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Early Detection Of Chronic Obstructive Pulmonary Disease In Asymptomatic Smoker's Using Spirometry

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ABSTRACT
Introduction: *COPD is currently the 4th leading cause of death in the world.The burden of COPD is projected to increase in the coming decades due to continued exposure to COPD risk factors and the changing age structure of the world's population.*
Aims:*Early Detection of COPD in Asymptomatic Smokers Using Spirometry. To find out correlation between age, smoking index and airflow limitation.*
Materials and methods:
cross sectional descriptive study in high risk population screening in out patients and in patients of Osmania general hospital. Total 370 Patients are Included for 2 years from Nov 2015 to Nov 2017.
Results: *Overall the mean smoking index in 370 subjects was 300.55 ± 219.48, airway obstruction was seen 42 subjects i, e 11.35%, Mild obstruction (GOLD stage 1) was seen in 31 subjects which corresponds to 73.80%, Moderate obstruction (GOLD stage 2) was seen in 11 subjects which constitutes 26.19%.Airway obstruction was noticed in 24 subjects out of a total of 121 subjects with smoking index >200, which corresponds to 19.8%.*
Conclusion
Early diagnosis provides an excellent opportunity to implement various smoking cessation measures and the earlier the smoker quits the larger the benefits for lung function, by delaying the diagnostic screening one may lose out on the health benefits of smoking cessation.Especially in smokers more than 40 years of age and with smoking index of more than 200, is likely to reduce the overall burden of disease and outweighs the draining of resources used for screening programmes.

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I. Introduction

COPDis the leading cause of chronic morbidity and mortality worldwide, which induces a major social and economic burden that is both substantial and increasing.It is currently the 4th leading cause of death in the world but, is projected to be the 3rd leading cause of death by 2020.[1]More than 3 million people died of COPDin 2012 which constitutes 6 % of the deaths globally.The burden of COPD isprojected to increase in the coming decades due to continued exposure to COPD riskfactors and the changing age structure of the world's population.The early symptoms of COPD in the form of cough and sputum production are usually not considered significant by the smokerand often by their physicians and no interventions are deemed necessary.Because of the increase in prevalence and mortality of COPD, and the medical costs associated with it, it is important to identify patients and to treat them before they reach the symptomatic and costly stages of disease.[1]

Spirometry is the best standardized, most reproducible and most objective measurement of air flow limitation which is the hallmark of COPD. Early diagnosis of COPD should provide support for smoking cessation initiatives and lead to reduction of the societal burden of the disease, but definitive confirmation of both proves elusive.FEV1 and FVC predict all cause mortality independent of tobacco smoking.

This has been the argument that screening spirometry should be used as global health assessment tool [1].However there are no data to indicate that screening spirometry is effective in directing management decisions or in improving COPD outcomes in patients who are identified before developing significant symptoms.The present study was undertaken for early detection of COPD in high risk population screening by using spirometry with the patients counselled regarding their lung function and the benefit of smoking cessation in the prevention of COPD.

II. Material And Methods

It is cross sectional descriptive study in high risk population screening in 370 out patients and in patients of Osmania general hospital in 2 years from November 2015-november 2017.

Presuming an average prevalence of 25.43% based on previous studies of early detection of COPD in asymptomatic smokers, sample size was calculated as per the formula 4pq/l2 (where P being the prevalence=1-P and l= allowable error around the prevalence). Considering 5% error at 95% confidence interval, the required sample size was to be a minimum of 303.

With 20% non-response rate, it was estimated to be 363.

Inclusion criteria: Regular male smokers and 30 years of age and above with no significant respiratory symptoms except for occasional cough and willing to undergo spirometry.

Exclusion criteria: Subjects with smoking cessation for one year or more before enrolment, with history suggestive of bronchial asthma, tuberculosis andon bronchodilators or inhaled corticosteroids.

Patients were explainedabout harmful effects of smoking in causing COPD and how smoking cessation can stop the progression of disease with the help of modified graph of Fletcher and Peto. They were also explained how COPD goesundetected in the initial stage and how with the help of spirometry this disease can be detected at an early stage thereby halting its progression by smoking cessation.

The quantum of smoking exposure was calculated based on smoking index, [31]which was calculated as the product of the average number of cigarettes or bidis smoked per day and the duration of smokingin years. In a country like ours where a pack of cigarette contains either ten or twenty cigarettes and the smoking habits include either cigarette or bidi smoking, smoking index is more appropriate than pack years. In comparative terms, 10 pack years is equivalent to smoking index of 200 (Smoking index=Pack years×20).

