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(RESEARCH ARTICLE)

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A comparative study on safety profile and efficacy of salmeterol and tiotropium in COPD Patients

Kenchugundu Jagadeesh *, Rayachooti Vandana, Bhyalla Akshay Varun, Dr. Gadwala Vinod and Bariki Rajasekhar

Department of Pharmacy Practice, St. Johns college of Pharmaceutical Sciences, Yemmiganur, Kurnool, Andhra Pradesh, India.

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Abstract

Aim and Objectives: The aim of the study is assess the safety profile and efficacy of salmeterol and Tiotropium in patients with COPD. The objective is to compare to evaluate the safety profile and efficacy of salmeterol and Tiotropium in patients with COPD.

Methodology: This was a prospective observational study conducted at secondary care hospital in India. In our study, we have included a total of 50 patients who are divided in to two groups based on their treatment and follow-ups was done for 12 weeks.

Results: Patients were divided into 2 equal groups to receive salmeterol and Tiotropium (25 subjects each). The mean FEV1 level at baseline was 63.72±3.0210 for Tiotropium group and 64.96±1.645 for Salmeterol group and the mean FEV1 level after 12 weeks of treatment was 72.12±1.423 for Tiotropium group and 70.68±1.973 for Salmeterol group. Tiotropium treatment were associated with significant decrease in FEV1 level from baseline to 12 weeks. (P*<0.05).

Conclusion: In our study, by performing the study, we concluded that tiotropium used once daily, produced superior bronchodilation and reduced dyspnea in patients with COPD when compared with salmeterol. Patients treated with tiotropium also indicated more improvement in their symptoms than those who treated with salmeterol. Because of these advantages, tiotropium should be considered first-line treatment in patients with COPD. While performing the safety parameters for a drug, side effects of tiotropium are less when compared to salmeterol.

Keywords: COPD; FEV1; Salmeterol; Tiotropium

1. Introduction

Chronic obstructive pulmonary disease (COPD) is a respiratory disease that causes progressive symptoms of breathlessness, cough and mucus build-up. It is the fourth or fifth most common cause of death worldwide and is associated with significant healthcare costs [1]. The uniformly identifiable feature is progressive airflow Obstruction, which is not fully reversible to inhaled or oral Pharmacotherapy. Guidelines developed by the global Initiative for chronic obstructive lung disease (GOLD) have Suggested an 'at risk' category, where patients have Typical symptoms of COPD but exhibit normal spirometry [2]. The disease encompasses multiple structural and functional components of which inflammation is at the core of the disease, affecting the lungs and other organs. Consequently, current treatment strategies are aimed at treating both the symptoms and the pulmonary inflammation underlying the complex pathophysiology of COPD. Smoking cessation is the only intervention currently shown to slow disease progression in

* Corresponding author: K. Jagadeesh

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COPD and decrease all-cause mortality, aside from lung transplant, lung-volume reduction surgery and oxygen therapy in selective patients. However, this intervention is difficult to achieve and sustain because of the addictive and chronic relapsing nature of cigarette smoking [3].

Management of chronic obstructive pulmonary disease (COPD) commonly involves a combination of long-acting bronchodilators including beta2-agonists (LABA) and muscarinic antagonists (LAMA). LABA and LAMA bronchodilators are now available in single-combination inhalers [4]. Additional SAMA on LABA could be a choice of treatment in a certain situation such as the on-demand use in COPD patients with exertional dyspnea [5].

2. Materials and Methods

- **Study Site:** The study is conducted in Devi Nursing Home Hospital, Adoni.
- **Duration of Study:** The study is conducted for a period of 6 months.
- **Study Design:** Prospective observational study.
- **Sample Size:** 50 patients.
- **Source of Data:** Patient data collection form, Interview with patient and their representative (attender or relatives), Patient investigation reports.
- **Study Criteria:** The patients will be selected based on following inclusion and exclusion criteria.

