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EVALUATION OF RISKFACTORS, PRESCRIBING PATTERN AND EFFECT OF PATIENT COUNSELLING ON KNOWLEDGE, ATTITUDE AND PRACTICE REGARDING ANTIBIOTICS USE IN PATIENTS WITH COPD EXACERBATION

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ABSTRACT

Chronic Obstructive Pulmonary Disease (COPD) exacerbation is one of the leading cause for morbidity and mortality.The objective of our study is to evaluate the riskfactors, prescribing patterns and effect of patient counselling on Knowledge, Attitude and Practice regarding antibiotics use in COPD exacerbation patients.T his was a hospital based prospective observational study. About 113 patients diagnosed with COPD exacerbation were included in the study. All information relevant to study were collected in suitably designed proforma from case records and discussions conducted with the inpatients and bystanders during ward rounds, with the support of a physician. From this patient's drug prescribing pattern and common riskfactors for COPD exacerbation were noted and plotted statistically. A suitably designed KAP questionnaire was administered on all the enrolled patients to assess the knowledge, attitude and practice (KAP) of the patients towards antibiotics use and proper counselling were given to patients and the score were statistically assessed before and after patient counselling. The riskfactors contributed to exacerbation of COPD are usually age, gender, smoking, education, duration of COPD, disease severity, comorbidities, compliance with treatment etc. From our study we identified a positive correlation between some of riskfactors and number of exacerbation in COPD. By evaluating the prescription pattern we found that antibiotics were prescribed for all COPD exacerbation patients and multiple drug therapy is preferred. Majority of drugs prescribed were in concordance with GOLD guidelines. Impact of patient counselling on knowledge, Attitude and practice towards antibiotics use provided a satisfactory result. The results showed a significant improvement after counselling.

KEYWORDS: COPD, riskfactors, prescribing pattern, antibiotics, GOLD guidelines.

INTRODUCTION
COPD is defined as "a chronic slowly progressive disease characterised by airflow obstruction that does not change markedly over several months".[1] COPD (Chronic obstructive Pulmonary Disease) EXACERBATIONS are defined as events of acute onset, characterized by worsening in respiratory symptoms beyond the day-to-day variations and that may warrant a change in regular medication of the COPD patient.[3] COPD is estimated to become the fifth-leading cause of years lost through early mortality by 2020, while according to World Health Organization estimates it is predicted to become the third-leading cause of global mortality by the year 2030. Predictive factors of exacerbation are still not completely understood. Identification of potential factors associated with the frequency of exacerbations and hospitalizations may assist in alleviating the patients' burden and the societal and economic burden of exacerbations.

Drug utilization studies can provide insights into a pattern, quality, determinants and outcomes of drug use. Drug utilization research is useful in achieving rational drug use as it can be the basis for suggesting improvements in drug guidelines.Global Initiative for Obstructive Lung Disease (GOLD) recommends guidelines for the management of COPD and its exacerbation. Management of exacerbation of COPD include antibiotics, oxygen therapy, β2-agonist, anticholinergics, Methylxanthines, and systemic steroids.Health education of patients, smoking cessation, pulmonary rehabilitation, good nutritional status, and early medical intervention are all considered helpful in preventing exacerbations.[5]

KAP studies tells us what people know about certain things, how they feel and also how they behave. The three topics that a KAP study measures are Knowledge, Attitude and Practice. The Knowledge possessed by a community refers to their understanding of any given topic COPD in this case. Attitude refers to their feelings towards this subject, as well as any preconceived ideas that they may have towards it. Practice refers to the ways in which they demonstrate their knowledge and attitude through their actions. According to GOLD guidelines antibiotics may be required in management infective exacerbation COPD who have increased incidence dyspnea, sputum volume, and sputum purulence. The choice depends on the local bacterial resistance pattern.[1] An aminopenicillin or a macrolide with increased activity against H. influenzae or oxytetracycline is generally suitable as a first-line agent. Sputum should be sent for culture in order to check the appropriateness of initial therapy, and the antibiotic changed if necessary.