All these subjects were subjected to spirometry using portable spirometer (RMS Helios 401). Spirometry was performed by an experienced respiratory technician as per therecommendations of American Thoracic Society FVC, FEV1 and FEV1% were measured after administrationof 400 µg of salbutamol as per the guidelines given by GOLD.Based on spirometry, subjects were classified as having mild COPD (FEV1/FEVC<0.70, FEV ≥80%of predicted normal value), moderate COPD (FEV1/FVC<0.70, FEV1 50-80% of predicted normal value), severe COPD (FEV1/FVC <0.70, FEV1 30-50% of predicted normal value) and very severe COPD (FEV1/FVC <0.7, FEV1 ≤ 30)as per GOLD guidelines. Subjects with abnormal spirometry were advised to report to our respiratory center for further evaluation and joining smoking cessation programmes.

Descriptive statistics were calculated using means ± SD. The chi-square test was applied for categorized data to find out the significance.

III. Results

In Present Study, the minimum age was 31years & Maximum age was 50 years.

Table 1: Age distribution in ranges

Age ranges (in years)	Number	percentage
31-35	**94**	**25.4**
36-40	**101**	**27.3**
41-45	**101**	**27.3**
46-50	**74**	**20**
Total	**370**	**100**
Distribution > than 40 years		
>40 Years	**175**	**47.29 %**
≤40 Years	**195**	**52.70 %**

In the present study it was observed that, out of a total of 370 subjects, 175 were more than 40 years of age which constitute around 47.29 %, where as those who are less than or equal to 40 years age constituted a 52.70 %. The mean age was 40.14 ± 5.47.

Table-2: Age distribution and SI comparison

Age ranges	Smoking index<200(%)	Smoking index>200(%)	Total
31-35	90(36)	4(3.5)	94
36-40	61(24.5)	40(35.7)	101
41-45	75(30.2)	26(23.2)	101
46-50	22(8.8)	52(46.4)	74
Total	249(67)	121	370

Age increases the smoking index increases beyond 35 years of age.

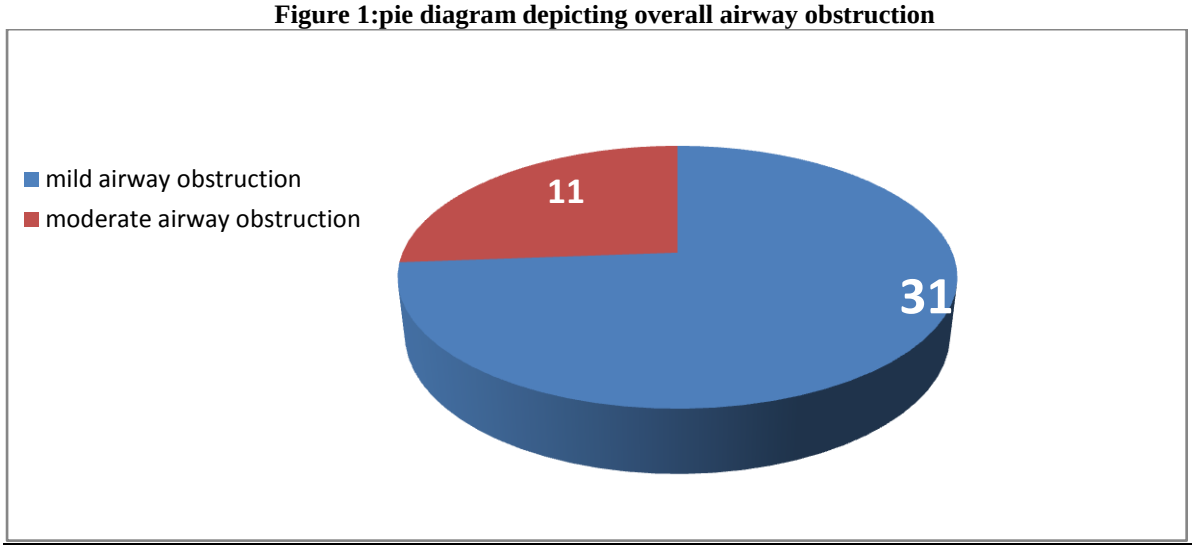
Table-3: comparison of mean SI with age group

Overall the mean smoking index in 370 subjects was 300.55 ± 219.48. In subjects >40 years of age mean SI was

Age group	Mean smoking index	N %
>40 years	371.88 ± 249.49	175 (47.29)
≤40 years	326.53 ± 164.59	195 (52.70)

