

BMJ Open Kerala Atrial Fibrillation Registry: a prospective observational study on clinical characteristics, treatment pattern and outcome of atrial fibrillation in Kerala, India, cohort profile

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ABSTRACT

Purpose Limited published data exist on the clinical epidemiology of atrial fibrillation (AF) in South Asia including India. Most of the published data are from the Western countries and the Far East. The Kerala AF registry was initiated to collect systematic, prospective data on clinical characteristics, risk factors, treatment pattern and outcomes of consecutive AF patients who consulted cardiologists across the state of Kerala, India.

Participants All newly diagnosed and previously reported patients aged ≥ 18 years with documented evidence of AF on ECG were included. Patients with transient AF due to infection, acute myocardial infarction, alcohol intoxication, metabolic abnormalities and AF seen in postoperative cases and critically ill patients with life expectancy less than 30 days were excluded.

Findings to date A total of 3421 patients were recruited from 53 hospitals across Kerala from April 2016 to April 2017. There were 51% (n=1744) women. The median age of the cohort was 65 (IQR 56–74) years. Hypertension, diabetes mellitus and dyslipidaemia were present in 53.8%, 34.5% and 42.2% patients, respectively. Chronic kidney disease was observed in 46.6%, coronary artery disease in 34.8% and heart failure (HF) in 26.5% of patients. Mean CHA₂DS₂-VASc score of the cohort was 2.9, and HAS-BLED score was 1.7. Detailed information of antithrombotic and antiarrhythmic drugs was collected at baseline and on follow-up. During 1-year follow-up, 443 deaths (12.9%) occurred of which 332 (9.7%) were cardiac death and 63 (1.8%) were due to stroke. There were 578 (16.8%) hospitalisations mainly due to acute coronary syndrome, arrhythmias and HF.

Future plans Currently, this is the largest prospective study on AF patients from India, and the cohort will be followed for 5 years to observe the treatment patterns and clinical outcomes. The investigators encourage collaborations with national and international AF researchers.

Strengths and limitations of this study

- Currently the largest prospective cohort of atrial fibrillation (AF) patients from South Asia.
- Fifty-three participating centres recruited patients from government hospitals, teaching institutions, private and corporate hospitals located both in urban and rural areas of Kerala state.
- The collected data included physical examination, electrocardiographic and echocardiographic findings, laboratory investigations of blood sample and follow-up outcomes.
- Although the study is limited to Kerala, results may provide an indication of future epidemiology of AF in India as Kerala is ahead of other states in epidemiological transition.
- However, these registry data may not reflect the true incidence or prevalence of AF in the state, since it is a hospital-based study.

Trial registration number CTRI/2017/10/010097.

INTRODUCTION

Atrial fibrillation (AF) is the most common cardiac arrhythmia seen in clinical practice, and it is an independent risk factor for death in men and women.¹ AF is associated with a fivefold increase in stroke risk and 25%–30% stroke seen in adults are associated with this arrhythmia.^{2,3} While AF is a global problem, much of the available epidemiological data are from the Western countries and the Far East.⁴ Limited published data

exist on the clinical epidemiology of AF in South Asia (see online supplementary table 1).

Kerala, the southernmost state of India, is witnessing an increase in the burden of patients with AF due to increased longevity, higher prevalence of cardiovascular risk factors and comorbid conditions.^{5,6} However, the treatment and care offered to these patients is generally perceived to be suboptimal especially with regard to stroke prevention strategy. Vitamin K antagonists (eg, warfarin) are the commonly used oral anticoagulants, but monitoring of international normalised ratio (INR) is highly erratic,⁷ and often low target values (International normalised ratio (INR) <2.0) is accepted by the physicians. Nevertheless, there is lack of information on the existing treatment strategy as well as how it compares with the guideline recommended management of AF.⁸ The Kerala AF registry aims to provide systematic, prospective data on clinical characteristics, risk factors, treatment pattern and outcomes of consecutive AF patients who consulted cardiologists across Kerala. The registry was instituted under the auspices of Cardiological Society of India, Kerala Chapter (CSI-K).

