EVALUATION OF EFICACY OF ROTAHALER WITH FLUTICASONE AND SALMETEROL MEDICATION IN ASTHMATIC CHILDREN

Suddapalli Sivaram Prasad¹

¹Associate Professor, Department of Pediatrics, Katuri Medical College & Hospital, Guntur.

ABSTRACT: AIM: To evaluate efficacy of Rotahaler with fluticasone and salmeterol medication in childhood bronchial asthma.

MATERIALS AND METHODS: A prospective study was planned with 30 patients of both sexes in the age group of 5-12 years, who reported to asthma clinic and fulfilled inclusion and exclusion criteria were included in the study after parental consent. All patients included in the trial were initially entered in to 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 base line symptoms and signs of asthma, PFT, amount of rescue medication and nocturnal awakening due to asthma symptoms were recorded and Rotahaler with test medication applied. Statistical analysis was performed on pre and post intervention data.

CONCLUSION: The present study demonstrated that Rotahaler a dry power devise is significantly effective in producing clinical and PFT improvement, in moderate persistent asthma in children.

KEYWORDS: Asthma, Children, Pulmonary Function Test (PFT), Rotahaler, Fluticasone, Salmeterol.

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INTRODUCTION: This study was conducted to assess the efficacy of Rotahaler 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, between 2012 and 2013. A prospective study was planned with 30 patients of both sexes in the age group of 5-12 years, who reported to asthma clinic and fulfilled inclusion and exclusion criteria were included in the study after parental consent. All patients included in the trial were initially entered in to 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 base line symptoms and signs of asthma, PFT, amount of rescue medication and nocturnal awakening due to asthma symptoms were recorded and Rotahaler 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 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 30 patient enrolled 27% were males and 73% were females. And 30% of children were in the age group of 5-8.9 years and 70% of the children were in the age group of 9-12 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.

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 whereas inhalation steroids with long acting bronchodilator indicated in moderate persistent and severe persistent asthma.

Our study aimed at evaluation of Rotahaler using drugs fluticasone propionate (100 micrograms) and salmeterol (50 micrograms) in patients of 5-12 age group suffering from moderate persistent asthma. A total of 30 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.

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Corresponding Author:

Dr. Suddapalli Sivaram Prasad,
Flat No. 4, First Floor, Amrutha Apartments,
Veterinary Colony, Road No. 5,
Vijayawada-5,
Andhra Pradesh, India.
E-mail: suddapalli2000@yahoo.com
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Pieters WR and others from a Netherland based study state both Discus (Accuhaller) and diskhaler proved to be equal in efficacy, safety and were well tolerated.³

Rakesh L from AIMS, New Delhi concluded that MDI and dry powder devices are equal in efficacy.⁴ However, Thomus M and Willium AE in their study titled 'Are outcomes the same with all dry powder inhalers?' indicate that, different levels of asthma control is possible with different devices even with same chemical entity.⁵

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

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No.	VALUE	COUGH			BREATHLESSNESS			SYMPTOM SCORE		
		Base	1 st	2 nd	Base	1 st	2 nd	Base	1 st	2 nd
1	Mean	2.166	0.900	0.366	2.000	0.233	0.667	4.166	1.133	0.433
2	S.D	0.379	0.403	0.490	0.001	0.001	0.254	0.379	0.629	0.626
3	S.Err	0.069	0.000	0.089	0.000	0.000	0.046	0.069	0.115	0.114
4	P-Value	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
5	Signi.	Significant			Significant			Significant		

Table 1: Comparison of Symptom Score

No.	VALUE	WHEEZE			USE OF ACESORY			SYMPTOM SCORE		
		Base	1 st	2 nd	Base	1 st	2 nd	Base	1 st	2 nd
1	Mean	2.033	0.233	0.066	0.206	0.200	0.667	4.100	0.043	0.100
2	S.D	1.183	0.504	0.254	0.254	0.407	0.254	0.403	0.774	0.403
3	S.Err	0.033	0.092	0.046	0.046	0.074	0.033	0.074	0.141	0.074
4	P-Value	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
5	Signi.	Significant			Significant			Significant		

Table 2: Comparison of Clinical Score

No.	VALUE	FEV1			FVC			PEFR		
		Base	1 st	2 nd	Base	1 st	2 nd	Base	1 st	2 nd
1	Mean	72.56	93.26	95.46	65.66	84.56	87.03	70.56	91.76	95.80
2	S.D	11.13	9.447	7.464	10.55	9.171	9.590	7.745	13.72	11.74
3	S.Err	2.032	1.725	1.363	1.927	1.674	1.751	1.414	2.506	2.144
4	P-Value	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
5	Signi.	Significant			Significant			Significant		

Table 3: Comparison of PFT Score

No.	VALUE	NOCTURNAL AWAKENING			RESCUE MEDICATION		
		Base	1 st	2 nd	Base	1 st	2 nd
1	Mean	4.166	1.067	0.300	2.000	0.233	0.733
2	S.D	0.648	0.907	0.651	0.001	0.001	1.701
3	S.Err	0.118	0.166	0.119	0.000	0.000	0.310
4	P-Value	0.001	0.001	0.001	0.001	0.001	0.01
5	Signi.	Significant			Significant		

Table 4: Comparison of Other Parameters