371.88 ± 249.49 and in subjects ≤40 years it was 326.53 ± 164.59

Figure 1:pie diagram depicting overall airway obstruction

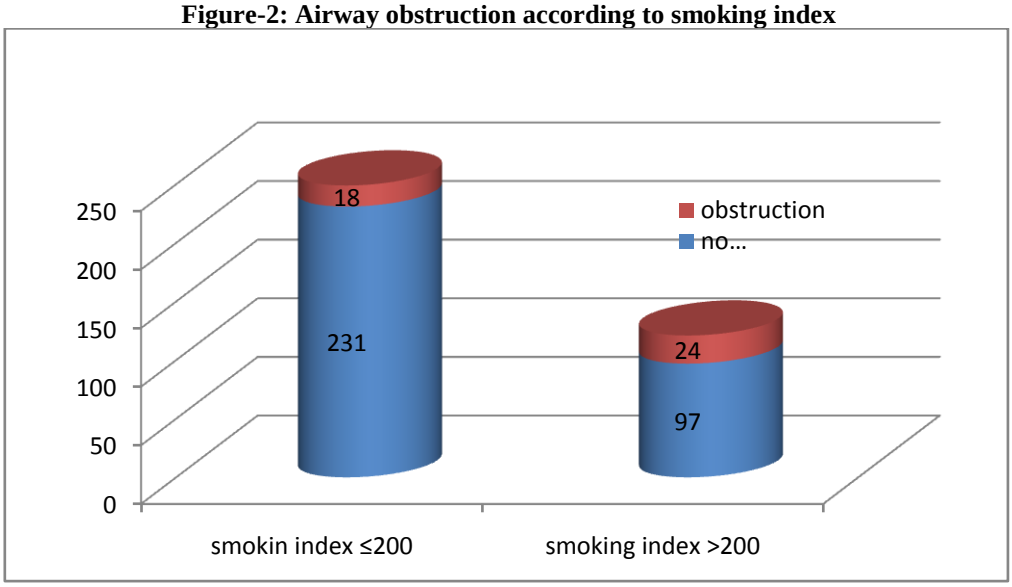


In total 370 patient's airway obstruction was seen 42 subjects i,e 11.35%.Mild obstruction (GOLD stage 1) was seen in 31 subjects which corresponds to 73.80%.Moderate obstruction (GOLD stage 2)was seen in 11 subjects which constitutes 26.19%.

Table-3: Airway obstruction in different age groups

Age group	Airway obstruction P value(<0.05)	percentage
>40 years	**29(n=175)**	**16.5%**
≤40 years	**13(n=195)**	**6.6 %**

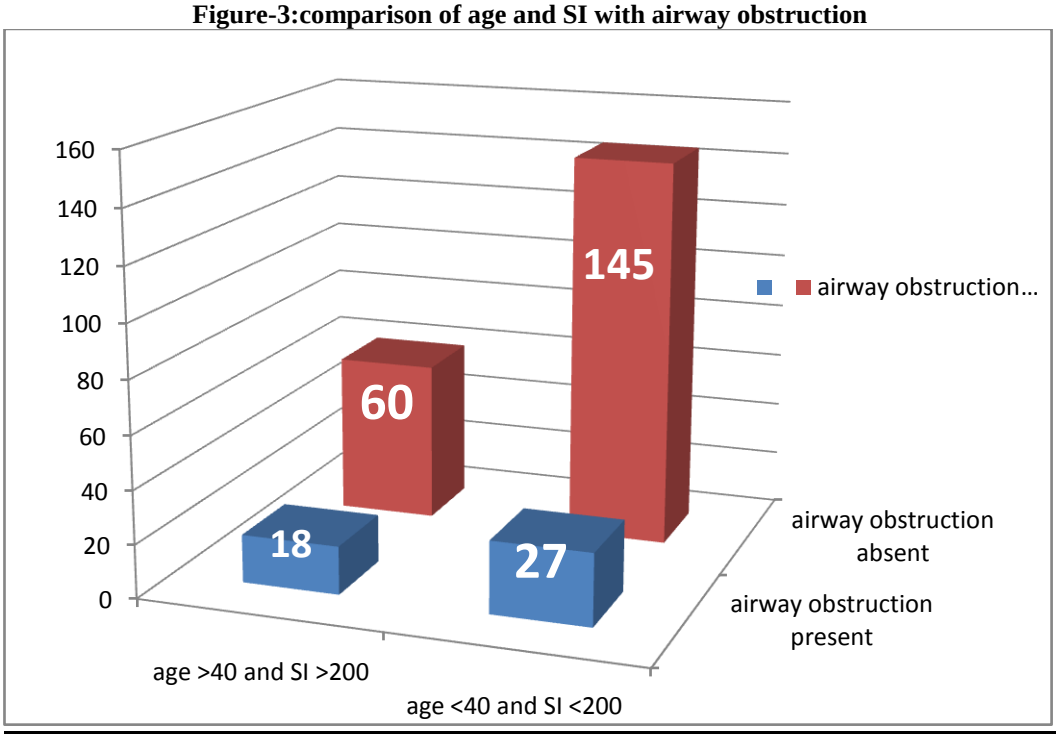
Figure-2: Airway obstruction according to smoking index



