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A Comparative Study between Beclate and Symbicort inhaler in Asthmatic Patients

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ABSTRACT

Asthma is a chronic inflammatory disease, which is characterized by reversible airflow obstruction in response to a variety of stimuli. Treatment is mainly with inhalers containing beta$_2$-agonists, typically taken as required to relieve bronchospasm, and inhaled corticosteroids (ICS) or combination therapy containing a long-acting beta agonist along with a corticosteroid (ICS/LABA) as regular-preventive therapy. The objective of this study is to compare between two drugs (Symbicort and Beclomethasone) that used in treatment of asthmatic patients and to evaluate their effects on disease control, quality of life, blood pressure, side effects in addition to response of patients to these drugs. The study revealed that the male group was the most common group in this study. Most of the patients appeared to have (1-5) years of disease. The majority of participants in this study were reported to have normal blood pressure. Apparently, most individuals had normal weight, with some individuals were overweight or obese. The majority of the Symbicort treated patients had a positive history of asthma disease (63.3%), and had better disease control (63.3%), better quality of life (60%), and better response to the medication (90%). On the other hand, the majority of the beclomethasone treated patients showed no history of the disease(55%), a lower quality of life (55%), need to take the drug regularly (60%), need to take other medications to relieve their symptoms, and had frequent side effects.

Keywords: Asthma, Symbicort, Beclomethasone, Medication.

I. INTRODUCTION

Asthma is a common chronic disorder of the airways that involves a complex interaction of airflow obstruction, bronchial hyper-responsiveness and an underlying inflammation. This interaction can be highly variable among patients and within patients over time. The inflammation and bronchoconstriction in asthma are reversible with medication (and sometimes spontaneously). It is common chronic respiratory disease affecting 1–18% of the population in different countries**.** It is defined by the history of respiratory symptoms, such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable expiratory airflow limitation [1]. The prevalence of asthma has increased exponentially in recent decades in parallel with urbanization. In 2015, asthma was the most common chronic respiratory disorder, with an estimated prevalence of 358 million cases [2].

Assessment of the scope of the disease is however confounded by misdiagnosis and bias in surveillance reports that result in over- or underestimation of cases.Nonetheless, it is clear that asthma burden has markedly increased in the past 50 years. In recent cohorts, 15–20% of the population have a diagnosis of asthma in some countries [3]. In fact, the World Health Organization, through extrapolation from existing data, predicts a further increase in the number of asthmatics by an additional 100 million in 2025 [4]. The prevalence of allergic diseases, including asthma, has been shown to be affected by migration. This principle is known as the "healthy immigrant phenomenon." This concept suggests

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that immigrants migrating to higher-income countries tend to be healthier than those born in that country. This protective phenomenon decreases reciprocally as the number of years residing in the high-prevalence country increases. Immigrants to these high-prevalence countries tend to develop asthma later in life as well as hypersensitivity to allergens. Diagnosis of asthma is based on clinical factors combined with measurement of lung function demonstrating obstruction, variability, and, typically, reversibility [5].

Spirometry is used to assess the volume of air that can be exhaled under maximal effort in an individual. The forced expiratory volume in 1 s (FEV1) as well as during the entire respiratory cycle (FVC) is assessed with spirometry. By comparing these two values, physicians can determine the presence of airflow obstruction in the lung. The FEV1/FVC ratio is predictable based on the patient's age, gender, ethnicity, and height. **A FEV1/FVC ratio less than 0.70–0.75** is generally indicative of airway obstruction; older patients may have a lower baseline without clinical obstruction and younger patients may exhibit airflow obstruction at higher ratio [6]. The cornerstone of asthma control is the use of inhaled corticosteroid (ICS) therapy. This is the most important pharmacologic component of asthma care. It does not provide immediate relief of symptoms but suppresses the inflammatory response in the airway that drives the underlying pathophysiology. Control of the inflammatory process is critical for long-term preservation of lung function, reduction in exacerbations, control of healthcare costs, and improvement in quality of life [7].

II. METHODS AND MATERIAL

This study is a cross-sectional study, it involved 50 patients suffering from asthma and treated by 2 different drugs. The Patients aged between (18- 60 Years) ,who were selectively collected and were suffering from asthma in In Al-Najaf Governorate, Iraq through a period which extend from September 2023 to December \2023. Many of information's were collected from each participant such as, age, height, weight, physical activity, smoking state, marital state, occupational state, disease control, response to treatment, duration of disease, type of treatment, presence of other disease and family history. Blood pressure for each participant also measured.

