Original Article

The first state-level public health program for obstructive airway disease in India: An early field-level evaluation

Soumya Gopakumar[1,5] , Mathew J. Valamparampil[2,3], Manu M S[3,5], Sanjeev Nair[4,5] , R. Kamala[4,5], Atulya Raj A[5], Bipin K. Gopal[3], Veena Babu[5], K. Vijayakumar[5]

[1]Department of Community Medicine, Government Medical College, Thiruvananthapuram, [2]Sree Chitra Tirunal Institute for Medical Science & Technology, [3]Directorate of Health Services, [4]Department of Pulmonary Medicine, Government Medical College, Thiruvananthapuram, [5]Health Action by People, Thiruvananthapuram, Kerala, India

Abstract

Background: Chronic obstructive pulmonary disease (COPD) is the second leading cause of mortality in India; however, there are no programs for COPD in India at primary care level. Kerala became the first state in India to implement a program at primary care for COPD, called the Step Wise Approach to Airway Syndrome program. **Objective:** The objective of the study was to evaluate and document the implementation status of a program for obstructive airway disease (OAD) in Trivandrum district of Kerala state in India and compare the treatment characteristics of patients with OAD seeking care from the centers implementing and not implementing this program for OADs. **Methods:** A cross-sectional study was done as early evaluation of a program for OAD implemented in Kerala state, India, from October 2018 to February 2019. **Results:** A reflection of the health-seeking behavior due to better facilities at the FHCs. There was no difference in the hospital visits or emergency department visits between the two groups. However, there was a statistically significant difference in the average number of visits per patient to health center for taking injectable drugs and visits for nebulization. Forty-nine (94%) of the COPD and 36 (100%) of the asthma patients underwent spirometry from implementing center itself. A higher proportion of patients receiving care from implementing centers (30.9%) never had to buy inhalers from outside. **Conclusion:** This is the first time that a public health programme for chronic respiratory disease management at primary care level was evaluated in India. The study has provided valuable insights on the need for strengthening the training for health care providers as well as patient education in bringing about a change in patient attitudes.

Keywords: Family health centers, obstructive airway disease, spirometry

Introduction

Obstructive airway disease (OAD) is a large spectrum of diseases which include chronic obstructive pulmonary disease (COPD), asthma, chronic bronchitis, bronchiectasis, and asthma COPD overlap syndromes. The diseases are characterized by frequent exacerbations and a prolonged course with dyspnea as the main symptom provoked by environmental triggers and activity.

Address for correspondence: Dr. Soumya Gopakumar, Suthalam, MRRA C9, Malloor Road, Vanchiyoor, Thiruvananthapuram - 695 035, Kerala, India.
E-mail: soumyagopakumar83@gmail.com

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COPD is a preventable and treatable condition characterized by persistent respiratory symptoms and airflow limitation due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases.[1] It is currently the third leading cause of mortality in the world.[1] Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness, and cough that vary over time and in intensity, together with variable expiratory airflow limitation.[2]

The Global Burden of Disease (GBD) study reports a prevalence of 251 million cases of COPD globally in 2016.[3] Globally, it is

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estimated that 3.19 million deaths were caused by the disease in 2017 (that is, 5% of all deaths globally in that year).[4] Globally, asthma is ranked 16th among the leading causes of years lived with disability and 28th among the leading causes of the burden of disease, as measured by disability-adjusted life years. Around 300 million people have asthma worldwide, and it is likely that by 2025, a further 100 million may be affected.[5] In India, COPD causes 717.79 deaths per 100,000 as per GBD 2017 estimates. As per these estimates, India is expected to overtake China with a burden of 751.73 deaths per 100,000.[6] The prevalence of asthma in adolescents was 13.1%.[7] In Kerala, there are 3613.3 and 3739.07 prevalent cases of COPD per 100,000 males and females, respectively, as per the GBD 2017 estimates.[6]

Kerala was the first state in India to address chronic respiratory diseases (CRDs) through a public health program. The state pilot tested the Practical Approach to Lung Health (PAL) strategy which showed benefits in terms of rational drug utilization.[8] Even though PAL could not be implemented, the lessons learned helped Kerala state to move toward developing and implementing a comprehensive primary care level public health program for OADs, named Step Wise Approach to Airway Syndromes (SWAASs). In the local language, "SWAAS" means "breath." National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases, and Stroke does address COPD, but the strategy is limited to smoking cessation. There are no guidelines for diagnosis or treatment; hence, the disease is often missed or misdiagnosed at primary care level.[9] The first program for COPD and asthma at primary care level was expected to improve the diagnosis and management of these important diseases and thereby allow for better health-seeking behavior and early diagnosis and prevention of progression of the chronic diseases.

