A STUDY ON DRUG UTILIZATION PATTERN, EFFICIENCY OF CORTICOSTEROIDS AND COMBINATION THERAPY OF CORTICOSTEROIDS IN THE MEDICINE DEPARTMENT

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Abstract:

Background: Corticosteroids are an artificial class of drugs that control inflammatory processes and dampens the activity of the immune system. The use of inhaled corticosteroid therapy, also known ICS, in combination with long-acting beta-adrenergic agonists enhances the effectiveness of treatment. The goal of this research is to study the drug utilization pattern of corticosteroids and combination therapy of corticosteroids and observe the efficiency of corticosteroids.

Objective: To study the utilization pattern, efficiency of corticosteroids and combination therapy of corticosteroids in medicine department.

Methods: This study is a prospective observational study and conducted in department of medicine at Government Cuddalore Medical College and Hospital (RMMCH), Chidambaram-608002. Study proforma (Data collection form) was designed and the study was carried out among the inpatients who were prescribed with corticosteroids under the department of medicine.

Results: Among the 270 patients analyzed, Duolin/Budecort was the most commonly prescribed medication (40%), particularly for respiratory conditions such as pneumonia (53%), tuberculosis (52%), acute bronchitis (63%), and pleural effusion (67%). Hydrocortisone was primarily used in cases of COPD (41%), bronchial asthma (43%), and anaphylactic shock (62%). Drug interactions were observed in 31% of patients. Among those receiving corticosteroids or combination inhalation therapies, the most common complications included diabetes mellitus (63%), recurrent tuberculosis (16%), hypotension (12%), and hypertension (9%). Clinical outcomes indicated that 31% of patients were cured, 67% showed symptomatic improvement, 1.5% remained unchanged, and 0.5% fell into other outcome categories.

Conclusion: The study highlights a high prevalence of corticosteroid and inhalation therapy use, particularly Duolin/Budecort and Hydrocortisone, in the management of various respiratory conditions. While these treatments were associated with favorable clinical outcomes in the majority of cases, a significant proportion of patients experienced drug interactions and corticosteroid-related complications, notably diabetes mellitus and recurrent tuberculosis. In order to maximize treatment efficacy and minimize side effects, these data highlight the significance of prudent prescribing and careful monitoring.

Keywords: Corticosteroids, combination therapy, Budecort, Hydrocortisone.

1. Introduction:

Corticosteroids are synthesized medicines that the adrenal glands excretes. Because of their strong immune system and inflammation suppression abilities, these potent anti-inflammatory medicines are used for treating different conditions. Main steroids from the adrenal cortex includes glucocorticoids such as cortisol and mineralocorticoids like

aldosterone. Aldosterone affects both water and sodium levels while cortisol prevents release of inflammation mediators associated with grievous bodily damage serves to help heal injuries to some degree.. Corticosteroids enhance ionic balance, Relief from specific chemical release aid in diminishing protective sapper forces put in place during great bodily harm - helps with recovery processes.corticosteroids suppress immune activity or use needlessly aggressive defenses(1). There are three classes under corticosteroids; Short acting-hydrocortisone,

Intermediate acting-prednisolone and methyl prednisolone, Long acting-dexamethasone, betamethasone(2). Aside from asthma, other conditions such as chronic obstructive pulmonary disease, pulmonary fibrosis ,pneumothorax ,meningoencephalitis ,poisoning ,anaphylactic shock, pneumonia, stings, acute pulmonary edema andacute gastroenteritis also require these medications.

Complications of corticosteroid includes osteoporosis, upper gastrointestinal bleeding, hyperglycaemia, hypertension, heart diseases.

The major objective is to study the drug utilization pattern of corticosteroids and combination therapy of corticosteroids in the medicine department. Efficacy of corticosteroids and combination therapy was determined by the following symptoms such as breathlessness, cough with expectoration, cough without expectation, inflammation and others and by the use of descriptive statistical analysis and chi-square test.

2. Materials and method:

The six-month prospective observational study contradicts from November 2023 until April 2024.Using inclusion and exclusion criteria, subjects are chosen. Prior to start the study, informed consent form from patient was obtained.