Antibiotics are viewed as most usually sold medication class in the developing countries. The irrational and abuse of antibiotics result not just in the resistant bacterial strains yet in addition in adverse responses and economical burden on national health system. Patient decisions to follow the recommended treatment are likely to be influenced by their beliefs about medicines as well as their beliefs about the illness that the medication is intended to treat or prevent.[12] High percentage of antibiotics being used without physician's consultation either directly from pharmacies as OTC or self-medication using sibling antibiotics and left-over antibiotics.[8] It is important to improve knowledge, attitude and practice regarding antibiotics use in patients with exacerbation as they need antibiotic therapy. Knowledge regarding the indications for antibiotic use, resistance due to misuse and safety are need to be educated to COPD patients as they receive antibiotics. The present study was conducted to assess the risk factors, prescribing pattern in COPD exacerbation patients. The study also evaluated the impact of patient counselling on Knowledge, Attitude and Practice (KAP) among COPD patients.

MATERIALS AND METHODS
This was a hospital based prospective observational study conducted in the department of pulmonary and critical care, Cosmopolitan hospital, a tertiary care centre, Thiruvananthapuram. The study was conducted for a period of 6 months. Patients with age group >35 yrs with physician diagnosed COPD exacerbation were included in study. Patients with incomplete medical records, patients with other respiratory diseases were excluded from the study. The study was conducted in 113 patients satisfying the inclusion and exclusion criteria. Written informed consent were obtained as per ICMR biomedical research guideline format from patients diagnosed with COPD exacerbation satisfying the inclusion and exclusion criteria. All informations relevant to the study were collected from case records and discussion conducted with the inpatients and bystanders during ward rounds with the support of a physician.

The sociodemographic charecterestics, clinical background, comorbidities, smoking history, COPD charecterestics (duration of COPD, number of exacerbations) and treatment were documented in profoma. The disease severity of patients were assessed according to the mMRC scale, CAT score and number of exacerbation.The extent of contribution of different risk factors for COPD exacerbation along with prescribing pattern was noted and plotted statistically.

A suitably designed KAP (knowledge, attitude and practice) questionnaires were administered to all the enrolled patients or bystanders to assess the knowledge, attitude and practice of patient towards antibiotic use. Proper counseling were given to patient or bystanders using suitable validated patient information leaflet. The post counseling effect was assessed by the same questionnaire. The pre and post counseling score was ststistically analysed.

Statistical analysis
For data entry we had used the microsoft excel and all the analysis were carried out with the help of statistical software SPSS v.21 version for WINDOWS. Mean and standard deviation were used as descriptive statstics for continuous study variables while frequency and percentage were used for categorical varables.Since the data donot obey normal distribution by Kolmogorov-Smirhov test, non parametric statistical procedures were adopted. The corelation between the riskfactors and the number of exacerbations were assessed using chi-square test. The effect of patient counselling on KAP level of patients was statistically assessed using Wilcoxon Signed Rank Test.The effect of counselling on KAP regarding antibiotic use were assessed using Kruskal Wallis Test. A calculated P value <0.05 is considered to be statistically significant.

RESULTS AND DISCUSSION
Sociodemographic characteristics
In this section background characteristics of patients were collected and analyzed.

Table 1 shows that the patients were divided into three age groups. It reveals that out of 113 patients, 7 (6.2%) were <60 years of age group, 57(50.4%) patients aged between 60 -75 years and 49(43.4%) were ≥76 years of age. The result shows that majority of patients were aged above 60 years. This suggests that the risk for developing exacerbation of COPD increases with age, probably because pulmonary function decreases with time and because of the accumulative effect of risk factors such as smoking. Alexpoulos et al showed that participating patients had a median age of 68.0 years. The study conducted by Uma et al and Sawant MP et al showed that majority of patients are in the age group of 61-70

years and mean age of 67.8 years. Out of total patients enrolled in the study, the prevalence of COPD exacerbation was higher in males (69.9%) compared to females (30.1%).This may be due to the increased risk of smoking among males than females.

Table 1: Frequency and percentage distribution based on sociodemographic character.