For all participants weight and height were calculated by using a sensitive balance after that the BMI is calculated by using this equation:

BMI= weight (Kg)/ height (m2).

According to their body mass index, the participants were divided into four categories: Underweight (BMI< 18.5 kg/m2), Normal (18.5-24.9 kg/m2), Overweight (25-29.9 kg/m2) and Obese (≥30 kg/m2)**.** Blood pressure was measured by standard electronic device in a sitting position and the cuff must be at the heart level.

Statistical analysis

The data analysis was performed using Microsoft Excel 2019. Microsoft Excel was used for editing, sorting, and coding. Descriptive statistics, frequencies, and percentage were used to summarize the result and presented using tables.

III. RESULTS AND DISCUSSION

According to the BMI, the beclomethasone-treated subjects were divided into four groups. The normal weight group was the most common group (70%) (equivalent to 14 patients), followed by the overweight group (15%) (equivalent to 3 patients), then the obese group（10%) (equivalent to 2 patients), while the underweight group is less common (5%) (equivalent to 1 patient). While the Symbicort treated group results showed that normal weight group as the most common group (60%) (equivalent to 18 out of 30 patients), followed by the overweight group (20%) (equivalent to 6 patients), and less frequently, the underweight and obese groups (each group 10%) (3 patients each). As in figure (1 & 2).

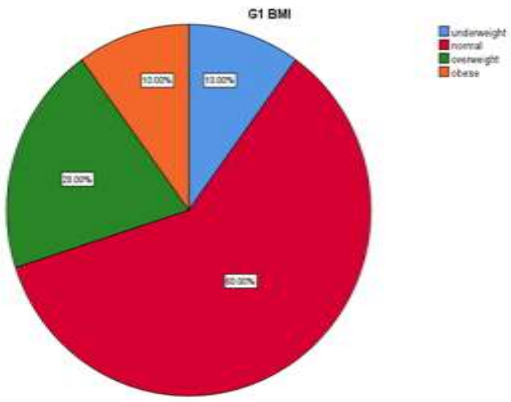

Fig 1: Distribution of BMI in Symbicort-treated group.

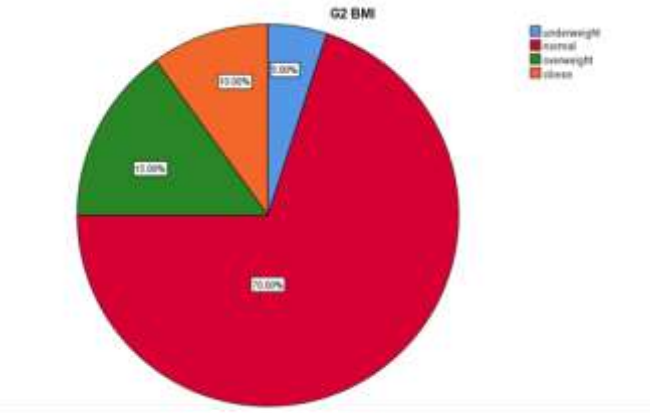

Fig 2: Distribution of BMI in beclomethasone-treated group.

Distribution of gender according to study participants

According to our study, 53.3 % (16 of 30 patients) of the Symbicort treated patients were males, while 46.7 % (14 of 30 patients) were females. On the other hand, 75%(15 out of 20 patients) of the beclomethasone treated group were males, and only 25 % (5 patients) were females. As in figure (3 & 4).

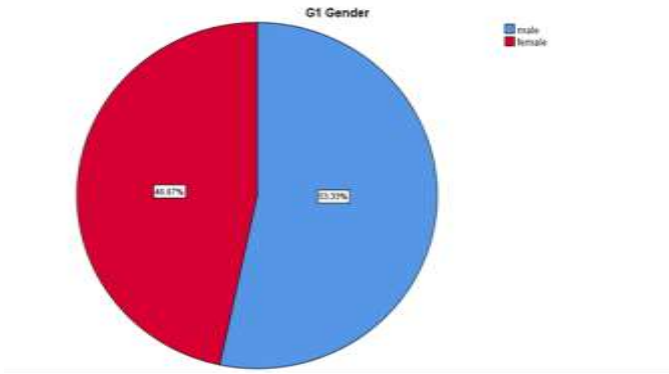

Fig 3: Distribution of gender in Symbicort-treated group.

