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THE EFFICIENCY OF TIOTROPIUM IN THE CHILDREN SUFFERING WITH THE DISEASE OF ASTHMA

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Abstract:
Objective: *The purpose of this research work is to enquire the medical effectiveness of tiotropium in children suffering with the disease of asthma.*
Methodology: *About 80 children with recently detected medium level asthma were the participants of this research work. The separation of the children carried out into the group of fluticasone propionate aerosol or the group of fluticasone propionate aerosol + tiotropium for consecutive twelve weeks.*
Results: *The function of the lungs was considerably better in all groups at four, eight and twelve weeks in accordance with the baseline. In addition, the function of the lung was better in the group of tiotropium as compared to the group of the controls. There was no important disparity in the occurrence of the serious nature asthma among the participants of both groups with 36.3% & 26.8% respectively. The amount of the days and the rates of the short-acting beta-two adrenoceptor agonist utilization were much lower in the group of tiotropium as compared to the group of controls. There were no serious side effects in the participants of both groups.*
Conclusion: *Tiotropium has the ability to improve the function of the lungs, decrease the utilization of the short acting beta two adrenoceptor agonists & increase the sleeping period in the patients of asthma especially children. There is an availability of some minor side effects.*
Key Words: *Asthma, Baseline, Hyper Sensitivity, Lenience, Tiotropium, cholinergic Receptor, Fluticasone.*

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INTRODUCTION:

Asthma is a complication of the air passage which has a relation with airway hyper sensitivity, leveled muscle spasm & hindrance in the airflow. In current times, the rate of this disease is increasing in the whole world. About seven million people are suffering from this disease in United State of America [1], in United Kingdom, one among 7 children from two to fifteen year of age has the symptoms of this disease with regular therapy [2] and in China, two hundred and thirty-two in ten thousand children below fourteen year of age in the city areas has the disease of asthma, this frequency was greater than the rate of ten years ago which was one hundred and fifty-four per ten thousand [3]. Inhaled glucocorticoids are thought to be the 1st therapy for the asthma patients [4, 5]. Majority of patients who are taking inhaled glucocorticoid are insufficiently managed which shows an important healthcare in the field of healthcare [6, 7]. In blend with LABAs (inhaled long acting beta two adrenoceptor agonists) can promote the control of asthma in children [8].

The utilization of the LABAs for long time has an association with lenience to the defensive impacts on bronchi & high danger of exacerbation of fatal asthma. The US FDA (Food and Drug Administration) have concerns about the LABAs safety & they advocate that patients should stop LABAs for the control of symptoms of asthma [9, 10]. So, a substitute treatment for the relief from bronchi is the requirement. Tiotropium is a long acting anti-cholinergic broncho-dilator [11] & many case studies proved that the impact of tiotropium is much better than the LABA [12, 13] which was effectual in COPD [14, 15]. Different research works have shown that tritropium is effectual in asthma therapy in adults [16, 17] & adolescents [18]. We present the information on the assessment of the safety & effectiveness of this medicine in only children.

METHODOLOGY:

About 80 children from six to fourteen year of age detected with the asthma in the hospital were the part of this research work. The duration of this research was from December 2017 to December 2018. The included children had not gotten corticosteroids, beta two adrenoceptor agonists or cholinergic receptor antagonists for twenty-eight days before the participation in the research work. No patient was engage in corticosteroids utilization, high blood pressure, coronary diseases or glaucoma. Ethical committee gave the approval for the conduction of this research work. Guardians of the patients gave the consent to participate in the research work. The patients could utilize the system of inhalation for the correct use of the tiotropium. Eighty children were arranged to inhale either one hundred and twenty-five micro gram fluticasone propionate aerosol two times in a day + placebo one time daily (in the group of controls), or one hundred and twenty-five micro gram fluticasone propionate aerosol two time in a day with eighteen micro gram dry powder of tiotropium one time in a day.

