



Comparison Of Treatment Persistence, Adherence, And Risk Of Exacerbations In Patients With Copd Treated With Single Inhaler Versus Multiple Inhaler Therapy

1.SHAIK RIZWANA, 2. V. VAMSI KRISHNA, 3. Dr. M. SRI RAMA CHANDRA, 4. Dr. G. AMBERNATH.

1,2 – PHARM D STUDENT, 3-PROFESSOR, 4 – PROFESSOR

1,2 – PHARM D STUDENT, 3 - DEPARTMENT OF PHARMACOLOGY

DR. K.V. SUBBAREDDY INSTITUTE OF PHARMACY, DUPADU, N.H.-7, KURNOOL-518218
ANDHRA PRADESH, INDIA

4- ASSISTANT PROFESSOR, DEPARTMENT OF PULMONARY MEDICINE, KURNOOL MEDICAL
COLLEGE, KURNOOL, ANDHRA PRADESH, INDIA.

Abstract:

Aim of The Study

The study mainly aims to compare treatment persistence, adherence, and risk of exacerbation among patients with COPD treated with single-inhaler therapy (SIT) versus multiple-inhaler therapy (MIT).

Methods

It is a prospective observational study which was conducted in Government General Hospital, Kurnool district in the department of pulmonary medicine.

Methodology includes the patient data collection form, and different scales like MMAS, mMRC, CAT, PFTs, are included to know the level of severity of the disease.

Results

Total 150 cases are collected among them 30 were lost during follow up. In this study it shown that there were more males (80%), when compared to female (20%). The Age group between 56-65 years are mostly affected to COPD. Among 120 patients smoking contributes 47.5% followed by occupational exposure 46.6%. During first visit the adherence rate is very low i.e., 85.83% and after follow there is an increased adherence is seen. The mMRC grade, CAT Scores and PFT shows the significant improvement in the severity of the disease condition during follow up when compared with first visit. There was more improvement seen in single inhaler users when compared to multiple inhaler users.

Conclusion

This study shows that there is a significant relation between the medication adherence and improvement in disease condition. This study concludes that, either use of single and multiple inhalers there is an effective response. But when compared with multiple inhaler users have lesser response when compared to single inhaler users.

KEYWORDS: COPD, Risk of exacerbation, single inhaler, multiple inhaler.

I. INTRODUCTION

Definition and Characteristics:

- COPD is a progressive lung disease characterized by airflow limitation and abnormal inflammatory response to noxious particles/gases.
- Host factors like genetic predisposition and environmental factors like tobacco smoke, occupational dust/chemicals are important.
- Cigarette smoking is the most common risk factor, accounting for 85-90% of COPD cases.¹

Symptoms:

- Shortness of breath, chronic cough with mucus, chest tightness, wheezing, swelling in feet/ankles/legs, lack of energy, frequent respiratory infections, unintended weight loss.

Diagnosis:

- Complete blood count, pulmonary function tests, COPD assessment test, chest X-ray, mMRC grade, CT scan, bronchoscopy, biopsy, pulse oximetry.²

Treatment Goals:

- Limit disease progression, improve health status, reduce symptoms, prevent/treat exacerbations, reduce mortality.

