Indian Journal of Traditional Knowledge
Vol 22(2), April 2023, pp 314-321
DOI: 10.56042/ijtk.v22i2.36672

Indian system of medicine used concurrently with standard conventional medicine improves quality of life in patients of cardio vascular diseases (C.V.D)

Pamila Dua[a], Sandeep Seth[b], Ravindra Mohan Pandey[c] & Subir Kumar Maulik[a]
[a]Department of Pharmacology, [b]Department of Cardiology, [c]Department of Biostatistics
All India Institute of Medical Sciences, New Delhi 110 029, India
*E-mail:drpamiladua@gmail.com

Received 01 June 2020; revised 07 March 2022; accepted 20 April 2022

Worldwide there is increased shift towards usage of traditional medicine in patients of chronic diseases like Cardio Vascular Disorders. In India, these medicines are used concurrently. Objective of the study was to ascertain prevalence and effect of concurrent traditional drug therapy with standard pharmacotherapy in patients with CVD. The present study used a cross sectional study design to assess the prevalence and a prospective cohort design to assess the effect of concurrent Ayurvedic medicines with standard pharmacotherapy in terms of quality of life. After screening 600 patients, 128 were found taking such medicines. Out of these, 100 were recruited as cases (Group-I), while 100 who were matched in terms of age, body mass index, ejection fraction, and receiving standard therapy only were recruited as controls (Group-II). Assessment parameters included demographic, biochemical, ejection fraction through echocardiography, distance covered in six Minute walk Test (6MWT), Quality of Life (QOL) through Kansas City Cardio-myopathy Questionnaire (KCCQ) and Seattle Angina Questionnaire (SAQ) with follow up at 6 months. *Prakriti* as mentioned in Ayurveda was also assessed using a questionnaire. Both groups were comparable at base line. Total 87 in Group-I and 91 in Group-II completed the study. Further, 76% patients were diagnosed with heart failure (HF) and 24% with coronary artery disease (CAD). There was no change in distance covered in 6MWT in both HF or CAD groups. But there was improvement in all cases in domains of KCCQ and SAQ as compared to controls. To conclude, concurrent use of traditional medicine with standard conventional care in CVD may improve quality of life in cardiovascular disorders.

Keywords: Cardiovascular disorders, Con-current, Indian System of Medicine, Quality of life

IPC Code: Int Cl.[23]: A61K 36/00, A61P 9/00

The incidence of cardio vascular disorders is increasing and has become a common cause of disease-related deaths in India[1].Augmentation in the usage of traditional remedies is attributed not only to self-medication, orientation towards preventive health care, growing desire of aging population to stay young and healthy but also due to increasing healthcare costs involved in conventional system of medicine[2].In India, 65% of the population in the rural areas uses ayurvedic medicines / medicinal plants to help meet their primary healthcare needs[3]. Worldwide there is evidence of increased shift towards the usage of traditional medicine[4]. In developed countries also, the complementary and alternative medicine (CAM) is gaining more acceptance. Nearly 66% of the American population is estimated using alternative medicine[4]. The past decade has witnessed renewed attention and interest in the practice of traditional medicine, globally. In 2002, the World Health Organization (WHO) launched a global campaign to formalize the use of traditional medicines[5]. The WHO strategy document 2014-2023 for traditional medicine accords priority to health services and systems, including products, practices, and practitioners of traditional and complementary medicine. Consequently, the effectiveness of traditional medicines is being evaluated and the adverse events being documented and monitored[6]. The recognized traditional Indian System of Medicine (ISM) are Ayurveda, Siddha, Sow and Unani besides Homeopathy, Yoga and Naturopathy[7]. Use of traditional medicine is more common in chronic disease conditions especially non communicable diseases like in cardiovascular diseases[8]. By virtue of establishing the biological activity of the plant extracts, attempts have been made to scientifically validate few traditional remedies[9,10]. There is no denying the fact that active ingredients used in many traditional medicines may be potentially

*Corresponding author

toxic and the usage of apparently ineffective non-toxic remedies can also inflict harm by depriving the patient of the standard of care[11].

