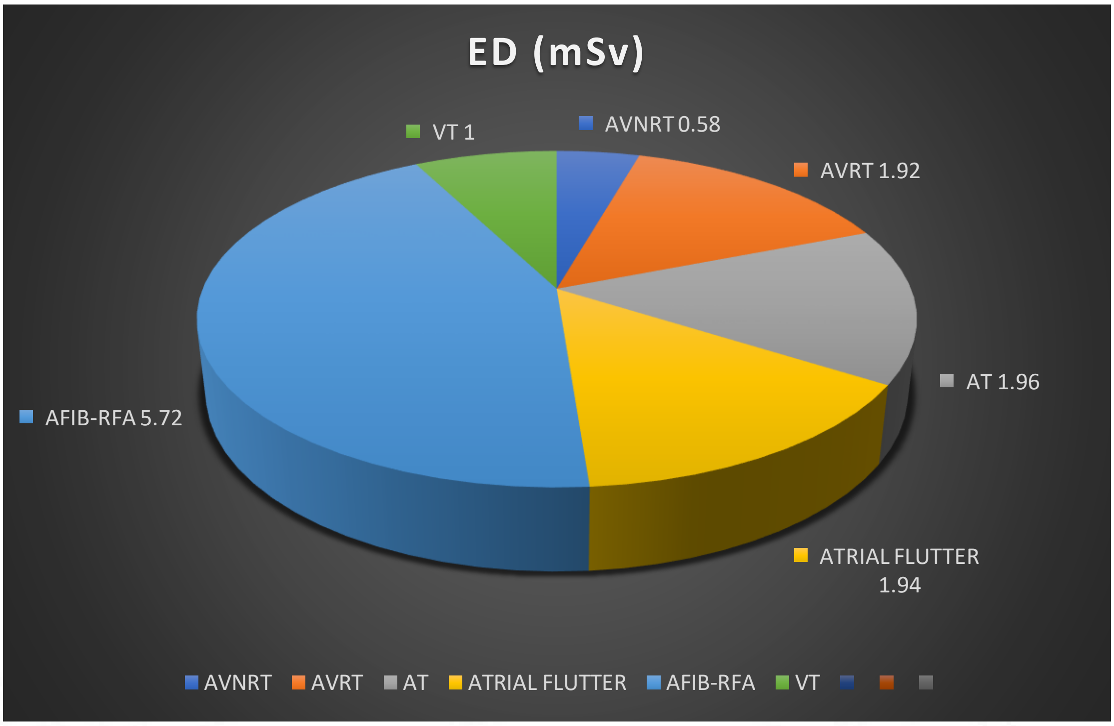

Fig 8: Pie chart showing the median ED among various ablation procedures. (ED-effective dose, RFA-radiofrequency ablation, AVNRT-atrioventricular nodal reentry tachycardia, AVRT-atrioventricular reciprocating, AT-atrial tachycardia, AFIB-atrial fibrillation, VT-ventricular tachycardia)

The pie chart shown in Fig 8 summarizes the median effective dose calculated for various ablation procedures according to the formula shown in the methodology section. The maximum median ED was observed with AFIB-RFA and the least median ED was observed with AVNRT ablation (AFIB-RFA: 5.72 mSv, AVNRT: 0.58 mSv).

Table 9: Radiation exposure in children (<18 years) for EP procedures and device implantations. (EPS-electrophysiological study, RFA-radiofrequency ablation, PPI-permanent pacemaker implantation, ICD-implantable cardioverter defibrillator, DAP-dose area product, AK-air kerma, ED-effective dose, LAR-lifetime attributable risk)

Parameters	EPS (n=3)	RFA (n=23)	PPI/ICD (n=6)
Fluoroscopy time, min	13.07 ± 7.14	22 ± 14	9.6 ± 4.87
DAP, cGy x cm^2	271.8 ± 242.8	760.2 ± 1282.6	94.5 ± 69.2
AK, mGy	31.9 ± 25.3	93.7 ± 149.6	9.5 ± 6.5
ED, mSv	1.09 ± 0.97	2.5 ± 3.69	0.33 ± 0.18
LAR, %	0.01 ± 0.01	0.02 ± 0.03	0.003 ± 0.002