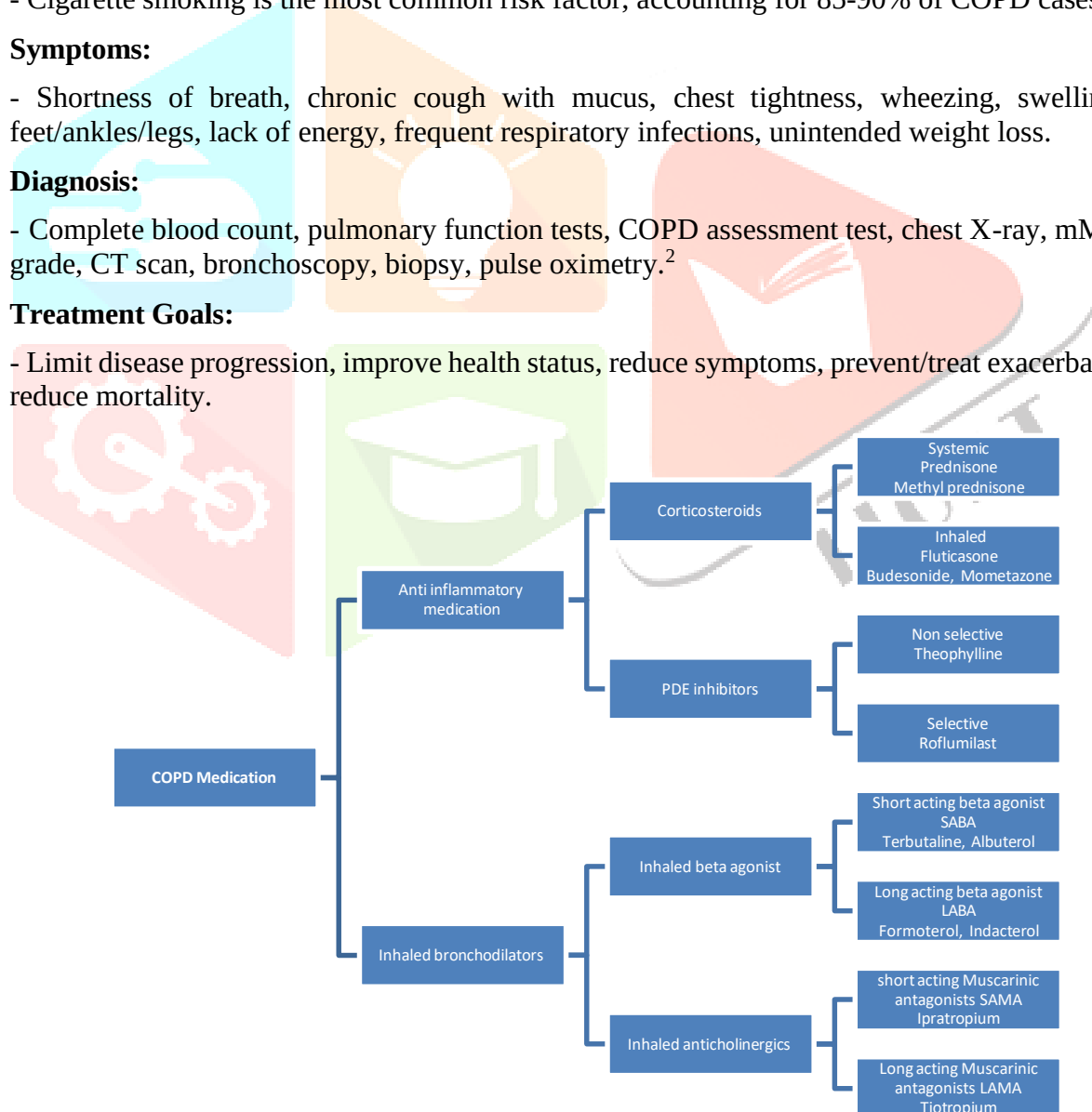


Fig 1.1 : Schematic Representation of Management in COPD

Non-Pharmacological Therapy:

- Smoking cessation, pulmonary rehabilitation, immunizations, long-term oxygen therapy, nutritional support, psychoeducational care.

Pharmacological Therapy:

- Bronchodilators, corticosteroids, combination bronchodilator-corticosteroids, alpha-1 antitrypsin replacement.

Inhaler Devices:

- Metered dose inhalers, dry powder inhalers, soft mist inhalers.
- Deliver medication directly to the lungs, manage chronic symptoms, provide rescue during attacks.

The key is a comprehensive approach combining lifestyle modifications, rehabilitation, and targeted pharmacological therapy tailored to the individual patient's needs.

II. AIMS AND OBJECTIVES:

- To assess the treatment Persistence in patients treated with single inhaler and multiple inhaler
- To assess the medication adherence in COPD patients
- To evaluate the risk of exacerbation in patients with COPD.

III. METHODOLOGY:

This study is a prospective observational study and the subjects involved are the In-patient and Out- patients in the Pulmonology department at Government general hospital, Kurnool. The subjects are selected on the basis of the inclusion and exclusion criteria.

3.1 Study Design:

Prospective, Observational study.

3.2 Study Site:

This study is conducted in Department of Pulmonary medicine, Government general hospital, Kurnool.

3.3 Study Duration:

6 months

3.4 Sample Size:

150

3.5 Inclusion Criteria:

- Patients newly diagnosed with COPD on inhaler therapy.
- Patients of age 30-85 years are included in our study.
- Either gender is considered.
- Patients on single inhaler therapy and multiple inhaler therapy.
- Novice COPD patients.

3.6 Exclusion Criteria:

- Patients who did not sign the consent form are excluded from the study.
- Patients, who are not co-operative.

3.7 METHODS

In this study different scales are used to describe the adherence and also severity of the disease.

3.7.1 MMAS (Morisky Medication Adherence Scale)³:

The Morisky Medication Adherence Scale is considered as the primary standard for assessing of adherence.

This scale consists of questionnaire form which consist of simple yes or no type 8 questions.

Based on the scoring, we assess patient as adherent and non-adherent.

If the score is high then the patient considered as more adherent.

3.7.2 mMRC (Modified Medical Research Council)⁴:

- The mMRC scale is used to determine the level of dyspnea in patients with respiratory diseases.
- This helps to assess the severity and also helps in treatment in patients with COPD
- This scale ranges from grade 0 to grade 4 which shows functional disability in the patients.

3.7.3 CAT (COPD Assessment Test)⁵

- COPD Assessment test is used to help the physician to evaluate the severity of the disease.
- This test helps to determine the patient's condition.
- CAT consist of 8 questions which should be answered by the patient, each question consist of 5 marks. If the severity is high it scores 5, and 0 indicates least severe.
- Based on the scores the physicians can easily evaluate the severity, which helps in the determination of the disease progression.

3.7.4 PFT (Pulmonary Function Test)⁶

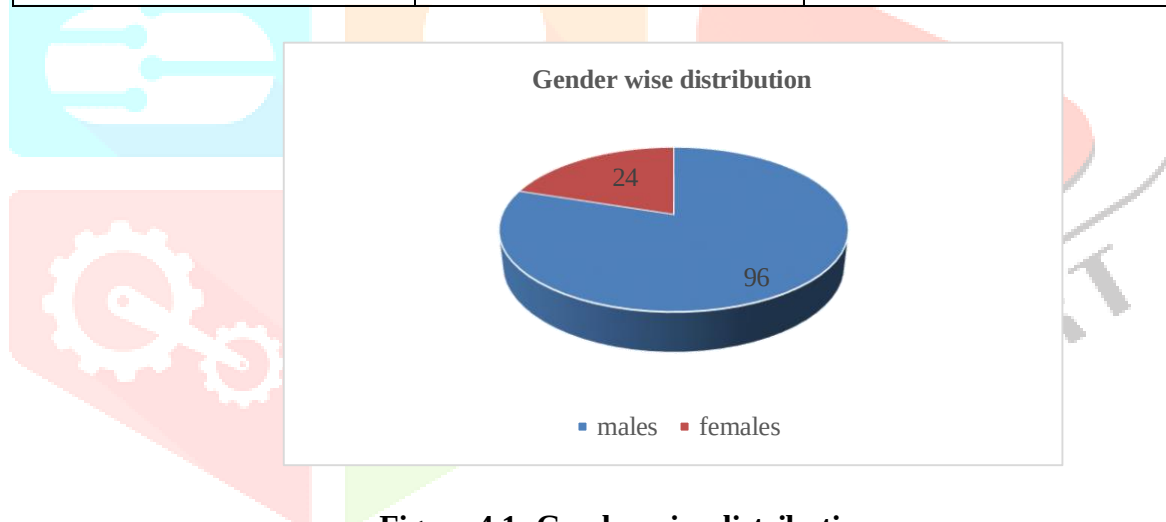
- Pulmonary Function Test consists of different parameters by which the lung functioning is estimated.
- Spirometry is one of the Essential PFT parameter which helps in determining the lung function
- Spirometry assess the lungs ability in inhaling and exhaling of gases and also to check the how fast the air blown out from lungs.⁷

IV. RESULTS**4.1 Gender:**

We have collected total 150 number of cases among them, 30 patients were lost to follow up. Among 120 patients, 96 were males and 24 were females.