This study evaluates and documents the implementation status of the SWAAS program in Trivandrum district of Kerala state in India and compares the treatment characteristics of patients with OAD seeking care from the centers implementing and not implementing this program for OADs, thereby hoping to highlight what improvements can be expected when a program for COPD and asthma is implanted at primary care level.

Methods

A cross-sectional study was conducted in Trivandrum district of Kerala in India from October of 2018 to February of 2019. The study setting included the primary level health care delivery institutions in India, known as Primary Health Centers (PHCs). In the state of Kerala, some of the PHCs were upgraded to Family Health Centers (FHCs). Initiated in 2017, SWAAS program was implemented in a phased manner at FHCs. The focus was on reframing the service delivery for OADs at primary care settings by contextualizing the concept of "nurse practitioner" in FHCs. SWAAS guidelines were prepared by state-level expert committee adhering to the international standards for the management of OADs.

Patients presenting at FHCs with symptoms of shortness of breath, breathlessness, chronic cough, and sputum are evaluated by a trained physician. In SWAAS program, the diagnosis is confirmed by a trained nurse using mini-spirometry which has been shown to be acceptable as an alternative to full spirometry.[9] Sputum smear examination for detecting tuberculosis, structured advices for smoking cessation, diet, and physical activity are provided by the nurse. Patients who do not respond adequately to the treatment and in those with complications and requiring medical support for smoking cessation are referred to a higher level of care. In the present study, FHCs are termed as "implementing centres" and the PHCs not implementing the SWAAS program are termed as the "nonimplementing centres."

The present study assessed the implementation status of SWAAS program at the implementing centers and additionally did a comparison of patient and treatment characteristics between the implementing centers and nonimplementing centres. The implementation status was assessed by reviewing the registers, facility assessment, stakeholder interviews, and a care bundle checklist for services offered. For comparison of patient and treatment characteristics, the patients enrolled under the new program in the implementing centers were compared with a group of patients who received the routine care for OADs during the same time period in the nonimplementing centers located in the same administrative unit as the implementing centers. This was done to eliminate differences in sociodemographic characteristics of patients and resource allocation to facilities from local self-government departments (LSGDs) in terms of financial and human resource support. The sample size was estimated to be 84 subjects each from the two groups of health care facilities with 90% power at 5% significance level expecting a 30% difference in the services received by patients in the two groups in the management of OADs. At the time of the study, the SWAAS program was implemented in 89 centers in the state of Kerala. The present study included all the 16 implementing centers in the district of Trivandrum, covering a population of 400,000. From the implementing centers, the study subjects were selected using simple random sampling using the sampling frame available from the SWAAS register at each institution. From each implementing center, 6–7 patients were requested to come to the institution on a convenient day. Of the 102 patients who were contacted, 97 patients participated in the study from the implementing centers. Of the total 110 PHCs (nonimplementing centers) in Trivandrum district, the PHCs in the comparator group were randomly selected from among the PHCs in the same administrative unit. The study participants (85) were recruited by the treating physician from the outpatient clinic as and when they came to the hospital (nonprobability). Patients who did not give consent or were not able to report to the implementing centers even after two attempts were excluded from the study [Figure 1].

The statistical analysis was done using IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp. The services received by patients and the status of implementation were expressed as percentages. Chi-square test

