

IMPACT OF INTEGRATED DISEASE AND DRUG THERAPY MANAGEMENT (IDDM) PROGRAM IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE PATIENTS

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ABSTRACT

There was a scarcity about evidence on effect of Integrated Disease and Drug Therapy Management (IDDM) program in chronic diseases India. The study aims to assess the Impact of IDDM program in Chronic Obstructive Pulmonary Disease (COPD) patients. This was an interventional study conducted in a secondary care referral hospital located in Anantapur district, Andhra Pradesh, India. The study was approved by institutional review board and registered in clinical trial registry of India. A suitable data collection form was used to collect information about socio-demographics, medical history, medication history, present medical condition, present medication and lung function tests FEV₁, FVC, FEV₁/FVC. Quality of Life of patients was measured by using Clinical COPD Questionnaire. Student 't' (paired) test was used to determine significance of difference between clinical outcomes of baseline and follow up parameters of the study subjects. A

total of 72 patients were participated in the study with all age groups. The study results showed that there is a significant impact of IDDM program in the patients in terms of positive outcomes of therapy and improved Quality of Life. IDDM Program is a new approach to improve patient care and health related quality of life. This program can also be implemented in other chronic diseases like Hypertension, Diabetes, and etc. for better outcomes in the patients.

1. INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a common lung disease which can be prevented and treated. COPD patients may have obstructive bronchiolitis, emphysema, or both conditions. The extent of any of the above conditions changes from person to person. Cigarette smoking is the main cause of COPD. The trend of increasing COPD mortality reflects the smoking period and complications associated with COPD. The mortality and morbidity of COPD is significant. IDDM is a program which brings together inputs, services related to diagnosis, therapy, pharmaceutical care and promotion of health. It includes all health care professionals like doctors, nurses and clinical pharmacist. For the health care provider treating the COPD patient, clinical integration is essential. In this setting, clinical integration is very broad in scope; it begins with knowing the symptoms and disability from the respiratory disease. This program consists of interventions pointing at smoking cessation, promoting regular exercise in activity, optimizing pharmacotherapy by following updated GOLD guidelines and guidelines from American Thoracic Society and medication therapy management services. It contains a broad range of health care activities like Performing and obtaining necessary diagnosis of the patients health status, Formulating a medication treatment plan, Selecting, initiating and modifying medication therapy, Therapeutic drug monitoring, safety and effectiveness and performs a comprehensive medication review for identifying, resolving and preventing drug-related problems including ADE. The treatment options for COPD are categorised according to the stages of disease severity. For Stage 1 (mild) $FEV_1/FVC < 0.70$, $FEV_1 \geq 80\%$ than predicted, Smoking cessation is the only intervention proven to decrease the decline in FEV_1 associated with COPD in mild stage. Short acting β_2 agonists like albuterol (Salbutamol) along short acting anti-cholinergic like ipratropium are prescribed in stage 1 COPD. Long acting β_2 agonists like salmeterol, formoterol along with long acting anti-cholinergic drugs like tiotropium bromide are prescribed in stage 2 (moderate) COPD in which $FEV_1/FVC < 0.70$, $50\% \leq FEV_1 < 80\%$ than predicted. For stage 3 (severe): $FEV_1/FVC < 0.70$, $30\% \leq FEV_1 < 50\%$ than predicted Systemic corticosteroids like prednisone along with broad spectrum antibiotics like amoxicillin, trimethoprim-sulfamethoxazole, doxycycline, quinolone antibiotics or second or third generation cephalosporin's, ciprofloxacin, levofloxacin are given as the treatment and for stage 4 (very severe), $FEV_1/FVC < 0.70$, $FEV_1 < 30\%$ than predicted, the treatment option will be inhaled corticosteroid like fluticasone, budesonide along with formoterol or salmeterol is indicated for the treatment of stage 4 COPD. Continuous oxygen therapy is also given if patient's SPO_2 falls below 70%.

2. MATERIALS AND METHODS

2.1. Study site

The study was conducted in a pulmonology department of a secondary care referral hospital located in resource limited settings of Anantapur District, Andhra Pradesh, India.

2.2. Study design

This is an interventional study design conducted to evaluate the outcomes of IDDM Program in COPD Patients.

2.3. Study criteria

Patients irrespective of age and gender were eligible to participate in the study on the basis of previous diagnosis of COPD, with post-bronchodilator $FEV_1 < 80\%$ and $FEV_1/FVC < 0.7\%$. Patients who are suffering from respiratory disorders which involved in narrowing of airways other than COPD and patients with terminal illness immobility and atopy were excluded in the study.

2.4. Study duration and Sample size

The study was carried out for a period of six months from May to October 2019 with a sample size of 72.

2.5. Ethical considerations

The protocol, data collection form, informed consent procedure was approved by the Institutional Review Board (IRB) before enrolment of the first participant in to the study. Confidentiality and anonymity of the data of participants was maintained through entire study. The study was explained to every patient and taken consent through informed consent form.