Table 4.1: Gender wise distribution of study population

Gender	Number (n = 120)	Percentage (%)
Males	96	80
Females	24	20

**Figure 4.1: Gender wise distribution****4.2 Age Wise Distribution:**

In this study, the age group range of 56-65 were most affected with the percentage of 40 and least affected age group is between 25-35.

Table 4.2: Age wise distribution in study population

Age group range	Number (n = 120)	Percentage (%)
25-35	1	0.83
36-45	8	6.66
46-55	26	21.6
56-65	48	40
66-75	30	25
76-85	7	5.83

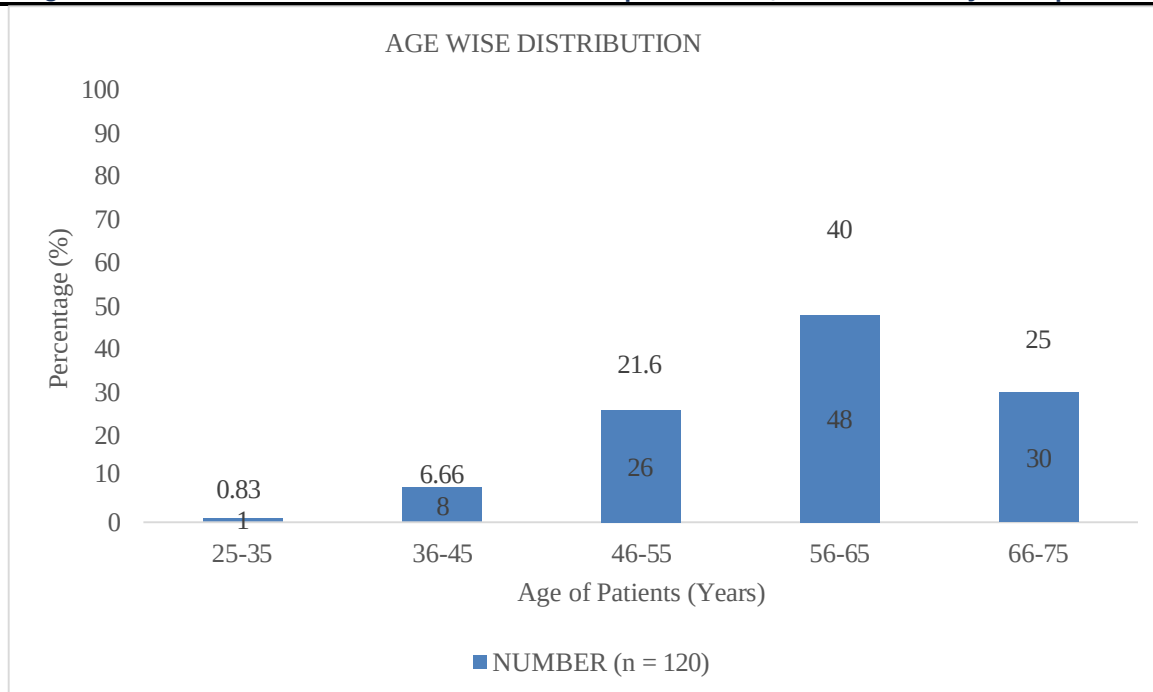


Figure 4.2: Age wise distribution in study population

4.3 Social Habits

In our study total 120 members are included among them 57 members are current smokers i.e., 47.5% and current alcoholics were 56 i.e., 46.6%.

Table 4.3: social habits in study population

Habits	Number (n = 120)	Percentage (%)
i. Smoking		
Current	57	47.5
Ex-smokers	33	27.5
Non-smokers	30	25
ii. Alcohol		
Current	56	46.6
Ex-alcoholics	29	24.1
Non-alcoholics	35	29.1

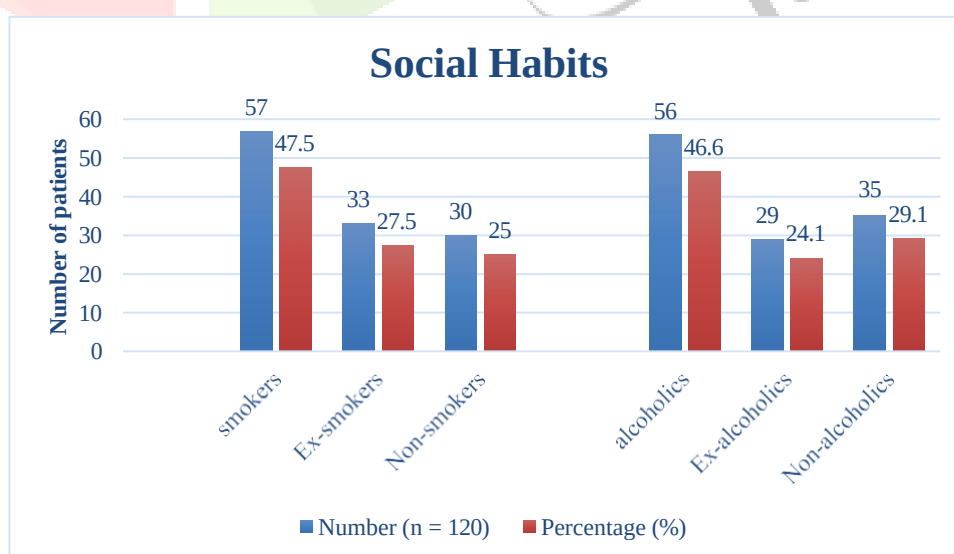


Figure 4.3: social habits in study population

4.4 Risk Factors:

In this study, Smoking is the major risk factor i.e., 47.5% (57), followed by occupational exposure 46.6% (56).

