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Research Article
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ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE FOR PATIENT WITH COPD, USING ST.GEORGE QUESTIONNAIRE: EVALUATE EFFICACY AND SAFETY OF TWO ANTICHOLINERGIC DRUGS IN TERRITORY CARE HOSPITAL

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ABSTRACT

BACK GROUND AIM: *Chronic obstructive pulmonary disease is a world 4th largest cause of death in the current years. But as par the latest news from WHO. COPD will come the world 3rd largest cause of death. This study was revealed that assessment of the health related quality of life patients with COPD also we evaluate the efficacy& safety of the tiotropium and ipratropium in COPD.* ***METHODOLOGY:*** *A prospective observational study which conducted in CRM hospital tirur total 205 patients are enrolled for assessment of health quality measures which used by st George questionnaire out this we had taken 120 patients for comparative study and we had take 60 patients for each group and duration of study was 3 months and we collected the details 3 times and also we used the spirometric evaluation and note important outcomes like FVC and FEV1 & PEF etc and the* ***RESULTS AND DISCUSSION****: Results has show that the quality of life has improved all patients in each visit and also tiotropium has shown significant improvement in all outcomes in the case FVC (20.5) and FEV1(41.1) also PEF(39.5) . Present study has shown a positive impact on patient education and proper inhalation usage in terms of their HRQL improvement.* ***CONCLUSION:*** *as a pharmacist we have to play a vital role in Smoking cessation and proper utilization of inhalers*

KEY WORDS

Chronic Obstructive Pulmonary Disease (COPD), Forced Vital Capacity (FVC), Forced Expiratory Volume in one second (FEV), Peak Expiratory Flow rate (PEF)

INTRODUCTION

The measurements of health related quality of life in chronic obstructive pulmonary disease (COPD), are nowadays frequently used as descriptive instruments or as outcome measures[4]. Since cure is still impossible for most COPD patients, a major goal of care is to improve HRQL. However, limited attempts have been made to identify the factors that are related to the different aspects of HRQL in COPD. Such analyses may also shed light on the properties of the questionnaires that are studied and also show their internal relations. Concerning the disease-specific [1]St George's Respiratory Questionnaire (SGRQ), exercise tolerance, dyspnoea, anxiety, wheezing, body composition, have all been reported as significantly related. The correlation to forced expiratory volume in one second (FEV_1) is somewhat stronger than to the SIP. Moreover, oxygen tension in arterial blood ($P_{a,O2}$) has been found to be significantly related to total SGRQ in patients with hypoxemia. This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it

affects your life. We are using it to find out which aspects of your illness cause you the most problem. It is designed for supervised self-administration. This means that the patients should complete the questionnaire themselves, but someone should be available to give advice if required. The chronic obstructive airway diseases are a group of lung diseases that share the common pathophysiologic property of chronic persistent airflow obstruction. These diseases include chronic bronchitis, emphysema, bronchiectasis, cystic fibrosis, bronchiolitis obliterans, and asthma. By virtue of common usage, however, chronic obstructive pulmonary disease (COPD) has come to refer specifically to chronic bronchitis and emphysema.

Primary therapy for COPD is directed at reducing airways resistance. To the extent that bronchial smooth muscle constriction and airway inflammation and mucous plugging contribute to airflow obstruction, bronchodilators (along with smoking cessation) can improve lung function. By comparison, there is currently no effective therapy for the irreversible airflow obstruction that results from airway obliteration, peribronchial and peribronchiolar fibrosis, and loss of elastic recoil. Both [1.]anticholinergic agents and beta adrenergic agonists are effective in reversing the reversible part of airway obstruction. However, inhaled ipratropium bromide is preferred over beta-2 agonists by many as the bronchodilator of choice in COPD for the following reasons:

- Its minimal cardiac stimulatory effects compared to those of beta agonists
- Its greater effectiveness than either beta agonist or methylxanthine bronchodilators in most studies of patients with COPD

As a manifestation of the importance of [3]Anticholinergic medications in the treatment of COPD, ipratropium bromide was the only bronchodilator studied in the landmark Lung Health Study]. In addition, combination therapy with both beta-agonist and anticholinergic bronchodilators may be helpful in some patients. [3]Tiotropium is used to prevent wheezing, shortness of breath, coughing, and chest tightness in patients with chronic obstructive pulmonary disease (COPD, a group of diseases that affect the lungs and airways) such as chronic bronchitis (swelling of the air passages that lead to the lungs) and emphysema (damage to air sacs in the lungs).Also ipratropium play a Maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema, used alone or in combination with other bronchodilators (inhalation); symptomatic relief of rhinorrhea associated with allergic and nonallergic rhinitis and symptomatic relief of rhinorrhea associated with the common cold (intranasal).