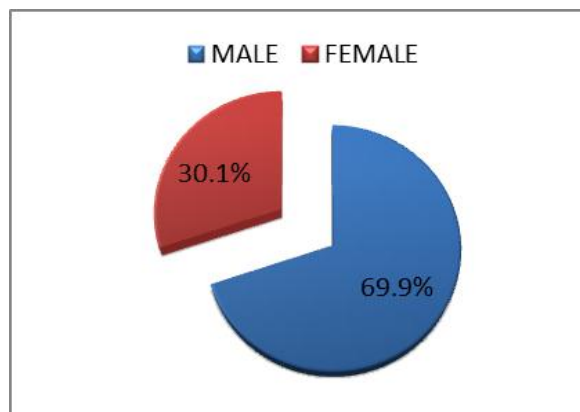|	Frequency	Percentage
AGE		
<60	7	6.2
60-75	57	50.4
≥76	49	43.4
SEX		
Male	79	69.9
Female	34	30.1
QUALIFICATION		
Professional degree	9	7.9
Graduate	11	9.7
Higher secondary	25	22.1
High school	40	35.3
Illiterate	28	25
SMOKING STATUS		
Ex smoker	70	61.9
Current smoker	10	8.8
Non smoker	33	29.2

Figure 1: Diagrammatic representation of distribution based on gender.

Fig 1 represents that majority of the patients were male (69.9%).Similar results were observed in a previous study conducted by Alexpoulos et.al in which 71.3 %were males. The results of the study conducted by Mahmoodan et.al shows that out of 100 patients 62 (62%) were males and 38 (38%) were females. Similar results were observed in studies conducted by J. Monstrate capdevila et.al, J.C Fernandez de cordova – Aguirre et al, Uma et.al, J. Garcia-Aymerich et al.

From table 1, it is observed that out of 113 patients, 9 (7.9%) patients were progessional degree, 11 (9.7%) patients were graduates, 25 (22.1%) were having higher secondary level of education, 40 (35.3%) patients were having high school education and 28(25%) patients were others. Also it is observed that majority of patients were

high school(35.6%). This result may vary in accordance with the area of living, economic status, family status etc. Our results on educational status shows that educational status has no relationship with the development of COPD. The study conducted by Mahmoodan et al reported that out of 100 patients 81% were illiterate and 19% were literate.

Also our study also shows that 70(61.9%) patients were past smokers, 10(8.8%) of patients were current smoker and 33(29.2%) patients were non-smokers. This suggests that the development of COPD has strong link to smoking status. That shows that, smoking is a prominent cause and risk factor for COPD and exacerbations.
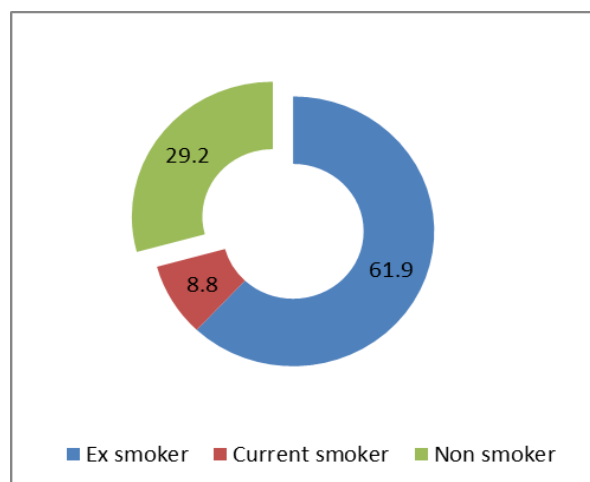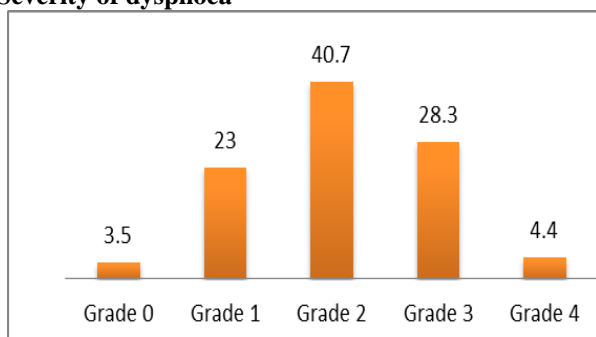

Figure 2: Diagrammatic representation of distribution based smoking status.