2.1. Inclusion criteria

- The patients who are diagnosed with COPD.
- Patients of either sex. Age between (20 to >60).
- Patients who are willing to give voluntary consent in order to participate in the study.
- Patients prescribed with either Salmeterol or Tiotropium

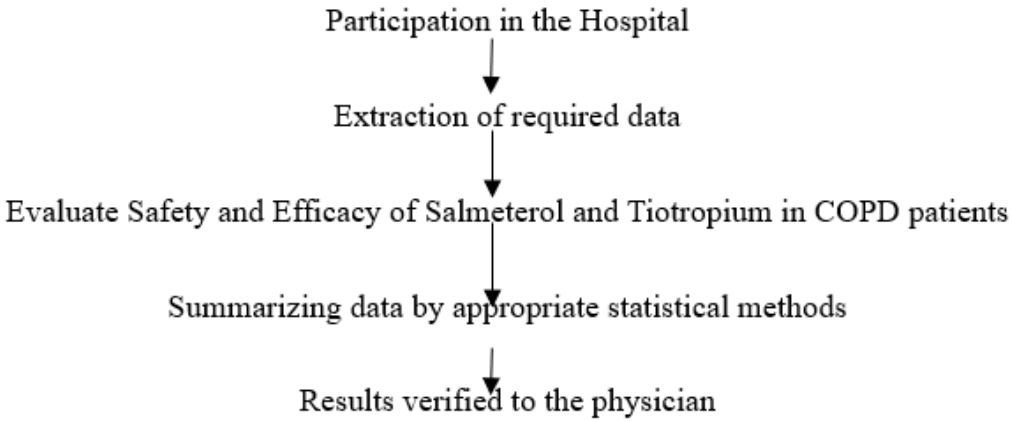
2.2. Exclusion criteria

- Patients other than COPD were excluded.
- Specialized population like pediatrics and pregnancy women were excluded.

2.3. Statistical method

Statistical test named Mean and Standard deviation is used to obtain results in the study.

2.3.1. Plan Of Study



3. Results

3.1. Age and gender wise distribution

Figure 1 It shows age wise distribution in which the patients are grouped based on their age. In the study, maximum number of subjects included in age group (20-30) i.e., 6% of total, 31-40 i.e., 20% of total ,41-50 i.e., 34% of total ,51-60 i.e., 26% of total, >60 i.e., 14% of total.

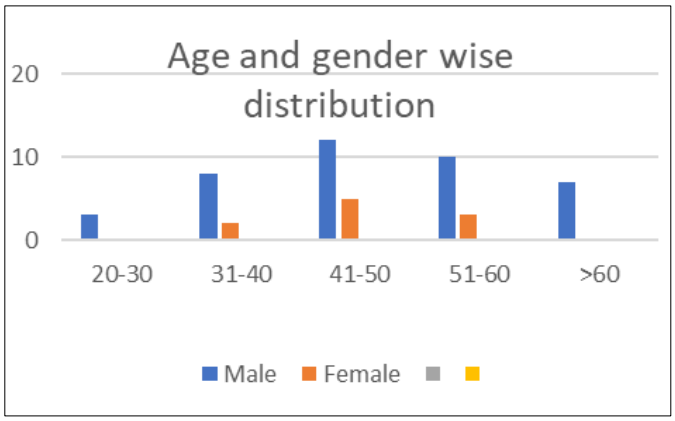


Figure 1 Age and gender wise distribution

3.2. Distribution of Patients Based on Age and Treatment Group:

Figure 2 According to distribution of pt.'s based on Age & treatment gap where Group-A (tiotropium), Group-B (Salmeterol), where 20-30 i.e., 3 men in total, 31-40 i.e., 10 men in total, 41-50 i.e., 17 men in total, 51-60 i.e., 13 men in total, above 60 i.e., 7 members in total.

