"AN EVALUATION OF INTRAVENOUS TO ORAL CONVERSION OF STEROIDS USED IN PULMONARY WARD IN A TERTIARY CARE HOSPITAL"

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ABSTRACT

Adrenal glands produce essential hormones like cortisol and aldosterone, which are synthesized into corticosteroids to reduce inflammation. Various steroids, including prednisolone (tablets), beclomethasone and fluticasone (inhalers/nasal sprays), methylprednisolone (injection), and hydrocortisone (creams), are widely used to treat conditions such as asthma, COPD, and bronchiectasis. However, these steroids can also suppress the immune system. This study aims to compare the conversion of intravenous (IV) and oral steroids in 100 patients with asthma, COPD, and bronchiectasis using a paired t-test. Methylprednisolone was commonly administered orally, while hydrocortisone was given intravenously. All patients received budesonide. Approximately 7% of the patients experienced insomnia and 5% reported appetite disruption. The average duration of IV treatment was 3.72 days for methylprednisolone and 3.66 days for hydrocortisone. The results indicated a p-value of less than 0.05 in all tables, leading us to reject the null hypothesis. Therefore, we conclude that there is a significant difference between the two groups.

KEYWORDS: Alpha-1 antitrypsin deficiency (AAT), Chronic obstructive pulmonary disease (COPD), HIV (Human Immunodeficiency Virus), High resolution computed

tomography (HRCT), inflammatory bowel disease (IBD), ICS (Inhaled Corticosteroids), IPF (Idiopathic Pulmonary Fibrosis), MPS (Methylprednisolone), Multiple Sclerosis (Ms), PEF (Peak expiratory flow rate), pulmonary tuberculosis (PTB), RA (Rheumatoid arthritis), ROA (Route of Administration), SOB (Shortness of Breath), SLE (Systemic Lupus Erythematosus), and TB (Tuberculosis).

INTRODUCTION

The hormones that are typically produced by the two tiny glands called the adrenal glands, which are located above the kidneys, are artificially synthesised as steroids.[1] Steroids are made to function similarly to these hormones in order to lower inflammation. Corticosteroids, another name for steroids, are anti-inflammatory drugs that are prescribed for a variety of ailments.

The primary glucocorticoid in humans is cortisol, often known as hydrocortisone, while the primary mineralocorticoid is aldosterone.[2]

Steroids come in many different forms.[3]

1]. Tablets, syrups and liquids – such as prednisolone

2]. Inhalers – such as Beclomethasone and fluticasone

3]. Nasal sprays – such as Beclomethasone and fluticasone

4]. Injections (given into joints, muscles or blood vessels) – such as methylprednisolone

5]. Creams, lotions and gels – such as hydrocortisone skin cream

Growth, development, sexual differentiation, and reproduction all depend on steroids. The body's natural protection against disease and infection, the immune system, is likewise less active when steroids are used.[4]

Various Diseases of Respiratory Ward

Asthma

A chronic inflammatory illness of the airways is what is known as asthma.[5,6] The chronic inflammation is linked to airway hyperresponsiveness, which causes recurring symptoms including coughing, dyspnea (shortness of breath), wheezing, and chest tightness in response to triggers like exercise and allergens.[7,8] Generally speaking, periods of symptoms are linked to a diffuse, albeit variable, blockage of airflow in the lungs, which is typically reversible either on its own or with the right asthma medication.[9]

Chronic Obstructive Pulmonary Disease

Limitation of lung airflow is a characteristic of chronic obstructive lung disease, which can result from exposure to toxic chemicals.[10] It is a prevalent cause of death globally.[11] It needs to be identified and treated right away to prevent the significant morbidity and death that come with it.[12] The assessment and management of chronic obstructive pulmonary disease are described in this exercise, which also emphasises the importance of the interprofessional team in diagnosing and treating individuals with this illness.[13]

Bronchiectasis

Because of recurrent infections that lead to bacterial invasion and mucus pooling throughout the bronchial tree, bronchiectasis is a chronic lung illness characterised by continuous and lifelong enlargement of the bronchial airways and loss of the function mucociliary transport mechanism.[14] This exercise goes over how to diagnose and treat bronchiectasis as well as how the interprofessional team can help individuals with this ailment receive better care.[15]

