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*Research Article*

# PROSPECTIVE OBSERVATIONAL STUDY ON SAFETY AND EFFICACY OF COMBINATION THERAPY OF INHALED CORTICOSTEROIDS AND LONG-ACTING – BETA 2 AGONISTS BRONCHODILATORS IN RESPIRATORY DISEASE

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**A R T I C L E I N F O**

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**A B S T R A C T**

**Aim:** To assess the effectiveness and safety of Long-acting beta 2 agonist bronchodilators combined with inhaled corticosteroids in the treatment of respiratory disorders. **Objectives:** A prospective observational study on the safety and efficacy of combination therapy of inhaled corticosteroids and long-acting beta 2 agonists bronchodilators in respiratory diseases. To evaluate the safety of combination therapy for respiratory diseases. To evaluate the negative impacts of the medications. To determine the effectiveness of a combination treatment for respiratory disorders. **Method:** A total of 200 cases were collected in the study and were followed for prospective study in Kim Sunshine Hospital, Secunderabad for 6 months. The following evaluation was made from the collected data. **Results:** A Total of 200 subjects were recruited for the research, consisting of 123 men and 77 women. When taking gender into account as a variable, It can be stated that males (61.5%) are treated with combination therapy (ICS and LABA) more often than females (38.5%) with respiratory disorders. The majority of patients were affected with COPD and Asthma (34% and 27.5%, respectively), while bronchitis and pleural effusion Patients are only 13% and 9.5% respectively. The combination of formoterol and budesonide was used most frequently (about 74.5%), while mometasone and formoterol were used the least frequently (9.5%). Combination therapy fully controlled 59% of the subjects, 22% of the subjects were cured, 17% of the subjects were relieved, and 2% of the subjects showed no change. **Conclusion:** From this study, we conclude that the effect of combinational therapy of inhaled corticosteroid and long-acting beta 2 agonist bronchodilators is more safe and effective in respiratory disease with minimum adverse drug reactions**.**



## INTRODUCTION

**Combination therapy of inhaled corticosteroid and Long-acting beta 2 agonist**

- A long-acting beta2 agonist (LABA), a bronchodilator that opens up the airways in the lungs, and a steroid, which helps manage the underlying inflammation in the lungs, are two drugs that are typically administered in separate inhalers and are combined in combination inhalers. Using this combo inhaler instead of multiple separate inhalers may make it simpler to take the medication.
- Formonide, Fluticasone and Salmeterol (marketed as Advair, Viani, or Seretide), and Budesonide and Formoterol (marketed as Symbicort) are some examples.

**SYMBICORT**

- Budesonide and formoterol are combined in the drug Symbicort. Inflammation in the body is decreased by the corticosteroid budesonide. In order to facilitate breathing, formoterol, a long-acting bronchodilator, relaxes the muscles around the airways.

**Mechanism of action**

- Budesonide and formoterol are the two active ingredient compositions in Symbicort. Formoterol is a long-acting beta2-agonist bronchodilator (LABA), which reduces resistance in the respiratory airways and promotes airflow to the lungs, whereas budesonide is an inhaled corticosteroid (ICS) that acts by lowering and preventing respiratory tract inflammation.

**Uses**

- Moreover, Symbicort is used to manage the signs and symptoms of emphysema and chronic bronchitis associated with chronic obstructive pulmonary disease (COPD). It is not recommended to use Symbicort to treat an asthma or bronchospasm attack.
- For those who have asthma, Symbicort should only be used if their condition is severe or is not adequately controlled by other long-term asthma medications.
- When administered alone, formoterol may make asthma sufferers more likely to pass away. Nevertheless, when

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budesonide and formoterol are administered as a combination product, this risk is not enhanced

**Adverse effects**

- Inflammation of the throat
- Respiratory tract illnesses
- Sinus mucous membrane inflammation (sinusitis)
- Back Discomfort
- Stomach ache
- Migraine

**ADVAIR**

- Fluticasone and salmeterol are both components of Advair. A steroid called fluticasone stops the body's natural inflammatory-causing chemicals from being released. A bronchodilator is salmeterol. To facilitate breathing, it relaxes the muscles surrounding the airways.
- To stop asthma attacks, use Advair inhalation, a combo medication. The chronic obstructive pulmonary disease (COPD) linked to chronic bronchitis and/or emphysema is also prevented from deteriorating or relapsing.