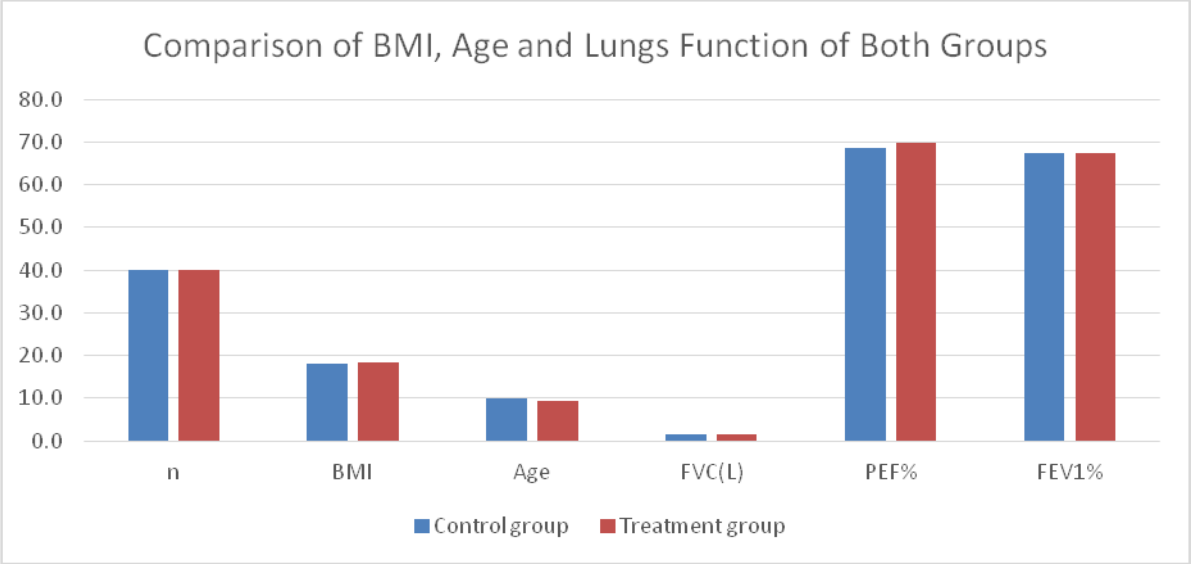
There was no important disparity among the both groups at baseline in age of the patients, gender, BMI, FEV1% (forced expiratory volume in one second), FVC (forced vital capacity) & PEF% (peak expiratory flow) as mentioned in Table-1. SPSS software version ten was in use for the statistical analysis of the collected information. Chi square method was in use for the analysis of the comparisons between both groups. The patients with coronary diseases, other diseases of the lungs infections and other severe complications were not included in this research work.

RESULTS:

Exclusion of the 2 participants from each group carried out because of having greater than two exacerbations of the serious asthma. These 4 participants were not the part of the statistical analysis. As displayed in Table-1, there were no important disparities for body mass index, age of the patients and the function of the lung among the participants of both groups.

Table-I: Comparisons of BMI, Age and Lung Function Between Two Groups ^T±s).

Groups	n	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	18.5+3.1	9.30 ± 5.20	1.530 ± 0.470	69.880 ± 3.550	67.310 ± 7.320

