

Comparative effectiveness of oral dexamethasone vs. oral prednisolone for acute exacerbation of asthma: A randomized control trial

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ABSTRACT

Background: Acute exacerbation of asthma is a common condition leading to emergency visits. Prednisolone is a commonly prescribed drug in the standard management of acute exacerbation of asthma along with other drugs. This study was planned to see the efficacy of oral dexamethasone when compared with oral prednisolone in the management of acute exacerbation of asthma. **Methods:** A single-center pilot study in the form of randomized control trial was done by recruiting children aged 2–14 years diagnosed with acute asthma exacerbation with mild to moderate severity. A total of 88 patients received oral dexamethasone (0.3 mg/kg) in two doses 24 h apart, which was compared with 87 patients who received oral prednisolone (1 mg/kg) in two divided doses 12 h apart for 5 days. The patients were assessed at the time of admission (zero hour), at 4th hour, and on the 5th day by various parameters such as respiratory rate, use of accessory muscles, Pediatric Respiratory Assessment Measure (PRAM) score, peak expiratory flow rate (PEFR), 6-h admission stay, and rate of hospital admission. **Results:** Baseline demographic profile, clinical characteristics, comorbidities, indoor pollution, and use of Metered Dose Inhaler (MDI) among the two study groups were comparable. Six-hour emergency stay and rate of admission were significantly lower in the dexamethasone group ($P < 0.05$). Improvement in PRAM score, PEFR, use of accessory muscles, and respiratory rate was also better in dexamethasone group at the 4th hour and 5th day ($P < 0.05$). In addition, oral dexamethasone was shown to have less incidence of vomiting/gastritis than prednisolone ($P < 0.05$). **Conclusion:** Oral dexamethasone can be considered a reliable and better option as compared with prednisolone due to its faster action and minimal side effects.

Keywords: Asthma, steroid, treatment

Introduction

Asthma is a common pediatric disease that results in significant limitation of activity and an estimated loss of 14.4 million school days in children.^[1] Acute exacerbation can be fatal and repeated asthma attacks have adverse impacts on a child's lung function trajectory and also lead to poor quality of life and has psychological impact on mental wellbeing of children.^[2]

The Royal College of Paediatrics and Child Health (RCPCH) has recommended that asthma attacks should be managed aggressively during the first hour of presentation as children are presented late to the hospital.^[3] The British guidelines on the management of asthma recommend commencing oral prednisolone early for children presenting with exacerbation of asthma and if they are discharged, continuing treatment for up to 3 days.^[4]

However, despite treatment with prednisolone, around 5%–25% of patients relapse and many require admission for management of subsequent exacerbations.^[5] This has been attributed to a

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prolonged treatment course, unpleasant bitter taste, side effects like vomiting, and reduction in patient compliance.^[6,7] There is definite role of primary care physicians (PCP) in outpatient management of acute asthma and treating in a step-wise fashion reduce symptom frequency, improve, control, and reduce future morbidities.^[8] Hence, primary care providers should be well versed with recent trials and studies on intervention of common conditions like bronchial asthma.

Dexamethasone has been proposed as an equivalent therapy to prednisolone for acute asthma exacerbations in pediatric patients.^[9] Dexamethasone has a longer half-life and has been used safely in other acute pediatric conditions like croup, etc.

Due to the long-acting nature of dexamethasone, different doses such as a single Intramuscular (IM) dose or two divided doses in 1 day or 2 days have been used.^[1] Dexamethasone is being recognized as an attractive alternative to prednisolone because of its longer duration of action and shorter treatment period, leading to better compliance and improved clinical outcomes.^[6]

Head-to-head trials on the comparison of effectiveness and safety of dexamethasone and prednisolone have been sparse and with variable results.^[10-12] Hence, we have planned this study to see the comparative effectiveness of oral dexamethasone vs. oral prednisolone in acute exacerbation of asthma.

Material and Methods

The present study was a single-center pilot study conducted in the Department of Pediatrics of a Tertiary care center in a semiurban/rural setting. Children aged 2–14 years diagnosed with acute asthma exacerbation consistent with mild to moderate severity were taken from Pediatrics OPD, Emergency, and Pediatrics indoor wards. The attendants/caregivers of children were explained about the study and written informed consent was taken from them. Ethical clearance was taken from institutional ethical committee. After taking a thorough history, each participant underwent detailed clinical examination, then was randomized into two groups. Clinical improvements were documented using Pediatric Respiratory Assessment Measure (PRAM) score.^[13]