COHORT DESCRIPTION

All newly and previously diagnosed patients aged ≥ 18 years with documented evidence of AF on ECG were included in the study from April 2016 to April 2017. The study was initiated in April 2016, and 53 hospitals across the state of Kerala have contributed patients during the 1 year enrolment period. In order to get the best representative data from both rural and urban areas of the whole state, patients were recruited from government, private and corporate hospitals from different regions of Kerala. At each site, one investigator and a study coordinator handled the patient recruitment. Kerala state has an area of 38 863 km² and a population of 37.3 million.⁹ For better coordination of the study, Kerala was divided in to three zones: south, middle and north with 20 participating sites from south, 21 from middle and 12 from north zone (figure 1). The three zones had one zonal coordinator each, who supervised the study conduct at their respective zones.

Patients with transient AF due to causes like acute myocardial infarction, infection, alcohol intoxication, metabolic abnormalities, postoperative cases and critically ill patients with life expectancy less than 30 days were excluded. Each patient was enrolled in the registry after examination by the cardiologist(s) of the participating centre. Detailed medical history, physical examination and laboratory investigation including echocardiography was done, and the results were entered in the case report form (CRF).

Patients were classified into AF with valvular heart disease (AFVHD) and non-valvular AF (NVAF). AFVHD is defined as those cases associated with mitral stenosis, prosthetic valve implantation and

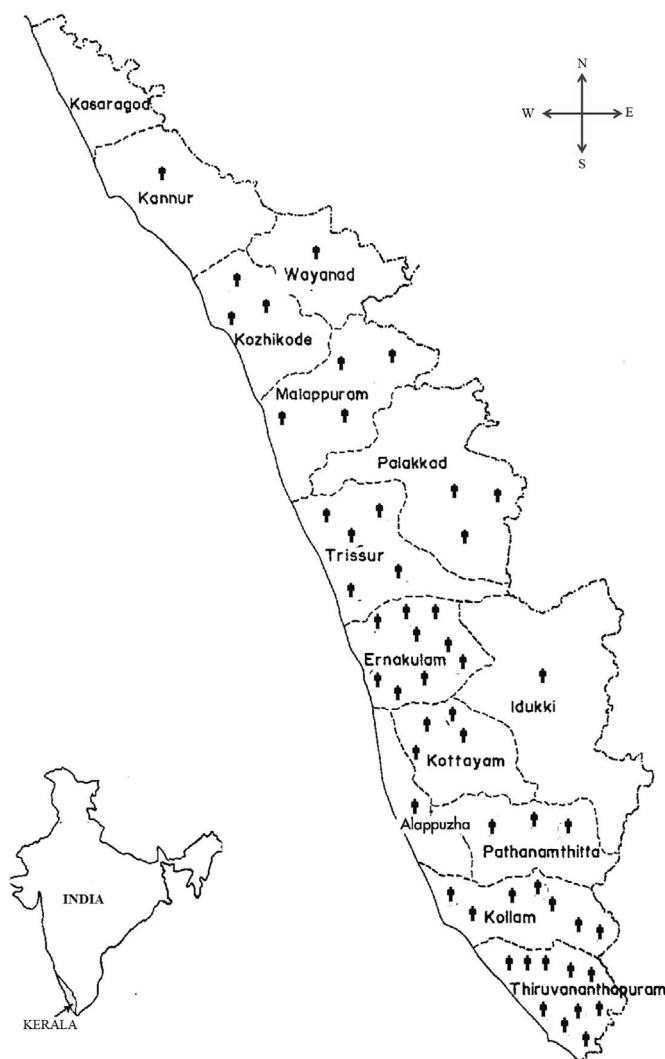


Figure 1 Map of Kerala showing the distribution of study sites.