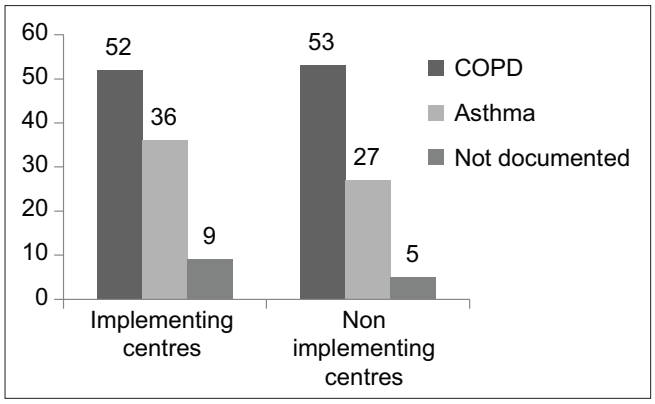

Figure 1: Diagnosis of airway disease in the implementing (*n* – 97) and nonimplementing (*n* – 85) centers

was used as test of significance and the odds ratio with 95% confidence interval was computed for determining the strength of association. Confidentiality was maintained, and any patient with suspected worsening of symptoms was promptly referred for further evaluation and management. The study subjects from implementing centers were reimbursed for their expenses. The study was approved by the Institutional Ethics Committee at Health Action by People (HAP) as per IEC No EC 1/P2/OCT/2018/HAP and permission from the Directorate of Health Services, Kerala, India, was also obtained. The study received research support through the project on "Prevention and control of Non-Communicable Diseases in Kerala" by Achutha Menon Centre for Health Science Studies under Sree Chitra Tirunal Institute for Medical Sciences and Technology.

Results

The study explored the implementation status in the implementing centers in Trivandrum district of Kerala, India, based on the availability of human resources, drugs, equipments, and the services provided. Following the implementation, the program registered and screened a total of 1555 symptomatic patients in implementing centers. Among them, spirometry was provided for 821 (52.8%) and 659 (42.4%) patients were started on treatment. The training was given to 39 of the 46 doctors, 47 of the 54 staff nurses, 116 of 122 junior public health nurses, and 13 of 26 pharmacists who were involved in the new program.

Among the patients registered at FHCs, 51 (98%) of the COPD and 36 (100%) of the asthma had undergone spirometry. Forty-nine (94%) of the COPD and 36 (100%) of the asthma patients underwent spirometry at the SWAAS center itself. In contrast, at the PHCs, 12 (23%) of COPD and 9 (25%) of asthma patients underwent spirometry. Smear microscopy for detecting tuberculosis was performed only on 32 (33%) patients in FHCs. Correct usage of inhaler technique was initially taught to 78 (80.4%) patients, which was verified during the follow-up visits in 73 (93.5%) among the 78 patients. Even though breathing exercises were taught to 31 (32%) patients and dietary advices were given to 30 patients (30.9%), only two of them received structured smoking cessation classes at implementing centers.

The following drugs were made available free of cost under the new program – formoterol, budesonide, and tiotropium and nebulizing solution of ipratropium. Salbutamol inhalers, nebulizer solution of salbutamol, and tablets of Deriphyllin and prednisolone were available even before the implementation of the new program. The equipments additionally supplied included mini-spirometer, pulse oxymeter, oxygen concentrator, oxygen mask, nebulizer, nasal prongs, and mouthpieces for spirometry. A quarter of the FHCs were found to be lacking in updating the registers ($n = 4$). Monthly reports were being sent from all implementing centers to the state nodal officer.

In this study, 97 patients from implementing centers and 85 patients from nonimplementing centers who were seeking treatment for OAD were compared. The mean (standard deviation [SD]) age of the participants was 59.9 (13.7) and 59.2 (18.9) years from implementing and nonimplementing centers, respectively. The baseline sociodemographic characteristics of gender, employment, education, and socioeconomic status were similar in both the groups [Table 1].

The median (interquartile range) duration of respiratory complaints was significantly higher (12 years [4–19.5]) in patients attending implementing centers (7 years [3–12], $P = 0.005$).

Diagnosis of airway disease in the implementing and nonimplementing centers is shown in Figure 1. Of the 105 COPD patients, 62 (59%) were smokers. As none of the female COPD patients were smokers, 91.1% of the male COPD patients were smokers. Among the patients registered at implementing centers, 51 (98%) of the COPD and 36 (100%) of the asthma patients underwent spirometry. Forty-nine (94%) of the COPD and 36 (100%) of the asthma patients underwent spirometry at the clinic in the implementing centers itself. In contrast, only 12 (23%) of COPD and 9 (25%) of asthma patients underwent spirometry at the nonimplementing centers for making a definite diagnosis. Inhaled medicines were initiated from the implementing centers for 34 (35.1%) patients and for 53 (54.6%) patients from other centers which includes medical colleges, government hospitals, other health centers, and private hospitals.