However, there is hardly any well-established literature showing effect of concurrent use of such medications along with standard conventional cardiovascular disorders in India. The present study was designed to address this lacuna. This study was planned to assess concurrent use and effect of those *Ayurvedic* medicines mentioned in ISM drug therapy in the list of single/formulations prepared with number of drugs mentioned in *Ayurvedic* Pharmacopoeia of India[12,13]. The assessment was done in terms of Quality of life through 6MWT[14] and KCCQ[15], SAQ[16] and Ejection fraction[17] through Echocardiography. Prakriti mentioned in Ayurveda was also assessed in all the participants through a questionnaire.

Methodology

Ethical approval from Institutional Ethics committee wide IEC/NP-358/08-10-2014 was obtained and the study was registered with Clinical Trial Registry of India wide CTRI/2018/04/013450. Study site was Cardiology OPD, AIIMS, New Delhi.

Study design

The present study used a cross sectional study design to assess the prevalence and a prospective cohort design to assess the effect of concurrent Ayurvedic medicines.

Demographic parameters like age, sex, weight, blood pressure, pulse rate, biochemical parameters likehemogram, fasting blood sugar, liver function tests, kidney function test and lipid profile were assessed. Quality of Life was assessed through the distance covered in six-minute walk test and other quality of life questionnaires mentioned earlier. Ejection Fraction was assessed through echocardiography and *Prakrit* assessment was done using a questionnaire. All data was collected from the files of the participants during their routine follow up in the OPD.

Exposures

Exposure in both groups include standard drug therapy like ACE Inhibitors, angiotensin receptor blockers, diuretics, β Blockers, and β and α adrenergic blockers, calcium channel blockers, vasodilators and statins etc. prescribed by consultant in cardiology OPD. In group-1, there were prescribed or self -administered concurrent ayurvedic medicines along with standard care.

Study population

Subjects recruited in the study were adults of age between 18 -70years with a documented diagnosis of a CVD, including heart failure, coronary artery disease, hypertension (stage I or II) and who were taking Ayurvedic drugs since any time were screened to assess for the prevalence. To assess the effect subjects taking such medication along with standard care at least for last six weeks, willing to give informed consent and to come for follow up after six months were recruited as cases. Age, BMI, ejection fraction and gender matched subjects taking standard care only were recruited as controls.

Sample size calculation

Sample size was calculated based on improvement in distance travelled in 6 min walk. Based on prior study, mean ± SD distance travelled in 6MWT in modern medicine was observed to be 9±4 meters. Anticipating an average increase of 3 meters (mean ± SD of 12±7), to detect this difference with 95% confidence level and 90% power, we needed at least 76 patients in each of the two groups. Considering 20% non-response, 100 patients in each of the two groups were enrolled.

Objectives

Primary objective was to assess the prevalence of the use of ISM (ayurvedic) drug therapy along with drugs of modern medicine.

Secondary Objective was to assess the effect of Ayurvedic drug therapy used along with modern drug therapy on quality of life in terms of 6MWT, KCCQ and SAQ and Ejection Fraction.

Clinical parameters

6 MWT

The six-minute walk test is a simple, cost-effective, and reproducible method for the assessment of exercise capacity[13]. The test was implemented using a 100 feet hallway only with markings at every one foot.

KCCQ

The Kansas City Cardio -myopathy Questionnaire (KCCQ)[14] is a self-administered, 23-items questionnaire to quantify the quality of life in patients of cardio vascular and respiratory disorders. There are different domains like Physical Limitation, Symptom Frequency, Symptom Severity, Symptom Stability, Overall Quality of Life, Self-Efficacy, Social Limitation, Functional Status and Overall Clinical Summary which are scored before and after treatment.

S A Q

Seattle Angina Questionnaire is a valuable measure of outcome in cardio vascular research[15]. It is 19 items self-administered questionnaire with different domains like physical limitation, anginal stability, angina frequency, treatment satisfaction and quality of life.

Ejection fraction through echocardiography

Ejection fraction (EF) is a measurement for CVD expressed as a percentage of how much blood the left ventricle pumps out with each contraction[16]. Echocardiogram is the most common method to assess ejection fraction[16]. It was measured in % unit.