Disease characteristics
Our analysis of disease characteristics reveals more about the severity of dyspnoea, duration of COPD, compliance with treatment and comorbidities.

Table 2: Frequency and percentage distribution based on disease characteristic.

|	FREQUENCY	PERCENTAGE
SEVERITY OF DYSPNOEA		
Grade 0	4	3.5
Grade 1	26	23
Grade 2	46	40.7
Grade 3	32	28.3
Grade 4	5	4.4
DURATION OF COPD		
≤ 5 yrs	15	13.3
6 – 10 yrs	47	41.6
≥ 11yrs	51	45.1
COMPLIANCE WITH TREATMENT		
Never/almost never forgets to take medication	58	51.3
Forgets medication (one/two times per month)	25	22.1
Forgets medication (once a week/more than once aweek/almost everyday)	30	26.5
COMORBIDITIES		
HTN	68	60.2
DM	46	40.7
Hypothyroidism	32	28.3
CAD	18	15.9
Respiratory failure	16	14.2
Others	31	27.4

Severity of dyspnoea

Figure 3: Diagrammatic representation of distribution based on severity of dyspnea.

The figure 3 and table 2 reveals the percentage distribution of sample according to severity of dyspnea. The severity of dyspnea was obtained from mMRC Dyspnea scale. It consists of 5 grades such as Grade 0, Grade 1, Grade 2, Grade 3 and Grade 4. Out of the 113 COPD exacerbation patients selected, 4 (3.5%) patients were having dyspnea grade 0, 26(23%) patients belonged to grade 1, 46 (40.7%) patients belonged to grade 2, 32 (28.3%) patients belonged to grade 3 and 5 (4.4%) patients belonged to grade 4. The graph shows that percentage of grade 2 dyspnea was higher compared to other grades.

Duration of COPD
The duration of COPD was divided into ≤5 years, 6-10 years and ≥11years. Figure 4 shows the percentage distribution of sample according to duration of COPD. From table 5 it is observed that, out of 113 COPD exacerbation patients 51(45.1%) patients were having a

duration ≥11 years, 47(41.6%) patients were having duration of COPD between 6-10 year and 15(13.3%) patients were having ≤5 years since diagnosis of COPD.
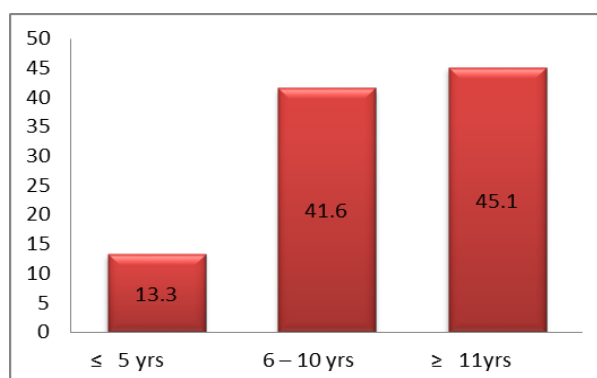
Figure 4: Diagrammatic representation of distribution based on duration of COPD.

This result (fig.4) suggests that more number of patients (86.7%) were having a duration of COPD greater than 5 years compared to duration less than 5 years (13.3%). It implies that COPD is a chronic disease that last life long and cannot be reversible.

Compliance with treatment
In table 2, the compliance with treatment were divided into three. From fig 5,3 represents the patients who never/almost never forgets to take medication, 2 represents the patients who forgets medication (one/two times per month) and 1 represents the patients who forgets medication (once a week/more than once aweek/almost everyday). This results revealed that 58(51.3%) patients were adherent with the treatment, 55

(48.6%) patients were shown non-compliance to the medication. Patient adherence in chronic diseases remains a task, resulting in poor health outcomes and increased health care expenditures.[11]
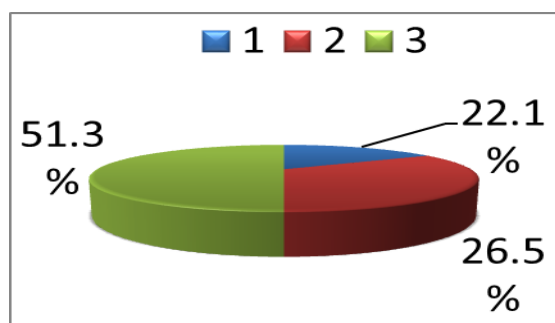

Figure 5: Distribution based on compliance with treatment.