MATERIALS AND METHOD

Primary objective

- To evaluate the efficacy of the Tiotropium and Ipratropium in COPD patients
- To investigate the Tiotropium and Ipratropium effect on COPD patients quality of life (QOL)
- Improvement of Quality of Life in Rehabilitation in COPD patients
- Asses the severity of the diseases

Secondary objectives

- To measure the quality of life in COPD patients
- Providing nutritional advise and possibly send them to a nutrition
- Ensuring COPD patients know what to do quickly when exacerbations occur
- Discussing with people how to recognize exacerbations early
- Ensuring COPD patients know how to use their inhalers correctly and care for them properly

Study site:

This study was conducted in outpatient department of CRM Hospital, Tirur, kerala. CRM Hospital is a territory care hospital in tirur having only specialized for chest diseases

Study design:

A prospective observational study was conducted to describe the st George questionnaire in COPD

Source of data and Materials:

1. Patient consent form.
2. Patient data collection form.
3. Prescriptions of patients.

4. Patient case sheet/medication chart.
5. COPD 6 (pulmano graph)

Study design:

A comparative study was conducted to describe the st George questionnaire in COPD. Study populations for health related quality of life consist of 205 COPD patients. Out of this 205 patients I had taken 120 patients are incorporated with drug comparisons 60 patients are taken ipratropium bromide and 60 patients are taken tiotropium bromide

Study Criteria:

- Patients with possible symptoms COPD
- Age between 40 and above to 70 years
- Patients can perform COPD 6
- FEV, < 65% predicted
- Smoking history of 10 pack- years

Exclusion Criteria:

- Possible symptoms with Asthma patients
- Seriously ill patient (very severe with acute exacerbations)
- Patient with coexisting illness (ishemic heart disease)
- Patients are regularly using domiciliary oxygen therapy

RESULTS

The present study was carried out in- patients department of CRM hospital tirur, malapuram dist, Kerala we are enrolled 205 patients for health related quality of life assessment and out of this I had taken 120 patients for drug comparison The present study shows 37(28.5%) belongs to the age of 40-50 years and 70(35) from 51-60 years and 93(46.5%) are coming under the age of 61-70 years also study was large number of patients are coming under the age group of 61-70 ages.

TABLE 1: SMOKING HABITS OF THE PATIENTS

Smoking habit	Cases	
	No patients	%
Non smokers	48	23.5
Former smokers	20	19.
Current smoker		
a) One pack / day	60	29
b) More than 1 pack / day	77	37.5
Total	205	100

TABLE-2 QUALITY OF LIFE IMPROVEMENT

Visit	Quality of life score as per St. George Questionnaire		
	Range	Mean	SD
1st visit	4 - 6	4.91	0.47
2nd visit	0 - 6	2.87	1.22
3rd visit	0 - 5	1.68	1.25
Improvement (Decrease in score from 1st visit to 3rd visit)	-1 to +6	3.23	1.23

TABLE 3: ACTION OF ANTICHOLINERGIC IN COPD SYMPTOMS

Symptoms	No.of cases present in Tiotropium group					Ipratropium group				
	1st Visit	2nd Visit	3rd Visit	Decrease	% of dec	1st Visit	2nd Visit	3rd Visit	Decrease	% of dec
Cough	51	31	11	40	78.4	46	34	23	23	50
Mucoid Sputum	48	23	9	39	81.3	43	18	16	27	62.8
Dyspnoea	25	11	3	22	88	16	12	11	5	31.3
Wheezing	25	11	3	22	88	18	11	10	8	44.4

TABLE 4-OUT COME RELIEFE OF FVC VALUES IN THE TWO ANTICOCHOLINERGIC DRUGS

Visit	FVC values in				't'	'p'
	Tiotropium group		Ipratropium group			
	Mean	SD	Mean	SD		
1st Visit	27.5	10.0	36.1	10.0	4.4074	0.0001 Significant
2nd Visit	42.5	9.2	36.1	10.0	3.6475	0.0004 Significant
3rd Visit	61.0	15.7	48.1	11.6	0.0549	0.0013 Significant
Increase	20.5	16.6	12.0	14.8	2.953	0.0038 Significant

