



ADVERSE DRUG REACTION PATTERN OF ORAL CORTICOSTEROIDS PRESCRIBED FOR BRONCHIAL ASTHMA IN A TERTIARY CARE HOSPITAL

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ABSTRACT **BACKGROUND:** Bronchial Asthma is one of the worldwide health problem associated with increased morbidity and mortality. Bronchial Asthma is a disease of airways that is characterized by hyper-responsiveness of the trachea-bronchial tree to various stimuli. Corticosteroids afford more complete and sustained symptomatic relief than other bronchodilators, but it has its own adverse effects worse than asthma itself. Assessment of adverse effects of oral corticosteroids in asthmatic patients, will play a vital role in alerting physicians regarding the possibility of such events, thereby helping them to protect the user population from such harm.

METHODOLOGY: The study was conducted at asthma OPD, Rajiv Gandhi Government General Hospital, Chennai, with 300 asthmatic patients on Oral corticosteroids, fulfilling the study criteria and were observed for three months. Their prescriptions &ADR forms were collected and analysed. The causality assessment was done by WHO-UMC assessment scale and severity by using Modified Hartwig-Seigel severity assessment scale.

RESULTS: Prednisolone was the most commonly prescribed oral corticosteroid drug. 18% of patients encountered Adverse Drug Reactions. Epigastric pain (33%) was the most common Adverse Drug Reaction encountered and was more common in elderly females (61-70 years). Most of the ADRs were mild and comes under possible category of WHO causality assessment scale.

CONCLUSION: Our study offers a representative idea of the ADR profile of oral corticosteroids. Oral corticosteroids though taken for limited period, is found to cause adverse effects. Hence it would be better to switch over to inhaled corticosteroids. If unavoidable, they can be used as a rescue therapy for short term (5-7 days).

KEYWORDS : Bronchial Asthma, Adverse Drug Reaction, Oral Corticosteroids (Prednisolone)

INTRODUCTION:

Asthma is a disease of airways that is characterized by increased responsiveness of the trachea bronchial tree to a multiplicity of stimuli. It is manifested physiologically by a wide spread narrowing of the passages, which may be relieved spontaneously as a result of therapy and clinically by paroxysms of dyspnoea, cough and wheezing.(1)

Asthma is one of the most common chronic diseases in the world. It is estimated that around 300 million people in the world currently have asthma.(2) There may be an additional 100 million persons with asthma by 2025.(3) It is estimated that asthma accounts for about 1 in every 250 deaths worldwide. Many of the deaths are preventable, being due to suboptimal long-term medical care and delay in obtaining help during the final attack. (4)

According to National Family Health Survey 2(NFHS-2) report, the estimated prevalence of asthma in India is 2468 per 100,000 persons. Due to increasing population, predicted increase in the prevalence of asthma will result in a marked increase in the number of asthmatics.(5)

Anti-asthmatic drugs commonly prescribed are Beta 2 agonists, Corticosteroids, Methylxanthines, Leukotriene modulators, Mast cell stabilisers and monoclonal IgE antibody according to the severity of Asthma. The drugs are aimed at relieve the acute attacks and maintain remission in the long term. Most commonly used drugs by the patients are Beta 2 agonists, followed by the Corticosteroids.(6)

Adverse Drug Reaction (ADR) is defined by WHO, "As a response which is noxious and unintended and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function."(7)

Drugs can be remarkably beneficial and improve quality of life by reducing symptoms and by producing a sense of well-being. As innovation in medicine continues and new drugs are being developed, there is potential for the occurrence of increasing number of ADRs.(8) Most of the drugs produce some adverse effects and carry the potential for causing injury, even if used properly.

As widely used drugs act by interfering with one or more aspects of molecular and cellular function, all of them have the risk of producing

some reaction which may not be desirable all the times.(9) Hence the goal of pharmacotherapy cannot be to prescribe a risk free regimen, but to ensure that the risks of drug therapy are kept as low as possible. Proper data about the adverse effects of drugs helps physicians to prescribe drugs, balancing the benefits and hazards.