**Uses**

- The airways' irritability and edema are lessened as a result of its action. Being a long-acting beta-agonist, salmeterol is a member of the drug family.
- The airways open up and may breathe more easily as a result of the relaxation of the muscles surrounding them.
- It is possible to cut down on time missed from work or school by managing breathing-related symptoms.
- Long-acting beta agonists (like salmeterol) rarely raise the risk of severe (and occasionally deadly) respiratory issues associated with asthma when used alone.
- Inhaled corticosteroid and long-acting beta agonist combinations, like the one in this medication, do not, however, raise the danger of severe breathing issues brought on by asthma.

**Adverse effects**

- Generation of sputum (mucus) is increasing.
- Fever; change in mucus colour.
- Chills.
- Worsening cough
- Worsening breathing issues

**METHODOLOGY**

**Study Site**

- Kim's-Sunshine Hospital in Secunderabad served as the research location.

**Study Period**

- A period of six months to complete the research.

**Sample Size**

- The endeavour involved following 200 prescriptions in total from the study.

**Sample Design**

- The investigation was an observational, prospective research.

**INCLUSION CRITERIA**

- The three categories of care are childhood, adulthood, and geriatrics.
- Those who have chronic conditions (HTN/CAD/DM/HYPOTHYROIDISM)
- A minimum of three days must pass after a patient is brought to the hospital.
- Who are prepared to agree as patients.
- Incontinent patients.
- It included both males and females.

**EXCLUSION CRITERIA**

- Uncooperative patients who won't agree.
- Those with amputations.
- Patients in psychiatry.
- Ladies who are pregnant and nursing mothers.
- Side effects of chemotherapy

**SELECTION CRITERIA**

**Study materials**

- Patient permission documents
- Patient biography template.
- Forms for gathering data
- Informational pamphlet for patients.

**Patient consent form**

- It includes information on the patients' demographics, the study's objectives, and a concise, in-depth English description of those objectives.

**Patient profile form**

- It includes the patient's name, age, sex, date of admission, date of discharge, complaints at admission, medical history, medication history, social history, family history, previous allergies, physical examination, provisional diagnosis, final diagnosis, progress chart, and medication chart. It also contains the patient's demographic information, such as name, age, sex, date of admission, and date of discharge.

**Data collection form**

- It includes information about the patient, such as name, age, sex, weight, height, IP number, date of admission, date of discharge, provisional diagnosis, medications, counselling aids used, topics covered during counselling sessions, languages known, counselling known to, barriers in counselling, amount of time spent counselling, patient counselling, and pharmacist notes.

## RESULTS

**Table 1** Age Wise Distribution Of Data

| Age group | No. Of patients | Percentage (%) |
|---|---|---|
| <21 | 7 | 3.5 |
| 21-30 | 10 | 5 |
| 31-40 | 19 | 9.5 |
| 41-50 | 25 | 12.5 |
| 51-60 | 30 | 15 |
| 61-70 | 42 | 21 |
| 71-80 | 55 | 27.5 |
| 81-90 | 6 | 3 |
| 91-100 | 6 | 3 |
| Total | 200 | 100 |