Airway obstruction was seen in 13 subjects aged ≤40 years (6.6%) and 29 subjects aged >40 years (16.5%)with a P value =0.002 which is highly significant.Airway obstruction was noticed in 18 subjects out of total of 249 subjects with smoking index ≤200, which corresponds to 7.22%.Airway obstruction was noticed in 24 subjects

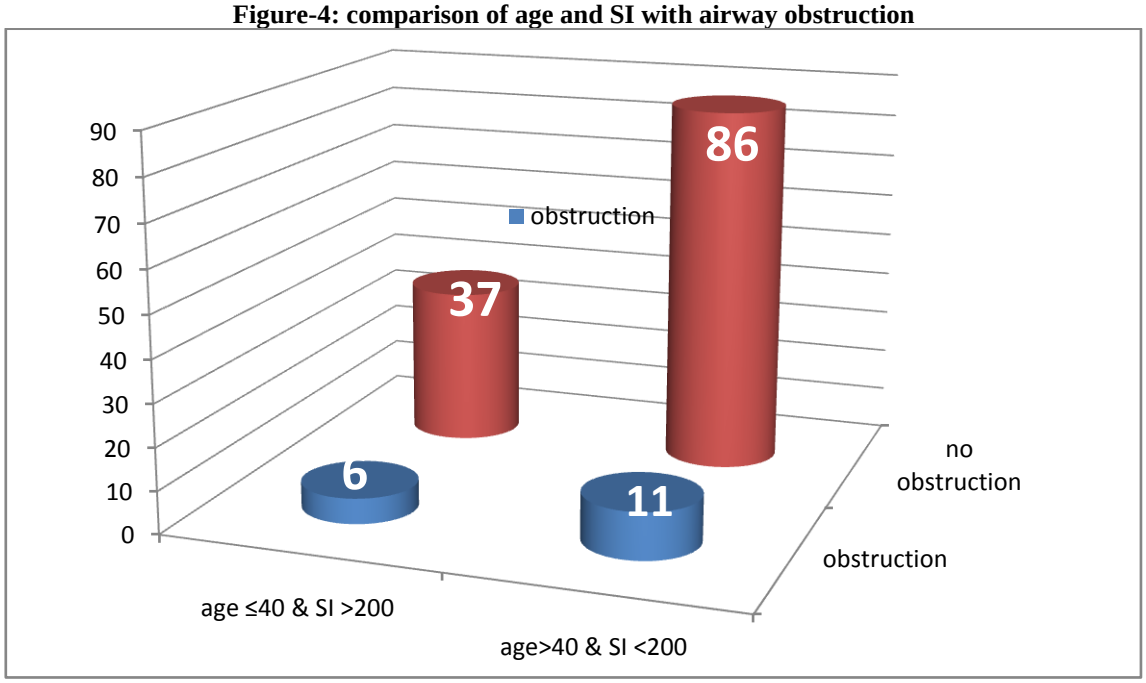
out of a total of 121 subjects with smoking index >200, which corresponds to 19.8%.The p value was calculated to be 0.0005 which is highly significant.