Children with clinical deterioration/not improving after two doses of dexamethasone, or who converted from moderate-to-severe asthma exacerbation in either group and those children whose parents refused to give consent to participate in study were excluded. Total sample size calculated as per previous studies' prevalence data was 166. To reduce margin of error and take into account some attrition, the total sample size taken was 175 (88 in one group and 87 in another group). Hence, 175 patients were enrolled in the study. The patients were randomized into two groups using computer-based block randomization. In group A, 88 patients received oral dexamethasone (0.3 mg/kg) in two doses 24 h apart, which was compared with group B, which consisted of 87 patients who received oral prednisolone (1 mg/kg) in two

divided doses 12 h apart for 5 days. The patients were assessed on the time of admission (zero hour), at the 4th hour, and on the 5th day. A telephonic call was made to each patient to return on the 5th day for assessment according to PRAM score in both groups.

Children were assessed for need for hospital admission; duration of 6-h stay in the emergency department. Other outcome measures were respiratory rate, use of accessory muscles, auscultatory findings, peak expiratory flow rate (PEFR), and development of tremor and vomiting/gastritis. The data were entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. Quantitative variables were compared using Mann–Whitney test (as the data sets were not normally distributed) between the two groups. Qualitative variables were compared using the Chi-square test/Fisher exact test. A *P* value of <0.05 was considered statistically significant.

Results

A total of 175 patients aged 2–14 years diagnosed with acute asthma exacerbation consistent with mild to moderate severity were included in the study. Eighty-eight patients received oral dexamethasone (0.3 mg/kg) in two doses 24 h apart. Eighty-seven patients received oral prednisolone (1 mg/kg) in two divided doses 12 h apart for 5 days. Baseline demographic characteristics such as age, gender, socioeconomic status, and family history were comparable among the two groups [Table 1].

The comorbidities, indoor pollution, and previous use of inhaler (MDI) distribution in this study were comparable among the two groups. In both Groups A and B, PRAM score was also comparable at the baseline [Table 1].

Dexamethasone group children had significantly less 6-h emergency stay (5.7% vs. 35.6%, *P* < .0001) and admissions rate was low (2.2% vs. 10.3%, *P* = 0.032) as compared with prednisolone group. Dexamethasone was found to show a significantly better improvement in the PRAM score on the 5th day (0.08 ± 0.43 vs. 0.21 ± 0.63 , *P* = 0.046). With the improvement in the PRAM score, there was a continuous improvement in the PEFR and decrease in respiratory rate and use of accessory muscles over time till 4 h to the end of the 5th day [Table 2].

The side effects profile comparison of both drugs showed that dexamethasone caused less vomiting/gastritis (17.1% vs. 73.6%, *P* < 0.001) as compared with prednisolone.

To sum up, dexamethasone significantly reduced the emergency stay and admissions of the children with acute asthma attacks with minimal side effects such as vomiting/gastritis.

Discussion

The present study was a randomized trial on 175 children aged 2–14 years diagnosed with acute asthma exacerbation

Table 1: Comparison of baseline characteristics between Group A (Dexamethasone group) and B (Prednisolone group)

Baseline characteristics	A (n=88)	B (n=87)	P
Age (years)	7.23±2.14	7.07±2.55	0.408
Gender			
Female	44 (50%)	39 (44.8%)	0.493
Male	44 (50%)	48 (55.2%)	
Comorbidities	8 (9.1%)	8 (9.2%)	0.981
Indoor pollution	53 (60.2%)	49 (56.3%)	0.600
Socioeconomic status			
Lower	80 (90.9%)	77 (80.1%)	0.601
Upper	8 (9.1%)	10 (11.5%)	
Family history of atopy	24 (27.3%)	24 (27.6%)	0.963
Previous MDI used	85 (96.6%)	81 (93.1%)	0.329
PRAM score (means±SD)	5.4±1.06	5.28±1.13	0.597
Heart rate			
Tachycardia	88 (100%)	87 (100%)	0.742
Respiratory rate			
Mild respiratory distress	2 (2.3%)	4 (4.6%)	0.444
Moderate respiratory distress	86 (97.7%)	83 (95.4%)	
Accessory muscles used	87 (98.9%)	87 (100%)	1.000
Presence of wheezing	27 (30.7%)	26 (29.9%)	0.790
Reduced peak expiratory flow rate	88 (100%)	87 (100%)	0.891

Table 2: Response to treatment in Group A (Dexamethasone group) and B (Prednisolone group)

