EVALUATION OF EFFICACY OF ACCUHALER WITH FLUTICASONE AND SALMETEROL MEDICATION IN ASTHMATIC CHILDREN

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ABSTRACT

AIM

To evaluate efficacy of Accuhaler with fluticasone and salmeterol medication in childhood bronchial asthma.

MATERIALS AND METHODS

A prospective study was planned with 52 patients of both sexes in the age group of 5-12 years, who reported to Asthma Clinic and fulfilled inclusion and exclusion criteria after parental consent. All patients included in the trial were initially entered into a run-in period of 2 weeks, during which a record was maintained of their clinical parameters and allowed to take their prescribed medication. At the end of run-in period the baseline symptoms and signs of asthma, PFT, amount of rescue medication and nocturnal awakening due to asthma symptoms were recorded and Accuhaler with test medication applied. Statistical analysis was performed on pre- and post-intervention data.

CONCLUSION

The present study demonstrated that Accuhaler, a dry power device, is significantly effective in producing clinical and PFT improvement in moderate persistent asthma of children.

KEYWORDS

Asthma, Children, Pulmonary Function Test (PFT), Accuhaler, DPI, Fluticasone, Salmeterol.

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INTRODUCTION

This study was conducted to assess the efficacy of Accuhaler with fluticasone and salmeterol in asthmatic children. Clinical PFT, use of rescue medication and nocturnal awakening due to asthma symptoms was assessed and compared between pre-intervention and post-intervention.

MATERIALS AND METHODS: This study was conducted in Asthma Clinic of the pediatric OPD, at Katuri Medical College and Hospital, Guntur, in 2012-2013. A prospective study was planned with 52 patients of both sexes in the age group of 5-12 years, who reported to Asthma Clinic and fulfilled inclusion and exclusion criteria after parental consent.

All patients included in the trial were initially entered into run-in period of 2 weeks, during which a record was maintained of their clinical parameters and allowed to take their prescribed medication. At the end of run-in period, the baseline symptoms and signs of asthma, PFT, amount of rescue medication and nocturnal awakening due to asthma symptoms were recorded and Accuhaler with fluticasone 100 micrograms and salmeterol 50 micrograms applied. Various parameters like symptom score (e.g., cough, breathlessness),

clinical score (e.g. wheeze, use of accessory muscles), PFT (e.g. FEV1, FVC, PEFr), nocturnal awakening (e.g. number of nights in a week patient awakened due to asthma symptoms as per history), use of rescue medication (number of salbutamol puffs patient required per week) were used to assess efficacy of device at monthly intervals for two months. Statistical analysis was performed on pre- and post-intervention data.

RESULTS: Of the 52 patients enrolled, 69% were males and 31% were females and 42% of children were in the age group of 5 to 8.9 years and 58% of the children were in the age group of 9 to 12 years age group. Significant improvement (P-value less than 0.001) was noticed in symptom scores, clinical scores, PFT, nocturnal awakening after 1st and 2nd review and significant improvement in use of rescue medication (P-value less than 0.01) after 1st and 2nd review recorded.

No.	VALUE	COUGH			BREATHLESSNESS			SYMPTOM SCORE		
		Base	1 st	2 nd	Base	1 st	2 nd	Base	1 st	2 nd
1	Mean	1.961	0.615	0.192	2.038	0.076	0.667	4.000	0.692	0.192
2	S.D	0.196	0.496	0.402	0.196	0.271	0.254	0.002	0.618	0.402
3	S.Err	0.380	0.970	0.790	0.038	0.052	0.046	0.021	0.121	0.079
4	P-Value	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
5	Significant	Significant			Significant			Significant		

Table 1: Comparison of Symptom Score

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No.	VALUE	WHEEZE			USE OF ACCESSORY			CLINICAL SCORE		
		Base	1st	2nd	Base	1st	2nd	Base	1st	2nd
1	Mean	1.807	0.233	0.230	0.200	0.030	0.031	3.807	0.003	0.090
2	S.D	0.491	0.004	0.004	0.007	0.003	0.300	0.491	0.004	0.382
3	S.Err	0.096	0.002	0.002	0.035	0.015	0.015	0.096	0.002	0.063
4	P-Value	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
5	Significant	Significant			Significant			Significant		

Table 2: Comparison of Clinical Score

No.	VALUE	FEV1			FVC			PEFR		
		Base	1st	2nd	Base	1st	2nd	Base	1st	2nd
1	Mean	65.34	92.69	93.26	58.53	84.08	83.92	70.96	94.07	98.84
2	S.D	11.12	9.507	8.637	10.31	11.24	10.32	11.74	16.13	15.64
3	S. Err	2.182	1.864	1.694	2.022	2.206	2.024	2.303	3.165	2.029
4	P-Value	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
5	Significant	Significant			Significant			Significant		

Table 3: Comparison of PFT Score

No.	VALUE	NOCTURNAL AWAKENING			RESCUE MEDICATION		
		Base	1st	2nd	Base	1st	2nd
1	Mean	4.076	0.538	0.230	14.80	0.230	0.653
2	S.D	0.688	0.859	0.652	4.271	1.704	1.719
3	S.Err	0.135	0.169	0.128	0.838	0.334	0.337
4	P-Value	0.001	0.001	0.001	0.001	0.001	0.01
5	Significant	Significant			Significant		

Table 4: Comparison of Other Parameters

DISCUSSION

In the present day scenario, bronchial asthma is a leading cause of morbidity in our society and more so in pediatric age group.¹ There have been revolutionary changes in the management of bronchial asthma during past few years. Aerosol therapy has come to stay as the backbone of therapy.

Acute attacks in the pediatric age group require hospital management and nebulization is primary mode of drug delivery to the lungs.² Inhalation steroids with long-acting bronchodilator indicated in moderate persistent and severe persistent asthma. The results of Campbell LM and other study demonstrates that the addition of a long-acting B2-agonist is an effective tool for achieving the goals of asthma treatment.³ Same results were shown by a randomized double blind study by Lee YS and others.⁴

Our study aimed at evaluation of Accuhaler using drugs fluticasone propionate (100 micrograms) and salmeterol (50 micrograms) in patients of 5-12 age group suffering from moderate persistent asthma. According to Williams J and Richards KA, Accuhaler inhaler was rated more favorably than the Turbuhaler inhaler in terms of ease of correct inhaler use, ease of telling how many doses were left, ease of knowing whether a dose had been inhaled and overall liking of the device.⁵

There are potential cost savings with the use of combination inhalers compared to separate inhalers with same clinical efficacy as per systemic review by Main C and others.⁶

A total of 52 subjects were evaluated before application of said medication and one month and two months after application of said medication with various disease parameters like symptom score, clinical score, PFT, nocturnal awakening due to asthma symptoms and rescue medication required. Data from baseline, one month after application of medication and two months after application of medication was analyzed.

At the end of one month, there was statistically significant difference between baseline data and first month review data for various parameters like cough, breathlessness, symptom score, wheeze, use of accessory muscles, clinical score, FEV₁, FVC, PEFR, nocturnal awakening and use of rescue medication. Moreover, it is true about second review at the end of second review.

One Chinese study by Zheng JP and others has also demonstrated efficacy of Accuhaler with same medicines in adult COPD patients.⁷ Pieters WR and others from a Netherland based study state both Discus (Accuhaler) and diskhaler proved to be equal in efficacy and safety.⁸ However, Accuhaler tend to be more costly than other inhalers.⁶

CONCLUSION

The present study demonstrated that Accuhaler with combination drugs of fluticasone and salmeterol is significantly effective in improving asthma symptomatology and pulmonary function test results.

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