Study Proforma (Data collection form) is designed to collect all the details like Inpatients number, name, age, chief complaints, history of present illness, patient past medical and medication history, drug chart details, prescribed dosage, frequency, Route of administration and clinical diagnosis.

The current study was conducted on patients who were prescribed corticosteroids by the Government Cuddalore Medical College and Hospital's [RMMCH] medical department.

The Chi-square test and appropriate descriptive statistical methods were used to analyse the collected data. The treatment's final outcome will be documented and calculated. The data gathered was recorded using Microsoft excel and analyse during relevant statistical tool to provide significant results.

2.1. Inclusion criteria:

Inpatients above 18 years of age and either gender admitted in the general medicine department and Intensive Care Unit prescribed with any type of corticosteroids.

2.2 Exclusion criteria:

1. Pregnant and lactating women
2. Patient who are not willing to participate in the study.

2.3. Sample size: 270

3. Observation and results:

In our study, individuals aged 56-65 accounted for 28.90% of the total. The predominant demographic of patients was male, accounting for 63% of the overall population. The majority of patients, 67.80%, reported no prior history of alcohol, tobacco, or smoking. 21.90% of patients were smokers, and the same percentage reported alcohol consumption. A very small group, 1.50%, had a history of tobacco use.

The most common diagnosis among patients was Lower Respiratory Tract Infections (LRTI) (25%), followed by Chronic Obstructive Pulmonary Disease (COPD) (15%) and Bronchial Asthma (8%), among other conditions. Our study shows that maximum number of patients (193 patients) received Duolin/ Budecort (40%).

The most frequently treated condition was Lower Respiratory Tract Infection (LRTI), with high usage of Duolin/Budecort (45 cases), Budecort (33), and Hydrocortisone (36). This was followed by COPD, treated with Duolin/Budecort (33), Hydrocortisone (35), and Budecort (13). Other commonly managed conditions included Bronchial Asthma, Acute Pulmonary Edema, Tuberculosis, and Aspiration Pneumonitis, all showing frequent administration of these drugs. Duolin/Budecort was the most commonly utilized drug overall.

In our study, 138 patients received 100 mg of hydrocortisone, while 27 received 200 mg. Prednisolone was used at 10 mg and 40 mg for 2 patients each. Methylprednisolone was administered at 500 mg (5 patients), 40 mg (2 patients), 1 g (2 patients), and 2 g (4 patients). Dexamethasone was given at 4 mg (1 patient), 6 mg (2 patients), 8 mg (10 patients), and 2 cc (5 patients). Duolin/Budecort was used in 190 cases with doses of 500 mcg + 1.25 mg / 2.5 ml / 0.5 mg / 2 ml. Ipravent/Budecort was given to 93 patients at 500 mcg / 0.5 ml / 2 ml. Budesonide was used for 2 patients at 0.5 mg / 2 ml.

The study shows that 248 patients were administered through nasal route (60%), 3 patients were administered through oral route (1%) and 162 patients were administered through intravenous route (39%).

Corticosteroids were administered for the symptoms includes breathlessness, cough with expectoration, cough without expectoration, inflammation and others (itching). From our study the significant majority of the patients presented with symptoms of breathlessness (48%). After initiation of Corticosteroids therapy, a progressive decline in symptoms intensity were recorded in our study. Over the course of seven days, a notable shift was seen from severe and moderate cases to mild or resolved conditions. Descriptive statistics demonstrated a notable reduction in mean severity scores, with most patients transitioning from severe symptoms to a cured state. Chi-square analysis confirmed that these changes were statistically significant ($p < 0.001$)

Among 270 patients, 83 individuals (31%) encountered drug interactions concurrent with the administration of corticosteroids. Majority of patients (63%) developed diabetes mellitus following corticosteroid administration.