Prakiti mentioned in Ayurveda

In Ayurveda, diagnosis, and treatment of diseases, including heart diseases are made based on Prakriti. Literature available in *Charaka Samhita* dated 200 BC[18] elaborates on assessment of *Prakriti* using the objective as well as subjective parameters. The biological specificity by virtue of cellular and genomic peculiarities that is predominantly held responsible for inter-individual differences in terms of appearance and functions is attributed to the concept of *Prakriti* explained in the classics of Ayurveda[19,20]. The Ayurvedic literature including physical, physiological, social, and behavioral features for *Prakriti* assessment and the format used in earlier studies[20] forms the premise for design of the *Prakriti* assessment questionnaire used in the present study. Here, it was also explored whether the different constitution types as described in Ayurveda have any impact on the predisposition to cardiac disease as well as its severity and consequent outcomes.

Biochemical tests

Biochemical tests like blood sugar fasting, liver function test, kidney function tests and lipid profile done on routine visit of the patient. Data was gathered from OPD files of the patient.

Statistical analysis

All the data was analyzed using SPSS 15.0. A complete case analysis within groups was done using paired Students' t-test and between the groups using independent simple Student's t test, $p<0.05$ was considered statistically significant and all values were expressed in terms of Mean and Standard Deviation. Data was normally distributed at baseline except the values of distance covered in 6MWT. So, base line values were adjusted using ANCOVA.

Results

Participants detail

Total of 600 patients, were screened, 128 of them were taking concurrent medications. Out of these, 100 individuals were identified as cases in Group-I, out of which 13 were lost in follow up. A total of 87 patients completed the study. Total 100 controls who were matched in terms of age, sex, body mass index, ejection fraction, and exclusively receiving standard therapy, were recruited in Group-II. A total of 91 patients completed the study as 9 patients were lost in follow up. Detail has been explained in Table 1.

Details of concurrent ayurvedic medicines

About 38% patients using ISM were having *Terminalia arjuna* in various forms like Cap Arjuna, Arjunachurna, Arjunakwath, Arjunarishta and rest 62% patients were using other drugs. Patients were using these drugs for their cardiac problems. Patients were using these medicines in form of a single herb or compound having mixture of more drugs. Only 41% patients consulted AYUSH practitioners to start ISM drug therapy and rest 59% patients were taking Ayurvedic medicine on their own or as advised by their family members or friends.

List of Ayurvedic drugs either mentioned in text or proprietary medicine, single herb or compound (multiple in one medicine), the scientific (botanical) names of the single and of main ingredient in compound and dosage which the patients were taking, all the details have been mentioned in Table 2.

Base line analysis

The recruitment was done from March, 2016-November, 2018. Six months follow up was

Table 1 — No. of participants in each group

Target number of patients in each group		Follow up	Lost in follow up
Point Pravelance: 600	Patients screened: 600	nil	
Group-I, Cases Patients having ayurvedic drugs along with standard care	Patients recruited: 100	87	13 (4 patients stopped ayurvedic medicine before 3 months, 9 patients did not come for follow up).
Group-II, Control Patients on conventional standard care	Patients recruited: 100	91	9 patients did not come for follow up

done from September 2016- April, 2019. Baseline assessment was done at the time of recruitment. Both the groups at base line were equally distributed except 6MWT which was adjusted using ANCOVA. All baseline results have been mentioned in Table 3.

Prakriti analysis

Prakriti analysis of Group –I, 56.3% patients were of Pitta Kaphaja Prakriti type and 43.75% patients were of Vatapittaja Prakriti type.

In Group –II, 42.9% patients were of Pitta Kaphaja Prakriti and 56% patients were of Vatapittaja type of Prakriti and only 1% patient was of Pittja Prakriti

Within group analysis - Group 1

In group I, comparison between baseline and after 6 months revealed that there was significant improvement in distance covered in 6 minute walk (p=0.018), QoL index KCCQ (p=0.001) and in overall QoL index SAQ (p=0.002). KCCQ Physical Limitation Score (p=0.009.), KCCQ Symptom frequency score(p=0.041), KCCQ Symptom severity score (p=0.001), KCCQ clinical summary score (p<0.0001), and the KCCQ Symptom stability score (p=0.036) also showed improvement. Though the p-value was insignificant, grouping the patients based on their *Prakriti* showed improvement in *Pitta-kaphaja Prakriti p*atients as compared to *Vata-Pittaja Prakriti* patients.