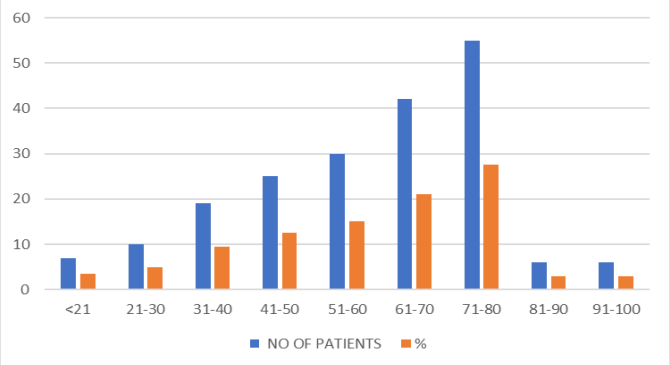

Fig. 1 Inhaled combination therapy was used to treat the bulk of the 200 hospitalized patients who had respiratory problems (27.5%) between the ages of 71 and 80, and the least amount (3%), between 91 and 100. Respiratory conditions compared to girls (38.5%).

**Table 2** Combinational Therapy Wise Distribution

| Combinational therapy | No.of patients received | Percentage |
|---|---|---|
| Formoterol + Budesonide | 149 | 74.5 |
| Salmeterol + Fluticasone | 32 | 16 |
| Formoterol + Mometasone | 19 | 9.5 |
| Total | 200 | 100 |

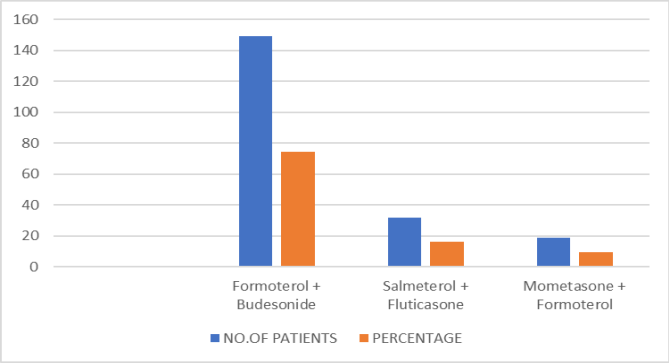


Fig. 2 The combination of formoterol and budesonide was used most frequently (about 74.5%), while mometasone and formoterol was used the least frequently (9.5%), as shown in the table and bar graph above.The P value found to be ( <0.00001)

**Table 3** Therapeutic Outcomes of Combination Therapy

| Therapeutic outcome | No. Of patients | Percentage% |
|---|---|---|
| Relieved | 34 | 17 |
| Controlled | 118 | 59 |
| Cured | 44 | 22 |
| No Improvement | 4 | 2 |

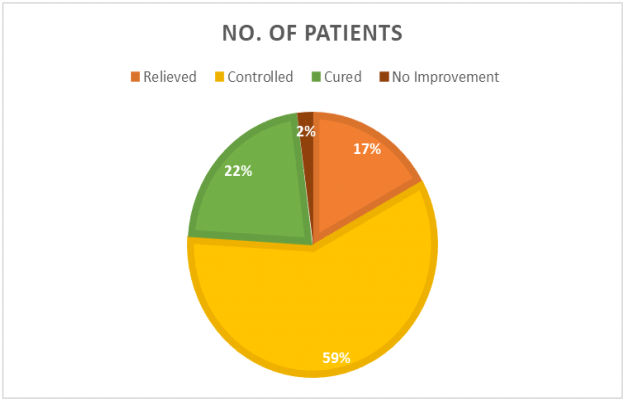


Fig. 3 According to the aforementioned table and pie chart, combination therapy fully controlled 59% of the subjects, 22% of the subjects were cured, 17% of the subjects were relieved, and 2% of the subjects showed no change.