mitral valve repair. These patients were further categorised as rheumatic or non-rheumatic and subcategorised as mitral, aortic or combined based on the clinical and echocardiographic findings. Out of the 914 AFVHD patients, 80.2% were rheumatic and 19.8% were non-rheumatic. The higher proportion of rheumatic aetiology seen in AFVHD patients could be due to the higher prevalence of rheumatic heart disease in Kerala. AF rhythm type was classified into paroxysmal, persistent and permanent. Stroke risk was estimated using the Congestive heart failure, Hypertension, Age ≥ 75 , Diabetes mellitus, Previous Stroke, Vascular disease, age 65 to 74, Sex category (CHA₂DS₂-VASc)¹⁰ score and bleeding risk using the Hypertension, Abnormal renal/ liver function, stroke, bleeding history or predisposition, labile INR, Elderly age >65 years, Drugs/ alcohol (HAS-BLED) score.¹¹ Detailed data on treatment, mainly stroke prophylaxis regimen, antiarrhythmic drug treatment, pacemaker implantation, AF ablation, surgery for AF and device closure of left atrial appendage and treatment

for comorbidities, were collected at the time of recruitment and follow-up. Data on major outcomes including death (all-cause as well as cardiac) and need for hospitalisation were documented at 30 days, 6 months and 1 year. The cohort will be followed up annually for 5 years through clinic visit or by telephonic contact. Five-year follow-up will be completed by April 2022.

Patient and public involvement

Patients were not involved in the design of the study. Once the patients were recruited in the study, they were explained the health consequences of AF and the need for stroke prevention and arrhythmia management by the cardiologist.

Statistical analysis

Data were entered using EpiData Entry 3.1 version software¹² and analysed using R software¹³ and Microsoft Excel package.

Findings to date

A total of 3421 patients were recruited between 4 April 2016 and 3 April 2017. Follow-up at 30 days, 6 months and 1 year was completed by April 2018. NVAF constituted 73.3% (n=2507) and AFVHD 26.7% (n=914) of patients. There were 49% (n=1677) men and 51% (n=1744) women. The median age of the cohort at recruitment was 65 years (IQR 56–74). The median body mass index of the study population was 24.22 kg/m² (IQR 21.6–26.5). Patient characteristics and prevalence of risk profile of the cohort at the time of recruitment is given in table 1. AFVHD was more common in women compared with men (67.4% vs 32.6%) (p<0.001), whereas NVAF was more common in men (55% vs 45%) (p<0.001). Hypertension, diabetes mellitus and dyslipidaemia were present in 53.8% (n=1840), 34.5% (n=1179) and 42.2% (n=1443) cases of AF, respectively. History of rheumatic fever was present 17.7% (n=607) of patients. Chronic kidney disease (creatinine clearance below 60 mL/min)¹⁴ was observed in 46.6% (n=1597) of patients, coronary artery disease in

Table 1 Baseline characteristics at the time of recruitment by gender

Parameters	Men (n=1677) n (%)	Women (n=1744) n (%)	Total (n=3421) n (%)
Age (in years) (median and IQR)	65 (56–74)	65 (56–74)	65 (56–74)
Height (cm) (mean±SD)	165 (±7.2)	155 (±7.0)	160.00 (±8.7)
Weight (kg) (mean±SD)	66.3 (±11)	58.4 (±10.8)	62.31 (±11.6)
CHA ₂ DS ₂ -VASc score (mean±SD)	2.60 (±1.7)	3.20 (±1.7)	2.91 (±1.7)
HAS-BLED score (mean±SD)	1.79 (±1.3)	1.59 (±1.2)	1.69 (±1.3)
Chronic heart failure	472 (28.2)	432 (24.9)	904 (26.5)
Hypertension	936 (55.8)	904 (51.8)	1840 (53.8)
Diabetes	611 (36.5)	568 (32.5)	1179 (34.5)
Stroke/TIA or systemic embolism	246 (14.7)	265 (15.3)	511 (14.9)
Coronary artery disease	764 (45.5)	423 (24.3)	1187 (34.8)
Dyslipidaemia	760 (45.3)	683 (39.1)	1443 (42.2)
Chronic kidney disease	247 (14.8)	104 (5.9)	351 (10.3)
Chronic liver disease	45 (2.7)	23 (1.3)	68 (1.9)
Respiratory disease	371 (22.8)	343 (19.7)	714 (17.7)
Congenital heart disease	37 (2.3)	43 (2.5)	80 (2.4)
Gastrointestinal bleed	77 (4.6)	46 (2.6)	123 (3.6)
Thyroid disease	228 (13.6)	357 (20.5)	585 (17.1)
NYHA Class I and II	1375 (81.9)	1443 (82.6)	2818 (82.4)
NYHA Class III and IV	299 (17.8)	302 (17.3)	601 (17.6)
Paroxysmal AF	706 (42.1)	643 (36.8)	1349 (39.4)
Persistent AF	261 (15.5)	230 (13.1)	491 (14.4)
Permanent AF	709 (42.2)	872 (50.0)	1581 (46.2)
AF with valvular heart disease	305 (18.8)	612 (34.4)	917 (26.7)
Non-valvular AF	1373 (81.9)	1131 (65.5)	2504 (73.2)
Cardiomyopathy	164 (9.7)	146 (8.4)	310 (9.1)

