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DRUG UTILISATION EVALUATION OF CORTICOSTEROIDS IN TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT: Objective: Steroids are widely prescribed and used by practitioners due to powerful anti-inflammatory and immunosuppressive actions. So, care should be exercised in the rational selection of steroids. The main aim of our study is to assess prescribing patterns, demographic and clinical variables such as drug interactions associated with corticosteroid administration and steroidal use in a tertiary care teaching hospital. **Methods:** This is a prospective observational study conducted for 6 months in all departments of a tertiary care hospital of various age groups in all the departments were included. The study was carried out by taking 310 participants into consideration, and their prescribing patterns were observed and analyzed. Statistical procedure of One way ANOVA was done in SPSS version 16 software. Two way ANOVA was done which showed that variability is observed in the gender groups with treatment about steroids treatment. **Results:** Steroids were prescribed for various age groups of patients; 84 patients are above 60 years of age. Among 310, 183 patients were male and 127 patients were female. The social history of each patient was collected and analyzed 116 patients are Smokers and 194 patients are non-smokers and 118 patients are Alcoholics and 192 patients are non-alcoholics. Budesonide was most widely used for about 39%. Systemic route (42.9%) is the most commonly used route of administration for the steroids. We found 13.5% Major interactions, 91.6% Moderate interactions, 20.3% Minor interactions. **Conclusion:** Our study reveals that there was a significant difference between the steroid treatments.

INTRODUCTION: There are no variations found in prescription patterns in health care professionals. though most of the drugs were prescribed rationally, clinical pharmacist involvement in patient care helps us in planning the therapy, prevention and early detection of adverse drug reactions will directly promote better patient compliance and drug safety. Most of the health care systems use drug utilization studies (DUS) as a potential tool for their evaluation.

These drug utilization studies (DUS) are otherwise called as drug utilization review (DUR) or medical utilization evaluation (MUE) are defined as an authorized, structured, ongoing review of prescribing, dispensing and use of medication.

DUR implies positive patient compliance and appropriate therapeutic decision making which ultimately achieved by reviewing patients before, ongoing and after histories¹. DUR always targets improved appropriate drug utility and gaining better health outcome by knowing how and why drugs are utilized. It examines local, national, institutional and population health care system levels and current developmental trends of drug usage. Drug utilization research contributes to rational drug use by describing the drug use pattern and interventions.

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Cross-sectional information provides a summary of drug use at a particular time ². Corticosteroids are some of the most important anti-inflammatory and immunosuppressive agents in the pharmacological treatment of several diseases including asthma, allergic rhinitis, rheumatoid arthritis, inflammatory bowel diseases, rejection of organ transplants, and shock symptoms. The ability of corticosteroids to act on different target tissues and exert biological responses depends in most cases on the presence of the glucocorticoid receptor (GR).

MATERIALS AND METHODS: ³

Study Site: The study entitled “Drug utilization evaluation of corticosteroids uses in a tertiary care teaching hospital” was carried out in all departments of Andhra Hospital which was a tertiary care hospital in Vijayawada, Andhra Pradesh.

Study Design: This prospective, observational study was planned and done for a period of six months from September 2017 to February 2018. The study protocol was approved by the Institutional Human Ethical Committee with registered number: IHEC/SIMS/2017/001.

Inclusion Criteria: All the patients of various age groups who received any category of steroid therapy in all the departments were included. Patients of either sex taking steroids containing prescription of any disease. Patients from the inpatient department using corticosteroids. Patients with a Minimum of 2 days of hospital stay are also included.

Exclusion Criteria: ⁴ Patients who met all the inclusion criteria but not willing to participate in the study were excluded - patients from the outpatient department. Pregnant and lactating women were excluded from the study. HIV and cancer chemotherapy patients were excluded from the study.