Patients' acceptance of the disease process and recommended treatment, knowledge about and faith in the treatment, effective patient-clinician interaction, and routinization of drug therapy are critical for optimal medication adherence in patients with COPD [12].

Comorbidities
In our study, only 4 patients were presented COPD exacerbation without comorbidities. Remaining 99 patients presented with comorbidities in which,

hypertension 68 (60.2%) was the most common comorbidity followed by DM (40.7%), hypothyroidism (28.3%), CAD (15.9%), respiratory failure(14.2%) and other (27.4%).
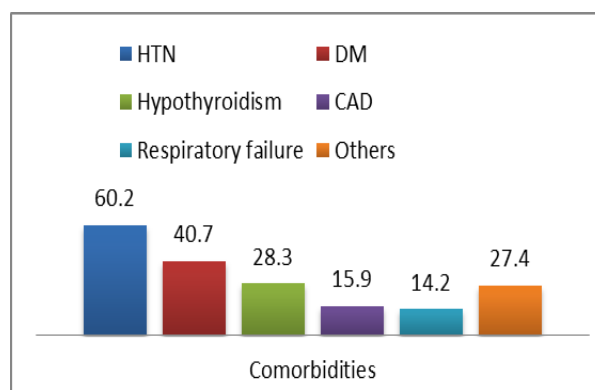

Figure 6: Frequency and percentage distribution based on comorbidities.

Association between the number of exacerbation of COPD with riskfactors
In this section chi-square test was used to assess co-relation between the number of exacerbation with some of risk factors.

Table 3: Frequency and percentage distribution of association between number of exacerbation and riskfactor.

Age	≤2 exacerbation	>2 exacerbation	P-value
<75 years	51(79.7%)	13(20.3%)	0.000*
≥ 76 years	19(38.8%)	30(61.2%)	
Gender			
Male	49(62.0%)	30(38.0%)	<0.05 (continuity correction)
Female	21(61.8%)	13(38.2%)	
Smoking status			
Ex smoker	42(60%)	28(40%)	0.000*
Current smoker	4(40%)	6(60%)	
Non smoker	24(72.7%)	9(27.3%)	
Disease severity			
Group A	3(100%)	0(0%)	0.000*
Group B	8(100%)	0(0%)	
Group C	17(81%)	4(19%)	
Group D	42(51.9%)	39(48.1%)	
Duration of COPD			
≤ 5 yrs	15(100%)	0(0%)	0.000*
6 – 10yrs	42(89.4%)	5(10.6%)	
≥ 11yrs	13(29.5%)	38(74.5%)	
Patient Compliance			
Never/almost never forgets to take medication	44(75.9%)	14(24.1%)	0.000*
Forgets medication (one/two times per month)	18(72%)	7(28%)	
Forgets medication (once a week/more than once a week / almost everyday)	8(26.7%)	22(73.3%)	

Number of exacerbation and age
From table 3, chi-square test showed that age and number of exacerbation of COPD are highly associated. Number of exacerbation significantly increased with

increase in age (p<0.05). Majority of patients of having ≤ 75 years of age reported ≤2 exacerbation (79.7%) while majority in age ≥76 years reported more that 2 exacerbation(61.2%). Alexpoulos et al showed similar

results to our study in which patients with age ≥76 years had more exacerbations compared to patients aged 61-75.[3]

Number of exacerbation and gender
The relation between number of exacerbation and gender showed that both males and females have similar association with number of exacerbation. 62% of male patients 61.2% female patients revealed ≤2 exacerbation and 38% male patients and 38.2% of female patients revealed ≥2 exacerbation. The results (table 3) showed no asssociation between number of exacerbation and male gender as riskfactor.