Within group analysis- Group-II

In group II, comparison between baseline and after 6 months revealed that though there was no significant improvement in distance covered in 6 min walk, yet QoL index KCCQ (p=0.046)' QoL index SAQ (p=0.009) and in KCCQ Physical Limitation domain (p=0.032) improved significantly.

Both groups after 6 months

When both groups were compared after 6 months, clinically there was marked improvement in group I in 6MWT. Also, there was significant improvement in all the domains of KCCQ including Physical Limitation Score (<0.0001), Symptom frequency score (p=0.002), Symptom severity score (p=0.023), Overall clinical summary score (<0.0001), Symptom stability score (p=0.002), Quality of Life Score (p=0.001). The domains of SAQ, Anginal Frequency

Table 2 — List of Ayurvedic drugs

S. No.	Name of the drug (Ayurvedic textual or proprietary)	Single/compound drug preparation	Scientific Name of single /Main ingredient in compound preparation	Dosage taken by the Patient in a day
1	Arjunarishta	compound	Terminalia Arjuna	15 mL twice
2	Arjuna Kwath	compound	Terminalia arjuna	10 g twice
3	Arogyavardhini Vati	compound	Picrorhizakurroa	2 tab twice
4.	Arjuna Churna	single	Terminalia arjuna	5 g once
5	Triphalachurna (Harad, Baheda, Amla)	compound	Terminalia chebula, Terminalia bellirica, Phyllanthus emblica	4-5g once
6	Trikatuchurna (Sonth, Marich, Pippali)	compound	Zingiber officinale, Piper nigrum, Piper longum	3-4 g once
7	Amla Churna	single	Phyllanthus emblica	4-5g once
8	Ashwagandha Churna	single	Withaniasomnifera	4-5 g once
9	Cap Ashwagandha	single	Withaniasomnifera	2 caps once
10	Hridaytmrit Ras	compound	Terminaliaarjuna and Phyllanthus emblica	2 tabs once
11	Chandra Prabhavati	compound	Commiphoramukul and Asphaltum	2 tabs twice
12	Ghrit Kumari Swarasa	single	Aloe vera	10 mL of juice
13	Giloy	single	Tinospora cordifolia	10-15 mL once
14	Nirgundi	single	Vitex negundo	2 tabs twice
15	Punarnava Guggul	compound	Boerhaviadiffusa	2 tab twice
16	Chitrkadi Vati	compound	Plumbago zeylanica, Apium graveolens, Piper nigrum,piper longum	2 tabs twice
17	Lavang	single	Syzygiumaromaticum	1 piece twice
18	Ela Churna	single	Elettaria cardamomum	1 g twice
19	Sarpagandha Mishran	compound	Rauvolfia serpentina	2 tablet twice
20	Hridrog Chintamani Ras	compound	Terminalia Arjuna, Nardostachysjatamansi, Agate powder	2 tablet twice
21	Cap Arjuna	single	Terminalia arjuna	1 cap twice
22	Amalki Swaras	single	Phyllanthus emblica	5-6 mL once
23	Lahsun powder	single	Alium Sativum	4-5 g once

(p<0.0001) and Quality of Life score (p=0.034) showed significant improvement. The details of the results in all domains of KCCQ and SAQ have been listed in Table 4.

Subgroup analysis

Patients recruited were mainly of two types: Heart Failure and Coronary Artery Disease.

76% patients were of Heart Failure patients and 24% patients were of CAD. Standard drug therapy advised to the patients of both types has been explained in detail in Table 5 and Table 6.

Heart Failure patients were assessed based on EF and KCCQ, there was significant improvement Group- I in Left Ventricular Ejection Fraction (p=0.001), KCCQ Symptom Severity Score (0.046), KCCQ Self Efficacy Score (p=0.004) as compared to Group-II after 6 months.

CAD patients were assessed only on 6 MWT and SAQ, there was significant improvement in 6 MWT (p=0.011) and SAQ Anginal Frequency Score (p= 0.035) in Group-I as compared to Group-II.