History of smoking was present in 45 (46.4%) in the implementing centers and 39 (45.9%) in the nonimplementing centers. The mean (SD) age of starting smoking was 19.7 (5.8) and 18.1 (3.6) years in the two groups, respectively ($P = 0.13$). Of those who had the habit of smoking, only 4 (8.9%) in the implementing centers and 8 (20.5%) in the comparator group were current smokers. Advice to quit smoking was provided to 3 of 4 patients in implementing centers group and 5 of 8 patients in the comparator group. After enrollment in the new program, 2 of 4 of the subjects quit smoking in the implementing centers.

Treatment characteristics, health-seeking behavior, and effect of the chronic illness on sleep and work were compared between the two groups [Table 2]. A significant decrease in visits for taking intravenous drugs ($P = 0.045$) and for nebulization ($P = 0.039$)

Table 1: Sociodemographic factors of study subjects in Family Health Centers and Primary Health Centers

Variable	Implementing centres (*n*=97), *n* (%)	Nonimplementing centres (*n*=85), *n* (%)
Gender		
Male	51 (52.6)	48 (56.5)
Female	46 (47.4)	37 (43.5)
Employment		
Unemployed/student/home maker/retired	45 (46.4)	42 (49.4)
Unskilled	34 (35.1)	31 (36.5)
Skilled	18 (18.6)	12 (14.1)
Education		
Illiterate	7 (7.2)	13 (15.3)
Primary	50 (51.1)	46 (54.1)
High school	32 (33)	25 (29.4)
Degree and above	6 (6.2)	1 (1.2)
SES*		
Pink	56 (57.7)	55 (64.7)
Yellow	6 (6.2)	5 (5.9)
Blue	23 (23.7)	18 (21.2)
White	11 (11.3)	6 (7.1)
No ration card	1 (1)	1 (1.2)

*SES was assessed using the color of the public distribution system card provided by the state government. Pink represents the lowest SES while white represents the highest. SES: Socioeconomic status

Table 2: Characteristics, health-seeking behavior, and effect of illness in patients seeing care

Variable	Mean (SD)		*P*
	Implementing centres (*n*=97)	Nonimplementing centres (*n*=85)	
Outpatient visits in last 3 months	7.5 (10.8)	7.8 (7.9)	0.867
ER visits in the last 1 month	1.1 (1.6)	1.3 (1.6)	0.615
Visits per patient to health center for taking intravenous drugs for symptom relief in the last 1 month	1.1 (3.6)	2.5 (5.2)	0.045
Visits per patient to health center for nebulization for symptom relief in the last 1 month	3.6 (10.4)	6.9 (11.3)	0.039
Days of sleep lost per patient in the last 1 month	6.84 (10.4)	5.6 (8.5)	0.414
Work days lost per patient in the last 1 month	0.8 (3.8)	0.4 (1.6)	0.468

SD: Standard deviation, ER: Emergency room

was observed among patients seeking care from implementing centers.

All medicines including the inhalers were provided free of cost from the implementing centers but not from the nonimplementing centers. Hence, the proportion of patients who had to buy medicines on their own was 9% and 26% in the implementing and nonimplementing centers, respectively [Table 3]. A higher proportion of patients receiving care from implementing centers (30.9%) never had to buy inhalers from outside ($P = 0.0004$) [Table 3].

Discussion

The current study was an early attempt to evaluate the first statewide, primary care level public health program on OADs. Coupled with epidemiological transition, risk factors such as atmospheric pollution, tobacco use,[10] and diabetes mellitus[11] pose grave challenges for OAD control in Kerala. This increases the burden at primary care level as it is the first point of contact for outpatient consultation and emergency management. In patients with OAD, pharmacological management alone may fail to produce optimal outcomes. Thus, multidimensional approaches are required for OAD management for ensuring effective symptom control, good quality of life, and reducing the hospitalization and emergency department visits.[12,13] Globally, various primary care models and approaches exist for the management of noncommunicable diseases.[14] However, a successful approach for the management of CRDs in the primary care setting is lacking in low- and middle-income countries because diagnosis and disease management for severe cases is done predominantly at tertiary care centers. A significant number of patients are getting registered and diagnosed appropriately under the new program. The median duration of respiratory symptoms and history of self-reported allergy was higher in the patients in the implementing centers. This might be due to an increase in the number of patients seeking care from the implementing centers who were not accessing the services earlier as better facilities and care were being provided under the new program in the implementing centers. The active involvement of the primary care nurse in the diagnosis and patient management was instrumental in providing better care to patients.