Number of exacerbation and smoking status
Both current smokers shows increased number of exacerbation than ex smoker and non smoker.

From table 3, majority of non smokers (72.7%) reported ≤2 exacerbation. 60% of current smoking patients showed increased number of exacerbation ie >2 than ex smokers (40%) and non smokers(27.3%). Smoking is a major factor in COPD exacerbations. This results revealed that there is a high prevalence of COPD exacerbations requiring admission to a hospital unit in those patients who continue to smoke. Most smokers admitted for exacerbation of COPD include in severe COPD group[9].Passive exposure to cigarette smoke may also contribute to increased respiratory symptoms by increasing the lung's total burden of inhaled particles and gases.

Number of exacerbation and disease severity
Table 3 shows that disease severity and number of exacerbation are highly associated. Number of exacerbation significantly increased with increase in disease severity. Severity of symptoms or risk of exacerbation were assesed using Modified medical research council questionnaire (mMRC), CAT^{TM} score and number of exacerbation. According to this the patients were classified into Group A, Group B, Group C and Group D.

From table 4, it is seen that majority of the exacerbation patients came under group D (71.7%).Group C included 21 (18.6%) patients, followed by group B (7.1%) and group A (2.7%). The results from table 3 showed that there is significant increase in number of exacerbations of COPD with increase in disease severity. All patients belongs to Group A and Group B reported ≤2 exacerbations.19% of Group C patients and 48.1% of Group D patients reported >2 exacerbations. Group D are at high risk of exacerbations.

Table 4: Frequency and percentage distribution of patients according to GOLD guidelines.

	Group a	Group b	Group c	Group d
Frequency	3	8	21	81
Percentage	2.7	7.1	18.6	71.7

Alexpoulos etal revealed that increased severity of COPD as defined by GOLD staging based on severity of airflow limitation was associated with an increased number of exacerbations. Specifically, compared to patients with GOLD stage I, those with GOLD stage III and IV are at higher risk of exacerbations. Increased disease severity has been linked with an increased frequency of exacerbation and ICU admissions.[3,7] The history of hospitalization is the most important riskfactor and its importance increases with time and with very frequent exacerbators.[4]

Number of exacerbation and duration of COPD
The results (table 3) reported that the number of exacerbation and duration of COPD diagnosis are correlated. Number of exacerbation significantly increased with increase in duration of COPD (p<0.05). Majority of patients(74.5%) with more than 10 years since diagnosis of COPD reported increased number of exacerbations of COPD (>2 exacerbations) than 5-10 years or <5 years sice COPD diagnosis.

Increased time since diagnosis of COPD increases the number of exacerbation.[3] Increase in duration of COPD is associated with increase in age of patient which negatively impact the health status and quality of life. Older patients might have fewer exacerbations that however might be more severe due to the longer duration of COPD leading to more hospitalizations.[3] The results from alexpoulos et al showed higher incidence rate ratio in both the 6-10 and ≥11 years since COPD diagnosis groups compared to those with ≤ 5 years since diagnosis.[3]

Number of exacerbation and patient compliance
From table 6 it is showed that majority of patients who forgets medication (once a week/more than once a week / almost everyday) reported >2 exacerbation (73.3%) while majoriy of patients who never/almost never forgets to take medication(75.9%) and forgets medication one/two times per month(72%) reported ≤2 exacerbations. Hence the asssociation between number of exacerbation and patient compliance are highly significant (p<0.05).