Drugsused in respiratory medicine ward

Methylprednisolone

Methylprednisolone, often known as Depo-Medrol, Medrol, or Solu-Medrol, is a synthetic glucocorticoid that is mostly administered for its immunosuppressive and anti-inflammatory properties. It is either used concurrently at high doses during acute flare-ups or at low doses for chronic conditions. It is possible to provide methylprednisolone and its derivatives parenterally or orally.[16]

Hydrocortisone

When used as a medicine, the hormone cortisol is known as hydrocortisone.[17] Adrenogenital syndrome, excessive blood calcium, thyroiditis, rheumatoid arthritis, dermatitis, asthma, and COPD are among the disorders for which it is used.[18] For adrenocortical insufficiency, it is the recommended course of treatment.[19] It can be administered intravenously, topically, or orally. After long-term use, medication should be stopped gradually.[20]

Prednisolone

One corticosteroid, prednisolone, is a steroid hormone that is used to treat cancer, autoimmune diseases, inflammation, and some forms of allergies.[21] Adrenocortical insufficiency, excessive blood calcium, dermatitis, rheumatoid arthritis, inflammation of the eyes, asthma, and multiple sclerosis are a few of these ailments. It can be applied topically as

a skin cream, injected into a vein, consumed orally, or utilised as ocular drops.[22] Three primary forms of IV to PO conversions exist.[23]

Sequential therapy

It describes the process of switching out a parenteral drug for its oral equivalent of the same molecule. As an example, the conversion of inj. 40 mg of methylprednisolone OD (one daily) in a tablet. 16 mg of methylprednisolone OD

Switch therapy

It explains the process of changing an IV drug into a PO equivalent that is of a different chemical but is still in the same class and potency. For instance, move away from inj. 40 mg of methylprednisolone OD (once daily) in a tab. 10 mg of OD prednisolone once daily.

Step down therapy

It is the process of changing an injectable drug to an oral drug in a different class or to a different drug within the same class, where there may be differences in frequency, dosage, and, in the case of antibiotics, the spectrum of activity. For instance, changing injectable hydrocortisone 100 mg OD (once daily) to a tabular form of 16 mg OD of methylprednisolone (once daily).

MATERIALS AND METHODS

SETTING: Tertiary care hospital

STUDY SITE: Respiratory Medicine Ward

STUDY DESIGN: Cross- sectional study

SAMPLE SIZE: 100 Patients

STUDY PARTICIPANTS: Aishwarya Joshi, Ishika Soni, JaswantSingh Shaktawat, Jeshurun Mathew James.

STUDY DURATION: 6 months

SAMPLING PROCEDURE

1. Inclusion Criteria

Patients recommended to take steroids.

Patients with case of COPD.

Patients with case of BRONCHIAL ASTHMA

Patients with case of BRONCHIECTASIS.

2. Exclusion Criteria

Those who are not willing to participate in the study.

Those patients who are allergic to steroids.

Patients with active PTB.

Patients on immunosuppressants other than steroids.

METHODOLOGY

This study would be done at Department of Respiratory medicine, Ananta Institute of medical sciences & Research centre, Rajsamand. Cross-sectional studies use statistical data including calculation of sample sizes. In order to have 95% power of the test we need 100 sample in each group.

List of variables Measurement plan	List of variables Measurement plan
Use of steroids in different studies. Duration and side effects. Conversion of IV to ORAL therapy.	To be calculated by doing cross sectional study.

Anticipated Biases in the study	Plan to address the anticipated biases
Selection bias	To select patients randomly

Analysis plan

The study is based on conversion of IV to oral steroids. The data of 100 patient should be collected. Collected data is completely based on three different diseases, particularly ASTHMA, COPD, BRONCHIECTASIS. Paired t.test will be used to calculate difference between IV and ORAL conversion and P value will be determined and checked level of significance at 95% C.I. The descriptive statistics have been described using frequencies and percentage.

