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EFFECTIVENESS OF TIOTROPIUM AMONG CHILDREN SUFFERING FROM ASTHMA

[1]Dr Muhammad Salman Akhtar, [2]Dr Sajjad Ahmad, [3]Dr Anab Baloch

[1]Bolan Medical Complex Quetta, [2]Nishter Hospital Multan, [3]Masoomeen Hospital Trust Karachi.

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Abstract:

Objective: *The aim of this research work is to study the effectiveness of Tiotropium among children suffering from asthma.*

Methodology: *In this research, there were eighty children who were the victim of asthma. We prescribed the Fluticasone Propionate Aerosol or the Fluticasone Propionate Aerosol in addition with Tiotropium to these children randomly for the duration of 12 weeks.*

Results: *There was a considerable better effect on the function of lungs in both of the groups during different intervals of week in comparison to the optimum level. Furthermore, as compared to healthy control group having significant level of P value less than 0.050, in Tiotropium group lungs function also improved. Yet there was no particular dissimilarity in the occurrence of chronic asthma between these groups (36.30% & 26.80% respectively; p>0.050). In the Tiotropium group, we had minimized the usage of SABAs (short acting beta2-adrenoceptor agonist) and quantity of days. It also reduced the awakenings during the night. In both study groups there were no any harmful effects.*

Conclusion: *By using Tiotropium the function of lungs improves notably, reduction in the utilization of SABAs and awakening also decreases in children suffering from asthma. Still, it has some unpleasant effects.*

Key Words: *Peak Expiratory Flow, Tiotropium, Forced Vital Capacity, Effectiveness, Awakenings, Asthma*

Corresponding author:

Dr. Muhammad Salman Akhtar,

Bolan Medical Complex Quetta.

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INTRODUCTION:

Asthma is an unceasing disease in which there is sensitivity of airway, contraction of muscles, and restrictions in the flow of air. Recently, there is a worldwide enhancement of the rate of this disease. In United States of America, almost 7.0 million infants and young people are suffering from asthma [1], In the United Kingdom, one of every seven children approaching from the age of two to fifteen are in requirement of proper cure [2], in China, the frequency is higher than the past ten year [3]. The preferred treatment of asthma patients is the inhalation of the Glucocorticoids [4, 5]. But patient who use glucocorticoid were habitual of its use.

This situation is the reason of anxiety for health care departments [6, 7]. There comes improvement in the control of asthma in children by the utilization of LABAs (long-acting beta2-adrenoceptor agonists) [8]. But the use of long acting Beta2- adrenoceptor agonists for long time can cause complications. The United States organization FDA (food & drug administration) worked to overcome this complication. They proposed that the victims can leave the use of these medicines in order to control their asthma. Now there is requisition of any other medicine to remove contractions in air ways. In alternate, researchers recommended Tiotropium, being a long acting dilator of bronchial muscles [11], and more effective than LABA [12, 13], which was useful in chronic obstructive pulmonary disease [14, 15]. In the recent few years, researches described that in asthma Tiotropium is much effective in adults [16, 17] and in younger ones [18]. The analysis of the effectiveness and safety of Tiotropium in children is the objective of this research. Children suffering from asthma examined for 3 months to observe the impact of asthma on the function of the lungs, sleeplessness and other complications.

METHODOLOGY:

During one year, we examined eighty children, having age from six to fourteen years. They were suffering from asthma of moderate level. The analytical method proposed by The National Pediatric Asthma Association used for these children. Before starting the process of analysis, entitled children had not given Corticosteroids, SABA, LABA or Cholinergic Receptor Antagonists systematically for the period of one month. The examination of all children showed that they had no restrictions for the use of Corticosteroids, any heart problem, eyesight problem or high blood pressure. This research work carried out in accordance with the Helsinki declaration. The Ethical committee of Hospital gave approval for the publication of this article. The guardians of all participants gave approval in written form for this research. Furthermore, for the appropriate utilization of Tiotropium the children used measureable inhalation system or metered inhaler. For healthy control group, we advised some children to take 125.0µg Fluticasone Propionate Aerosol daily for two times, in addition to, Placebo daily for one time. For patient group, we recommended 125.0µg Fluticasone Propionate Aerosol daily for two times, in addition to, 18.0µg Tiotropium dry-powder inhaler daily for one time. The duration of the study was 3 months. During the research procedure if the children faced severe indications of asthma, for safe medication, we allowed the use of SABAs, as 100µg Albuterol Aerosol. At optimum level, there was no any considerable dissimilarity between the two under-observation groups. They were of approximately same age groups, gender, FEV1% (Forced Expiratory Volume in one second), BMI (Body Mass Index), FVC & PEF% (Peak Expiratory Flow) (Table-1).