Figure-3:comparison of age and SI with airway obstruction



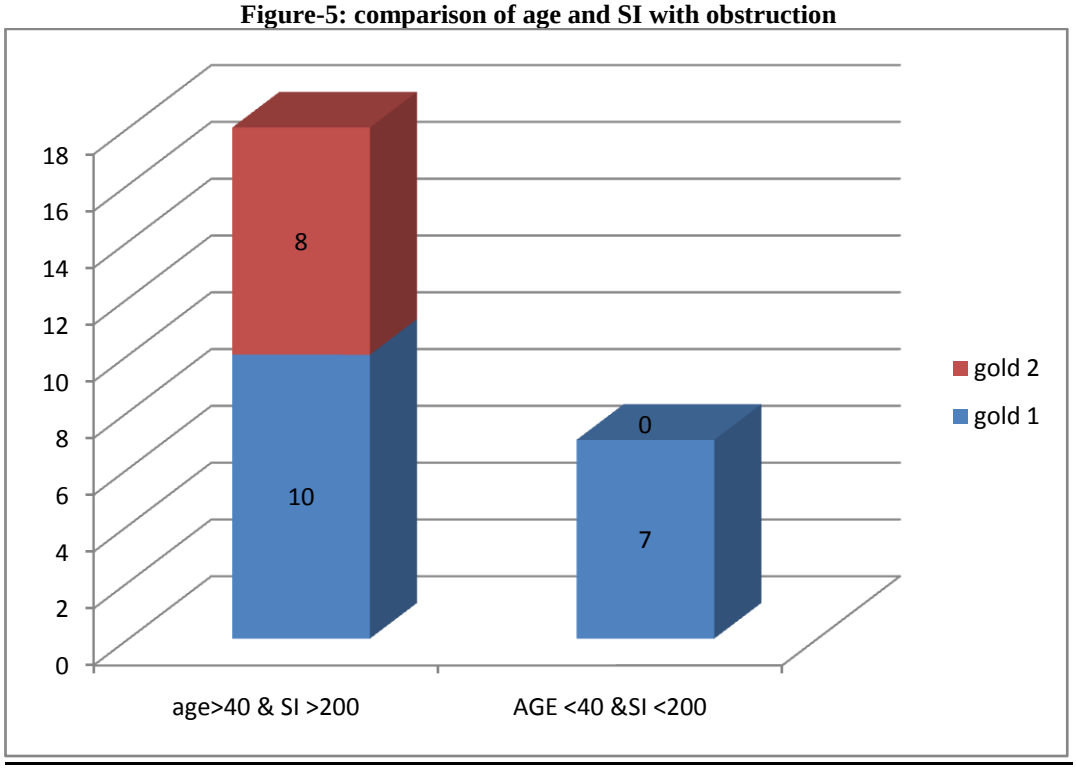
In smokers, more than 40 years of age and with smoking index more than 200 (n=78), 18 (23.07%) had obstruction and in smokers less than 40 years of age and smoking index less than 200 (n=152), 27(17.7%) had obstruction (p<0.005)

Figure-4: comparison of age and SI with airway obstruction



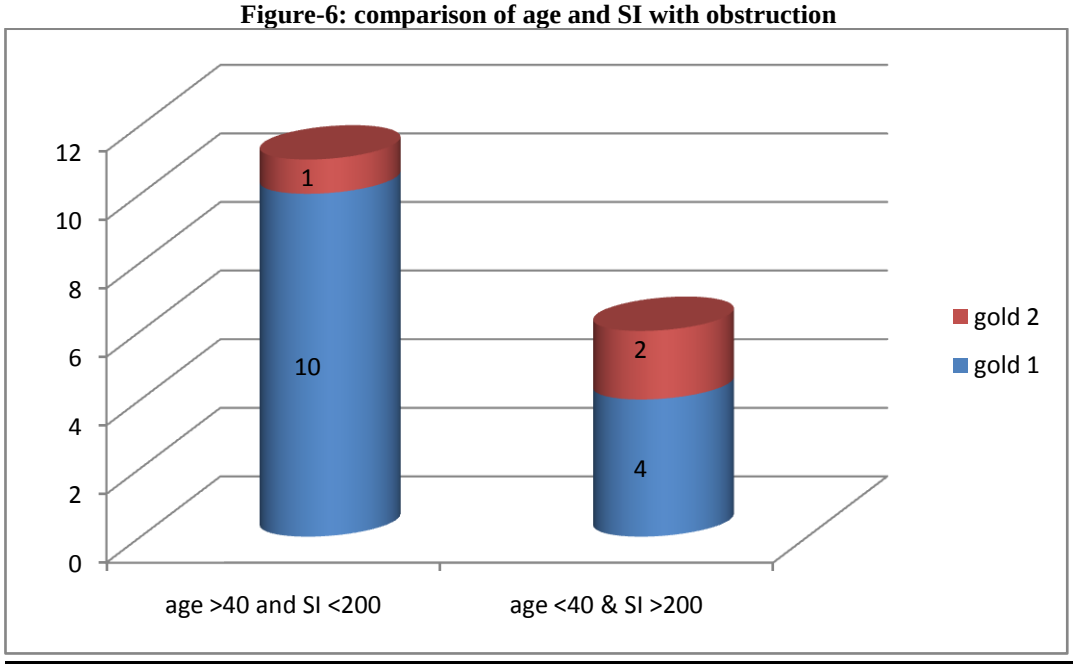
In smokers, more than 40 years of age and with smoking index less than 200 (n=97), 11 (11.34%) had obstruction and in smokers less than 40 years of age and smoking index more than 200 (n=43), 6(13.9%) had obstruction (p<0.005).

Figure-5: comparison of age and SI with obstruction



In smokers, more than 40 years of age and with smoking index more than 200 (n=78), 10 had mild obstruction (GOLD 1) and 8 had moderate obstruction . in smokers, less than 40 years of age and smoking index less than 200 (n=152), 7 had mild obstruction.