Patients who omitt their medication to have an increased frequency of both exacerbations and hospitalizations. Adherance in COPD is commonly influenced by factors such as patient age, cost of the drug, comorbidities and dosing frequency[3]

PRESCRIBING PATTERN ANALYSIS
By evaluating the prescription pattern we found that antibiotics were prescribed for all COPD exacerbation patients and multiple drug therapy is preferred (Fig 7). Majority of drugs prescribed were in concordance with GOLD guidelines.
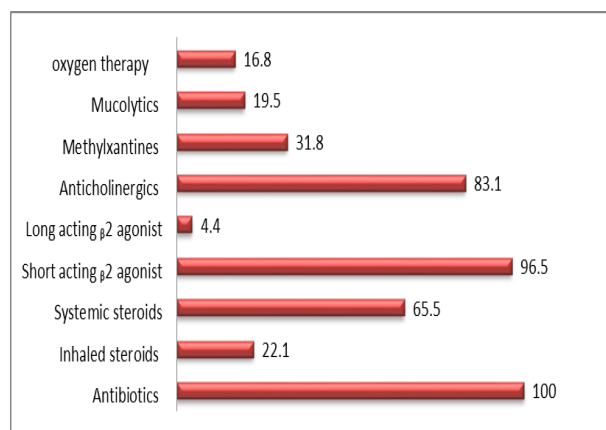
Figure 7: Distribution according to treatment options.

KAP REGARDING ANTIBIOTICS USE
The Knowledge, Attitude and Practice regarding antibiotics use were assessed among the patients before and after counseling using a structured questionnaire.In this section scores on KAP of patients were selected converted in to percentage scale,and computed mean, standard deviation, median and range before the counselling and after counselling. The effectiveness of counselling was tested for significance using Wilcoxon Signed rank test,the details are given below:
Frequency and percentage distribution of level of knowledge,attitude and practice on antibiotics use before counselling

Table 5: Frequency and percentage distribution of KAP regarding antibiotics use in patients before counseling.

Knowledge	Frequency	Percentage
POOR	51	45.1
AVERAGE	46	40.7
GOOD	16	14.2
ATTITUDE		
POOR	50	44.2
AVERAGE	57	50.4
GOOD	6	5.3
PRACTICE		
POOR	32	28.3
AVERAGE	68	60.2
GOOD	13	11.5

Knowledge assessment
From table 5, it is noted that 51 out of 113(45.1%) patients had poor knowledge, 46/113 (40.7%) had average knowledge and 16/113(14.2%) had high knowledge.Hence more than 85% of patients reported either a poor or average knowledge.

Attitude assessment
In case of attitude towards antibiotics use,out of 113 patients 50(44.2%) showed negative attitude and 57% showed moderately positive and 6 (5.3%)patients showed highly positive attitude.

Practice assessment
Considering the practices, the pre-counseling practice on antibiotic use were poor in 32 patients (28.3%) out of 113 patients and 68(60.2%) were having moderate practices and 13 patients were having better antibiotic usage practice.

Effect of patient counseling on Knowledge, Attitude and Practice (KAP) regarding antibiotics use in patients with COPD exacerbation
Patient education and counseling was provided after questionnaire session and the KAP was reassessed during follow up visit. Apart from verbal messages, a patientinformation leaflet in the local language (Malayalam) was provided to patients. The distribution of knowledge scores, attitude scores and practice scores (table 6,7 & 8) shows significant differences in the scores both before and after counseling session. It signifies that there was sufficient increase in the KAP scores after counseling.

Effectiveness of patient counselling on knowledge
The table 6, represents the effectiveness of counseling on knowledge. It is observed that before counseling, the patients reported a mean value of knowledge score 44.6 with standard deviation 11.71. The knowledge level varies from 4.35 – 73.91.

Table 6: Effectiveness of Counseling on Knowledge Regarding Antibiotic Use.

Stage	Mean	Standard deviation	Median	Range	P value
Before	44.67	11.71	43.47	4.35 – 73.91	0.000*
After	88.57	11.91	47.5	47.83 – 99.00	

*: significant at 5% level (P<0.05)

After counselling the mean knowledge towards antibiotics use significantly increased to 88.57 with standard deviation 11.91and knowledge score ranges from 47.83 – 99.00. Thus the result is significant (p<0.05). It shows that there is increase in the knowledge of the patients after the counseling session. Thus the counseling provided was effective for improving the knowledge of the patients.