Radiation exposure for children (<18 years) who underwent EPS, RFA and PPI/ICD in our institution is summarized in Table 9. The mean fluoroscopy time was highest for RFA (22 ±14 min) followed by EPS (13.07 ±7.14 min) and PPI/ICD implantation (9.6 ±4.87). The mean effective dose was higher for EPS compared to PPI/ICD (1.09 ±0.97 vs 0.33 ±0.18), though p value could not be obtained due to the small sample size.

Table 10: Comparison of adult and pediatric radiation dose. (FT-fluoroscopy time, EPS-electrophysiological study, RFA-radiofrequency ablation, PPI-permanent pacemaker implantation, ICD-implantable cardioverter defibrillator, DAP-dose area product, AK-air kerma, ED-effective dose, LAR-lifetime attributable risk)

Parameters	Adult	Paediatric	P value
FT (min)			
- EPS	7.72 ± 7.56	13.07 ± 7.14	0.1
- RFA	20.18 ± 17.1	22 ± 14	0.27
- PPI/ICD	9.1 ± 7	9.6 ± 4.87	0.5
DAP (cGy x cm^2)			
- EPS	407.84 ± 841.6	271.8 ± 242.8	0.6
- RFA	840 ± 1600	760.2 ± 1282.6	0.2
- PPI/ICD	309 ± 410.8	94.5 ± 69.2	0.04
AK (mGy)			
- EPS	48.1 ± 102	31.9 ± 25.3	0.6
- RFA	94.9 ± 178.2	93.7 ± 149.6	0.4
- PPI/ICD	32.1 ± 47.5	9.5 ± 6.5	0.05
ED (mSv)			
- EPS	1.02 ± 2.2	1.09 ± 0.97	0.47
- RFA	2.06 ± 4.25	2.5 ± 3.69	0.5
- PPI/ICD	0.73 ± 0.98	0.33 ± 0.18	0.37
LAR (%)			
- EPS	0.01 ± 0.02	0.01 ± 0.01	0.47
- RFA	0.02 ± 0.04	0.02 ± 0.03	0.5
- PPI/ICD	0.007 ± 0.01	0.003 ± 0.002	0.37

Table 10 shows the comparison of radiation dose between adult and paediatric EP procedures and device implantations. The mean fluoroscopy time for paediatric procedures, including EPS, RFA, and PPI/ICD was slightly higher than adult procedures though not statistically significant. There was no significant difference in mean effective dose between adult and paediatric EPS and RFA (EPS: Adult-1.02 ±2.2 mSv vs Paediatric-1.09 ±0.97 mSv, p=0.47; RFA: Adult-2.06 ±4.25 mSv vs 2.5 ±3.69 mSv). The mean dose area product and mean air kerma for PPI/ICD implantation were significantly higher for adults compared to paediatric procedures (DAP: 309±410.8 vs 94.5±69.2, p=0.04; AK: 32.1±47.5 vs 9.5±6.5, p=0.05), though the calculated mean effective dose did not show a statistically significant difference (0.73±0.98 vs 0.33±0.18, p=0.37).

5 DISCUSSION:

In this study, we have analysed the complete radiation exposure of all the individual electrophysiological procedures and device implantations done in our cardiac catheterization lab from November 2020 to June 2022, including a total of 606 patients. This study was conducted primarily to provide systematic fluoroscopic data among electrophysiological procedures, as none so far is available from India.

Baseline characteristics:

The mean age of our study population was 50.5 ± 18 years. Of the total study population, 48% were males and 52% were females. The majority of the EP procedures (95%) were done in adults. Ablations represented almost half of the total EP procedures. Analysis of fluoroscopy time and radiation exposure for electrophysiological procedures and device implantations between men and women (Table 8) did not show any statistically significant difference (median ED for men-0.48 mSv, for women-0.67 mSv; p=0.12), though slightly higher fluoroscopy time and median ED was observed in females. A study by Subban et al (30) showed among coronary interventions, the male gender had a significant contribution to higher radiation dose, though females represented only 29% of the cohort.