In a study done in Trivandrum district by Arjun *et al.*, only 18.27% of patients were offered spirometry for diagnosis and

Table 3: Availability of medicines in Family Health Centers and Primary Health Centers

Variable	Implementing centres (*n*=97), *n* (%)	Nonimplementing centres (*n*=85), *n* (%)	OR (95% CI)	*P*
Never had to buy inhalers from outside	30 (30.9)	9 (10.5)	3.8 (1.7-8.5)	0.0004
Never received oral medicines from the health-care facility	9 (9.3)	3 (3.5)	2.8 (0.7-10.6)	0.06
Never received free inhalers from the health-care facility	9 (9.3)	22 (25.9)	0.3 (0.1-0.6)	0.002

OR: Odds ratio, CI: Confidence interval

those very few patients were given a firm diagnosis before they reached tertiary care. The current study showed that after implementation of the program, a high proportion of patients were given a diagnosis based on spirometry in the implementing centers. In contrast, the centers not implementing the program did spirometry in only 23% of COPD and 25% of asthma patients, which is what is expected as per the study by Arjun *et al.*

Higher proportions of patients were trained for correct usage of inhalers which was rechecked by the designated nurse during further visits. As incorrect inhaler use is associated with poor symptom control, repeated patient education by a health-care provider is essential for improved self-management. Studies in the past have shown that the inhaler technique for patients using inhalers in Trivandrum is poor.[15] The provision of inhalers without training patients in correct inhaler use would lead to wastage of scarce resources.

The demands for injectable drugs and nebulizations reduced significantly at the implementing centers because of better management of patients and control of the symptoms among patients attending the implementing centers. This would help to reduce the workload in very busy PHCs.

Irregular smoking cessation services could be due to the unawareness regarding the importance of such advices or due to inadequate documentation of the same. Even 5 years after the launch of National Program for COPD Control in Finland, only half of the registered patients had a documented history of smoking habits.[16] As smoking cessation has long-term effects in modifying the natural history of COPD and prevents worsening of lung function in patients with COPD,[17] smoking cessation sessions should become one of the indicators for program monitoring.

Community-based interventions and integrated health-care delivery are found to give varying results in different studies.[18] The lack of a significant decrease in outpatient and emergency room visits could be due to the chronic nature of the diseases under consideration. There was also no statistically significant difference between the two groups in the average number of workdays lost or the average days of sleep lost. COPD/asthma being a chronic disease, a longer time of therapy might be needed for these differences to become apparent, and since the SWAAS program has just been started, it might be too early to detect such changes. In addition, data from longer duration were not captured so as to avoid recall bias. Definite conclusions could not be made regarding the out-of-pocket expenditures as verifiable data were not available from a larger number of participants.

Strengths of the study are that all the centers implementing a new program for OADs at primary care level were evaluated and compared to a similar number of centers which have still not implemented the program and are continuing the traditional care for OADs. COPD being the second leading cause of mortality in India, a program for this disease at primary care is the need of the hour and is still to be done in any other state of India. This study not only documents the program but also evaluates it, allowing for other states of India to develop their own program for COPD at the primary care level.

Limitations of the study are that the evaluation of the program has been limited to only one district of Kerala. Further representative sampling needs to be done in other districts of Kerala too. We could not explore the differences in quality of life and psychosocial outcomes associated with the program and services such as pulmonary rehabilitation and smoking cessation which have not been completely incorporated into the program. Since the program was rolled out in a phased manner in the implementing centers and the present study being cross sectional, long-term benefits could not be assessed. As time since establishment of various FHCs is not adjusted for, implementation status in different FHCs could not be compared.

Conclusions

This is the first time that a public health program for CRD management at the primary care level was evaluated in India. The current study being an early evaluation has provided valuable insights on how a program for COPD and asthma at the primary care level can improve the diagnosis and management of COPD and asthma at the primary care level.

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Conflicts of interest

There are no conflicts of interest.

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