**Table 4** Adr Based on Age Group Wise

| Age | No of ADR(n=13) | Percentage % |
|---|---|---|
| <20 | 1 | 7.6 |
| 21-50 | 3 | 23 |
| 51-80 | 7 | 53.8 |
| >81 | 2 | 15.3 |

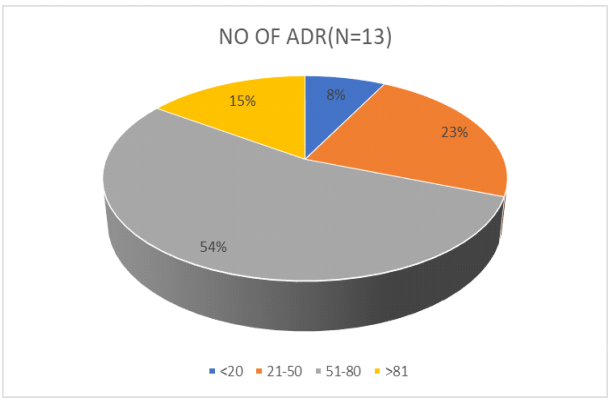


Fig 4 The table and bar graph stated above revealed that subjects in the 51-80 years (53.8%) age group were more likely to experience ADRs. followed by 7.6% for those under 20 and 15.3% for those over 81, and 23% for those between the ages of 21 and 50.

**Table 5** Combinational Drugs Causing ADR

| Combination | Number of ADR (13) | Percentage% |
|---|---|---|
| Formoterol + Budesonide | 1 | 7.6 |
| Salmeterol + Fluticasone | 9 | 69.2 |
| Formoterol + Mometasone | 3 | 23 |

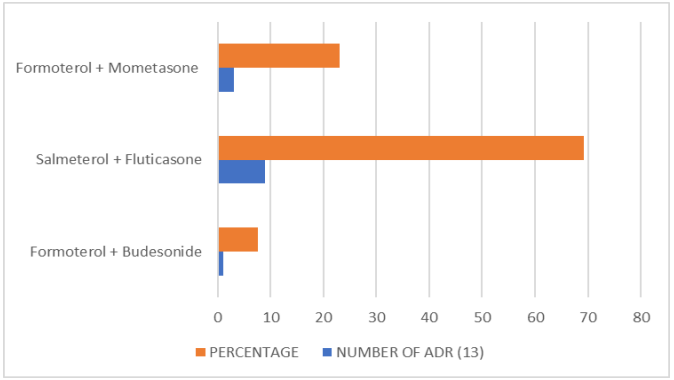


Fig 5 Salmeterol + Fluticasone had the highest rate of ADRs (69.2%), formoterol + Mometasone was second (23%), and formoterol + Budesonide the lowest rate of ADRs (7.6%).

**Table 6** Undesirable Effects of Combination Therapy

| Effects | No .of patients observed | Percentage % |
|---|---|---|
| Throat irritation | 4 | 30.7 |
| Headache | 1 | 7.6 |
| Stomach upset | 2 | 15.3 |
| Pneumonia | 3 | 23 |
| Increase mucus production | 3 | 23 |
| Total | 13 | 100 |

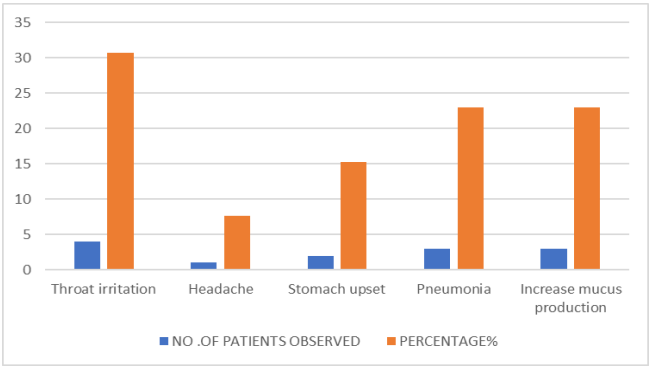


Fig 6 The table and bar graph stated above demonstrate that throat infection, which affected 30% of patients, and headache, which affected 7.6% of patients, as the most unfavourable effects. The P value was found to be( <0.00001).