Figure-6: comparison of age and SI with obstruction



In smokers, more than 40 years of age and with smoking index less than 200 (n=97), 10 had mild obstruction (GOLD 1) and 1 had moderate obstruction . in smokers, less than 40 years of age and smoking index more than 200 (n=43), 4 had mild obstruction and 2 had moderate obstruction.
In smokers, more than 40 years of age and with smoking index more than 200 (n=78), 10 had mild obstruction (GOLD 1) and 8 had moderate obstruction.

Table-4: Comparison of age , SI and obstruction

Age & SI	Total(n)	Obstruction (n)	%
>40 and > 200	78	18	23.07
<40 and < 200	152	7	4.6

In smokers, more than 40 years of age and with smoking index more than 200 (n=78), 23.07% had obstruction and in smokers less than 40years of age and smoking index less than 200 (n=152), 4.6 % had obstruction ($p<0.005$).

Table-5: Mean FEV 1, FVCand FEV1/FVC

Spirometric parameters	Mean	±SD
FEV1	3.8	0.38
FVC	4.8	0.35
FEV1/FVC	77.60	6.32

IV. Discussion

A total of 370 individuals who met the inclusion criteria were evaluated with spirometry compared with the study by *Barthwal et al* , where 460 individuals were evaluated.All the subjects were male with mean age of 40.14 ± 5.47 compared to the study by Barthwal where mean age was 39.72±8.76

Table-6: Comparison between the present study and Barthwal and Singh

Parameters	Present study	*MS Barthwal ,Singh*[2]
Number	370	460
Mean age	40.14±5.47	39.72 ± 8.76
Subjects >40 years	175	188
Subjects <40 years	195	272
Mean Smoking Index In subjects >40 years	371.88±249.49	452.59±289.61
Mean Smoking Index In subjects <40 years	326.53±164.59	213.88±106.19
Overall airway obstruction	42	58
Mild obstruction	11	40
Moderate obstruction	31	18
Airway obstruction in subjects >40years	29	34
Airway obstruction in subjects <40 years	13	24
Subjects with SI>200	121	170
Subjects with SI<200	249	290
Airway obstruction in subjects SI>200	24	42
Airway obstruction in subjects with SI<200	18	16
Subjects >4oyears with SI >200	78	184
Subjects <40years with SI <200	152	276
Airway obstruction >4oyears and SI >200	18	48
Airway obstruction <40years and SI <200	7	15

Early diagnosis of COPD with spirometry should provide support for smoking cessation initiatives and lead to reduction of the societal burden of disease, but there are no confirmative data available for thesame. In Finnish[3], a national prevention and treatment programme for chronic bronchitis and COPD was launched in 1998 in which early diagnosis of COPD was made possible with spirometry followed by management in smoking cessation clinics.The Finnish National Programme for Chronic Bronchitis and COPD, 1998–2007 was set up to reduce the prevalence of COPD, improve COPD diagnosis and care, reduce the number of moderate to severe cases of the disease, and reduce hospitalizationsand treatment costs due to COPD.[3]Smoking decreased in males from 30% to 26% ($p<0.001$) and in females from 20% to 17% ($p<0.001$). Significant improvements in the quality of spirometry were obtained. Hospitalization decreased by 39.7% ($p<0.001$). COPD costs were 88% lower than had been anticipated from earlier investigation.

By 2003,decline in smoking prevalence and admissions for COPD were recorded providing evidence of the effect of early diagnosis on natural history and burden of COPD [4].In combination with other efforts, the Finnish 10-year COPD Programme had significant positive consequences: no further increases in COPD prevalence, reduced smoking prevalence, improved quality of diagnosis, and reduction in COPD-related hospitalizations.In this study, high risk population screening by spirometry was implemented in asymptomatic male smokers.We selected subjects 30 years and above, since although most of the smokers start smoking at much early stage, yet the compromise of lung function progresses with age and COPD is more prevalent in more elderly populations [4] .

Most of the population based studies have taken subjects above 30-40 years of age for screening early COPD.All the subjects were counselled regarding the harmful effects of smoking on lung function and also its relation to the development of lung cancer and coronary artery disease.In subjects with documented airflow limitation special emphasis was given, by showing them the modified chart of *Fletcher and peto* .[5]

Subjects with airflow limitation on spirometry appeared to be more motivated than in persons without airflow limitation in joining smoking cessation programs.

Since this is an observational study patients were not followed up but the expected result would be decrease in the prevalence of COPD and also hospitalizations.Large scale prospective studies in India need to be done to find out the usefulness of early detection of COPD.[6,7]Ideally female smokers should also have been included but because of the lower incidence of smoking in females in developing countries they were not included.However, the scenario may be changing and further studies are needed to be done, since the incidence of women smokers is gradually increasing in developing countries also.