Effectiveness of counselling on attitude towards antibiotics use
The table 7 represents the effectiveness of counseling on attitude of patients. The mean value of attitude score before counseling was 41.00 with standard deviation 13.50. The attitude score varies from 25 -91.67. Wilcoxon signed rank test showed that counselling has significant effect in improving atttitude towards

antibiotics use in COPD exacerbation patients(P<0.05). After the counselling the mean knowledge level significantly increased to 87.16 with standard deviation 7.4 and score ranges from 75.00-93.9. It shows that there is increase in the attitude score of the patients after counseling session.Thus the counseling provided was effective in improving the attitude of patients with COPD exacerbation.

Table 7: Effectiveness of counseling on attitu*de.*

Stage	Mean	Standard deviation	Median	Range	P value
Before	41.00	13.50	41.66	25-91.67	0.000*
After	87.16	7.04	91.66	75.00 – 93.9	

*: significant at 5% level (P<0.05)

Effectiveness of counselling on practice towards antibiotic use
Table 8: Effectiveness of counseling on practice.

Stage	Mean	Standard deviation	Median	Range	P value
Before	46.81	11.91	47.5	20.0-72.50	0.000*
After	88.20	8.10	90.0	67.50 – 91.2	

*: significant at 5% level (P<0.05)

The table 8 represents the effectiveness of counseling on attitude of patients. The mean value of attitude score before counseling was 46.81 with standard deviation 11.91. The attitude score varies from 20.0-72.50. Wilkoxon signed rank test showed that counselling has significant effect in improving practice towards antibiotics use in COPD exacerbation patients(P<0.05).After the counselling the mean practice scores significantly increased to 88.20 with standard deviation 8.10 and score ranges from 67.50 – 91.2. It shows that there is increase in the practice score of the patients after counseling session.Thus the counseling provided was effective in improving the practice of patients with COPD exacerbation.
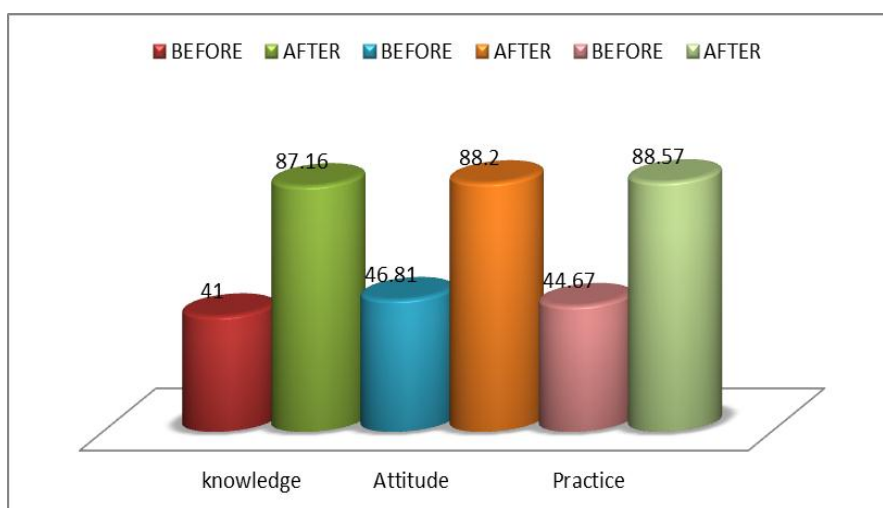

Fig. 8: Distribution of knowledge, attitude and practice scores.

CONCLUSION
The present study was conducted to assess the risk factors, prescribing patterns and effect of patient counselling on antibiotic use in COPD exacerbation patients. The risk factors that contributed to the exacerbation of COPD was found to be age, gender, smoking, duration, disease severity, comorbidities and compliance with the treatment. From this study we identified a positive correlation between risk factors and number of exacerbations in COPD. On evaluating the prescribing patterns, antibiotics were frequently prescribed drugs among exacerbation patients and multiple therapy was preferred. The baseline KAP result suggested that patient had a poor perception of their disease. Patient counselling improved the KAP of the patient and they were able to answer the same questions that were posed during baseline. The result showed a significant improvement after counselling. For patients with COPD, health education focusing on disease and need for long term treatment provided by the clinical pharmacist plays an important role in improving the ability to cope up with illness and health status. Pharmacists are the ones that are in an ideal position to provide patient education and patient care optimization.

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