Table 4.4: Distribution of risk factors in study population

Risk factors	Number of patients	Percentage (%)
Smoking	57	47.5
Occupational exposure	56	46.6
Pollution	25	20.8
Biomass exposure	21	17.5
Weather change	15	12.5

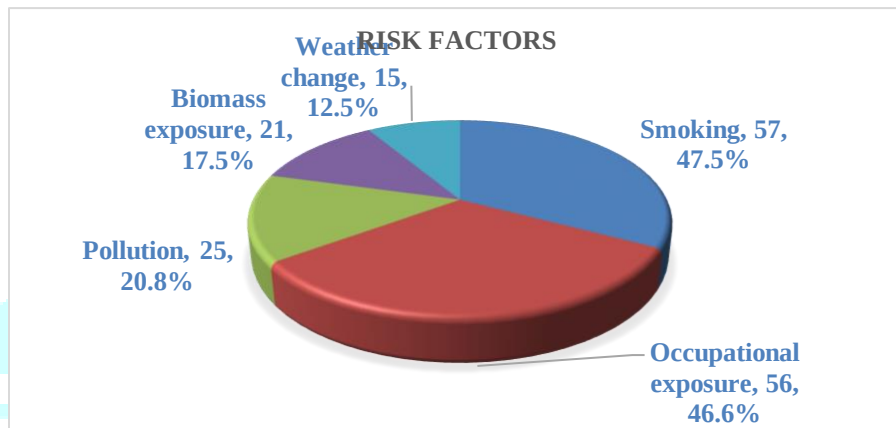


Figure 4.4: Distribution of risk factors in study population

4.5 Medication Adherence

In this study during first visit 85.83% (103) patients were low adherent to the inhalers, 14.16% (17) were moderately adherent.

Medication adherence of study population during 6 months follow up, among them 57.5% (69) were moderately adherent

Table 4.5: Medication adherence in the study population

MMAS Score	During First Visit		During Follow up	
	Number (n = 120)	Percentage (%)	Number (n = 120)	Percentage (%)
High Adherence	0	0	0	0
Medium Adherence	17	14.16	69	57.5
Low Adherence	103	85.83	51	42.5

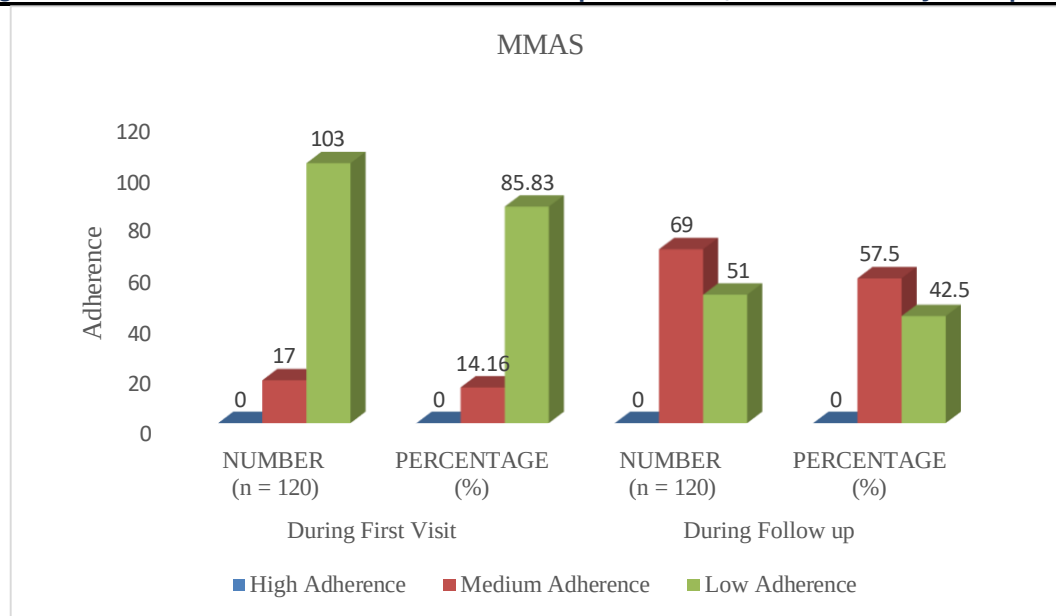


Figure 4.5: Medication adherence in the study population

4.6 mMRC (modified Medical Research Council) grade

In this study during first visit, 43.33% with mMRC grade 2 followed by 31.66% mMRC grade 3.

During follow up there is increased percentage in grade 2(54.1) patients when compared with grade 3(14.1).

Table 4.6: Distribution of mMRC grade in study population

mMRC Grade	During first visit		During follow up	
	Number (n=120)	Percentage (%)	Number (n = 120)	Percentage (%)
grade 0	0	0	0	0
grade 1	19	15.83	33	27.5
grade 2	52	43.33	65	54.1
grade 3	38	31.66	17	14.1
grade 4	11	9.11	5	4.1