Implication of Study

This study will contribute in having better assessment tools for the summative assessment of PHARM. D students.

RESULTS

Table No. 1: Patient receiving IV drug as a treating therapy in different diseases.

		COPD (40)	BRONCHIAL ASTHMA (30)	BRONCHIECTASIS (30)
IV	**HYDROCORT**	27	20	19
	METHYLPREDNISOLONE	11	10	9
	PREDNISOLONE	0	0	0

Figure No. 1: Patient receiving IV drug as a treating therapy in different diseases.

FIGURE 1; The above bar diagram is representing about the patient receiving iv steroid drug as treating therapy in different diseases like Bronchial Asthma, COPD, Bronchiectasis. We have included total no. of 100 patients among which 96 patients were prescribed iv steroid drug as treating therapy. Doctors have mainly prescribed 3 types of iv steroid drugs Hydrocort, Methylprednisolone, Prednisolone to the patients. The drugs Hydrocort was prescribed to 66 patients, methylprednisolone to 30 patients and no patients were on prednisolone iv therapy in different diseases.

Table No. 2: Patient receiving oral drug as a treating therapy in different diseases.

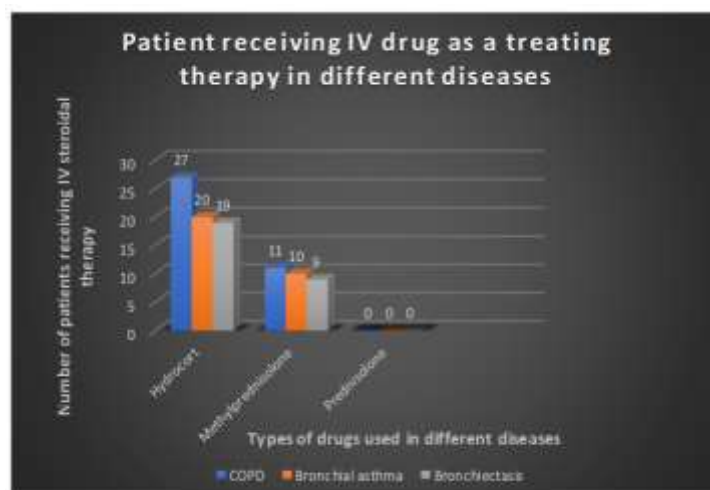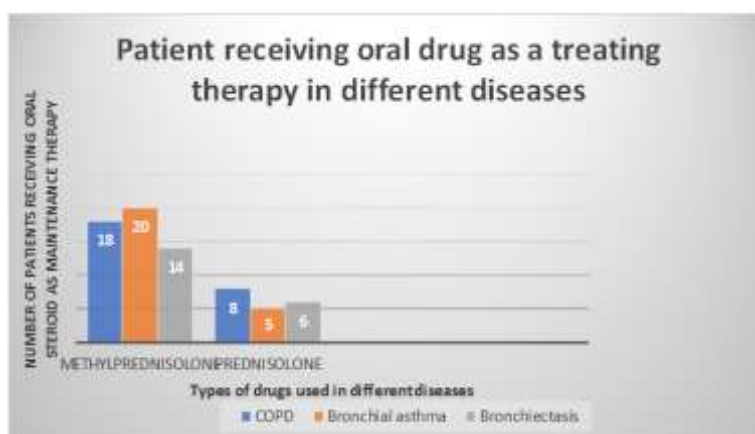|		COPD (40)	BRONCHIAL ASTHMA (30)	BRONCHIECTASIS (30)
ORAL	**METHYLPREDNISOLONE**	18	20	14
	PREDNISOLONE	8	5	6

Figure No. 2: Patient receiving oral drug as a treating therapy in different diseases.

FIGURE 2; The above bar diagram is representing about the patient receiving oral steroid drug as maintenance therapy in different diseases like Bronchial Asthma, COPD, Bronchiectasis. We have included total no. of 100 patients among which 71 patients were prescribed oral steroid drug as maintenance therapy. Doctors have mainly prescribed 2 types of oral steroid drugs Methylprednisolone, prednisolone to the patients. Methylprednisolone was prescribed to 52 patients and 19 patients were on prednisolone oral therapy in different diseases.