Parameters	A (n=88)	B (n=87)	P
6-h emergency stay	5 (5.7%)	31 (35.6%)	<.0001
Admission	2 (2.3%)	9 (10.3%)	0.032
Grading according to PRAM Score			
Before any therapy			
Mild asthma (0-4)	69 (78.4%)	67 (77%)	0.968
Moderate asthma (5-7)	19 (21.6%)	20 (22.9%)	
At 4 h			
Mild asthma	15 (17%)	23 (26.4%)	0.086
Moderate asthma	4 (4.5%)	9 (10.3%)	
At 5 th day			
Mild asthma	2 (2.3%)	7 (8%)	<0.05
Moderate asthma	-	-	
PRAM score (Means±SD)			
Before any therapy	5.4±1.06	5.28±1.13	0.597
At 4 h	1.48±0.99	1.47±0.91	0.873
At 5 th day	0.08±0.43	0.21±0.63	0.046
Presence of tachypnea			
Before any therapy	88 (100%)	87 (100%)	0.444
At 4 h	15 (17%)	28 (32.2%)	<0.05
At 5 th day	1 (1.1%)	4 (4.6%)	<0.001
Accessory muscles used			
Before any therapy	87 (98.9%)	87 (100%)	1
At 4 h	7 (7.9%)	16 (18.4%)	<0.05
At 5 th day	0 (0%)	1 (1.1%)	<0.001
Presence of wheezing			
Before any therapy	27 (30.7%)	26 (29.8%)	0.79
At 4 h	18 (20.4%)	53 (60.9%)	<0.05
At 5 th day	6 (68.1%)	13 (14.9%)	<0.05
PEFR reduced			
Before any therapy	88 (100%)	87 (100%)	
At 4 h	10 (11.4%)	23 (26.4%)	<0.05
At 5 th day	1 (1.1%)	14 (16.1%)	<0.001

consistent with mild to moderate severity where we compared the effectiveness of oral dexamethasone against oral prednisolone for treating asthma exacerbation.

The randomization ensured that the baseline demographic (age, gender) and clinical characteristics, comorbidities, indoor pollution, socioeconomic status, family history, and use of inhaler (MDI) among the two study groups were comparable and any differences in the outcomes were purely due to the intervention.^[14]

Age distribution in our study ranged from 2 to 14 years and similar age group has been reported in other studies conducted on this subgroup of population.^[5,15] The gender distribution in this study showed slight male predominance with 52.57% males and 47.43% females with male to female (M:F) ratio of 1.1:1. Other studies have also shown similar male to female ratio.^[5,15,16]

Children are the most vulnerable in terms of effects of potential indoor air pollution on health effects as they tend to spend more time in the home. Indoor environmental factors that are believed to change severity of asthma consist of pollutants. Other studies have also shown similar indoor pollution distribution.^[17]

Prevalence of asthma is disproportionately increased in children who belonged to low-income families. Because of the extensive prevalence of asthma among children, there is a necessity for a better understanding of the socioeconomic determinants of asthma control for improving current management in children with asthma.^[18] The comparable socioeconomic status ensured that no bias was created in the outcomes.

Recently, several studies have determined to evaluate the role of family history of asthma as an explanatory variable for the disproportionate rates of asthma in the case of underserved minorities, which suggests ethnicity is a risk factor for asthma irrespective of socioeconomic status (SES). Research focuses on parental influence, particularly genetic predisposition, maternal asthma, and birth order.^[19] Elkharwili *et al.*^[15] also reported that family history was similar in those who used dexamethasone and prednisolone. Thus, it becomes essential that family history is comparable among the two groups as was seen in our study.

A majority of patients in both groups were already on MDI. Other studies like Gordon *et al.*^[7] and Elkharwili *et al.*^[15] have also shown similar use of inhaler (MDI) distribution. All the enrolled patients underwent treatment with either dexamethasone or prednisolone along with nebulization for controlling the acute exacerbation episode.

It was seen that dexamethasone group children had better control of the acute episode and showed significantly less 6-h emergency stay and admissions as compared with prednisolone group. This may be due to the effective action of the dexamethasone in a shorter period rather than prednisolone.

Parikh *et al.*^[16] also found that length of stay was significantly short in the dexamethasone group than prednisolone group; however, no difference in admission rates was found. Among other studies, Cai *et al.*^[20] found that stay in emergency department was statistically different between dexamethasone and prednisolone groups, but may not be clinically meaningful. In a similar study by Paniagua *et al.*,^[5] the efficacy of two doses of dexamethasone (0.6 mg/kg/dose) was compared with a 5-day course of prednisolone (1.5 mg/kg/day, followed by 1 mg/kg/day on *days 2–5*). Follow-up was done at 7 and 15 days. It was found that emergency department length of stay was similar in both groups.