Limitations

The present study was an observational study, therefore, the data collection was done only by available sources both at base line and after 6 months.

Discussion

There are evidences in support of usage of traditional medicines worldwide by a big population. These medicines are not only used by the rural masses[21] in the developing countries but also by the people in the developed countries. People have started accepting the traditional/complementary/ alternative

Table 3 — Base line parameters of both groups in Mean± SD

Parameters	Group- I (mean ±SD) n=87	Group –II (mean ± SD) n=91	p value
Pulse rate (per minute)	78±9	79± 0	0.419
Systolic Blood pressure (mm Hg)	108±14	111±15	0.141
Diastolic Blood Pressure (mm Hg)	69±10	71±10	0.421
LVEF (%)	31±10	33±11	0.103
Hemoglobin (g/dL)	12.2±1.4	12.1±1.5	0.642
TLC (per cu.mm)	7560±1828	7419±1465	0.572
ESR in mm (mm fall 1st hour)	20±11	20±10	0.488
Platelet count x 10^3/uL	181071±6143	181461±5156	0.930
Total S. Bilirubin (mg %)	0.88±0.22	0.90±0.27	0.505
SGOT (I.U.)	30±9	31±12	0.504
SGPT (I.U.)	29±13	32±16	0.187
Serum Alkaline Phosphatase (I.U.)	110±28	110±29	0.891
Urea (mg %)	34±9	33±9	0.863
S. Creatinine (mg %)	1.1±0.28	1.02±0.27	0.084
Uric Acid (mg %)	5.12±1.07	5.4±0.95	0.051
Total Cholesterol (mg/dL)	166±43	162±41	0.554
LDL (mg/dL)	103±33	99±32	0.434
HDL (mg/dL)	42±9	43±7	0.493
Triglycerides (mg/dL)	117±43	121±57	0.633
Distance travelled in 6 min walk test (meters)	348±69	328±75	0.070
KCCQ Physical Limitation Score	78±16	74±15	0.120
KCCQ Symptom frequency score	71±18	65±21	0.072
KCCQ Symptom severity score	65±18	62±19	0.218
KCCQ Symptom Score	68±19	57±21	0.099
KCCQ Symptom stability score	52±21	59±19	0.119
KCCQ Quality of Life Score	59±20	56±15	0.258
KCCQ Self Efficacy Score	71±18	65±19	0.024
KCCQ Social Limitation Score	65±28	62±17	0.391
KCCQ Functional Status Score	72±14	68±16	0.065
KCCQ Clinical Summary Score	69±15	66±14	0.121
SAQ Physical limitation	8±2	8±2	0.065
SAQ Anginal Frequency	10±1.6	9±2.0	0.002
SAQ Quality of Life	10±2	9±2	0.086
Treatment Satisfaction	11±2	10±2	0.170

Table 4 — Change in Score in KCCQ and SAQ after 6 months in both groups

Parameters	Group- I N=87 (Mean ± SD)	Group –II N=91 (Mean ± SD)	p value
6 Min Walk Test	359.3±71.5	325.02±79.1	0.212
KCCQ Physical Limitation Score	82.5±14.9	72.5±18.1	<0.0001
KCCQ Symptom Frequency Score	75.6±20.2	65.4±22.7	.002
KCCQ Symptom Severity Score	72.1±18.3	64.9±22.7	.023
KCCQ Symptom Score	74.02±18.5	65.2±21.4	.004
KCCQ Symptom Stability Score	62.5±23.3	51.4±23.8	.002
KCCQ Quality of Life Score	67.1±16.3	58.4±17.7	.001
KCCQ Self Efficacy Score	74.7±16.2	64.9±20.1	<0.0001
KCCQ Social Limitation Score	69.1±29.2	61.5±18.8	.039
KCCQ Functional Status Score	77.5±15.5	68.4±18.4	.001
KCCQ Clinical Summary Score	74.4±15.3	63.8±19.9	<0.0001
SAQ Quality of Life	10.6±2.02	9.9±2.2	.034
SAQ Physical Limitation	8.9±2.2	8.2±1.9	.055
SAQ Anginal Frequency	10.4±1.4	9.1±2.0	<0.0001
SAQ Treatment Satisfaction	11.3±1.9	10.9±2.1	.172