2.6. Study procedure

The demographic details of the patients along with history of present illness, past medical history and social history were taken from the patients, then all laboratory parameters (lung function tests) used for the diagnosis of COPD were collected which are taken as baseline parameters. On basis of laboratory reports we suggested physician to develop therapy regimen for the individual patients by following updated GOLD guidelines and guidelines from American Thoracic Society. Then IDDM Program was implemented in the recruited study population. At the time of dispensing medication the patient counselling had given

regarding the administration of drugs, directions regarding usage of inhalers, maintenance of medication adherence mainly for antibiotics and smoking cessation program through various methods like chewing of nicotine gums and the patients were educated regarding the harmful effects of smoking etc. Patients were asked to fill CCQ questionnaire to assess the Quality Of Life before implementing IDDM Program which is considered as baseline parameter. At the time of follow up, the laboratory reports and CCQ questionnaire are taken for second time which are considered as follow up parameters. Then both baseline and follow up parameters are compared by using statistical analysis and the results were calculated.

2.7.Data collection

A separate data collection form was prepared which contains patient details like name, age, gender, weight, height, past medical history, past medication history, history of present illness, diagnosis and laboratory reports of the subjects like FEV₁, FEV₁/FVC ratio and DLCO and quality of life score measured by using CCQ for outcome measurement.

2.8.Statistical Analysis

Student 't' (paired) test was used to determine significance of difference between clinical outcomes of baseline and follow up parameters of the study subjects.

3. RESULTS

Table 1: Demographic distribution of study population (n=72).

Age (years)		0-20	21-40	41-60	>60
Gender	Male	1	13	12	21
	Female	0	7	12	6

A total number of 72 patients were enrolled out of which 47 were males and 25 were females.

Table 2: Distribution of study population according to smoking habits.

Smokers	Non-smokers
32	40

Out of 72 subjects 32 are smokers and remaining 40 are non-smokers. Among the 32 smokers almost all of them were males.

Table 3: Therapeutic classification of drugs prescribed to the subjects.

Class of drugs	Number of patients receiving the drugs
Short acting beta 2 agonists	33
Long acting beta 2 agonists	40
Short acting Anticholinergic drugs	32
Long acting Anticholinergic drugs	38
Antibiotics	34
Inhaled corticosteroids	26
Theophylline	32

Treatment given to the study population during the study period

Table 4: Comparison of spirometry tests, baseline and follow up of subjects.

Parameter	Baseline	Follow up	p value
FEV ₁	0.9699±0.2390	1.4158±0.3244	0.0001*
FEV ₁ /FVC	0.6198±0.0783	0.7014±0.0655	0.0001*
DLCO	14.1211±4.3878	17.140±11.9459	0.046*
QOL	35.222±5.3028	28.9583±13.366	0.003*

*Significant at P<0.05

The mean FEV₁ for subjects at baseline is 0.9699±0.2390 and at follow up is 1.4158±0.3244 with a significant p value of 0.0001. The mean FEV₁/FVC for subjects at baseline is 0.6198±0.0783 and at follow up is 0.7014±0.0655 with a significant p value of 0.0001. The mean DLCO for subjects at baseline is 14.1211±4.3878 and at follow up is 17.140±11.9459 with a significant p value of 0.046. The mean CCQ score for measuring QOL for subjects at baseline is 35.222±5.3028 and at the follow up is 28.9583±13.366 with a significant p value of 0.003.

The results also showed that there is a significant difference between clinical outcomes at the baseline and follow up. There is a significant difference of mean CCQ score between the baseline and follow up of the subjects.

4. DISCUSSION

The present study demonstrates the effectiveness of Integrated Disease and Drug therapy Management Program in COPD patients to prevent rehospitalisation and to improve quality of life. Furthermore we demonstrated a reduction in number of hospital days when applying this IDDM Program. This is of utmost importance, as hospitalizations and number of hospital days contribute to the highest burden and costs in patients with COPD. Recent guidelines and evidence suggest that patients with frequent exacerbations may benefit from use of long acting anti cholinergic drugs in COPD. Addition of long acting anti cholinergic

drugs to inhaled corticosteroids and long acting beta 2 agonists therapy has been shown to reduce exacerbations and improve quality of life in patients. In our study, we also suggested this therapy regimen to the physician which showed positive outcomes. A study by V V Jain et al. shows improvement of mean values of FEV1 from 1.78 ± 0.80 pre-CLDP to 1.82 ± 0.77 post-CLDP. In our study showed the improvement of mean values FEV1 from 0.9699 ± 0.2390 to 1.4158 ± 0.3244 at base line and follow up respectively. The mean difference of 0.4 for CCQ was found in between intervention and usual care groups in study by Annemarije L Kruis, whereas in our study the means of total CCQ score at base line and follow up was found to be 35.222 and 28.968 respectively. The limitations of the study was, impact of this program on reducing the number of hospitalizations and functional exercise capacity were not analysed. Further continuing the study is useful in analysing this impact. It also includes possible bias from poor reporting of data and lack of publication of supporting evidence articles.

5. CONCLUSION

Integrated Disease and Drug therapy Management Program is a new approach to improve patient care and health related QOL. IDDM program implemented in our study showed positive outcomes in terms of improving patient health outcomes and health related quality of life. Similar type of studies can be done in case of chronic disease conditions to improve patient care.

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7. CONFLICT OF INTEREST

NIL.

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