TABLE-5 OUT COME RELIEFE OF FEV1 VALUES TWO ANTICOCHOLINERGIC DRUGS

Visit	FEV1 values in				't'	'p'
	Tiotropium group		Ipratropium group			
	Mean	SD	Mean	SD		
1st Visit	20.5	5.9	39.1	5.4	17.8396	0.0001 Significant
2nd Visit	42.9	5.0	39.9	5.3	3.1576	0.002 Significant
3rd Visit	61.6	7.6	46.5	8.7	10.1115	0.0001 Significant
Increase	41.1	8.7	7.5	9.1	20.6964	0.0001 Significant

DISCUSSION

The present study was large number of patients are coming under the age group of 61-70 ages because increasing the age copd become more worse Which currently show that the disease prevalence's was higher being in the side smoking habits peoples as compared to non smokers prevalence of COPD was very high in males as compared with female might be because of smoking habits similarly office of national statistics 2008 has done a survey also show that smoking habits is very high in male side . This study population has shows that a statistically significant difference was observed between patient with moderate and mild type copd and those suffering from severe and very severe has improved their quality of life from first visit to third visit because of either drug treatments or quality of life which shows in large number of severe and very severe copd patients has changed their severity to mild and moderate P.J. Wijkstra et al 1993 has found that pulmorehabilation and drug therapy has shown significant improvement their quality life in short

intervals. Also from this study Which clearly show that a significant improvement in the tiotropium group as compared to ipratropium group Which shows the improvement 3.87 also the similar study has conducted mr. Antonello Nicolini 2011 has explained that Addition of tiotropium to chronic administration of a beta adrenergic drug such as salmeterol can effect an increase in pulmonary function parameters and in exercise capacity suggesting that association of the two drugs can be more efficient for treatment of disease and improvement of daily living activities than beta-adrenergics.

Also from the collected data we got an given idea about the symptom relief of two drugs here we mainly take four symptoms which is there in most of the copd patients like cough , mucoid sputum, dyspnoea ,wheezing and the marked decrease has observe from tiotropium group has shown the significant reduction in all symptoms as compare with ipratropium and the similar results as shown another study which conducted mr. David A lipson et al 2006 tiotropium has improve exercise tolerance, dynamic hyperinflation, and breathlessness. Also These medications improve quality of life measures and decrease the risk of exacerbation. Also they have the added advantage of once-daily dosing and more specific cholinergic receptor targets.

Also from study show that significant improvement also quite high in tiotropium side in the same conclusion has show in nord J.A et al 2000 has mention that Trough, peak, and mean FEV1 response and trough and mean FVC response showed greater improvement with tiotropium than with ipratropium.

This study has shows that a significant improvement in FEV1 in tiotropium a compared with ipratropium in follow up visit tiotropium has shown in significant improvement 42(sd5.0) in second visit and 61(sd7.6) in third visit but in the case ipratropium has shown also improvement but compare tiotropium it was less . the similar result get it from mr.kenji koshmura et all 2012 study which shows Forced expiratory volume in 1 second and forced vital capacity were significantly larger in the tiotropium treatment group.

CONCLUSION

This study has shown that the st George COPD questionnaire easy to understand. It gives information on the different aspects of health related quality of life that is described to COPD.

The health related quality of life having improvement in all aspects and it will improve in initial visit to follow up visit. That clearly shows that the patient education and proper medication usage play a vital role in COPD patients.

In case of drug comparison between the tiotropium and ipratropium, which show that there is statistically a significant improvement has shown tiotropium as compared with ipratropium.

These study has support the statements of the latest gold guidelines (2011)which recommend the use of tiotropium as first line therapy for the long term maintenance treatment of patient with airflow obstruction due to COPD.

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PATIENT DATA COLLECTION FORM

Assessment of health related quality of life for patient with COPD, Using St. George questionnaire: evaluate efficacy and safety of two anti cholinergic drugs in territory care hospital

SL.NO:

Drugs – Tiotropium bromide ☐ Ipratropium bromide ☐

DEMOGRAPHIC DETAILS:

Name: Gender: M F ☐ ☐ Age: yrs

Height: cm Weight: Kg

Address of the patient:

_____

_____

Contact No:

EDUCATIONAL QUALIFICATION:

Illiterate ☐ Primary school ☐ High school ☐ Pre-university ☐ Degree ☐ Others ☐

OCCUPATION

Business ☐ Employed ☐ Farmer ☐ House wife ☐ Retired ☐ Others ☐

Possible risk factors;

Are you a smoker? Yes ☐ No ☐

If yes, how frequently will you smoke?