Table 5 — Standard conventional drugs of heart failure Grop I patients

Category of Standard Drugs	Percentage of Patients
ACE Inhibitors	54%
Angiotensin Receptor Blocker	11%
Angiotensin receptor/neprilysin inhibitor	13%
β Blockers	63%
Calcium Channel Blockers	17%
Diuretics	55%
Statins /Cholesterol Lowering Drugs	40%
Antianginal-Trimetazidine	4%
Anticoagulants	32%
Digoxin	24%
Anti Diabetic Agents	8%
Supplements-	40%
Benzodiazepines	4%
Others	5%
Antacids	42%

Table 6 — Standard conventional drugs of heart failure Grop II patients

Category of Standard Drugs	Percentage of Patients Taking
ACE Inhibitors	54%
Angiotensin receptor blocker	37%
Angiotensin receptor/neprilysin inhibitor	13%
β Blockers	63%
Calcium Channel Blockers	17%
Diuretics	55%
Statins /Cholesterol lowering drugs	90%
Trimetazidine	58%
Anticoagulants	68%
Digoxin	7%
Anti diabetic agents	29%
Supplements like Iron, Calcium, Vitamin D, zevit,cap a-z,ensure	8%
Benzodiazepines	10%
Others	29%
Antacids	67%

medicines parallel to the mainstream medical system in the UK and the rest of Europe. In North America and Australia, where conventional medical system is the dominating system, people have started resorting to traditional medicines[22]. Many modern drugs have been originated from traditional medicines like *reserprine,* a known antihypertensive from *Rauvalfia serpentina, pilocarpin* from *Pilocarpus jaborandi, quinine* from C*inchona bubscense* and many more[23]. China is a good example of amalgamation of modern medicine and traditional system of medicine in overall health care coverage[23]. Recent years of COVID-19 pandemic, no doubt has made the people to learn the lessons of Ayurveda like appropriate body behavior, food habits, exercises through yoga[24] to get better quality of life. But it's an era of evidence based medicine. There are many preclinical and clinical studies done/going on in exploring the affectivity of traditional medicines used individually or concurrently[25,26]. A Saudi Arabian study has indicated that among adults with CVDs, the usage of non-prescription medication was common, the study reported that 43% of population was using herbal drugs along with modern medicines[27]. The instant study is perhaps the first of its kind to assess the concurrent use of ISM therapy with standard treatment of CVDs in a tertiary care hospital in India. Adouble-blind placebo controlled randomized trial of *Terminalia arjuna* in heart failure patients, conducted in AIIMS, New Delhi proved that[20]. In the present study, 38% of the patients were using *Arjuna* in many forms and the others were using different Ayurvedic drugs. Despite several meticulously conducted trials

published in peer-reviewed journals, apprehension apprehensions about the safety and effectiveness of the traditional medicines. Further large-scale studies to generate evidence of their effectiveness and safety are the need of the hour to make a strong case for their mainstreaming. Our study indicates that the integration at grass root level is happening even in absence of formal integration of the different medical systems. The patients get benefitted in terms of improvement in their quality of life, but are afraid to share the information with their treating consultant. It is recommended that clinical experts may consider over the results of this study so that the benefits of integrated approach to the management of CVD patients can be formally extended to the needy. This will not only help in better compliance and faster recovery of the patients but will also reduce the patient load, cost of treatment and wastage of resources in the tertiary care hospitals. But at the same time physicians and patients both should use caution while taking these medicines to avoid the known dangerous herb-drug interactions[29]. Needless to say, that adequate documentation from the pharmacovigilance perspective and research regarding the possibility of herb-drug interactions indeed forms a pre-requisite. Keeping in view the exponential increase in the lifestyle related disorders, it is the need of the hour to document and validate Indian traditional knowledge especially Indian Systems of Medicine before they vanish with the passage of time or are hijacked[28]. Moreover, formal integration of the healthcare systems would require not only the patronage but also the evidence generated through state of the art studies conducted jointly with the involvement of experts from respective specialties to scientifically validate the supremacy of the holistic approach of amalgamating the conventional medicine with the traditional wisdom in ameliorate the lifestyle related sufferings of the mankind.