Impact of BMI on radiation dose:

Overall, 38% were overweight, 16% were obese and an increase in BMI was associated with significantly increased radiation to the patient, both in ablations and device implantation procedures. This finding was consistent with the previous study by Shah et al (25) where he observed that with an increase in patient BMI, there was a higher radiation dose received during the coronary angiogram. A study by Ector et al (8) showed that the amount of effective radiation dose received by obese patients was more than twice that received by normal-weight patients.

Comparison of our study with previously published series in the literature.

Table 11: Comparison of EPS:

TYPE OF PROCEDURE	REFERENCE	YEAR	TYPE OF STUDY	NUMBER OF PATIENTS	FLUOROSCOPY TIME (min)	DAP ($cGycm^2$)	EFFECTIVE DOSE (mSv)
EPS	Pantos I et al (31)	2009	Retrospective	237	9 (0.1-25.8)	1450	3.2 (1.3-23.9)
	Smith IR et al (32)	2009	Retrospective	732	2.1 (1.3-3.3)	240 (150-390)	0.3 (0.2-0.5)
	Heidbuchel H et al (1)	2014	EHRA practical guide				3.2 (1.3-23.9)
	Casella M et al (33)	2018	Retrospective	1329	2 (0.5-5)	347 (148-882)	0.8 (0.3-2)
	Index study	**2022**	**Observational**	**37**	**5.23 (4-10.54)**	**109 (66.3-219)**	**0.3 (0.16-0.43)**

Our study had a lesser number of EPS compared to other studies. The median fluoroscopy time was 5.23 minutes, which was comparable to other studies and the median ED was 0.3 mSv, which was significantly less compared to previous studies (details are given in Table 11).

Table 12: Comparison of SVT ablation:

TYPE OF PROCEDURE	REFERENCE	YEAR	TYPE OF STUDY	NUMBER OF PATIENTS	FLUOROSCOPY TIME (min)	DAP ($cGycm^2$)	EFFECTIVE DOSE (mSv)
SVT	Smith IR et al (32)	2009	Retrospective	AFl 498 AVNRT 270 AVRT 135 AT 124	16.8 (9.5-30.5) 2.1 (1.3-4.5) 23.8 (13.4-45.3) 14.9 (7.7-28)	1890 (1130-3530) 260 (170-610) 2690 (1600-5410) 1770 (900-3510)	
	Rogers DP et al (34)	2011	Observational	Pre DRM 214 Post DRM 417		2040 ± 2690 800 ± 1030	3.3 1.24
	Heidbuchel H et al (1)	2014	EHRA practical guide				4.4 (1.6-25)
	Lehrmann H et al (35)	2016	Observational	AVNRT 187	8 (6–13)	158 (78–338)	0.4 (0.2–0.8)
	Casella M et al (33)	2016	Multicentre randomized	Pre DRM 128 Post DRM 134	14.32 (9.08-22.43) 0 (0-0.2)	2036 (54–5297) 278 (80–791)	8.87 (3.67–22.01) 0 (0–0.08)
	Giaccardi M et al (36)	2016	Retrospective	Pre DRM 144 Post DRM 250	19.32 ± 13.88 0.23 ± 0.1	10963.3 ± 10472.2 283.4 ± 56.8	
	See J et al (37)	2016	Observational	Pre DRM AVNRT 66 Post DRM AVNRT 35	20.3 ± 10.6 6.8 ± 5.8	1361.9 ± 976.9 392.0 ± 462.5	
	Casella M et al (33)	2018	Retrospective	Afl/AT 468 SVT 979	14 (7-24) 13 (6-21)	3231 (1381-6958) 1721 (727-3884)	7.3 (3.1-14.7) 4.1 (1.8-9.1)
	Index study	**2022**	**Observational**	**AVNRT 146** **AVRT 65** **AT 8** **AFL 20**	**10.46 (8-16.1)** **24.1 (15.1-34.2)** **32.17 (25-51.8)** **25.6 (17.9-40.8)**	**223.5 (136-373)** **826 (305-1930)** **764 (316-1370)** **820.5 (642-1665)**	**0.58 (0.35-0.95)** **1.92 (0.84-4.2)** **1.96 (0.9-3.5)** **1.94 (1.28-3.47)**