Table No. 3: Patients who were receiving nebulisation with Budesonide.

		COPD (40)	BRONCHIAL ASTHMA (30)	BRONCHIECTASIS (30)
Neb.	BUDECORT	40	30	30
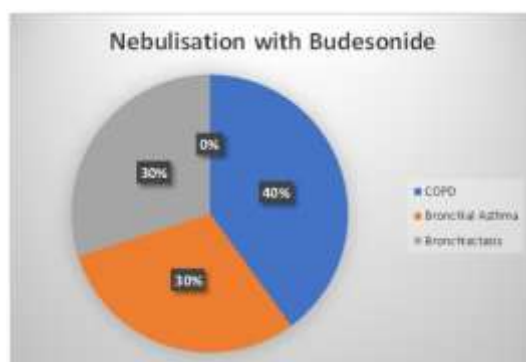
Figure No. 3: Patients who were receiving nebulisation with Budesonide.

FIGURE 3; The above Pie Chart is representing us the percentage criteria of patients receiving budesonide drug in nebulisation. 40 % of COPD, 30% of Bronchial asthma patients and 30% of bronchiectasis patients were prescribed budesonide drug in nebulisation form. So we can say that all the patients who were included in our study were taking steroid also in nebulisation form.

Table No. 4: Gender wise classification of diseases.

NO. OF PATIENTS	DIAGNOSIS		
	COPD (40)	BRONCHIAL ASTHMA (30)	BRONCHIECTASIS (30)
NO. OF FEMALE PATIENTS	6	20	4
NO. OF MALE PATIENTS	34	10	26

Figure No. 4: Bar graph showing genderwise classification of diseases.
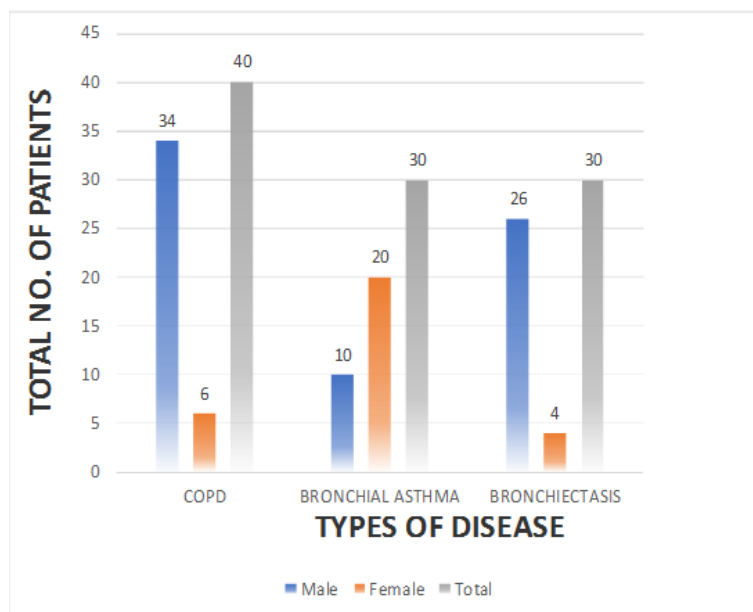
We have taken total no. of 40 COPD patients among which 34 were male and 6 female patients, 30 Bronchial Asthma patients among which 10 were male and 20 were female patients and 30 patients of Bronchiectasis among which 26 were male patients and only 4 female patients.

Table No. 5: Side effects shown in patients who were taking steroids.

SIDE EFFECTS SHOWN IN PATIENTS WHO WERE TAKING STEROIDS	TOTAL PATIENTS (%) (100)
INSOMNIA	7%
LOSS OF APPETITE	5%

Among 100 patients, only 12% of the patients faced some sort of side effects, Insomnia is the problem faced by 7% of the patients and 5% of the patient faced decreased appetite.

Table No. 6: Side effects shown in patients who were taking steroids.