Conclusion

Concurrent use of Ayurveda therapy with standard conventional care in CVD may improve quality of life. Further *Prakriti* assessment may help in ascertaining the segregated response. Hence it is recommended that such patients should not be discouraged or counseled to discontinue their concurrent therapy provided they are prescribed by qualified practitioners of Indian System of Medicine. COVID-19 has taught us many lessons to survive with holistic approach, so, involving logical fusion of modern medical science and ancient wisdom of traditional medicines is poised to better equip the existing health care system not only for disease prevention but also for better, sustainable and cost-effective disease management.

Acknowledgements

This research was supported by a financial grant as Research associate fellowship to the first author from Indian Council of Medical Research, Government of India. We also express our extreme gratitude to participants and their family members for their co-operation.

Conflict of Interest

There is no conflict of interest to declare.

Author's Contributions

PD: Contributed in study concept, design, data collection, data report, interpretation of the data, analysis, authoring the manuscript and subsequent revision; SS: Contributed in study concept, design, data collection, interpretation of the data and critical review of the manuscript; RMP: Contributed in conceptualizing the study, data interpretation and analysis; and SKM: Contributed in study concept, design, critical review, and revision of the manuscript.

References

1 Reddy K S, Shah B, Varghese C & Ramadoss, A, Responding to the threat of chronic diseases in India, *Lancet*, 366 (9498) (2005) 1744-1749.

2 Ekor & Martins, The growing use of herbal medicines: issues relating to adverse reactions and challenges in monitoring safety, *Front Pharmacol*, (4) (2014) 177.

3 Pattanaik C, Reddy C S, Murthy M S R & Reddy P M, Ethnomedicinal observation among the tribal people of Koraput district Orissa, India, *Indian Res J Bot*, 1 (3) (2006) 125-128.

4 Eisenberg D M, Davis R B, Ettner S L, Appel S, Wilkey S, *et al*., Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey, *JAMA*, 280 (18) (1998) 1569-1575.

5 World Health Organization, Developing regional guidelines on minimum requirements for the registration of herbal medicinal products. *Report of a workshop, Abu Dhabi, United Arab Emirates,* 7-9 June 2003 (No. WHO-EM/EDB/043/E). World Health Organization. Regional Office for the Eastern Mediterranean.

6 Ravishankar B & Shukla V J, Indian systems of medicine: A brief profile, *African J Tradit Complement Altern Med*, 4 (3) (2007) 319-337.

7 Sarvananda L, Potential uses of ancient herbal preparations against non-communicable diseases, *J Med Plants,* 5 (5) (2017) 142-145.

8 Shedlin M G, Anastasi J K, Decena C U, Rivera J O, Beltran O, *et al*., Use of complementary and alternative medicines

and supplements by Mexican-origin patients in a US–Mexico border HIV clinic, *J Assoc Nurses AIDS Care,* 24 (5) (2013) 396-410.

9 Park K M, You J S, Lee H Y, Baek N I & Hwang J K, Kuwanon G: an antibacterial agent from the root bark of Morus alba against oral pathogens, *J Ethnopharmacol,* 84 (2-3) (2003) 181-185.

10 Chung J Y, Choo J H, Lee M H & Hwang J K, Anticariogenic activity of macelignan isolated from Myristica fragrans (nutmeg) against Streptococcus mutans, *Phytomedicine*, 13(4) (2006) 261-266.

11 Karunamoorthi K, Jegajeevanram K, Vijayalakshmi J & Mengistie E, Traditional medicinal plants: a source of phytotherapeutic modality in resource-constrained health care settings, *J Evidbased Complement Alternat Med,* 18 (1), (2013) 67-74.

12 Joshi V K, Joshi A & Dhiman K S, The Ayurvedic Pharmacopoeia of India, development, and perspectives, *J ethnopharmacol*, 197 (2017) 32-38.

13 Katoch D, Sharma J S, Banerjee S, Biswas R, Das B, *et al*., Government policies and initiatives for development of Ayurveda, *J Ethnopharmacol*, 197 (2017) 25-31.