After the intervals of four weeks, we examined the lung function of under observation children by using Jaeger Master Screen Pulmonary Function Testing System, imported from Germany, in order to get analysis of the tidal breathing flow volume curve. We also examined the FEV1%, FVC, and PEF of these children.

In case of acute asthma or when lungs function decreased by 30% as compared to optimum level, cure by oral corticosteroids or hospitalization became necessary. We excluded the patients from the observation, when the occurrence of acute asthma was more than two times during the research period. We also recorded the awakenings at night, quantity of days and frequency of the utilization of SABAs.

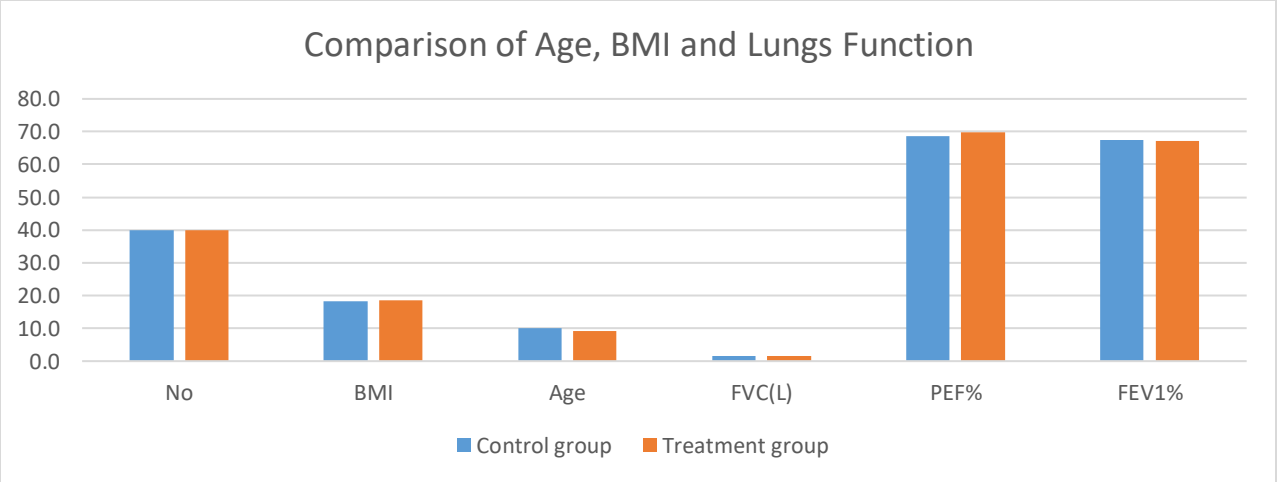
We performed a statistical analysis by the usage of SPSS V.10 software. We presented the results in means ± SD. We analyzed the numerical data by a pared T-test. We examined between-group probability by the utilization of a Chi-square test. The value of P was less than 0.050.

RESULTS:

We selected the two children from each group suffering from severe asthma. We did not include these 4 patients in our analysis. As mentioned in Table-1, body mass index, lungs function and age was almost same for the both groups ($P > 0.050$).

Table-I: Comparisons of BMI, age and lung function between two groups

Groups	No	BMI	Age	FVC(L)	PEF%	FEV1%
Control group	40.0	18.20 ± 3.00	10.10 ± 4.80	1.550 ± 0.560	68.570 ± 3.420	67.410 ± 8.510
Treatment group	40.0	18.50 ± 3.10	9.30 ± 5.20	1.530 ± 0.470	69.880 ± 3.550	67.310 ± 7.320