(DRM-dose reduction measure)

Regarding SVT ablations, the total number of patients were 239, comparable to previous studies. The FT and median ED of AVRT, AT and AFL were not significantly different, though a slightly higher median ED was observed with AT. Overall FT and median ED of SVT ablations were significantly less in our study compared to previous studies (refer to Table 12), where they initially reported higher radiation dose, and later came down after dose reduction measures.

Table 13: Comparison of VT ablation:

TYPE OF PROCEDURE	REFERENCE	YEAR	TYPE OF STUDY	NUMBER OF PATIENTS	FLUOROSCOPY TIME (min)	DAP ($cGycm^2$)	EFFECTIVE DOSE (mSv)
VT/PVC	Smith IR et al (32)	2009	Retrospective	97	17.4 (9.7-26.4)	2080 (1150-3150)	2.9 (1.6-4.4)
	Heidbuchel H et al (1)	2014	EHRA practical guide				12.5 (3-≥45)
	Casella M et al (33)	2018	Retrospective	VT 453 PVC 450	36 (24-49) 13 (7-22)	13849 (5606-23429) 2609 (925-6178)	28.4 (11.7-47.7) 6.2 (2.1-13.5)
	Index study	**2022**	**Observational**	**VT 51**	**19.2 (11.4-29.3)**	**478 (210-743)**	**1 (0.5-1.8)**

(PVC-premature ventricular complex)

We had 51 VT ablations in our study, significantly less in number compared to other larger studies (Table 13). The median FT was 19 minutes, almost similar values were reported in previous studies. However, the median DAP and ED were significantly less in our study. Possible reasons could be a lesser number of ischemic VT ablations, the use of a 3D anatomical mapping system for VT ablations, and a low frame rate in all ablations.

Table 14: Comparison of PPI/ICD implantation:

TYPE OF PROCEDURE	REFERENCE	YEAR	TYPE OF STUDY	NUMBER OF PATIENTS	FLUOROSCOPY TIME (min)	DAP ($cGycm^2$)	EFFECTIVE DOSE (mSv)
PM/ICD	Tsalafoutas IA et al (19)	2005	Observational	55	6.6	1104	
	Compagnone G et al (38)	2012	Observational	68	7.5	2570	
	Heidbuchel H et al (1)	2014	EHRA practical guide				4 (1.4-17)
	van Dijk JD et al (39)	2017	Retrospective	Pre DRM 408 Post DRM 364		1640 ± 1850 520 ± 660	
	Attanasio P et al (40)	2016	Retrospective	Pre DRM 280 Post DRM 304	13 ± 15 13 ± 15	3792±5025 1372±2659	
	Casella M et al (33)	2018	Retrospective	1743	4 (2.5-7)	545 (257-1181)	1.2 (0.6-2.6)
	Index study	**2022**	**Observational**	**167**	**7.5 (4.57-11.59)**	**171 (89.6-325)**	**0.38 (0.2-0.7)**

(DRM-dose reduction measure)

We analyzed a total of 167 PPI/ICD implantations. The median FT was 7.5 minutes, similar to the ones reported in previous studies (Table 14). The median DAP and ED were significantly less compared to previous studies. A total of 14 patients underwent LBBP in our study. The median FT was 16.34 minutes and the median DAP was 961.5 minutes. There was a more than 2-fold increase in FT and a more than 5-fold increase in median DAP during LBBP compared to conventional PPI/ICD implantations.