	DRUGS NAME	INITIAL PHASE	CONTINUOUS PHASE
NEB.	BUDECORT	100	100
IV	HYDROCORT	61	4
	METHYLPREDNISOLONE	31	0
	PREDNISOLONE	0	0
ORAL	METHYLPREDNISOLONE	0	52
	PREDNISOLONE	0	19

The below table is showing us that total no. of 100 patients have taken Budesonide in nebulisation form in both initial and continuous phase. 61 Patients have taken hydrocort in IV form in initial phase and only 4 patients took it in continuous phase. 31 Patients have taken Methylprednisolone in IV form in initial phase and No patient took it in continuous phase. 52 patients have taken Methylprednisolone in oral form in continuous phase and no patient have taken it in oral form in initial phase. 19 patients have taken Prednisolone in oral form in continuous phase and no patient have taken it in oral form in initial phase.

Table No. 7: Hydrocort (IV) TO MPS (PO) On the basis of dose of drug.

PATIENT NO.	IV TOTAL DOSE (mg)	ORAL TOTAL DOSE (mg)
1	800	32
2	200	48
3	200	16
4	200	32
5	200	32
6	100	16
7	800	80
8	100	48
9	800	48
10	200	48
11	200	80
12	200	64
13	200	16
14	100	48
15	800	48
16	100	32
17	900	32
18	800	32
19	700	48
20	800	16
21	700	48
22	800	32
23	700	48
24	800	16
25	700	48
26	100	32
27	800	16
28	800	32
29	200	16
30	200	32
31	200	32
32	100	32
33	800	80
34	100	80
35	800	16

36	800	48
37	200	32
38	200	64

Step down therapy is given to total 38 patients and after giving the therapy, the total data is collected and to find the statistical difference we applied paired t-test at 95% confidence interval and the value calculated is 0.0038180. Because the p-value is less than 0.05, we reject the null hypothesis and state that there is significant difference.

Table No. 08: Hydrocort (IV) TO Prednisolone (PO) On the basis of dose of drug.

PATIENT NO.	IV TOTAL DOSE (mg)	ORAL TOTAL DOSE (mg)
1	100	100
2	900	40
3	100	30
4	1200	100
5	900	40
6	100	40
7	200	30
8	200	30
9	200	30
10	200	30
11	200	30
12	100	100
13	900	40
14	100	30
15	1200	100

Step down therapy is given to total 15 patients and after giving the therapy, the total data is collected on the basis of dose of drug and to find the statistical difference we applied paired t-test at 95% confidence interval and the value calculated is 0.0362. Because the p-value is less than 0.05, we reject the null hypothesis and state that there is significant difference.

Table No. 09: MPS (IV) TO MPS (PO) On the basis of dose of drug.

PATIENT NO.	IV TOTAL DOSE (mg)	ORAL TOTAL DOSE (mg)
1	240	80
2	240	80
3	240	80
4	240	64
5	240	64
6	240	64
7	120	64
8	240	64
9	240	80
10	240	48

11	120	64
12	240	112
13	120	64
14	240	32

Sequential therapy is given to total 11 patients and after giving the therapy , the total data is collected on the basis of dose of drug and to find the statistical difference we applied paired t-test at 95% confidence interval and the value calculated is 0.000165754. Because the p-value is less than 0.05, we accept the null hypothesis and state that there is no significant difference.

TABLE NO. 10: MPS (IV) to MPS (PO) On the basis of dose of drug.

PATIENT NO.	IV TOTAL DOSE (mg)	ORAL TOTAL DOSE (mg)
1	320	40
2	320	40
3	320	40
4	160	40

Switch therapy is given to total 4 patients and after giving the therapy, the total data is collected on the basis of dose of drug and to find the statistical difference we applied paired t-test at 95% confidence interval and the value calculated is 0.009273. Because the p-value is less than 0.05, we reject the null hypothesis and state that there is significant difference.

Table No. 11: Hydrocort (IV) to MPS (PO) On the basis of duration of the drug therapy.