Spirometry v/s questionnaire in early diagnosis of COPD :

In *DIDASCO* Study (Differential Diagnosis between Asthma and COPD),a population based study, individuals aged 35 to 70 years were subjected to spirometry for early detection of airflow limitation [8] .In the didstudy the objective was to determine if spirometry is essential for the early detection of COPD in general practice, compared to the screening value of a short questionnaire.The use of a spirometer is mandatory if early stages of COPD are to be detected in general practice. Screening for airflow obstruction almost doubles the number of known patients with COPD.

Prevalence of COPD :

Most of Indian studies have screened population for COPD above 30 years of age [9].The overall prevalence of COPD in adults is estimated at 4-10% [10]. in this study the prevalence of copd was around 11 %.However, a prevalence of 30-50% has been reported in high risk population such as long-term smokers, depending on the characteristics of the population under study and on the spirometry Criteria used for diagnosis [11].

Previous studies have used two methods for early detection of COPD: high risk population screening1 and case Finding [12]. Both methods have their advantages and disadvantages making them complimentary. We chose the high risk population screening method because of better infrastructure and resources.In Our study subjects 30 years and above were selected , since although most of the smokers start smoking at much early stage, yet the compromise of lung function progresses with age and COPD is more prevalent in more elderly populations.

High risk population screening :-

High risk population screening for COPDhave been investigated and implemented in Poland.*Gorecka, et al*[13] from Poland demonstrated that diagnosis of airflow limitation combined with smoking cessation advice increased smoking cessation rate.In a population spirometric screening of 11,027 subjects who were at risk for COPD in 12 Polish cities, airflow limitation was detected in 30.6% of smokers who were 39 years of age who had a smoking history of 10 pack-years.

In our study overall airway limitation was seen in 11.35%.whereas in subjects with age >40 and smoking index >200obstruction was seen in 23.07 %. The lower percentage of airflow limitation seen in our study is because; the sample consisted of only asymptomatic smokers.In the study by *Gorecka et al*,[13] obstruction was diagnosed in 41% of patients who were at risk for COPD, most of whom (63%) were in a mild stage of COPD.

Where in our study mild obstruction was seen in 73% subjects which is higher. It is worth mentioning that these subjects had spirometry performed for the first time in their life and learned only then about their disease.

Smoking cessation advice by modified Fletcher and Peto graph:-

Gorecka, et al[13] from Poland demonstrated that diagnosis of Airflow limitation combined with smoking cessation advice increased smoking cessation rateAll current smokers in our study were advised to stop smoking. The advice was individualized, and all were acquainted withthe modified graph of *Fletcher and Peto*[5] to visualize the age of their lungs and the perspectives on FEV1 decline if they stopped smoking or if they continued to smoke.

Smokers with airflow limitation were strongly warned about the progression of the disease. Smokers with no limitation of flowwere informed that they still had healthy lungs but were warned about the risk of developing COPD in the future if they continued to smoke. The intensity of the advice to stop smoking was intended to be the same in both groups, however, smokers with newly diagnosed disease showed concern about the diagnosis.Smoking intervention preferably should target smokers with no limitation of flow or those with mild and moderate disease to prevent the inevitable progression of the disease.

In the *Lung Health Study* (LHS) [14]an intensive group therapy intervention with behaviour modification techniques and nicotine gum therapy in moderately obstructed patients yielded an exceptionally high cross-

sectional success rate of 35% for 5 years, with a sustained quit rate at the end of the study of 22%. In the study by *Gorecka et al*[13] all smokers, irrespective of their lung function, tried to modify their habit as the result of screening for COPD.

The diagnosis of limitation of flow, and, presumably, symptoms of COPD, motivated a quit attempt in smokers with moderate and severe airflow limitation. Fewer smokers with mild disease and with no limitation of flow tried to modify their habits.Older age, lower tobacco exposure, and poorer lung function were predictors of success in smoking cessation.However In our study the effect of screening spirometry in the cessation of smoking could not be determined because it is only an observational study and patients were not followed up.
There is a need to conduct prospective studies with a proper follow up so that the data can be used to initiate necessary public health programmes , probably integrated with other health programmes so that health providers can prevent the progression of the disease which contributes to high mortality and morbidity especially in resource poor countries like India .

Comparison of airflow limitation with age and smoking index:

In the present study, airflow obstruction was seen in 11.35% of total subjects with 16.5% in above 40 years of age and 6.6% in below 40 years of age.In Lung health study [15] a multi-centric studyconducted in Canada and USA, spirometry screening of more than 73,000 smokers aged 35 to 60 years was performed in 10 centres.Airway obstruction was seen in 21.8% to 35.7% (mean 25%) cases and severe obstruction (FEV1 <50% of predicted) was seen in5% of total cases.