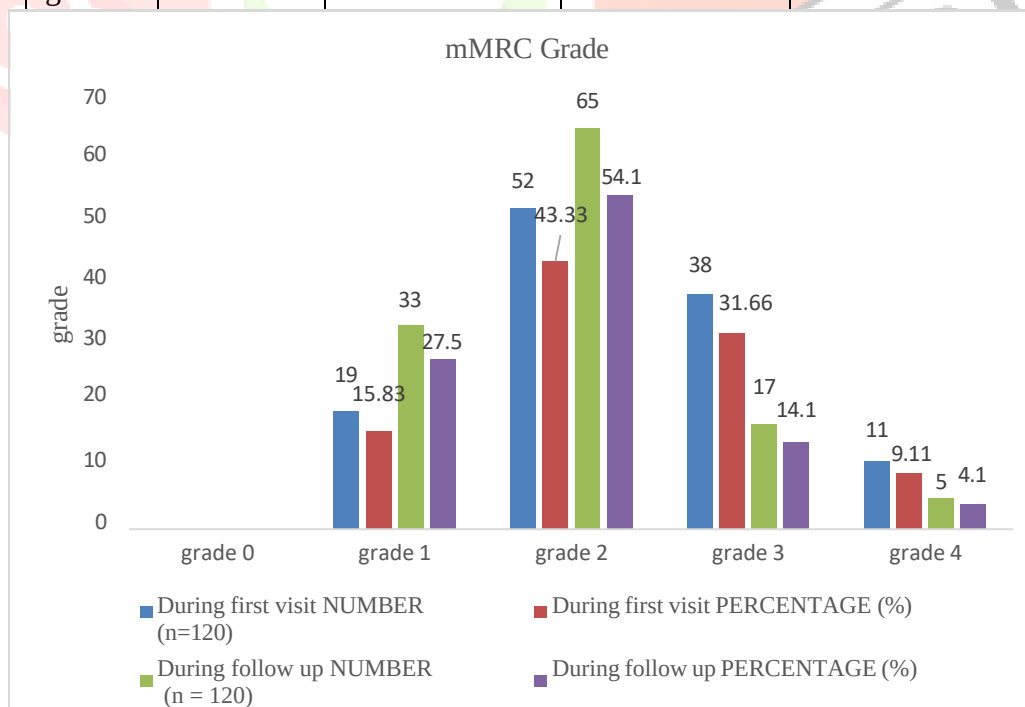


Figure 4.6: mMRC Grade Distribution in study population

4.7 CAT Score

The CAT Scores of the study population during first visit shows, 60% of patients having high range score followed by 34.16% were very high. During follow up there is a increased percentage of medium score.

Table 4.7: CAT Score distribution in study population

CAT Score	During first visit		During follow up	
	Number (n = 120)	Percentage (%)	Number (n = 120)	Percentage (%)
<10 (low)	0	0	0	0
10-20 (medium)	7	5.83	43	35.8
21-30 (high)	72	60	52	43.33
>30 (very high)	41	34.16	25	20.83

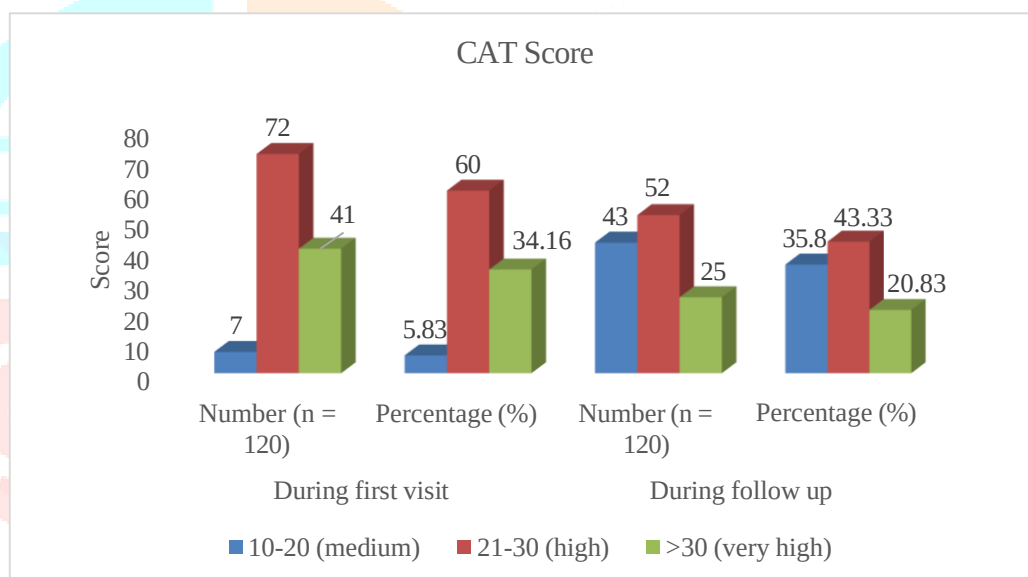


Figure 4.7: Distribution of CAT Score in study population

4.8 Pulmonary Function Test

PFT results shows, 43.33% of study population were mild, moderately affected were 39.16% during first visit to hospital. During follow up there is a decreased number of moderately affected, when compared with mild.

Table 4.8: Distribution of PFT score in study population

PFT RANGE %	During first visit		During follow up	
	Number (n = 120)	Percentage (%)	Number (n = 120)	Percentage (%)
> 70 (normal)	0	0	25	20.83
60-69(mild)	52	43.33	56	46.6
50-59(moderate)	47	39.16	30	25
< 50(severe)	21	17.51	9	7.5

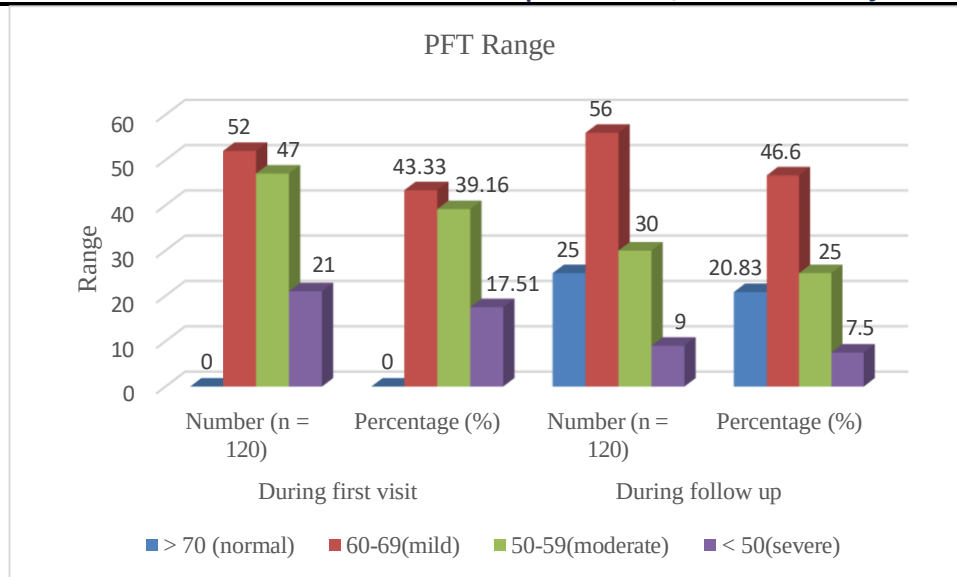


Figure 4.8: PFT Score distribution in study population

4.9 Inhalers

In this study both the single inhaler users and multiple inhaler users are involved, this study shows, there were 72.5% of single inhaler users and 27.5% multiple inhaler users