PATIENT S. NO.	IV DOSE (TOTAL DAYS)	ORAL DOSE (TOTAL DAYS)
	HYDROCORT	METHYL PREDNISOLONE
1	4	1
2	3	3
3	3	1
4	2	2
5	3	1
6	8	1
7	4	5
8	3	5
9	4	1
10	3	3
11	3	1
12	2	2
13	3	1
14	8	1
15	3	5
16	5	3
17	3	1
18	5	3

19	5	3
20	3	1
21	5	3
22	3	1
23	5	3
24	3	1
25	4	1
26	3	3
27	3	1
28	2	2
29	3	1
30	8	1
31	4	5
32	3	5
33	4	1
34	3	3
35	3	1
36	2	2
37	2	2
38	2	4

Step down therapy is given to total 38 patients and after giving the therapy , the total data is collected on the basis of duration of therapy and to find the statistical difference we applied paired t-test at 95% confidence interval and the value calculated is 0.000304. Because the p-value is less than 0.05, we reject the null hypothesis and state that there is significant difference.

Table No. 12: Hydrocort (IV) to Prednisolone (PO) On the basis of duration of the drug therapy.

PATIENT S. NO.	IV DOSE (TOTAL DAYS)	ORAL DOSE (TOTAL DAYS)
	HYDROCORT	PREDNISOLONE
1	4	2
2	3	3
3	4	2
5	3	3
6	4	3
7	4	3
8	4	3
9	4	3
10	4	3
11	4	2
12	3	3
13	3	2
14	4	2
15	3	3

Step down therapy is given to total 15 patients and after giving the therapy, the total data is collected on the basis of duration of therapy and to find the statistical difference we applied paired t-test at 95% confidence interval and the value calculated is 0.00036623. Because the p-value is less than 0.05, we reject the null hypothesis and state that there is significant difference.

TABLE NO. 13: MPS (IV) to MPS (PO) On the basis of duration of the drug therapy.

PATIENT S. NO.	IV DOSE (TOTAL DAYS)	ORAL DOSE (TOTAL DAYS)
	METHYL PREDNISOLONE	METHYL PREDNISOLONE
1	6	2
2	6	2
3	3	3
4	3	3
5	3	3
6	3	3
7	3	3
8	3	3
9	3	3
10	3	3
11	3	3
12	3	3
13	3	2
14	6	2

Switch therapy is given to total 14 patients and after giving the therapy , the total data is collected on the basis of duration of therapy and to find the statistical difference we applied paired t-test at 95% confidence interval and the value calculated is 0.042548. Because the p-value is less than 0.05, we reject the null hypothesis and state that there is significant difference.

TABLE NO. 14: MPS (IV) to Prednisolone (PO) On the basis of duration of the drug therapy.

PATIENT S. NO.	IV DOSE (TOTAL DAYS)	ORAL DOSE (TOTAL DAYS)
	METHYL PREDNISOLONE	PREDNISOLONE
1	4	2
2	4	2
3	4	2
4	4	2

Switch therapy is given to total 4 patients and after giving the therapy, the total data is collected on the basis of duration of therapy and to find the statistical difference we applied paired t-test at 95% confidence interval and the value calculated is 0.002896. Because the p-value is less than 0.05, we reject the null hypothesis and state that there is significant difference.

SUMMARY

1. **APPLICATION OF STEROIDS:** Methylprednisolone was frequently used orally, while hydrocortisone was most frequently utilised intravenously for all disorders. All patients received budesonide as a necessary treatment.

2. **SIDE EFFECTS OF STEROIDS:** Approximately 7% of patients experienced insomnia, and 5% experienced appetite disruption.

3. **DURATION OF STEROID THERAPY**: The average duration of methylprednisolone in IV form is 3.72222, while the average duration of hydrocortisone is 3.657895. As a result, both exhibit roughly the same therapeutic average across all patients. The average dose of methylprednisolone orally is 2.3461538.

4. **INITIATION AND CONTINUOUS THERAPY**: In initiation therapy, 100% of IV/ORAL patients received budesonide, and in continuous therapy, 64% of patients received hydrocortisone.

5. **Modifications Made to the Conversion of IV to Oral Therapy**: IV Hydrocortisone was changed to oral.

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