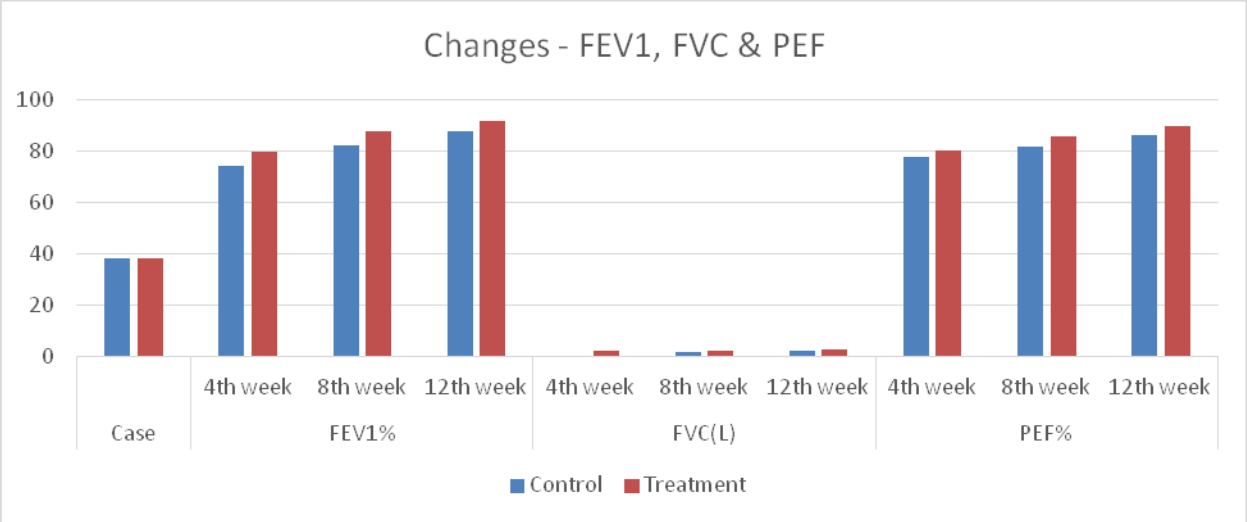


The FEV1 percentage, FVC & PEF percentage in the participants of both groups was improving at weeks four, eight and twelve as compared to the baseline as described in Table-2. Moreover, betterment in the function of lung in the group of patients was greater than the patients of the control the improvement in lung function in the treatment group was significantly greater than in the control group of controls. The occurrence of the serious asthma was more than thirty-eight percent in the group of controls and more than twenty-six percent in the group of patients but there was no important disparity among the members of both groups.

Table-II: Changes of FEV1%, FVC and PEF% Before and After Treatment in Two Groups (X+s).

Groups		Control Group		Treatment Group	
Case		38.0		38.0	
FEV1%	4th week	73.910 + 5.660	▲	79.560 + 7.010	▲ #
	8th week	82.340 + 5.020	▲	87.440 ± 6.740	▲#
	12th week	87.530 + 5.760	▲	91.610 + 5.730	▲ *
FVC(L)	4th week	1.630 + 0.470	▲	1.870 + 0.420	▲ *
	8th week	1.700 + 0.510	▲	1.950 + 0.480	▲ *
	12th week	1.800 + 0.590	▲	2.420 + 0.550	▲ #
PEF%	4th week	77.390 + 3.560	▲	80.00 + 3.680	▲ #
	8th week	81.630 + 4.760	▲	85.520 + 3.90	▲ #
	12th week	86.350 + 3.650	▲	89.670 + 4.140	▲ #

▲ Vs before the treatment $P < 0.01$; * vs. control group $P < 0.05$, # $P < 0.01$.