14 Enright P L, The six-minute walk test, *Respiratory care*, 48 (8) (2003) 783-785.

15 Green C P, Porter C B, Bresnahan D R & Spertus J A, Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: A new health status measure for heart failure, *J Am Coll Cardiol*, 35 (5) (2000) 1245-1255.

16 Spertus J A, Winder J A, Dewhurst T A, Deyo R A, Prodzinski J, *et al*., Development and evaluation of the Seattle Angina Questionnaire: A new functional status measure for coronary artery disease, *J Am Coll Cardiol*, 25 (2) (1995) 333-341.

17 Alam M G R, Khan A M, Shejuty M F, Zubayear S I, Shariar M N, *et al*., Ejection Fraction estimation using deep semantic segmentation neural network, *J Supercomput*, 79 (1) (2023) 27-50.

18 Warsame R M & Hayes S N, Mayo Clinic's 5-step policy for responding to bias incidents, *AMA J eEhics*, 21 (6) (2019) 521-529.

19 Tripathi B N, Charaka, Agnivesh Krit Charaka Samhita, Commentary, Vimana Sthana, 8th Chapter, 96th Shloka, 2008.

20 Bhushan P, Kalpana J & Arvind C, Classification of human population based on HLA gene polymorphism and the concept of Prakriti in Ayurveda, *J Altern Complement Med*, (11) (2005) 349-53.

21 Prasher B, Negi S, Aggarwal S, Mandal A K, Sethi T P, *et al*., Whole genome expression and biochemical correlates of extreme constitutional types defined in Ayurveda, *J Transl Medi*, 6 (1) (2008) 1-12.

22 Maulik S K, Wilson V, Seth S, Bhargava B, Dua P, *et al*., Clinical efficacy of water extract of stem bark of Terminalia arjuna (Roxb. ex-DC.) Wight & Arn. in patients of chronic heart failure: A double-blind, randomized controlled trial, *Phytomedicine*, 23(11) (2016) 1211-1219.

23 Ballabh B & Chaurasia O P, Traditional medicinal plants of cold desert Ladakh-Used in treatment of cold, cough and fever, *J Ethnopharmacol,* 112 (2) (2007) 341-349.

24 Dashtdar M, Dashtdar M R, Dashtdar B, Kardi K & Khabaz Shirazi M, The concept of wind in traditional Chinese medicine, *J Pharmacopunct*, 19 (4) 2016 293.

25 Vedavathy S, Scope and importance of traditional medicine, *Indian J Traditi Know (IJTK),* 2 (3) (2003) 236-239.

26 Shankar R, Balkrishna A, Srivastava A, Joshi B & Mishra R K, Role of traditional medicines as a challenge for Coronavirus (Covid-19), *Indian J Tradit Know*, 17 (19) (2021) 110-118.

27 Shankar R, Balkrishna A, Srivastava A, Joshi B & Mishra R K, Role of traditional medicines as a challenge for Coronavirus (Covid-19), *Indian J Tradit Know*, 17 (19) (2021) 110-118.

28 Jamshidi N & Cohen M M, The clinical efficacy and safety of Tulsi in humans: A systematic review of the literature, *Evidence-Based Complement Alternat Med*: eCAM, 2017, 9217567.

29 Kapoor D, Vijayvergiya R & Dhawan V, Terminalia arjuna in coronary artery disease: ethnopharmacology, pre-clinical, clinical & safety evaluation, *J Ethnopharmacol*, 155 (2) (2014) 1029-45.

30 Shorog E M & Alburikan K A, The utilization of nonprescription medications in Saudi patients with cardiovascular diseases, *Saudi Pharm J,* 26 (1) (2018) 120-124.

31 Ansari M A, Sharmaa S K, Roy S S, Ramakrishna Y, *et al.,* Documenting the agriculture based indigenous traditional knowledge in Manipur State of North Eastern India, *Indian J Tradit Know,* 11, 20 (4) (2021) 1065-74.

32 Wilson V & Maulik S K, Herb-drug interactions in neurological disorders: A critical appraisal, *Curr Drug Metab*, 19 (5) (2018) 443-53.