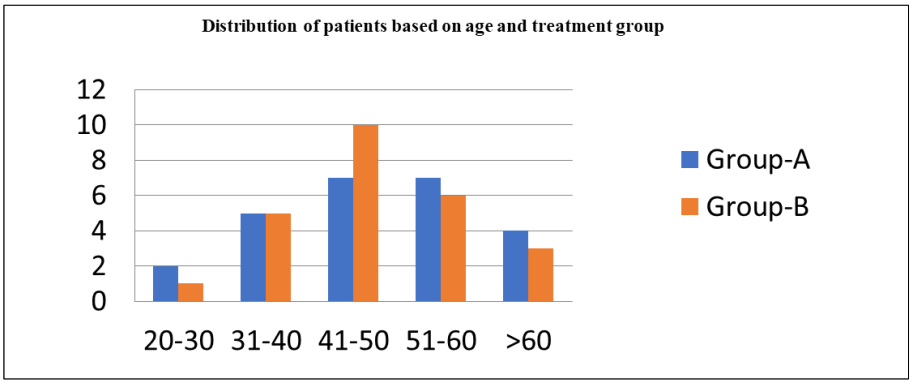


Figure 2 Distribution of Patients Based on Age and Treatment Group

3.3. Patients Distribution According to the baseline FEV1

Figure 3 It shows patients distribution according to the baseline FEV1 levels in which patients are grouped on their baseline FEV1 levels. Then the mean baseline (0 weeks) FEV1 values for Tiotropium 63.72±3.0210 and for Salmeterol 64.96±1.645.

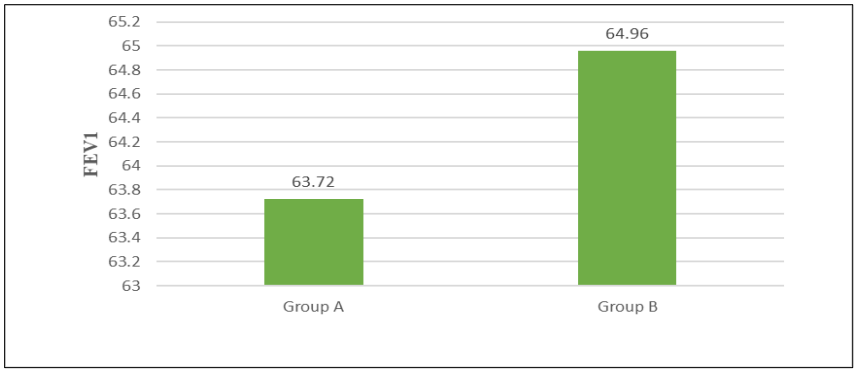


Figure 3 Patients' distribution according to the baseline FEV1

3.4. Patient distribution after the treatment

Figure 4 It shows patients distribution according to the baseline FEV1 levels after the 12 weeks of treatment in which patients are grouped on their 12 weeks of treatment. Then the mean baseline (12 weeks) FEV1 values for Tiotropium 72.12±1.423 and for Salmeterol 70.68±1.973.

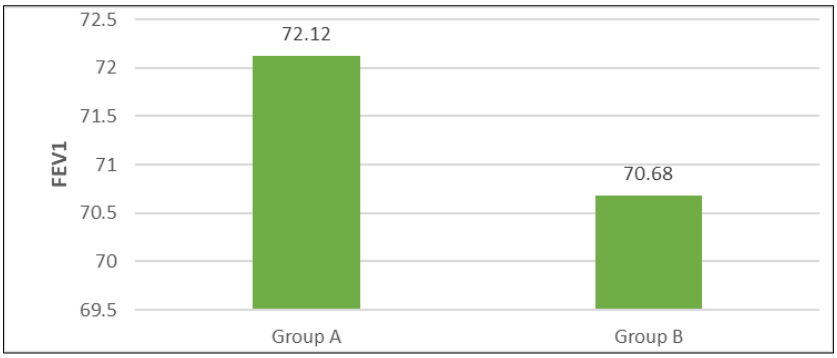


Figure 4 Patient distribution after the treatment

3.5. Risk factors causing COPD

Figure 5 It shows the risk factors causing in COPD, where smokers and alcoholic are equally observed i.e., 20 members in each parameter (40%).