Table 4.9: Inhaler users in study population

Inhalers	Number (n = 120)	Percentage (%)
Single inhaler therapy	87	72.5
Multiple inhaler therapy	33	27.5

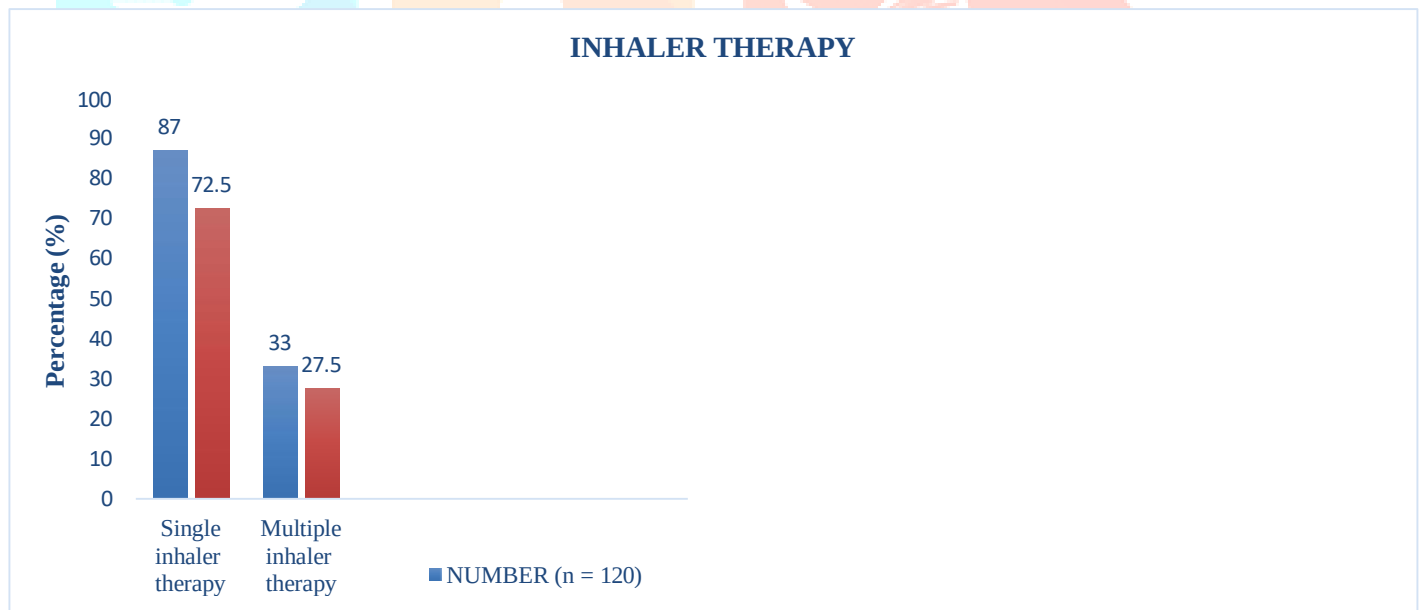


Figure 4.9: Percentage of inhaler users in study population

4.10 Types of Inhalers

In this study both single inhaler and multiple inhalers using patients are considered, in single inhaler it includes both dual therapy and triple therapy

Table 4.10: Distribution of inhaler therapy in study population

INHALER Therapy	Number (N= 120)	Percentage
Single inhaler Dual Therapy	58	48.33
Single inhaler Triple Therapy	29	24.16
Multiple inhaler Therapy	33	27.5

4.11 Comparison of percentage adherence between Single inhaler and Multiple inhaler therapy

Percentage of Adherence comparison between single inhaler and multiple inhalers shows that, there is an increased adherence in both single and multiple inhaler therapy.

When compared with multiple inhalers, single inhaler users had increased adherence

Table 4.11: Comparison of percentage adherence between Single inhaler and Multiple inhaler therapy

	Single inhalers %			Multiple inhalers%		
	High	Medium	Low	High	Medium	Low
First visit	0	10	63.33	0	2.5	24.16
Follow-up	1.66	29.16	42.5	0.83	10	15.83

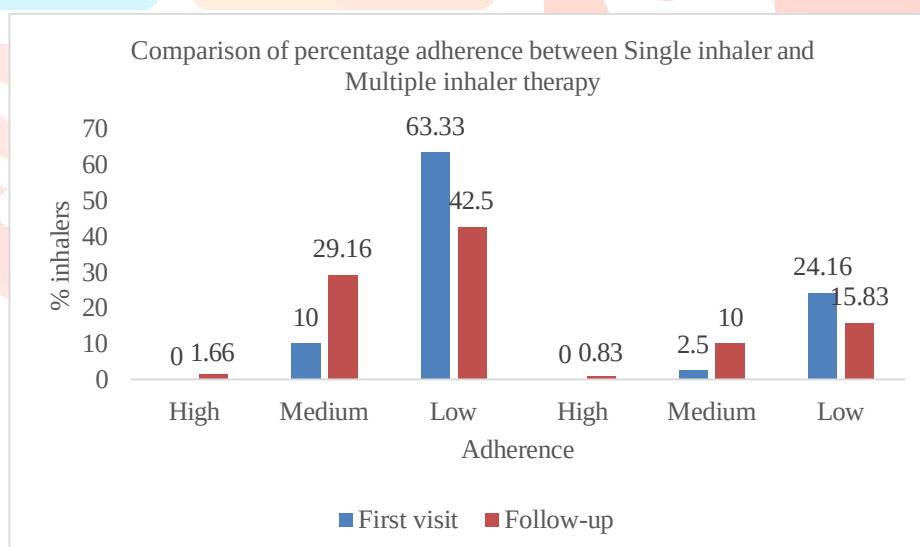


Figure 4.11: Comparison of percentage adherence between Single inhaler and Multiple inhaler therapy

4.12 Comparison of percentage mMRC Grade in single inhaler and multiple inhaler therapy

In this study, there is comparative reduction in the grade of mMRC after follow up, there is more decrease in single inhaler therapy.