Occasional ☐ one pack per day ☐

formar ☐ more than one pack day ☐

Are you an alcoholic? Yes ☐ No ☐

SYMPTOMS;

SEVERITY

		1ST VISIT	2ND VISIT	3RD VISIT
MILD	FVC			
	FEV1			
	FVC1/FVC			
	PEF			
MODERATE	FVC			
	FEV1			
	FVC1/FVC			
	PEF			
SEVERE	FVC			
	FEV1			
	FVC1/FVC			
	PEF			
VERY SEVERE	FVC			
	FEV1			
	FVC1/FVC			
	PEF			

TREATEMENT

NAME OF THE DRUG	DOSE	

1-Over the last year, I have had attacks of wheezing :

1- Most days a week
2- Several days a week
3- A few days a week
4- Only with chest infections
5- Not at all

2- During the last year, how many severe unpleasant attacks of chest trouble have you had :

1- More than 3 attacks
2- 3 attacks
3- 2 attacks
4- 1 attack
5- No attack

3-During the last year, how many time you had short of breath at rest

1- Most days a week
2- Several days a week
3- A few days a week
4- Only with chest infections
5- Not at all

4-During the last year, how many time you had short of breath doing physical activity

1- Most days a week
2- Several days a week
3- A few days a week
4- Only with chest infections
5- Not at all

5-During the last year, how many time you concern about getting a cold or your Breathing getting worse

1- Most days a week
2- Several days a week
3- A few days a week
4- Only with chest infections
5- Not at all

6-During the last year, how many times you have depressed because of your breathing problem

1- Most days a week
2- Several days a week
3- A few days a week
4- Only with chest infections

5- Not at all

7-During the last year, how many time you have cough ☐

1- Most time of a day
2- Several time of a day
3- A few times a day
4- Only with chest infections
5- Not at all

8-During the last year, how many time you produce phlegm ☐

1- Most time of a day
2- Several time of a day
3- A few times a day
4- Only with chest infections
5- Not at all

9- Over the last year, your breathing problem how stop your strenuous physical activities (Climbing stairs, hurrying, doing sports) ☐

1- Never
2- Few times
3- Several Times
4- A great many times
5- All most all the time

10- Over the last year, your breathing problem how stop your moderate physical activities (Walking, House work) ☐

1- Never
2- Few times
3- Several Times
4- A great many times
5- All most all the time

11- Over the last year, your breathing problem how stop your daily activities (Dressing, washing) ☐

1- Never
2- Few times
3- Several Times
4- A great many times
5- All most all the time

12- Over the last year, your breathing problem how stop your social activities (Talking, being with children) ☐

1- Never
2- Few times

3- Several Times
4- A great many times
5- All most all the time

13- How long did the worst attack of chest trouble last? ☐

1- A week or more
2- 3 or more days
3- 1 or 2 days
4- Less than a day

14- Over the last year, in an average week, how many good days (with little chest trouble) have you had : ☐

1- No good days
2- 1 or 2 good days
3- 3 or 4 good days
4- Nearly every day is good
5- Every day is good

15- How would you describe your chest condition : ☐

1- The most important problem I have.
2- Causes me quite a lot of problems.
3- Causes me quite a few problems.
4- Causes me no problem.

16- If you have ever had paid employment, please choose one of these answers: ☐

1- My chest trouble made me stop work.
2- My chest trouble interferes with my work or made me change my work.
3- My chest trouble interferes with regular intervell
4- My chest trouble does not affect my work

If No, what is the reason?

Complex dosing regimen ☐ Confusion ☐ Forgetfulness ☐ Visual impairments ☐

Impaired dexterity ☐ Illiteracy ☐ Poverty ☐

How many times you skip dose Yes ☐ No ☐

ADVERSE DRUG REACTIONS

TIOTROPIUM	Y/N	IPRATROPIUM	Y/N
Dry mouth		Swelling of your face,lips	
glucoma		bronchospasm	
Urinary difficulty		Stuffy nose	
Respiratory tract infection		Burning at time urination	
Chest pain		hypotension	
Others		Others	

PATIENT WRITEN INFORMED CONSENT

I understand that my participation in voluntary and that I may withdraw from this study at any time without giving any reason or to answer any particular questions in the study .I consent the member of the study to have access to my response and public the result provided my identified is not revealed. I voluntary agree to participate in the study

Name and signature of the patient:

Name and Signature of the Student: Signature of the Guide:

Date:

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