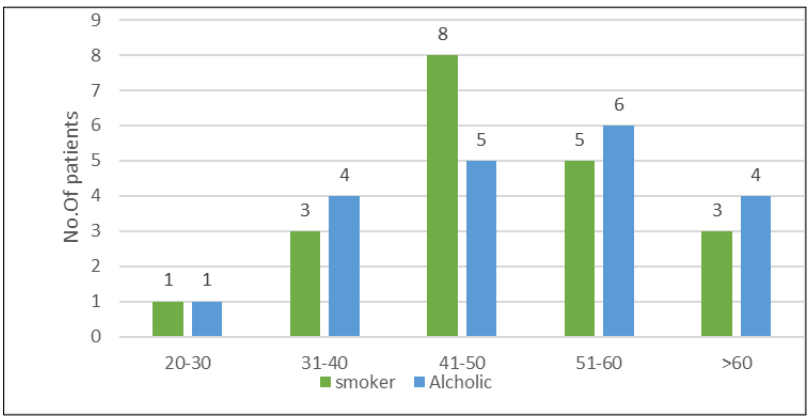


Figure 5 Risk factors causing COPD

3.6. Comparison of treatments

Figure 6 It shows the effect of treatment on FEV1 values on both study group. The mean FEV1 at baseline (0 weeks) for Group A 63.72±3.0210 and Group B was 64.96±1.645 and at 6 weeks of treatment for Tiotropium 66.88±2.006 and Salmeterol 67.84±1.06 and at 12 weeks of treatment for Tiotropium 72.12±1.423 and Salmeterol 70.68±1.973 with P value 0.0796, 0.0416, 0.0049 respectively.

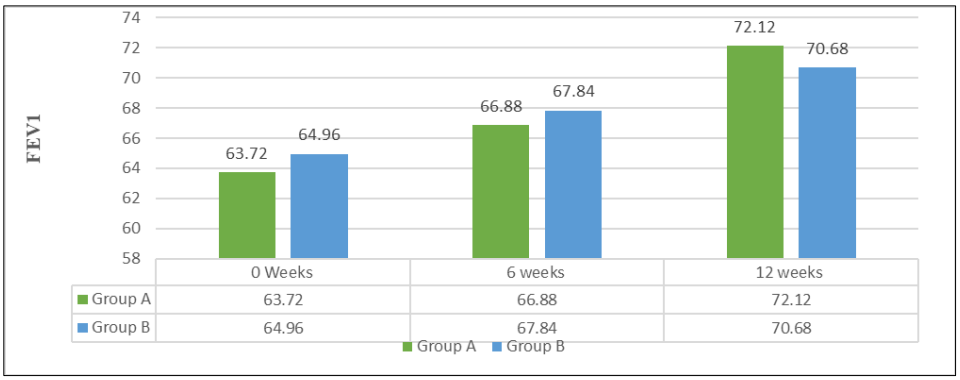


Figure 6 Comparison of treatments

3.7. Comparison of two treatments

Figure 7 It shows the comparison of treatment i.e., before and after treatment. The p value is observed at 2 different weeks i.e., 0 weeks (0.0796) and 12 weeks (0.0049).

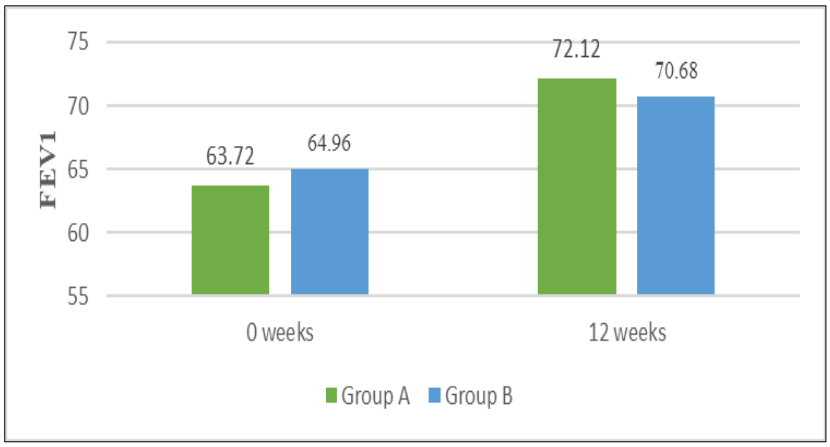


Figure 7 Comparison of two treatments

3.8. Safety parameters

Figure 8 It shows the safety parameters between 2 groups i.e., group A(tiotropium) group B(salmeterol) where it includes headache, dry mouth, nervousness, group A is of 7mem (14%) , group B is of 10mem (20%).