Table 15: Comparison of CRT implantation:

TYPE OF PROCEDURE	REFERENCE	YEAR	TYPE OF STUDY	NUMBER OF PATIENTS	FLUOROSCOPY TIME (min)	DAP ($cGycm^2$)	EFFECTIVE DOSE (mSv)
CRT	Butter C et al (24)	2010	Observational	104	20.3 ± 16	11100 ± 10100	
	Morris M et al (42)	2014	Retrospective	1316	18.7 ± 0.3	2510 ± 1300	
	Heidbuchel H et al (1)	2014	EHRA practical guide				22 (2.2-95)
	Thibault B et al (43)	2015	Observational	MG 60 CONV 70	6.5 (4.3-10.7) 19.1 (10.2-25.3)	769 (491-2182) 2608 (1333-5345)	
	van Dijk JD et al (39)	2017	Retrospective	Pre DRM 183 Post DRM 230		7210 ± 6000 1780 ± 1740	
	Casella M et al (33)	2018	Retrospective	312	17 (11-29)	4094 (2028-8210)	8.7 (4.7-17.1)
	Index study	**2022**	**Observational**	**17**	**27.29 (21.57-54.03)**	**2000 (715-4880)**	**4.34 (1.51-9.76)**

(DRM-dose reduction measure)

There were 17 CRT implantations in our study. Though the median FT was higher compared to other studies (shown in Table 15), the median DAP and ED were found to be less in our study.

Table 16: Comparison of AF ablation:

TYPE OF PROCEDURE	REFERENCE	YEAR	TYPE OF STUDY	NUMBER OF PATIENTS	FLUOROSCOPY TIME (min)	DAP ($cGycm^2$)	EFFECTIVE DOSE (mSv)
AF	Ector J et al (8)	2007	Observational	85	83 ± 26	11960 (1390-44630)	25.3 ± 13.8
	Smith IR et al (32)	2009	Retrospective	202	43.3 (28.5-58.8)	5330 (3440-7300)	7.4 (4.8-10.2)
	Rogers DP et al (34)	2011	Observational	Pre DRM 79 Post DRM 263		6330 ± 5010 3280 ± 3170	2.83
	Heidbuchel H et al (1)	2014	EHRA practical guide				16.6 (6.6-59.6)
	Pontone G et al (44)	2015	Retrospective	200			32.8 ± 23.5
	Jourda F et al (45)	2015	Observational	RF 75	21.5 ± 8.5	4748 ± 2411	
	Squara F et al (46)	2015	Observational	RF 198	19.3 ± 8.2	4273 ± 2934	
	Schneider R et al (47)	2015	Observational	Pre DRM 101 Post DRM 105	29.9 ± 11.3 13.3 ± 8.3	8690 ± 5727 837 ± 647	
	Lee G et al (48)	2015	Retrospective	Pre DRM 1005 Post DRM 510	41 (28.8) 9.5 (9.8)	357.10 (452.7) 104.35 (105.0)	

(DRM-dose reduction measure)

Table 16 CONT… Comparison of AF ablation

TYPE OF PROCEDURE	REFERENCE	YEAR	TYPE OF STUDY	NUMBER OF PATIENTS	FLUOROSCOPY TIME (min)	DAP (cGycm^2)	EFFECTIVE DOSE (mSv)
AF	Straube F et al (49)	2016	Observational	RF 180	16.0 (13.0–23.0)	2663 (1646–3958)	
	Wynn GJ et al (50)	2016	Multicenter randomized controlled	124	22.6 ± 12.7	3065 ± 4853	
	Kleemann T et al (51)	2016	Observational	Pre DRM 6617 Post DRM 526	26 (17–41) 23 (13–49)	3400 (1800–6400) 800 (300–3700)	
	Blockhaus C et al (52)	2016	Observational	Pre DRM 37 Post DRM 15	16.8 ± 8.8 9.5 ± 3.1	6208 ± 3314 4342 ± 2073	
	Lehrmann H et al (35)	2016	Observational	Pre DRM 2005: 52 Post DRM 2015: 52	53 (41–71) 5 (4–6)	4635 (3155–6357) 185 (117–286)	9.3 (6.4–13.4) 0.4 (0.3–0.6)
	Lee JH et al (53)	2017	Retrospective	Pre DRM 57 Post DRM 76	24.4 (17.5–34.9) 15.1 (10.7–20.1)	599.9 (371.4–1337.5) 392.0 (289.7–591.4)	1.1 (0.7–2.5) 0.7 (0.6–1.1)
	Attanasio P et al (54)	2017	Observational	Pre DRM 75 Post DRM 75	14.22 ± 4.47 13.62 ± 7.11	630.28 ± 550.96 226.44 ± 277.44	
	Casella M et al (33)	2018	Retrospective	1809	24 (15-36)	7178 (3668-13423)	15.7 (7.9-28.6)
	Index study	**2022**	**Observational**	**RF 5**	**56.1 (42.1-80.3)**	**2210 (1920-2860)**	**5.72 (3.84-6.09)**