According to our study findings, COPD symptoms were relieved within 3-7 days, LRTI within 3-8 days, BA within 3-4 days, pneumothorax within 5-10 days, meningoencephalitis within 5-10 days, poisoning within 3-7 days, stings within 3 days, APE within3-5 days, hanging within 3-7 days, AB 3-5 days, hepatitis within 3-6 days, pulmonary TB within 3-10 days, LLC within 3-10 days, lung abscess within 3 days, anaphylactic shock within 3-5 days, pneumonia within 3-10 days, ILD within 6-7 days, septic shock within 3-5 days, pleural effusion within 3-7 days, pulmonary fibrosis within 8 days and aspiration pneumonitis within 4-7 days.

Clinical outcomes indicated that majority of patients(67%) got relieved following administration of corticosteroids.

Table 01. patient demographic details

Parameters	No of patients	percentage
1.1 Age wise distribution of patients		
18-25	17	6.30%
26-35	21	7.80%
36-45	30	11.10%
46-55	48	17.80%
56-65	78	28.90%
66-75	56	20.70%
76-85	20	7.40%
1.2 Gender wise distribution		
Male	170	63%
Female	100	37%
1.3 Personal history of patients		
Tobacco	4	1.50%
Smoker	59	21.90%
Alcohol	59	21.90%
None	183	67.80%

Table 02. vitals of the patients

S.no	Vitals	No of patients							
		Before treatment	After treatment						
			Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	**Blood pressure**								
	Low BP	80	125	126	123	73	43	20	14
	Normal BP	146	44	60	85	39	36	19	13
	High BP	44	101	83	60	32	22	11	4
2	**Pulse rate**								
	Low BP	10	2	0	0	5	4	0	0
	Normal BP	220	195	233	240	125	86	37	28
	High BP	40	73	36	27	13	9	12	5
3	**Respiratory rate**								
	Low BP	0	0	0	0	0	0	0	0
	Normal BP	250	208	231	240	124	88	42	31
	High BP	20	49	24	14	10	9	8	2
4	**Spo2**								
	Low BP	25	64	25	15	11	10	6	4
	Normal BP	245	204	242	251	131	90	43	29

	High BP	0	0	0	0	0	0	0	0
5	**CBG**								
	Low BP	0	0	1	1	1	0	0	0
	Normal BP	134	33	36	41	21	25	8	9
	High BP	19	122	117	106	59	37	22	11

DRUG UTILIZATION PATTERN:

Conditions of the patients

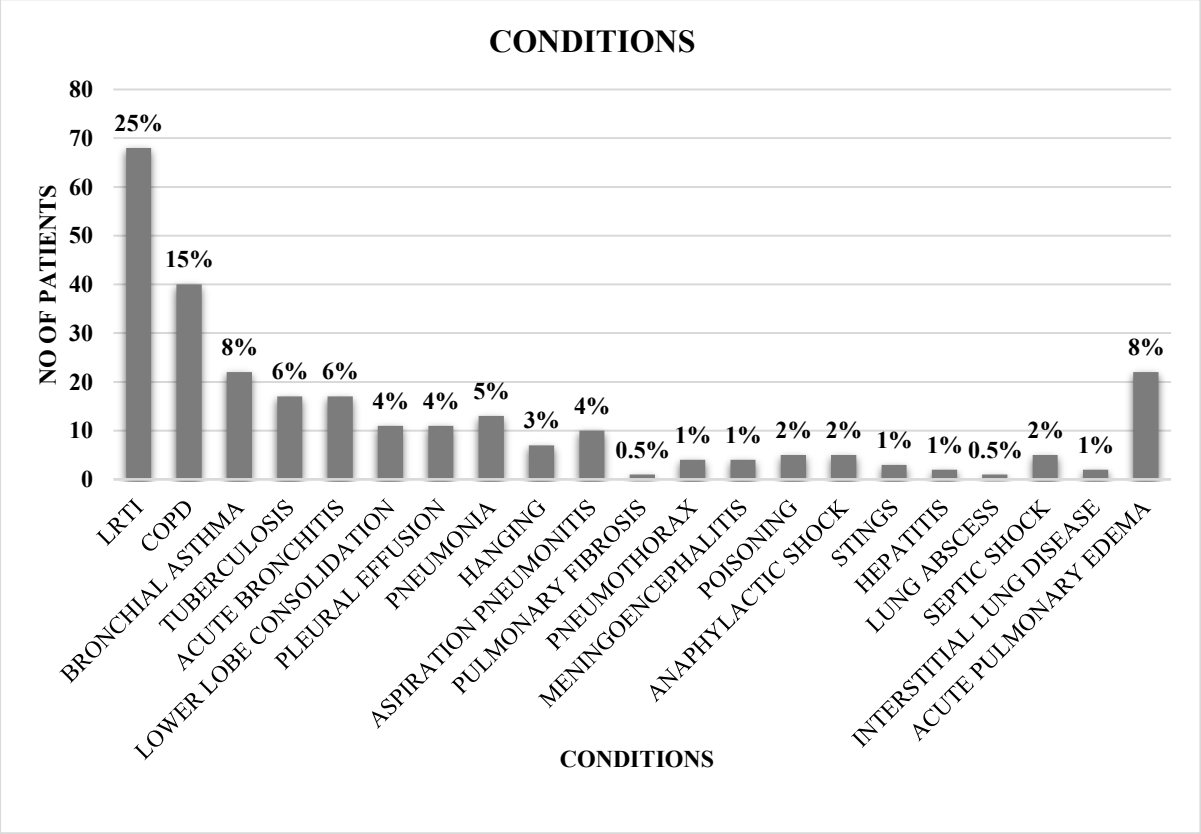

Figure 01: Demographic data on conditions

Table 03: Type of drugs prescribed to each patient

S.No	Drugs	No of patients	Percentage
1	Prednisolone	3	1%
2	Hydrocortisone	154	32%
3	Dexamethasone	18	3%
4	Methylprednisolone	9	2%
5	Duolin / Budecort	193	40%
6	Ipravent / Budecort	95	20%
7	Budesonide	2	1%
8	Foracort	3	1%

Table 04: Assessment of corticosteroids usage across medical

CONDITIONS	DRUGS						
	Prednisolone	Hydro	Duolin/ Budecort	Ipravent/ Budecort	Methyl prednisolone	dexa	Foracort
LRTI	1	36	45	33	1	1	1
COPD	1	35	33	13	1	1	1
Bronchial asthma	0	19	15	9	0	0	1
Tuberculosis	0	6	13	6	0	0	0
Acute bronchitis	0	5	14	3	0	0	0
Lower lobe consolidation	0	4	10	1	0	0	0
Pleural effusion	0	2	8	2	0	0	0
Pneumonia	0	5	10	2	0	2	0
Hanging	0	3	3	1	7	1	0
Aspiration pneumonitis	0	6	7	5	0	1	0
Pulmonary fibrosis	0	1	1	0	0	0	0
Pneumothorax	0	2	3	4	0	0	0
Meningoencephalitis	0	1	2	0	0	4	0
Poisoning	0	4	3	1	0	1	0
Acute pulmonary edema	0	13	17	11	0	0	0
Anaphylactic shock	0	5	1	0	0	2	0
stings	0	2	0	0	0	2	0
Hepatitis	0	1	0	0	0	1	0
Lung abscess	0	0	1	0	0	0	0
Septic shock	0	1	2	2	0	2	0
Interstitial lung disease	1	1	1	0	0	0	0

EFFICACY MONITORING:

Table 05: Efficacy monitoring based on symptoms reduction

Symptoms	Breathlessness		Cough with expectoration		Cough without expectoration		Inflammation		Others	
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
Severe	205	0	175	0	3	0	35	0	6	0
Moderate	15	0	11	0	0	0	4	0	2	0
Mild	0	19	0	13	0	2	0	0	0	0
Cured	0	201	0	162	0	1	0	39	0	8

INTERVENTIONS:

Table 06: Drug Interactions of each patient

S.No	Drug interactions	No of patients	Percentage
1	Yes	83	31.00%
2	No	187	69.00%

Table 07: Complications of each patient

3	Hypertension	4	9%
4	Diabetes Mellitus	27	63%
5	Recurrent TB	7	16%

6	Hypotension	5	12%

Table 08: Treatment outcome of the patients

7	Cured	83	31%
8	Relieved	182	67%
9	Unchanged	4	1.5%%
10	Worse	0	0%
11	Others	1	0.5%
12	Expired	0	0%

DISCUSSION:

In our study 270 patients were enrolled in the study from the department of medicine. Male patients were 63% and 37% were females. The higher number of male patients visits hospital could explain the larger proportion of male patients in this study. A majority of the population (28.90%) was in the 56–65 years age group. Our study found that 21.90% of the patients consumed alcohol and an equal proportion were smokers. These factors are recognized risk contributors, particularly among individuals with respiratory conditions, and may be associated with the increased use of corticosteroids. However, in their study on drug utilization evaluation of corticosteroids, Vishwanath Gouda et al. identified a higher number of male patients than female patients, with the majority of these patients being elderly. (3)

Throughout our study, we came across multiple reports highlighting corticosteroid administration in cases of asthma, chronic obstructive pulmonary disease, pulmonary fibrosis, pneumothorax, meningoencephalitis, poisoning, anaphylactic shock, pneumonia, stings, acute pulmonary oedema. Among these, several diseases were discussed by Janahi IA et al., (4)

Our study found that most commonly used drugs for the following diseases and conditions include Hydrocortisone(41%) for COPD, Duolin / Budecort (38%) for LRTI , Hydrocortisone (43%) for BA, Hydrocortisone (62%) for Anaphylactic shock, Duolin / Budecort (53%) for Pneumonia, Duolin / Budecort (37%) for Aspiration pneumonitis, Duolin / Budecort (41%) for Acute pulmonary edema, Methylprednisolone (46%) for hanging, Duolin / Budecort (52%) for TB, Duolin / Budecort (63%) for Acute bronchitis, Duolin / Budecort (67%) for Pleural effusion, Ipravent / Budecort (45%) for Pneumothorax, Hydrocortisone (45%) for Poisoning, Dexamethasone (57%) foe meningoencephalitis, Duolin / Budecort (67%) for lower lobe consolidation, Duolin / Budecort (50%) and Hydrocortisone (50%) for pulmonary fibrosis, Ipravent / Budecort (29%) and Dexamethasone (29%) for septic shock, Duolin / Budecort (50%) and Hydrocortisone (50%) for pulmonary fibrosis, Dexamethasone (50%) and Hydrocortisone (50%) for stings, Prednisolone (34%) for interstial lung disease, Dexamethasone (50%) and Hydrocortisone (50%) for hepatitis, Duolin / Budecort (100%) for lung abscess. The study shows that 248 patients were administered through nasal route (60%), 3 patients were administered through oral route (1%) and 162 patients were administered through intravenous route (39%). However, Vishwanath Gouda et al., study stated that nine different Corticosteroidal drugs were utilized, such as Budesonide, Hydrocortisone, Prednisolone, Dexamethasone, Betamethasone, Methylprednisolone, Fluticasone, Deflazacort, Beclomethasone with Budesonide being the most frequently prescribed. The inhalation route emerged as the most commonly preferred method of administration across these medications.(30)

In this study, Hydrocortisone (100mg & 200mg), Prednisolone (10mg & 40mg), Methylprednisolone (500mg, 40mg, 1g & 2g), Dexamethasone (4mg, 6mg, 8mg & 2cc), Duolin / Budecort [(500mcg+1.25mg / 2.5ml) / (0.5mg / 2ml)], Ipravent / Budecort [500mcg / (0.5m / 2ml)] and Budesonide (0.5mg / 2ml) were given.