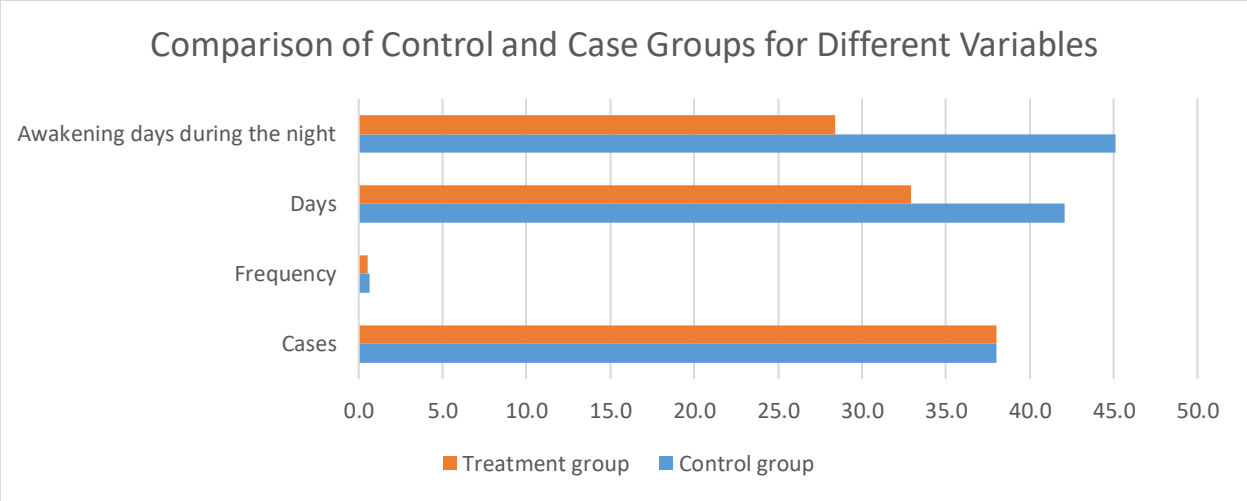


In comparison to optimum level (p<0.010), the forced vital capacity, peak expiratory flow and forced expiratory volume in one second of patients, improved in the intervals of 30 days. Furthermore, lungs function improvement was considerably greater in patient group. All identifiers had the value of P less than 0.010 while the value of forced expiratory volume in one second (FEV1%) after 3 months and the value of forced vital capacity (FVC) after 2 months was p<0.050. The chance of occurrence of the acute asthma was 26.30% in patient group and 36.80% in healthy control group. While between these two groups there was no any considerable difference ($\chi 2$=0.540, *P* >0.050). The quantity of days and frequency of the utilization of SABAs decreased in patient group in comparison to healthy control group (*P* < 0.050; Table-2). Moreover, there were some cases of awakenings at night in the patient group.

Table-II: Comparisons of frequency and days of use of short acting beta 2 receptor

Groups	Cases	Frequency	Days	Awakening days during the night
Control group	38.0	0.650 +0.340	42.10+16.50	45.10+10.60
Treatment group	38.0	0.510 + 0.230*	32.90 + 14.30*	28.40 + 6.90**

Vs. control group *P < 0.05, **P < 0.0.



There were three reports of adverse reactions in the patient group. We analyzed throat soreness and xerostomia in all of these three patients. But these indications vanished, when the patients increased the use of water. There were two adverse reactions in healthy control group. One patient suffered with harsh voice and the other suffered with white patches in the oral cavity. We treated these infections with Myclin and oral nursing successfully. There was no any report of high blood pressure, heart or eye-sight problem in both groups.

DISCUSSION:

The standard identifiers of lung functions are FVC, FEV1%, and PEF%. According to our observation, inhaled corticosteroids are effective in both groups. The findings of Pauwels were similar to the results of current case work [19]. Instead of placebo, the use of Tiotropium improved the lung function of the patient group. Sub-type of Tiotropium is responsible for this result [20]. The demonstration of Vogelberg is similar to our research, though end point is dissimilar [21]. Awakening at night is a serious issue that affects the lives of asthma patients. Warvik [22] analyzed that 39.0% asthma patients were awaking every night, and 74.0% asthma patients were awaking once a week. Moreover, 70.0% of deaths occurred during sleep due to asthma. According to our research, Tiotropium can minimize the awakenings during the night, quantity of days and frequency of the utilization of SABAs. The reason is that in case of asthma that occurs mostly at night, Parasympathetic nervous system is the main mechanism [23] and Tiotropium has a long half-life of about 35 hours and its effectiveness remains for a full day [24]. The research of Vogelberg did not describe it [21]. According to some researches, the use of Tiotropium reduces the complications of asthma. Our research shows that occurrence of acute asthma is less in patient group, in comparison to healthy control group. But there is no considerable dissimilarity between results. So, there is no any useful effect of Tiotropium in case of acute asthma. Some factors as nasosinusitis and allergic inflammations can cause problems in the process of treatment [25].

CONCLUSION:

Tiotropium a LACAs (long-acting cholinergic receptor antagonist), is effective for the improvement of lung function. It decreases the requirement of SABAs (short-acting beta2-adrenoceptor agonists) and improves the morbidity of acute asthma among children. Moreover, it also has a few harmful effects. All of these points show that it is effective to use Tiotropium for the cure of asthma among children.

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