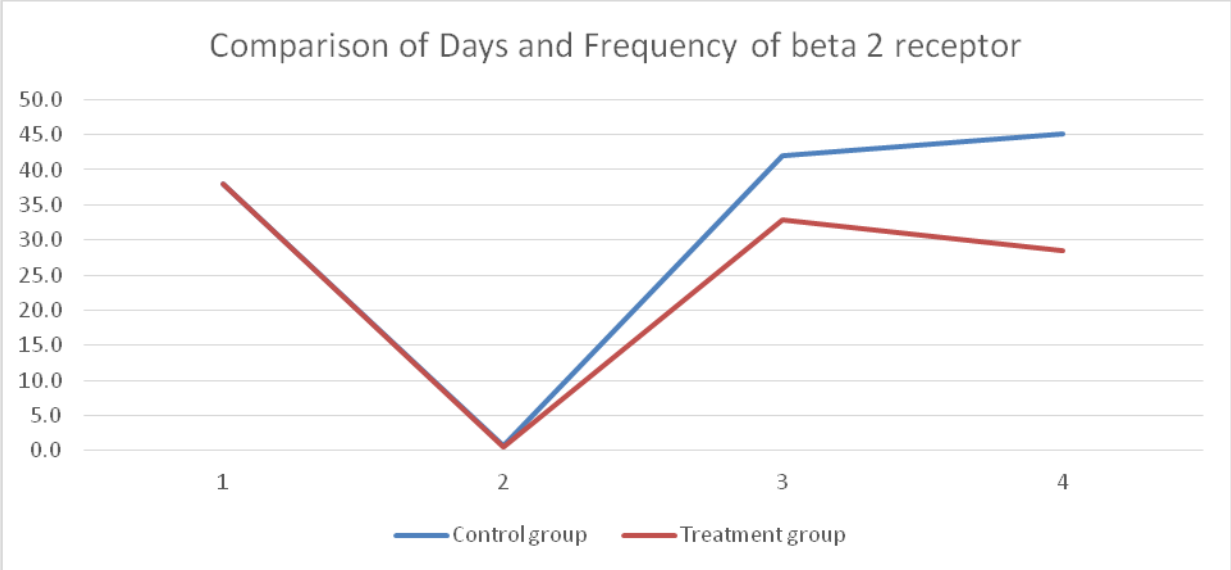


The rate and amount of days of utilization of short acting beta two adrenoceptor agonists decreased in the group of patients as compared to the participants of the control group as mentioned in Table-3. In the group of patients, there were only three reports of the side effects and all the patients were suffering with xerostomia &discomfort of the throat. Two patients were suffering of side effects in the group of controls. One patient was suffering with hoarseness & other patient was suffering with thrush, both patients recovered from medication.

Table-III: Comparisons of Frequency and Days of Use of Short Acting Beta 2 Receptor

Class	Patients	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 +	32.90 +	28.40 + 6.90**

Vs. control group *P < 0.050, **P < 0.010.



DISCUSSION:

FEV1%, FVC & PEF percentage are the ideal factors for the functions of lungs. Our findings display that inhaled corticosteroids has the ability to improve the

function of lung in both groups; this outcome is similar to the outcome of the Pauwels [19]. When mixed with the tiotropium, the function of the lung of patient group was much better than the placebo. The finding should have a connection with the selectivity of the subtype of the tiotropium [20]. Research work of Vogelberg had showed the similar impacts on the children, although the finishing point was not similar with the finding of our result [21]. Night sleeplessness is very vital factor that influences the QOC (quality of life) in every asthma patient. A large enquiry by Warvik [22] concluded that thirty-nine percent asthma patients were awaking every night due to the symptoms of asthma and seventy-four percent patients stated awakening at least one time in a week. Furthermore, seventy percent deaths occur at night time during sleep because of asthma. This research work concluded that tiotropium can decrease the rate and amount of days of utilizing the short acting beta two adrenoceptor agonists & decrease the awakening at night times. The cause may be that the parasympathetic central nervous system is a vital method in the symptoms of nocturnal asthma [23] & large length of the period of tiotropium' half-life which is about thirty-five hours which is about thirty-five hours & its effectiveness can last for complete twenty-four hours [24].

The research work of Vogelberg had not described that issue [21]. Some research works displays that the mixing of the tiotropium has the ability to decrease the dangers of the episodes of the deterioration. This research work described the occurrence of the serious asthma was very less in the group of the patients as compared to the members of the control group, but the disparity among two groups was not of much importance. Therefore, a valuable impact of the drug of tiotropium on danger of serious asthma could not declare with confirmation. There are some other normal features of the exacerbations of serious asthma i.e. allergic rhinitis & nasosinusitis have the ability to complicate the treatment [25].

CONCLUSION:

Conclusions described that tiotropium has the ability to improve the function of the lung, decrease the requirement of the on demand less acting beta two adrenoceptor agonists & promote the nocturnal signs in the children suffering with the disease of asthma. In addition, tiotropium has very less side effects in the patients. These benefits show that tiotropium provide a hopeful outcome for therapy against the asthma.

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