Table 4.12: Comparison of percentage mMRC Grade in single inhaler and multiple inhaler therapy

	Single inhaler therapy %					Multiple inhaler therapy %				
mMRC Grade	grade 0	grade 1	grade 2	grade 3	grade 4	grade 0	grade 1	grade 2	grade 3	grade 4
First visit	0	10	34.1	23.3	5	0	5.8	10	9.6	4.16
Follow up	0	20.8	41.6	7.5	2.5	0	6.6	12.5	6.6	1.6

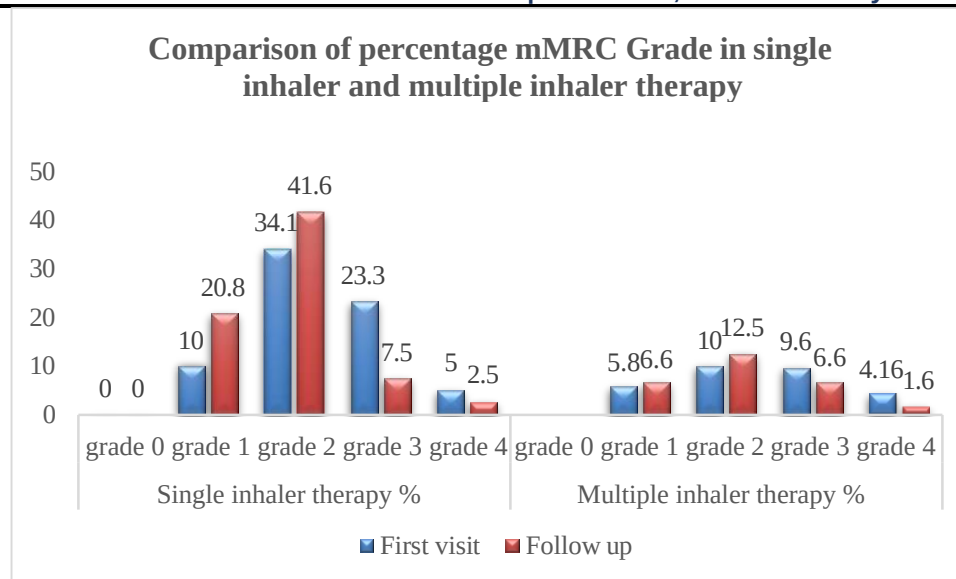


Figure 4.12: Comparison of percentage mMRC Grade in single inhaler and multiple inhaler therapy

4.13 Comparison of percentage CAT score in single inhaler and multiple inhaler therapy In this study comparison of percentage CAT score shows there is an decreased score in single inhaler users when compared with multiple inhaler.

Table 4.13: Comparison of percentage CAT score in single inhaler and multiple inhaler therapy

	Single inhaler therapy %				multiple inhaler therapy %			
CAT Score	Low	Medium	High	Very high	Low	Medium	High	Very high
First visit	0	3.33	47.5	21.66	0	2.5	12.5	12.5
Follow up	0	22.5	35	15	0	13.33	8.33	5.83

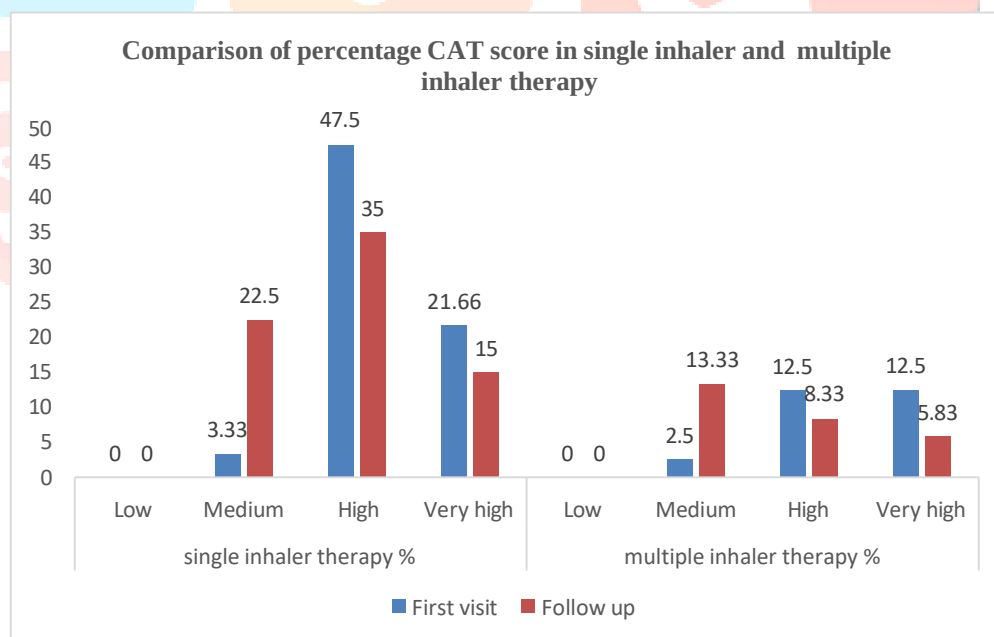


Figure 4.13: Comparison of percentage CAT score in single inhaler and multiple inhaler therapy

4.14 comparison of percentage PFT Score in single inhaler and multiple inhaler therapy

In this study, there is a improvement in the PFT score during follow up. When compared to multiple inhaler single inhaler users had more improvement

Table 4.14: comparison of percentage PFT Score in single inhaler and multiple inhaler therapy

	single inhaler therapy %				Multiple inhaler therapy %			
Ranges	Normal	Mild	Moderate	Severe	Normal	Mild	Moderate	Severe
First visit	0	33.3	28.3	10.83	0	10	10.83	6.6
Follow up	11.6	35.8	18.3	6.6	7.5	10	7.5	2.5