AF, atrial fibrillation; NYHA, New York Heart Association; TIA, transient ischaemic attack.

Table 2 List of medication at baseline and first follow-up (30 days)

	Medication at baseline			Medication at first follow-up		
	Men n (%)	Women n (%)	Total n (%)	Men n (%)	Women n (%)	Total n (%)
Warfarin	501 (29.8)	660 (37.8)	1161 (34)	769 (45.9)	975 (55.9)	1744 (50.9)
Acitrom	134 (8.0)	148 (8.5)	282 (8.2)	221 (13.1)	225 (12.9)	446 (13.1)
Phenindione	7 (0.4)	2 (0.1)	9 (0.2)	2 (0.1)	1 (0.05)	3 (0.9)
Dabigatran	31 (1.8)	15 (0.9)	46 (1.3)	58 (3.5)	42 (2.4)	100 (2.9)
Apixaban	11 (0.7)	7 (0.40)	18 (0.5)	38 (2.3)	19 (1.1)	57 (1.6)
Rivaroxaban	3 (0.17)	1 (0.06)	4 (0.1)	21 (1.2)	13 (0.74)	34 (1.0)
ASA	382 (22.7)	285 (16.1)	667 (19.5)	524 (31.3)	390 (22.3)	914 (26.7)
Clopidogrel	334 (19.9)	245 (14.0)	579 (16.9)	517 (30.8)	411 (23.5)	928 (27.1)
Prasugrel	2 (0.1)	3 (0.17)	5 (0.14)	2 (0.1)	3 (0.2)	5 (0.1)
Ticagrelor	2 (0.1)	1 (<0.1)	3 (0.1)	9 (0.5)	2 (0.1)	11 (0.3)
Amiodarone	138 (8.2)	116 (6.6)	254 (7.4)	265 (15.8)	241 (13.8)	506 (14.8)
Propafenone	4 (0.2)	3 (0.1)	7 (0.2)	2 (0.1)	3 (0.2)	5 (0.1)
Flecainide	8 (0.5)	9 (0.5)	17 (0.5)	6 (0.4)	10 (0.6)	16 (0.4)
Sotalol	2 (0.11)	0	2 (0.1)	3 (0.2)	0	3 (0.9)
Beta blockers	541 (32.2)	519 (29.7)	1060 (30.9)	840 (50.1)	786 (45.0)	1626 (47.5)
ACE inhibitors	97 (5.7)	77 (4.4)	174 (5.1)	163 (9.7)	116 (6.6)	279 (8.1)
ARB	167 (9.9)	246 (14.1)	413 (12.0)	245 (14.6)	328 (18.8)	573 (16.7)
Digoxin	296 (17.6)	466 (26.3)	762 (22.2)	424 (25.2)	621 (35.6)	1045 (30.5)

ARB, angiotensin receptor blockers; ASA, acetyl salicylic acid (aspirin).