In our study, corticosteroids were administered to manage symptoms such as breathlessness, cough with expectoration, cough without expectoration, inflammation, and other complaints including itching. In the research conducted by Alastair D. Hay et al., the documented symptoms encompassed of dysphnea, wheezing, thoracic discomfort, irregular peak expiratory flow and productive cough.(5)

In our study, out of 270 patients, 83 (31%) were found to have drug interactions with corticosteroids. Similarly, Mani Pandey et al. reported that corticosteroids accounted for approximately 31.9% of the documented drug–drug interactions in their study, supporting the high prevalence observed in our findings. (6)

In our study ,the complications experienced in patients acquiring corticosteroids and combination therapy were DM (63%), hypertension (9%), recurrent TB (16%) and hypotension (12%).However, Darrell Hulisz et al,Seo Yun Kim et al,Jia-Xu Li et al,Jick SS et al stated in their article that Glucocorticoid therapy has been linked to metabolic complications, including steroid-induced diabetes mellitus (14.7% in one study), particularly in older adults. Long-term use can impair insulin function and Prolonged use may compromise insulin efficacy and elevate the likelihood of developing type 2 diabetes. Additionally, it increases the risk of TB, warranting latent TB screening before treatment. Additionally, fludrocortisone use in elderly patients has been associated with drug-induced hypertension. (7, 8, 9, 10)

According to our study findings, COPD symptoms were relieved within 3-7 days, LRTI within 3-8 days, BA within 3-4 days, pneumothorax within 5-10 days, meningoencephalitis within 5-10 days, poisoning within 3-7 days, stings within 3 days, APE within3-5 days, hanging within 3-7 days, AB 3-5 days, hepatitis within 3-6 days, pulmonary TB within 3-10 days, LLC within 3-10 days, lung abscess within 3 days, anaphylactic shock within 3-5 days, pneumonia within 3-10 days, ILD within 6-7 days, septic shock within 3-5 days, pleural effusion within 3-7 days, pulmonary fibrosis within 8 days and aspiration pneumonitis within 4-7 days.

However, Walters et al. asserted that a five-day course of systemic corticosteroids is likely as effective as a 10–14 day regimen for therapy.(11)

Out of 270 patients 83 (31%) were cured, 182 (67%) were relieved, 4 (1.5%) were unchanged and others 1 (0.5%).

Descriptive measures and the Chi-square test of treatment effectiveness:

All the symptoms show very high Chi-square values and extremely low p-values (< 0.001) and indicates that the improvement after treatment is statistically significant. The mean symptom score dropped drastically showing strong effectiveness of corticosteroids.

Table 09: Descriptive statistical analysis and Chi-square test

Parameters	Breathlessness		Cough with expectoration		Cough without expectoration		Inflammation		Others	
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
Mean	3.07	0.09	3.06	0.07	3.00	0.67	2.90	0.00	2.75	0.00
Median	3	0	3	0	3	1	3	0	3	0
Mode	3	0	3	0	3	1	3	0	3	0
Standard deviation	~0.26	~0.39	~0.27	~0.38	0	~0.47	~0.33	0	~0.46	0
Chi-square	≈ 412.35		≈350.6		≈6.0		≈70.4		≈14.2	
P-value	<0.001		<0.001		~0.05		<0.001		<0.01	

BT: Before treatment AT: After treatment

CONCLUSION:

The drug utilization pattern consists of Hydrocortisone (32%), prednisolone (1%), dexamethasone (3%), methylprednisolone (2%), Duolin / Budecort (40%), Ipravent / Budecort (20%), budesonide (1%) and foracort (1%). Hence combination therapy of duolin / budecort were utilized the most. Foracort (formoterol fumerate / budesonide) was prescribed after the patient discharged for the prophylaxis treatment. Most of the drugs were prescribed nasal and IV route. Among 270 patients, Majority of patients (63%) developed diabetes mellitus following corticosteroid administration. From the study we can see the absolute improvement from the severity of symptoms like breathlessness, cough with expectoration, cough without expectoration, inflammation and others (itching) after the corticosteroid treatment. Chi-square analysis revealed statistically significant shifts in symptom severity distributions before and after treatment. Most symptoms demonstrated p-values less than 0.001, confirming that the observed improvements were highly significant and not attributable to random variation. Combination therapy was found to be more efficient. Most of the patients relieved within 5 to 10 days after corticosteroid therapy based on the severity of the symptoms. Corticosteroids were found to interact with the following drugs such as Furosemide, Insulin, Phenytoin, Ciprofloxacin and Heparin. Following corticosteroids administration, a significant proportion of patients exhibited relief of symptoms.

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