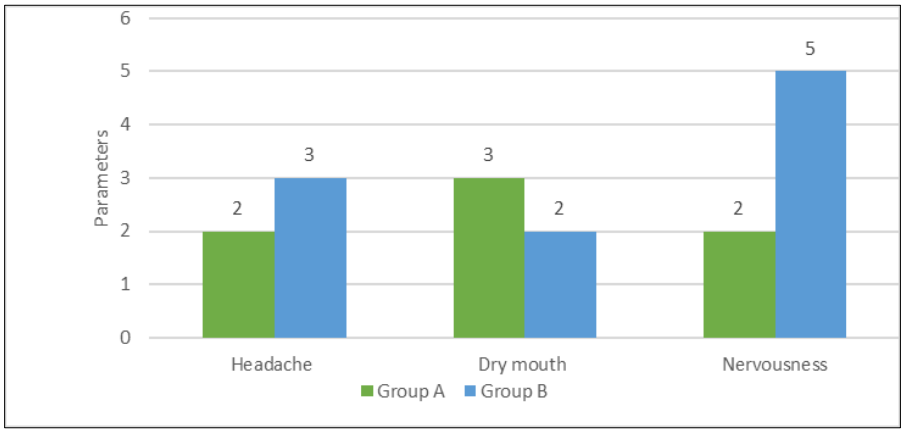


Figure 8 Safety Parameters

4. Discussion

The treatment for COPD patients given by salmeterol and Tiotropium has the potential to reduce and normalised FEV1 levels. This treatment raises the hope that Tiotropium is mostly prescribed for the patients with COPD.

The present study was carried out by taking 50 subjects, divided into two groups as Group A was given with Tiotropium and Group B was given with Salmeterol.

Figure 1 It shows age wise distribution in which the patients are grouped based on their age. In the study, maximum number of subjects included in Age group (20-30) i.e., 6% of total, 31-40 i.e., 20% of total, 41-50 i.e., 34% of total, 51-60 i.e., 26% of total, >60 i.e., 14% of total.

Figure 2 According to distribution of pt.'s based on Age & treatment gap were tiotropium, Salmeterol, where 20-30 i.e., 3 men in total, 31-40 i.e., 10 men in total, 41-50 i.e., 17 men in total, 51-60 i.e., 13 men in total, above 60 i.e., 7 members in total.

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Figure 4 It shows patients distribution according to the baseline FEV1 levels after the 12 weeks of treatment in which patients are grouped on their 12 weeks of treatment. Then the mean baseline (12 weeks) FEV1 values for Group A 72.12±1.423 and for Group B 70.68±1.973.

Figure 5 It shows the risk factors causing in COPD, where smokers and alcoholic are equally observed i.e., 20 members in each parameter (40%).

Figure 6 It shows the effect of treatment on FEV1 values on both study group. The mean FEV1 at baseline (0 weeks) for Group A 63.72±3.0210 and Group B was 64.96±1.645 and at 6 weeks of treatment for Group A was 66.88±2.006 and Group B was 67.84±1.06 and at 12 weeks of treatment for Group A was 72.12±1.423 and Group B was 70.68±1.973 with P value 0.0796, 0.0416, 0.0049 respectively.

Figure 7 It shows the comparison of treatment i.e., before and after treatment. The p value is observed at 2 different weeks i.e., 0 weeks (0.0796) and 12 weeks (0.0049).

Figure 8 It shows the safety parameters between 2 groups i.e., group A(tiotropium) group B(salmeterol) where it includes headache, dry mouth, nervousness, group A is of 7mem (14%) , group B is of 10mem (20%).

In accordance with the results of comparison of present study, showed significant improvement in FEV1 levels in Tiotropium when compared with Salmeterol from baseline to 6 months.

5. Conclusion

- By performing the study, we concluded that tiotropium used patients has reduced dyspnoea with COPD when compared with salmeterol.
- Patients treated with tiotropium indicated more improvement in their symptoms than, those who treated with salmeterol. Based on these advantages, tiotropium should be considered first-line treatment in patients with COPD.
- While performing, safety parameters for a drug, side effects of tiotropium are less when compared to salmeterol.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of ethical approval

The study is Initiated after clearance of Institutional Ethics Committee.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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