34.8% (n=1187) and heart failure in 26.5% (n=904) of patients. Mean CHA₂DS-VASc score of the cohort was 2.9, and HAS-BLED score was 1.7. Daily use of medication at baseline and at 1-month follow-up are reported in [table 2](#). A total of 443 (12.9%) deaths and 578 (16.8%) hospitalisation occurred during 1-year follow-up ([table 3](#)). In all age groups, majority of hospitalisation and death

occurred during the first half of follow-up period (61.8% and 62.3%, respectively) than the second half ([figures 2 and 3](#)). In the Indian Heart Rhythm Society-Atrial Fibrillation registry,⁷ the mortality and the hospitalisation rates were 6.5% and 8%, respectively. In the EURObservational Research Programme Atrial Fibrillation registry,¹⁵ 1-year mortality was 5.7%.

Table 3 Death and hospitalisation at different time periods

Events	Recruitment to 1 month	1–6 months	6 months–1 year	Total in 1 year (%)
Death (all causes)	69	207	167	443 (12.9)
Cardiac	54	157	121	332 (9.7)
Stroke	11	21	31	63 (1.8)
Other	4	29	16	49 (1.4)
Hospitalisation (all causes)	147	210	221	578 (16.9)
Stroke	15	12	24	51 (1.5)
Transient ischaemic attack	3	3	6	12 (0.4)
Acute coronary syndrome	42	94	66	202 (5.9)
Arrhythmia	29	56	90	175 (5.1)
Heart failure	34	23	17	74 (2.2)
Systemic embolism other than stroke	3	4	4	11 (0.3)
Gastrointestinal bleed	10	5	8	23 (0.7)
Intracranial bleed	1	4	2	7 (0.2)
Minor bleed	10	9	4	23 (0.7)

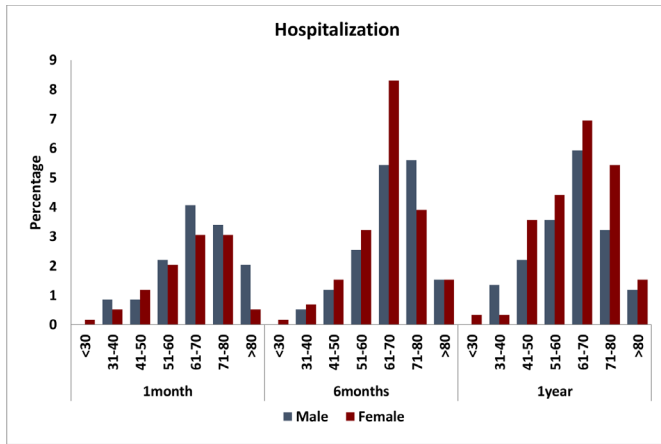


Figure 2 Incidence of hospitalisations among different age groups of male and female patients with AF.

Comparison with other published AF cohorts

Literature review showed three studies on patients with AF from South Asia, of which two are prospective cohort studies. The Indian Heart Rhythm Society-Atrial Fibrillation (IHRSAF)⁷ registry, with 1537 patients from 12 cities across India was the only available study exclusively on Indian patients with AF with study sites predominantly from secondary or tertiary referral cardiac centres. Even though the multinational cross-sectional study, the Real-Life Global Survey Evaluating Patients with Atrial Fibrillation^{16 17} had an Indian cohort of 301 patients, all were recruited from private healthcare institutions located in 15 urban areas. The Randomized Evaluation of Long-Term Anticoagulation Therapy¹⁸ was a prospective registry on patients with AF presenting to the emergency department in 46 countries including 2536 Indian patients from 22 hospitals in India. The Kerala AF Registry is the largest prospective cohort of patients with AF from India.