(DRM-dose reduction measure)

We had 5 patients who underwent RFA for AF. The median FT in our study was 56.1 minutes which was higher in comparison to other studies (Table 16). The radiation dose received was significantly higher for AF ablation compared to other ablations. However, the median DAP and ED were significantly less when compared to most of the previous studies.

LIMITATIONS:

This was a single-centre observational study. The number of procedures was relatively less due to the prevailing Covid pandemic. Estimation of ED was done with simplified formula suggested by EHRA practical guide. A more accurate estimation of ED could have been done with complex models (i.e., Monte Carlo simulation). This might slightly underestimate the real ED and the estimated lifetime attributable to cancer risk. We calculated the peak skin dose from the values recorded in the machine and did not place any dosimeters over the patient. There might be a slight difference from the actual skin dose measured from the dosimeter. A reference dose of 80-kV tube voltage was used for calculating the effective radiation dose for each procedure. Obese patients require higher tube voltages (90-100 kV) during procedures which lead to higher ED for a particular DAP value. Hence, our study results may underestimate the effect of obesity on the ED to some extent during these procedures.

6 SUMMARY AND CONCLUSIONS:

- The majority of the EP procedures (95%) were done in adults. 48% were males and 52% were females. Ablations represent almost 50% of the total EP procedures.
- In the study population, 38% were overweight and 16% were obese. Among RF ablations, the median overall ED of overweight patients was 42% ($p=0.03$) higher and obese patients were 109% ($p=0.02$) higher than normal-weight patients. Among device implantations, the median overall ED of obese patients was 61.5% higher than normal-weight patients ($p=0.05$). There was no significant increase in the fluoroscopy time with an increase in body mass index ($p=0.5$).
- There was no gender-wise difference in the radiation exposure.
- Among device implantations, the highest radiation was associated with CRT (median ED-4.34) followed by LBBP (median ED-2.3) and PPI/ICD (ED-0.38). There was a more than 2-fold increase in FT and a more than 5-fold increase in median DAP during LBBP compared to conventional PPI/ICD implantations.
- Among EP ablations, radiation exposure of AF ablation > AVRT=AT=AFL > VT.
- No significant difference in fluoroscopy time or mean ED was observed between adult and paediatric EP procedures, though mean DAP was significantly higher for adult PPI/ICD implantations.
- Overall radiation exposure to patients in our study was less than that observed in most of the previous studies.

CONCLUSION

- Overall radiation exposure to patients during electrophysiological procedures and device implantations was less in our study which could be due to the use of a low frame rate in fluoroscopy and acquisition. Other contributing factors could be the use of an advanced X-ray imaging system and appropriate use of radiation safety measures in the Cath lab.
- Obesity was associated with significantly increased radiation exposure to the patient.
- There was no significant difference in radiation exposure between adult and paediatric age groups for electrophysiological procedures and device implantations.