## DISCUSSION

- This research uses combination therapy (ICS/LABA) to treat respiratory diseases in a prospective observational setting.
- The pulmonary section of the KIMS-SUNSHINE hospital in Secunderabad was the site of this study.
- There is enough evidence to demonstrate the effectiveness and safety of combination treatment for respiratory disorders.
- For the prospective observation research on combination therapy in respiratory disorders, 200 samples total, ranging in age from 5 to 90 years old, were gathered.
- Patients' demographic information, subjective and objective evidence, assessments, treatment plans, reports from diagnostic tests, progress charts, and other information were included in the patient sample data collection forms that were collected.
- Age, gender, disease type, family history, and symptoms are used to segment the data.
- There are numerous papers in books that are referenced for authoritative viewpoints and in-depth information. Patients who are 71 to 80 years old make up the bulk of the study's participants.
- 200 cases altogether were included in the research. This research, in which 60% of participants were men and 40% were women, demonstrates that, when it comes to treating respiratory disorders, men are more likely to use ICS or LABA.
- The age range of 61–70 (21%) and 71–80 (27.5%) comprised the largest proportion of cases.
- This demonstrates that patients who got ICS/LABA were under the age of 60, when they are more susceptible to respiratory illnesses.
- 42.5% of the patients who were eligible for enrollment in our research.
- Asthma (27.5%), COPD (34%) and other diseases accounted for the majority of the patients who participated in our research. (16%) have asthma Chest infection (13%)
  (8.9%) Pleural fluid
- Most of the patients who participated in our research were being treated with combination medications, such as FORMOTEROL + BUDESONIDE (74.5%), SALMETEROL + FLUTICASONE (16%), and FORMOTEROL + MOMETASONE
  (9.5%).
- In our research, we found that the majority of patients (74.5%) were treated with FORMOTEROL + BUDESONIDE in combination.

## CONCLUSION

- The effectiveness and safety of combination therapy in treating respiratory disease may be assessed in the current research.
- FORMOTEROL and BUDESONIDE are the two medications that are given together the most frequently (74.5%), followed by SALMETEROL and FLUTICASONE (16%) and MOMETASONE and FORMOTEROL (9.5%).
- Asthma is the primary condition affecting the majority of the people (34.5%), followed by COPD (34%).
- Treatment of COPD, Asthma, Pneumonia, Bronchitis, and Pleural effusion frequently involves ICS and LABA combination medication.
- Due to the decreased likelihood of a pathogen or tumour having multiple drug resistances at once, combination therapy reduces the formation of drug resistance.
- In order to reduce therapeutic failure rates, combination therapy is used.
- Most patients experience optimal control of their respiratory conditions when a long-acting 2-agonist (LABA) is added to an inhaled corticosteroid (ICS). As a result, two fixed combination inhalers-salmeterol/fluticasone and formoterol/budesonide-are being used more frequently as convenient controllers in patients with asthma and COPD. The combination of these two drug classes is supported by solid scientific evidence.
- A nebulizer is a tool for administering medications by misting them into the airways.
- Instead of inhalation, the nasal route was recommended in the majority of instances.
- However, nebulizers only take liquid solution-based medications.
- Asthma and COPD can be effectively controlled with long-acting beta 2 agonist, corticosteroid inhaler treatment. Without significant side effects in the bulk of patients.
- In our studies, we have now shown the clinical advantages of combining a long-acting beta 2 agonist with an inhaled corticosteroid in patients with mild, moderate, and severe persistent respiratory diseases.
- In fact, the combination of a long-acting beta 2 agonist and an inhaled corticosteroid is currently the most efficient way to control respiratory diseases in the majority of patients.
- Throat irritation, headaches, and increased production are some of the frequent adverse events mentioned in the study that are typically not severe.
- This leads us to the conclusion that combination therapy combining a long acting beta 2 agonist with an inhaled corticosteroid may be more beneficial for improving lung function and decreasing

exacerbations and symptoms than treatment with either component alone.

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