Unique aspects of the study include close collaboration of a wide range of contributing centres and systematic collection of outcome data. The registry recruited patients from government hospitals, teaching institutions, private and corporate hospitals

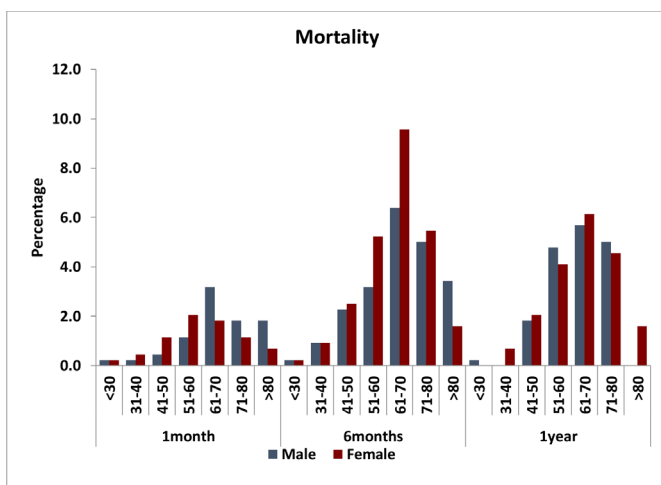


Figure 3 Incidence of mortality among different age groups of male and female patients with AF.

located both in urban and rural areas of Kerala state. This has enabled the cohort to have patients from different socioeconomic backgrounds and lifestyle. Furthermore, many registries globally are sponsored by pharmaceutical or device companies, and the data collected may be influenced by the focus on patients with AF treated by their drugs or devices, leading to the possibility of selection bias.¹⁹ This study, however, has been sponsored by the professional association of cardiologists in the state, which is the CSI-K. Many published AF registries^{7 16-24} (see online supplementary tables 1 and 2) have emphasised the need for adherence to the evidence-based treatment for reducing the stroke risk and overall mortality. Even though multiple AF databases are available from many countries that focus on various aspects of AF, there has been lack of coordination between these registries. An International Collaborative Partnership for the Study of Atrial Fibrillation, a worldwide partnership for investigators and countries has been initiated to capture all types of treatment patterns offered to the ever increasing population of patients with AF.²⁵ The global burden of AF is likely to grow in an epidemic proportion as observed by the World Heart Federation.²⁶ Although this phenomenon is observed from high-income countries,²⁷⁻²⁹ the clinical observations indicate the signal for a steady increase in the burden of patients with AF in India too.³⁰ Currently, the available data from India have been inadequate to provide exact prevalence, morbidity, mortality and standard of care of patients with AF. Furthermore, the existing studies reveal lower usage of oral anticoagulants for stroke prevention in patients with AF. India being a large country with interstate variations in terms of epidemiology of diseases and other health indicators, a state-wide collection and compilation of data seem to be the ideal way for generating national data.³¹ The Kerala AF registry was therefore initiated as a state-wide collection of data on patients with AF who seek medical advice, which could provide more information about the clinical profile, sociodemographic characteristics and existing standard of treatment for patients with AF and how it differs from national and global data.

Ethical considerations

The study was conducted according to the ethical guidelines of Indian Council of Medical Research and as per the ethical principles specified in Declaration of Helsinki. Informed consent was taken from all participants. Data collected are held centrally in a secure data base and only deidentified information were used for analysis.