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Publications

S. No.	Publications	Type of Article	Year
1	**Sundaram C**, Shriramganesh RT, Sangeetha G. Hemophagocytic lymphohistiocytosis following reactivation of Epstein– Barr virus infection – A rare case report. Indian J Med Sci 2021;73(2):264-5.	Case Report	2021
2	**Sundaram C**, Kartik S V, Namboodiri N, Ajitkumar VK. A Novel pacing option in patients with endomyocardial fibrosis: A case series. Indian Pacing Electrophysiol J. 2021 Sep-Oct;21(5):303-307. doi: 10.1016/j.ipej.2021.05.007. Epub 2021 May 24. PMID: 34044159; PMCID: PMC8414184.	Case series	2021
3	**Sundaram C**, Namboodiri N, Ajitkumar VK, Mohanan Nair KK. Two pacing spikes on the T wave in a single-chamber pacemaker: What is the mechanism? Indian Pacing Electrophysiol J. 2022 Jan-Feb;22(1):42-43.doi: 10.1016/j.ipej.2021.09.003. Epub 2021 Oct 1. PMID: 34601109; PMCID: PMC8811285.	Case Report	2022

Published Abstracts

S. No.	Title	Journal	Year
1	Acute and long-term results of radio-frequency ablation in children-a single centre experience	IPEJ	2022

APPENDIX A: ETHICS COMMITTEE APPROVAL

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेंद्रम - 695 011, केरल, भारत
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY
TRIVANDRUM - 695 011, KERALA, INDIA
(एक राष्ट्रीय महत्व का संस्थान, विज्ञान एवं प्रौद्योगिकी विभाग, भारत सरकार)
(An Institution of National Importance, Department of Science and Technology, Government of India)
टेलीफोन न./Telephone No.: 0471-2443152 फैक्स/Fax: 0471-2446433, 2550728
ई-मेल/E-mail: sct@sctimst.ac.in वेबसाइट/Website: www.sctimst.ac.in

Institutional Ethics Committee

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

SCT/IEC/1568 /OCTOBER-2020 24.12.2020

Dr. Sundaram C
Senior Resident
Department of Cardiology
SCTIMST, Thiruvananthapuram

Dear Dr. Sundaram,
Thank you for submitting documents related to your proposal titled "**RADIATION EXPOSURE IN CARDIAC ELECTRO-PHYSIOLOGY: A PROSPECTIVE OBSERVATIONAL STUDY IN A TERTIARY CARE CENTRE** (IEC/1568)" to the IEC for review.

The following documents were reviewed:

1. Check list
2. Study Proposal
3. IEC Application dully signed by the PI
4. Covering letter addressed to Chairman dated 13.08.2020 endorsed by the HoD, Dr.Krishnamoorthy
5. Thesis Proforma
6. TAC Approval letter with appendix 1 dated 27/07/2020
7. Patient Information Sheet (English)
8. Patient Information Sheet (Malayalam)
9. Consent form(English)
10. Consent form(Malayalam)
11. Signed CV of PI ,Dr.Sundaram, with TNMC Number
12. Signed CV of Co.PI Dr.Krishnamoorthy with TCMC Number
13. Signed CV of Dr.Narayan Namboodiri with TMC Number
14. Signed CV of Dr.Mukund Prabhu with TCMC Number
15. Covering letter to the Chairman, IEC dated 13.08.2020 from Dr.Sundaram

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The following members of the Students Sub-Committee of the Institutional Ethics Committee participated in the discussions held between August 23-October 29, 2020 at the offices and residences of the members

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. R V G Menon	M Tech, PhD	Male	Lay Person (Chairman)	No
2.	Dr. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
3.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
4.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
5.	Dr. Rema M. N	MD	Female	Basic Medical Scientist	No
6.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
7.	Dr. Mala Ramanathan	PhD	Female	Social Scientist (Member Secretary)	Yes

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

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

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

Sincerely,

Mala Ramanathan
Member Secretary, IEC

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APPENDIX B: PLAGIARISM CHECK REPORT

Ouriginal by Turnitin

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Analyzed document	Sundaram thesis.docx (D142864039)
Submitted	2022-08-12 17:39:00
Submitted by	Dr P K Dash
Submitter email	dash@sctimst.ac.in
Similarity	2%
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Sources included in the report

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SYNOPSIS