As compared with other studies, findings of this study regarding emergency stay and hospital admission are clinically important and offer strong evidence related to the role of dexamethasone as an important option to prednisolone for managing nonlife-threatening asthma in the emergency department. However, there are many factors that can influence hospital admission, like inpatient care criteria, medical decisions, accessibility to healthcare facilities, and treatment protocols implementation that may have caused the variations among different studies.

In our study, we included patients with PRAM scores showing mild to moderate severity of asthma at the baseline, which decreased with the use of both dexamethasone and prednisolone till the 5th day of the acute episode. There was continuous improvement in the PEF, respiratory distress, and use of accessory muscles over time till the end of the 5th day with the use of dexamethasone and prednisolone but improvement was more with dexamethasone. Elkharwili *et al.*^[15] observed that there was no significant difference in PRAM score in dexamethasone compared with prednisolone groups (1.45 ± 1.10 vs. 1.35 ± 1.14 , $P = 0.947$). Gordon *et al.*^[7] conducted a study including children who received either a single dose of IM dexamethasone phosphate or 5 days of oral prednisolone. No significant difference was observed in the mean asthma score. Altamimi *et al.*^[21] in the study including pediatric patients compared a single dose of oral dexamethasone with 5 days of oral prednisolone. Because of the inadequate number of patients, the findings of the study did not reach statistical significance; however, it indicated that there was similarity in patient self-assessment scores of return-to-baseline levels when evaluation was done again at *day 5*.

Cronin *et al.*^[12] compared single dose of oral dexamethasone with 3 days of prednisolone among children with acute exacerbations of asthma and found that a single dose of oral dexamethasone was noninferior to a 3-day course of oral prednisolone when it was assessed by the mean PRAM score on the 4th day.

The side-effects profile comparison of both drugs showed that dexamethasone caused less vomiting/gastritis as compared with prednisolone. Similar to present study, Keeney *et al.*,^[6] in a meta-analysis included children less than 18 years with acute exacerbation, oral/IM dexamethasone reduced episodes

of vomiting in the emergency department, and at home in comparison with a 5-day course of prednisolone. However, in several other studies which compared dexamethasone with prednisolone, vomiting was the main side effect; however, statistically, most of the studies found no difference among the two groups.^[5,15,22,23] Fewer episodes of vomiting can be because dexamethasone is reported to be more palatable compared with prednisolone.

To sum up, dexamethasone seems to be a reliable and better option as compared with prednisolone due to its faster action and minimal side effects. In the treatment of asthma exacerbations in children, oral prednisolone was the corticosteroid used traditionally. This study will throw some light on the effectiveness of oral dexamethasone as compared with oral prednisolone for acute exacerbation of asthma in children.

Many children with acute exacerbation of asthma are treated in primary healthcare settings and primary care physician is, therefore, in a very important position to recognize and manage the acute episode.^[24] It has been found that there is variability in PCP glucocorticoid management of acute asthma; hence, such studies will help to formulate uniform treatment guidelines.^[25] Moreover, there is a dearth of studies in India that evaluated the effectiveness of dexamethasone and oral prednisolone for acute exacerbation in pediatric asthma. Thus, our study can act as a stepping zone for further larger studies to find out, which drug is a better option in the management of pediatric asthma in emergency department setting.

The strength of our study was that a fairly reasonable number of cases were studied. So, it gives a fair idea of the effectiveness of oral dexamethasone versus oral prednisolone for acute exacerbation of pediatric asthma across various age groups and gender encountered in an emergency department setting.

Limitations of the study were that some parameters were not evaluated such as readmissions and adherence to treatment. These parameters are also important in comparing the effectiveness of dexamethasone and prednisolone in children with asthma. The follow-up till the 5th day was also small as other studies have followed up till *day 15*.

Conclusion

Two doses of dexamethasone 24 h apart are more effective and safer than a 5-day course of prednisolone in children who have mild-to-moderate asthma exacerbation treated in the emergency, particularly by primary care physicians. Dexamethasone significantly reduces the emergency stay and admissions of the children with acute asthma attacks with minimal side effects such as vomiting/gastritis. Considering baseline differences within the heterogeneous population of children needing acute care for asthma, more randomized controlled trials should be conducted for providing strong evidence on this topic to design an optimal dexamethasone regimen.

Key points

- Early recognition and better understanding of management strategies of acute exacerbation of asthma by primary care physicians will help to reduce future morbidities in children with bronchial asthma.
- Prednisolone is the most recommended and widely used drug in the standard management of acute exacerbation of asthma.
- Two doses of dexamethasone 24 h apart are more effective and safer than the 5-day course of prednisolone in children who have mild-to-moderate asthma exacerbation.

Key take-home message

Oral dexamethasone has been found to be more efficacious than oral prednisolone in treating acute exacerbation of asthma in an outpatient setting.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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