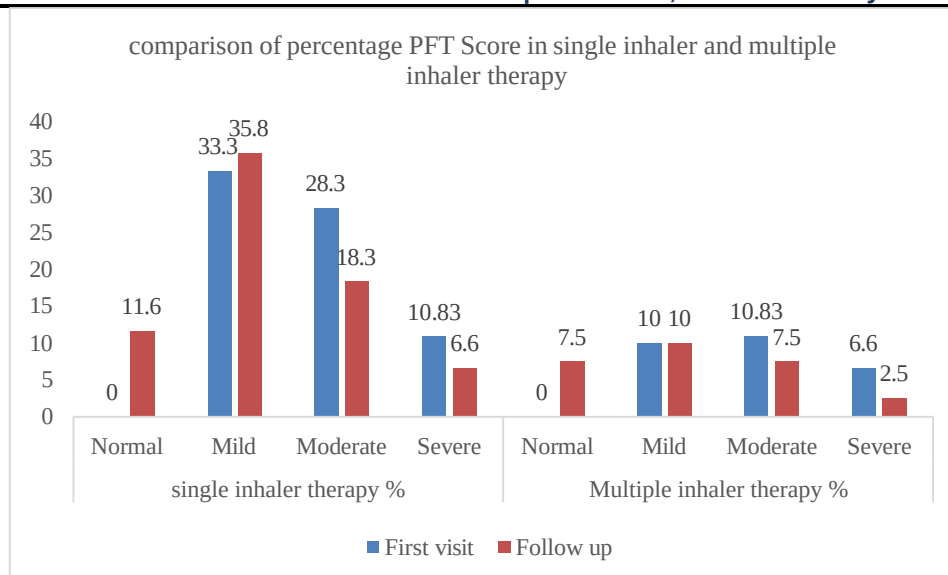


Figure 4.14: comparison of percentage PFT Score in single inhaler and multiple inhaler therapy

V. DISCUSSION

In this study, total 150 patients were enrolled among them 30 were lost during follow up.

Among 120 patients, 96 were males and 24 were females. This finding was similar to the study conducted by the **Miravittles M, Soriano JB et al.,⁸** in which the prevalence of COPD was higher in men than in women. This study shows that, the age group range from 56-65 years were most affected with the percentage of 40, followed by 46-55 years (21.66). In a study conducted by **Alcazar Navarrete B et al.,⁹** showed that the age group 45-64 years had higher prevalence of COPD. This finding resembled with the current study.

In our study total 120 members are included among them 57 members are current smokers i.e., 47.5% and current alcoholics were 56 i.e., 46.6%. This finding is different from the study conducted by **Alcazar Navarrete B et al.,⁹** in which the Ex-smokers were more when compared to current smokers.

Smoking is the major risk factor as the chemicals in smoking weakens the lungs defensive mechanism. In this study, smoking contributes i.e., 47.5% (57), followed by occupational exposure 46.6% (56) and remaining risk factors include pollution, Biomass exposure, and weather change. This finding correlated with a study on COPD by **JC Fernandez de Cordova Aguirre et al.,¹⁰** which showed smoking as a major risk factor followed by occupational exposure.

In this study during first visit 85.83% (103) patients were low adherent to the inhalers, 14.16% (17) were moderately adherent. **Hometowska H et al.,¹¹** studied showed that majority of patients reported with Noncompliance with inhaled medications. Coming to the follow up visit there is a increased adherence in patients i.e., 57.5% were moderately adherent this is because of the proper patient counselling provided to the patients by community pharmacist.

In this study during first visit, 43.33% with mMRC grade 2 followed by 31.66% mMRC grade 3. During follow up there is increased percentage in grade 2 (54.1) patients when compared with grade 3 (14.1). **Atsushi Hayata et al.,²⁸** stated that mMRC score increases with respect to severity of disease in this study mMRC grade decreased during the follow up visit when compared to previous visit this finding is similar to current study.

The CAT Scores of the study population during first visit shows, 60% of patients having high range score followed by 34.16% were very high. During follow up there is an increased percentage of medium score. The study by **Ghobadi H et al.,¹³** stated that severity of disease is directly proportional to the CAT score

PFT results shows, 43.33% of study population were mild, moderately affected were 39.16% during first visit to hospital. During follow up there is a decreased number of moderately affected, and increased number in normal range is seen where it shows there is a improvement in the lung condition whereas, the percentage of the severity is decreased in severe range i.e., from 17.51% to 7.5%. The study done by **Atsushi Hayata et al.,¹⁴** concluded that PFT score decreased during follow up, when compared to previous visit.

Percentage of Adherence comparison between single inhaler and multiple inhalers shows that, there is an increased adherence in both single and multiple inhaler therapy. When compared with multiple inhalers, single inhaler users had increased adherence. The findings of current study were similar with the studies done by **Andrew P. Yu, et al., Bogart et al., Mannino et al.,¹⁵** which showed that the adherence was more with SIT when compared with MIT

In this study, there is comparative reduction in the grade of mMRC after follow up, there is more decrease in single inhaler therapy. Study by **David M G Halphin, et al.**¹⁶, the of the study is differed from current study in which the results showed that the mMRC grade majorly decreased with MIT

In this study comparison of percentage CAT score shows there is an decreased score in single inhaler users when compared with multiple inhaler. **David M G Halphin, et al.**,¹⁶ results concluded that improvement in CAT score were observed in both SIT and MIT, but improvements were more prominent with SIT

In this study, there is a improvement in the PFT score during follow up. When compared to multiple inhaler single inhaler users had more improvement. **Lin L, Liu C et al.**,¹⁷ showed that PFT score was lower in SIT than MIT.

VI. CONCLUSION

COPD is the one of the major health condition which is causing mortality

This study Shows that there is significant relation between the medication adherence and improvement in disease condition

Majorly, men are affected than women.

The major risk factor associated with exacerbations are smoking, followed by occupational exposure.

Either of single inhaler and multiple inhalers have effective response if Patients are adhered to treatment, but single inhaler users have higher response when compared with multiple inhalers

This study conclude that single inhaler users are more adherent and had improved the disease condition by limiting to risk factors.

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