10-15% of all patients receiving medications are affected by ADR. The incidence of serious ADRs is 6.7%. Expenses related to management of ADR accounts for 5 to 9 % of hospital costs. ADRs had been recognised as a major public health issue since they contribute to a sizeable percentage of hospital admissions and also to economic burden to the society.(10)

Corticosteroids afford more complete and sustained symptomatic relief than other bronchodilators in asthma. But with prolonged usage, adverse effects becomes prominent, which limits the use of corticosteroids in chronic disease. Oral corticosteroid drugs are associated with adverse effects which may be worse than asthma itself and therefore affect the compliance and course of treatment. Hence creating awareness about the adverse effects of these drugs and their preventability can foster safe use of these medicines. Assessment of adverse effects of oral corticosteroids in asthmatic patients, will play a vital role in alerting physicians regarding the possibility of such events, thereby helping them to protect the user population from such harm.(11)

In India, only very few reports are available on the ADR profile of oral corticosteroids among asthmatic patients. Hence this study was undertaken to evaluate the ADR profile of oral corticosteroids among the asthmatic patients in a tertiary care hospital.

AIM & OBJECTIVE:

To study the pattern of Adverse Drug Reactions of oral corticosteroids in patients attending Asthma out- patient department at Rajiv Gandhi Government General Hospital, Madras Medical College, Chennai.

METHODOLOGY:

Study Design: Prospective Observational study

Study Population: Adult patients attending Asthma outpatient department taking oral corticosteroids.

Study Centre:

Department of Medicine, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai.

Sample Size: 300

Study Duration: 3 months.

Inclusion Criteria:

- Age between 18-70 years.
- Gender: both male and female
- Asthmatic patients on oral corticosteroids (Prednisolone (1 mg/kg) for 7 - 14 days)
- Patients willing to give informed consent.

Exclusion Criteria:

- Age below 18 and above 70.
- Pregnant and lactating females.
- Patients with acute severe asthma.
- Patients on corticosteroids for other disorders
- Patients on Intravenous steroids
- Patients with any other systemic illness
- Patients not willing to give informed consent

Study Procedure:

After getting approval from the Institutional ethics committee, patients with Bronchial Asthma receiving oral corticosteroids (prednisolone) at out-patient department of Asthma were selected for the study. Patients were explained about the study purpose in their local language. Written informed consent was obtained from those who are willing to participate in the study.

The following parameters were recorded :

- Age
- Gender
- Oral corticosteroids drugs(Prednisolone) prescribed
- Duration of treatment
- Adverse Drug Reaction pattern

-Incidence and Severity

Causality assessment of the ADR was done by establishing the temporal association of drug use with ADR using WHO causality assessment scale. Severity was assessed using Modified Hartwig Siegel severity assessment scale.

RESULTS:

524 prescriptions were screened. 300 prescriptions which fulfilled the inclusion criteria were analysed. The results of our study are as follows

I. Demographic Profile Of The Study Population

I. Age Distribution

Table:1 Age Distribution Of The Patient

AGE GROUP	NUMBER OF PATIENTS	PERCENTAGE
19-30yrs	15	5%
31-40 yrs	36	12%
41-50 yrs	54	18%
51-60 yrs	84	28%
61-70 yrs	111	37%
TOTAL	300	100%

Table 1 shows the age distribution of the patients.

- Most of the patients were in the age group of 61-70 years followed by 51-60 years.
- Incidence was more in older age.

II. Sex Distribution

Table: 2 Sex Distribution

SEX	NUMBER OF PATIENTS	PERCENTAGE
MALE	102	34%
FEMALE	198	66%
TOTAL	300	100%

Table 2 Represents The Sex Distribution Of The Patients.

- 34% were Males
- Females constituted 66%
- Female to Male ratio was 1.9:1
- Age and sex distribution correlates with the epidemiology of Bronchial Asthma.