The lower prevalence of airflow obstruction in our study was because of inclusion of only asymptomatic smokers whereas in LHS study symptomatic smokers were also included.

in our study smokers above 40 years and with smoking index above 200 showed obstruction in 23% on spirometry.*Zielinski et al* of "*Know the age of your lung studygroup*" evaluated the efficacy of mass spirometry in detection of airflow obstruction in high risk population above 39 years of age[16].11027 subjects were screened with mean age of 51.8 ± 12.5 years and meansmoking history of 26.1 ± 16.8 pack-years (equivalent smoking index 522±336). Overall obstruction was found in 24.3% cases. Mild obstruction was seen in 9.5%, moderate in 9.6% and severe in 5.2% subjects.

In our study the mean age was 40.13 ±5.47 .The mean smoking index was 300.55 ±219.48

The difference from our study by is again explainedby high mean age and high smoking index in this study.Analysis of sub-groups in the study by *Zielinski* et al[16] showed that obstruction seen in 30.6% of smokers above 40 years of age with smoking history of more than 10pack years (equivalent to smoking index >200) as compared to 8.3% of smokers below 40 years of age and having smoking history of less than 10 pack years (equivalent to smoking index <200).

The same correlation was observed in our study, i.e. airway obstruction was seen in 23% subjects above 40 years and having smoking index > 200 compared to only 4.6% of subjects below 40 years with smoking index < 200.A study was conducted by *Geiger RMM et al*[11] to find out the prevalence of undetected persistent airflow obstruction in male smokers 40-65 years old .The prevalence of undetected persistent airflow obstruction in middle-aged smokers is high. Targeted screening therefore, especially in smokers aged 40–65 years needs to be considered

Airflow obstruction in smokers is often diagnosed relatively late. Earlier detection of airflow obstruction and smoking cessation may result in significant health gain. In this cross-sectional study among 805 male smokers aged 40–65 years spirometry was performed according to ATS recommendations.In participants with low lung function (FEV1 85% predicted) a bronchodilator test was performed. In 702 participants [mean age 50 years (SD 6.6), mean number of pack years 24.7 (SD 9.6)] with acceptable spirometric curves, previously undetected airflow obstruction was found in 210 subjects (29.9%; 95% CI 26.5–33.4): mild airflow obstruction (GOLD stage 1) in 182 subjects (25.9%; 22.7–29.3) and moderate airflow obstruction (GOLD stage 2) in 28 (4.0%; 2.7–5.7).

Similarly in our study smokers above 40 years and with smoking index above 200 showed obstruction in 23% on spirometry. In subjects with 30 pack years the prevalence of airflow obstruction was 45% versus 20% among those with 20 pack years. In smokers reporting coughing the prevalence was 47% versus 25% in those not reporting this symptom.The prevalence of undetected persistent airflow obstruction in middle-aged smokers is high. Targeted screening therefore, especially in smokers aged 40–65 years needs to be considered.

Limitations of the study

1) Ideally female smokers should also have been included but because of the lower incidence of smoking in females in developing countries they were not included.
2) The effect of screening spirometry on persons exposed to indoor/outdoor air pollution (ex:house wives/policemen) in preventing COPD could not be determined , since only smokers were taken in this study.

3) The main limitation was follow-up. Since this is an observational study the effect of screening spirometry in smoking cessation , delaying the onset of severe COPD , preventing morbidity and mortality , and ultimately decreasing the prevalence of COPD could not be found out. Further prospective studies need to be conducted in the Indian scenario to have significant evidence.

One recommendation would be to compare COPD questionnaires in the native languages and screening spirometry in the early detection of COPD , which would be especially useful in resource poor countries like India

V. Conclusions

This study shows that early detection yield of COPD increases with increasing age and quantum of smoking making the screening method more cost effective in symptomatic than in asymptomatic smokers. Since early diagnosis provides an excellent opportunity to implement various smoking cessation measures and the earlier the smoker quits the larger the benefits for lung function, by delaying the diagnostic screening one may lose out on the health benefits of smoking cessation. Right now we do not have confirmatory evidence in support of the assertion that early diagnosis of COPD may improve the smoking cessation but in view of not so significant impact of primary prevention of COPD in the form of smoking cessation, the early diagnosis of COPDby spirometry, especially in smokers more than 40 years of age and with smoking index of more than 200, is likely to reduce the overall burden of disease and outweighs the draining of resources used for screening programmes. One way to reduce the cost of such screening programmes is to link spirometry with other screening programmes like detection of diabetes, hypertension and cervical cancer and mammography in women.

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