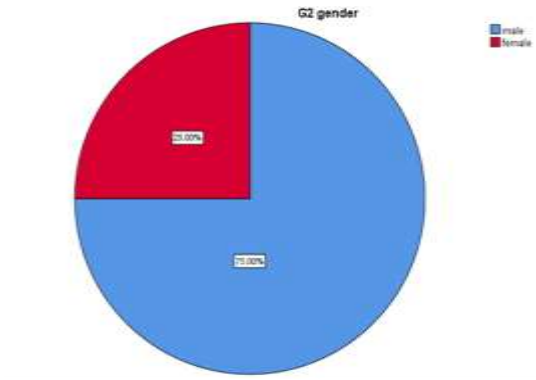

Fig 4: Distribution of gender in beclomethasone-treated group.

Distribution of study participant according to duration of disease:

According to the duration of disease, the results of the Symbicort treated patients showed that patients with (1-5) years of disease are the most common group with 36.7 % (11 of 30 patients), followed by patients with (> 11) years of disease and patients (6-11) years of disease, respectively (33.3 % and 30%, respectively). While the results of the beclomethasone treated group showed that patients with (1-5 years) of disease are the most common patients with 45% (9 of 20 patients), followed by patients with (>11) years of disease and patients (6-11) years of disease, respectively (40% and 15 %, respectively).

TABLE I: DISTRIBUTION OF SYMBICORT-TREATED GROUP ACCORDING TO DURATION OF DISEASE.

Duration of disease	Frequency	Percent
1-5 years	11	36.7
6-11 years	9	30.0
> 11 years	10	33.3
Total	30	100

TABLE II: DISTRIBUTION OF BECLOMETHASONE-TREATED GROUP ACCORDING TO DURATION OF DISEASE

Duration of disease	Frequency	Percent
1-5 years	9	45.0
6-11 years	3	15.0
> 11 years	8	40.0
Total	20	100

Distribution of study participants according to drug use:

Regarding using the drug regularly or on need, our findings showed that 50% (15 of 30) of the Symbicort - treated group are taking the drug regularly, while 50 % (15 of 30) of the patients are using the drug on need. On the contrary, the patients who are taking beclomethasone in our study were reported to take the drug in the regular form in 60% of the patients while 40% were taking the drug on need.

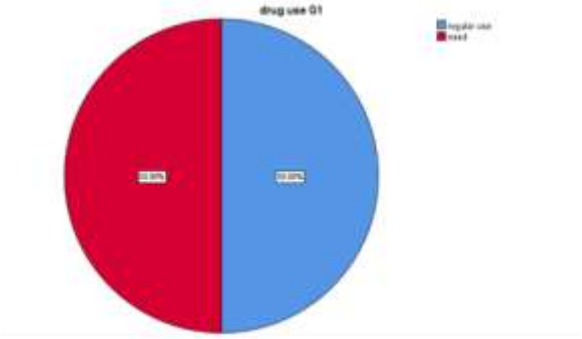

Fig 5: Distribution of Symbicort-treated group according to drug use.

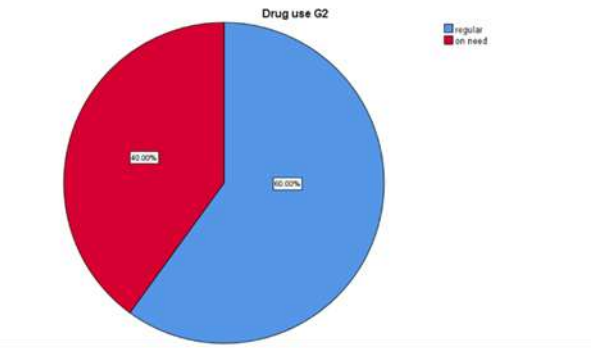

Fig 6: Distribution of beclomethasone-treated group according to drug use.

Distribution of study participants according to patients' response to drugs:

Regarding the patient response to the medication, our results indicate that 90% (27 of 30 individuals) of the patients receiving Symbicort showed good response, and only 10% (3 of 30 individuals) had poor response. On the other hand, 80% (16 of 20 individuals) of the patients who take beclomethasone showed good response while 20% (4 of 20) had bad response to the medication. As shown in tables (III & IV).

TABLE III: DISTRIBUTION OF SYMBICORT-TREATED GROUP ACCORDING TO RESPONSE TO DRUG.

Patients' response to drug 1 (Symbicort)	Frequency	Percent
Good	27	90.0
Bad	3	10.0
Total	30	100

TABLE IV: DISTRIBUTION OF BECLOMETHASONE -TREATED GROUP ACCORDING TO RESPONSE TO DRUG.