III. Adverse Drug Reactions Encountered

Table: 3. Percentage Of Patients With ADRs

ADR	NUMBER OF PATIENTS	PERCENTAGE
PATIENTS WITH ADRs	54	18%
PATIENTS WITHOUT ADRs	256	82%
TOTAL	300	100%

Table 4 Represents Percentage Of Patients With ADRs

- 18 % Of Patients Encountered ADRs

IV. Adverse Drug Reaction Pattern Of Corticosteroids

Table. 4 Shows The Adverse Drug Pattern Of Corticosteroids

ADVERSE EFFECTS	NO.OF PATIENTS	PERCENTAGE
MOUTH ULCERS	14	26%
EPIGASTRIC PAIN	18	33%
MYALGIA	6	11%
VOMITING	10	19%
MOOD CHANGES	6	11%
TOTAL	54	100%

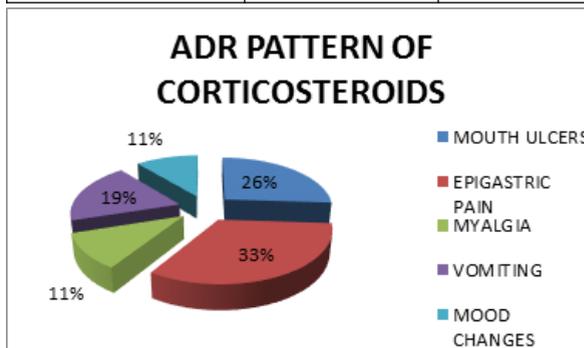


Fig. 4 Shows The Adverse Drug Reactions Of Corticosteroids

- Epigastric pain (33%) was the most common ADR in the Corticosteroid group, followed by mouth ulcers (26%), vomiting (19%), myalgia (11%), mood changes(11%)

V. Severity Assessment

Table 5: Severity Assessment Of Adverse Drug Reactions By Modified Hartwig Siegel Severity Assessment Scale.

ASSESSMENT CATEGORY	NO.OF PATIENTS	PERCENTAGE
MILD	51	95%
MODERATE	3	5%
SEVERE	0	0
TOTAL	54	100%

Adverse Drug Reactions were categorised as

- 95% - Mild
- 5% - Moderate
- Most of them are mild, manageable as per protocol

VI. Causality Assessment:

Table 6: Causality Assessment Of Adverse Drug Reactions Using WHO Causality Assessment Scale

ASSESSMENT CATEGORY	NO.OF PATIENTS	PERCENTAGE
CERTAIN	3	5%
PROBABLE	17	32%
POSSIBLE	34	63%
TOTAL	54	100%

Table 6 represents causality assessment of Adverse Drug Reaction

- 32% - Probable
- 63% - Possible
- 5%- Certain

DISCUSSION:

Bronchial Asthma is one of the worldwide health problem associated with increased morbidity and mortality. As a result of high prevalence, onset at an earlier age and chronic persistence, they contribute substantially to the burden of illness worldwide.

In our study, 300 patients were evaluated for Adverse Drug Reactions of oral corticosteroids. Most of the patients were in the age group of 61-70 years. Males constituted 34% and females 66%.

Oral Prednisolone (1 mg/kg) was the most commonly prescribed corticosteroid drug. Oral Prednisolone was given as single morning dose. Among 300 patients who were on oral corticosteroids, 54 patients developed at least one Adverse Drug Reaction (18%). Adverse Drug Reactions were more common in elder females (61-70 years). Epigastric pain (33%) was the most common Adverse Drug Reaction encountered.

About 63% of ADR comes under possible category of WHO causality assessment scale. Most of the ADRs were mild (95%). The Adverse Drug Reaction pattern reported in our study correlates with the results of studies conducted by Waljee et al(12), Manson et al(13), Sullivan et al(14).

Our study offers a representative idea of the ADR profile of oral corticosteroids. Constant vigil in detecting ADRs and subsequent dose adjustments can make therapy with oral corticosteroids safer and more effective. This, in turn, will improve the compliance among patients. Oral corticosteroids though taken for limited period, is found to cause adverse effects. Hence it would be better to switch over to safer inhaled corticosteroids. If unavoidable, they can be used as a rescue therapy for short term (5-7 days).

CONCLUSION:

- Oral Prednisolone was the most commonly prescribed oral corticosteroid drug.
- 18% of patients were encountered Adverse Drug Reactions.
- Adverse Drug Reactions were more common in elderly females.
- Epigastric pain was the most common Adverse Drug Reaction encountered.
- Most of ADRs were mild and comes under possible category of WHO causality assessment scale.

DECLARATIONS:

- *Funding: None*
- *Conflict of interest: None*
- *Ethical approval: Approved*

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