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Collaborators Cardiologists from government public hospitals, teaching institutions, private and corporate hospitals located both in urban and rural areas of Kerala state contributed towards the cohort. The group of investigators under the professional association Cardiologists Society of India- Kerala Chapter, strongly encourages national and international collaborations. There is an urgent need for national data on AF representing all states. Interested researchers can contact Dr. C G Bahuleyan at bahuleyan2001@yahoo.co.uk Kerala AF Registry Investigators: Charanthyayil Gopalan Bahuleyan. MD, DM (Ananthapuri Hospitals and Research Institute, Trivandrum); Narayanan Namboodiri. MD, DM (Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum); Abdullakutty Jabir. MD, DM (Lisie Heart Institute, Ernakulam); Krishnana Nair Venugopal. MD, DM (Pushpagiri Medical College, Thiruvalla); Raju George. MD, DM (Medical college Hospital, Kottayam); Govindan Unni. MD, DM (Jubilee Hrudhayalaya, Trichur); Geevar Zachariah. MD, DM (Mother Hospital, Trichur); K.U Natarajan. MD, DM (Amrita Institute of Medical sciences, Kochi); N. Syam. MD, DM (District Hospital, Kollam); Anil Roby. MD, DM (Dr. Damodaran Memorial Hospital, Kollam); P.B.Jayagopal. MD, DM (Lakshmi Hospital, Palakkad); A. George Koshy. MD, DM (Government Medical College Hospital, Trivandrum); Eappen Punnose. MD, DM (MOSC Medical College, Ernakulam); Johnny Joseph. MD, DM (Caritas Hospital, Kottayam); Rachel Daniel. MD, DM (NS Memorial Institute of Medical Sciences, Kollam); Asokan Nambiar. MD, DM (Baby Memorial Hospital, Calicut); C.G. Sajeev. MD, DM, PhD (Calicut Medical College Hospital, Calicut); Stigi Joseph. MD, DM (Little Flower Hospital, Angamally); Koshy Eapen. MD, DM (Samaritan Hospital, Ernakulam); Raghu Ram. MD, DM (Alshifa Hospital, Perinthalmanna); Cibu Mathew. MD, DM (Government Medical College Hospital, Trichur); Ali Faizal. MD, DM (MIMS- Hearts Malabar Cardiac Centre, Kottakal); Biju Issac. MD, DM (Marian Medical Centre, Palai); Sujay Renga. MD, DM (Bishop Benziger Hospital, Kollam); Jaideep Menon. MD, DM (SN Hospital, Manjali); D. Harikrishna. MD, DM (PVS Hospital, Ernakulam); K. Suresh. MD, DM (S K Hospital, Edapazhinji, Trivandrum); Tiny Nair. MD, DM (PRS Hospital, Karamana, Trivandrum); S.S. Susanth. MD, DM (Bharat Hospital, Kottayam); R. Anil Kumar. MD, DM (Aster Medicity, Kochi); T.P. Abilash. MD, DM (Gokulam Heart Foundation, Thiruvananthapuram); P.Sreekala. MD, DM (SIMS Hospital, Kollam); E. Rajeev. MD, DM (MES Medical College Hospital, Perinthalmanna); Arun Raj. MD, DM (General Hospital, Trivandrum); Ramdas Naik. MD, DM (Rajagiri, Aluva); Rajalekshmi. MD, DM (SUTHospital, Trivandrum); Anoop Gopinath. MD, DM (Welcare Hospital, Palakkad); R.Binu. MD, DM (Upasana Hospital, Kollam); Jossy Chacko. MD, DM (Holy Cross Hospital, Kottiyam); P T. Iqbal. MD, DM (Daya General Hospital

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Contributors CGB conceptualised the study and drafted the manuscript. GYHL, JLA, SM and SB contributed in the design and conduct of the study and were involved in the preparation of the manuscript. NN, JA, AGK, VK, RG, AN, UG, GZ, NKU, SCG, SN, AR, KVV, AMP and RD contributed towards planning, designing and implementation of the study. All authors have read and approved the manuscript.

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Patient consent for publication Obtained.

Ethics approval The study was approved by the following ethics committees: Institutional Ethics Committee, Ananthapuri Hospitals and Research Institute; Institutional Ethics Committee, Sree Chitra Tirunal Institute of Medical Sciences and Technology; Ethics Committee, Lisie Heart Institute; Institutional Ethics Committee, Amrita Institute of Medical Sciences; Human Ethics Committee, Government Medical College, Trivandrum; Institutional Ethics Committee, Caritas Hospital, Kottayam; Institutional Ethics Committee, Sree Narayana Institute of Medical Sciences, Institutional Ethics Committee, Government Medical College, Calicut as well as by the Independent Ethics Committee of CSI-K.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The data are owned by the Cardiologists Society of India-Kerala Chapter and may be available after the study has been completed.

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