Patients' response to drug 1 (Symbicort)	Frequency	Percent
Good	16	80.0
Bad	4	20.0
Total	20	100

To discuss the results, the treatment with ICS/LABA combination (Symbicort) therapy appeared to perform as well or better than ICS (Beclomathason) alone in disease control and reducing severe asthma exacerbations; this included multiple high-risk subgroups. Our study revealed that the control of disease in the Symbicort -treated population is better than Beclomethasone-treated population and most Symbicort-treated patients meet GINA requirements for controlled asthma. The significant protective effect of ICS/LABA combination therapy among individuals with moderate to severe asthma is consistent with current guideline recommendations regarding the timing of supplemental LABA therapy (GINA 2023). Our results are also similar to several other randomized clinical trials. In a study by Lemanske and colleagues, 12.2% of patients treated with both an ICS and add-on salmeterol experienced treatment failure (i.e., use of oral corticosteroids, asthma-related emergency department visit, or asthma-related hospitalization) when compared with 47.4% of patients treated with ICS alone [8]. Several recent observational studies have examined the effect of combining LABA and ICS on asthma control. For example, Thomas et al. estimated ICS and LABA exposure from prescription data; they observed better control in patients treated with LABA step-up therapy as opposed to step-up with a higher ICS dose [9].

Additionally, Quality of life in the Symbicort-treated group was better than beclomethasone-treated group. More than half patients of beclomethasone treated group showed a lower quality of life. The statistics highlight that the disease limits their daily life activities through social, emotional, physical and occupational impacts. Furthermore, our study found that the patient response to Symbicort is superior to the response received from those patients who are taking beclomethasone alone. Additionally, the results of our study showed that patients who are taking Symbicort have less need to take other drugs for their symptoms, while patients who are taking beclomethasone, on the other hand, showed higher need to take other medications for symptoms relief. Results of the study showed that the combination inhaled corticosteroid-long acting β agonists appear to be superior to inhaled corticosteroid alone in the overweight patients. There is now abundant evidence that the obese do not respond as well to standard controller therapy. Forno E found that overweight and obese are less responsive to ICS in terms of lung function [10]. Telenga ED showed that obese had decreased FEV1 response to steroids [11]. The pathogenesis of asthma is altered in obesity, and obese patients do not respond as well to standard controller therapy. Adipose tissue produces a number of cytokines and adipokines which may have a synergistic adverse effect on the airways. Cytokines produced by adipose tissue include plasminogen activator inhibitor-1, monocyte chemotactic factor-1, interleukins 6 and which

may affect the airway such as plasminogen activator inhibitor-1, monocyte chemotactic factor-1, IL-6 and 8, and adipokines such as leptin and adiponectin. The precise role of many of these mediators in the pathogenesis of allergic airway disease is not well known; however, a number of studies have shown the potential role of adiponectin (which is decreased in obesity) and leptin (which increases in obesity) in allergic asthma [12,13].

In this study, the gender distribution of individuals taking Symbicort showed the female group was more than males, while the predominant gender group taking beclomethasone alone was the male group. This result suggests that females need better asthma control measures than males and this finding agree with study by Tantisira KG, et al. and Schatz M, Camargo CA., that found "after puberty, asthma becomes more prevalent and severe in women [14,15]. Also, several studies suggest women with asthma are at higher risk for severe asthma, required a higher use of asthma medications, and have a higher risk for emergency room visits, hospitalization, and admission to the intensive care unit [16].

Several studies indicates that estrogen may act directly on the immune system to increase the severity of asthma symptoms [17]. It may also act indirectly to damage lung mechanics and increase inflammation**.** In contrast, oral contraceptive may be protective and decrease the risk of exacerbation in asthmatic women [18]. As sex hormones levels decrease with menopause, the age adjusted risk of asthma may drop in postmenopausal compared to premenopausal women. This protective effect of menopause is reversed by postmenopausal hormone replacement therapy. Testosterone, on the other hand, has a positive effect on the immune system, according to a recent study at the Walter and Eliza Hall Institute of Medical Research in Melbourne, Australia. Testosterone triggers innate lymphoid cells to be less reactive, resulting in a significant decrease in the incidence and severity of asthma [19,20].

IV. CONCLUSION

In this observational study, we found that exposure to ICS/LABA combination therapy (Symbicort) appeared to have better control and an overall protective effect on asthma exacerbations that was as good or better than that observed for ICS (Beclomethasone) treatment alone; this included multiple high-risk subgroups. This study demonstrated that the protective effect of Symbicort (ICS/LABA combination therapy) appeared particularly effective in the following clinically relevant subgroups: individuals with ≥6 years of the disease, females, individuals with family history of the disease, overweight, and individuals with either moderate-severe or severe asthma at baseline. While Corticosteroid therapy (Beclomethasone) alone was effective in mild asthma cases, particularly in male patients.

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