Study Population: ⁵ 310 subjects who are in patients for at least 2 days and who are on steroid therapy are selected for the study. Structured data collection form was prepared which includes patient demographic and medication-related information. 310 prescriptions were collected from September 2014 to February 2015. All necessary information for the study was collected from all

departments, laboratory investigations, prescription and interview with patients.

All the prescriptions were reviewed prospectively and monitored extensively for utilization pattern of corticosteroids category, indication, the rationality of the prescription (number of corticosteroids, appropriateness of dosage form, and duration of therapy) and number of drugs in prescriptions. Drug-drug interactions were checked by using MICROMEDEX software, DRUG.COM and STOCKLEY’s drug interaction book.

Data collected was analyzed and expressed in MS-word and MS-excel ⁶. All patients who met the inclusion criteria were involved in the study after giving suitably informed consent (IC) before starting the study. Basic patients demographics, prescription chart, diseases prescribed with steroids, gender-wise distribution, age groups with maximum use of steroids, route of administration, type of steroid based on potency. Most widely used steroids in the department, Co-morbidities of the patient, Past medical history of the patient ⁷.

RESULTS AND DISCUSSION: A total of 310 patients have enrolled in the study out of which 183 patients were male, and 127 patients were female as shown in **Table 1**. So, we found that the majority of the males use corticosteroids with about 59% when compared to females of about 41%.

Gender of Patients Taking Steroids :

TABLE 1: BASIC DEMOGRAPHIC DETAILS

Gender	Frequency	Percent	Valid Percent	Cumulative Percent
Male	183	59.0	59.0	59.0
Female	127	41.0	41.0	100.0
Total	310	100.0	100.0	

Age Wise Categorization of Patients Consuming Steroids:

TABLE 2: AGE OF THE PATIENTS TAKING STEROIDS

Age	Frequency	Percent	Valid Percent	Cumulative Percent
0-10	36	11.6	11.6	11.6
11-20	14	4.5	4.5	16.1
21-30	42	13.5	13.5	29.7
31-40	35	11.3	11.3	41.0
41-50	48	15.5	15.5	56.5
51-60	51	16.5	16.5	72.9
>60	84	27.1	27.1	100.0
Total	310	100.0	100.0	

Among the 310 patients, we found that 84 patients are from the age group of >60 years of age, and 51

patients are from the age group of 51-60 years, and 48 patients are from 41-50 years of age group and 42 are from 21-30 years age group and 36 are from 1 day- 1 year age group and 35 patients are from 31-40 age group, and 14 patients are from 11-20

years of age group. Percentages of age group under steroid treatment were given in **Table 2**. Cross-tabulation of age group with gender was shown in **Table 3**.

Cross Tabulation of Age vs. Gender:

TABLE 3: AGE vs. GENDER CROSSTABULATION

Age of patient taking steroids	Gender		Total
	Male	Female	
0-10 yrs	25	11	36
11-20 yrs	6	8	14
21-30 yrs	18	24	42
31-40 yrs	21	14	35
41-50 yrs	30	18	48
51-60 yrs	26	25	51
>60 yrs	57	27	84
Total	183	127	310

In **Table 4**, Age group along with their use of particular steroids is differentiated.

Cross Tabulation of Age vs. Treatment:

TABLE 4: AGE vs. TREATMENT

Age	Treatment with steroids								Total
	Dexamethasone	Prednisolone	Budesonide	Hydrocortisone	Methylprednisolone	Clobetasol	Deflazacort	Betamethasone	
0-10	20	12	0	3	1	0	0	0	36
11-20	4	4	2	2	1	0	0	1	14
21-30	8	8	11	11	2	0	0	2	42
31-40	7	3	10	6	6	1	1	1	35
41-50	6	3	27	10	2	0	0	0	48
51-60	6	3	27	14	0	1	0	0	51
>60	4	9	44	25	2	0	0	0	84
Total	55	42	121	71	14	2	1	4	310

Smoking Associated with Steroid Use:⁸ Out of 310 cases, the social history of each patient was collected and analyzed. We found that 116 patients are Smokers and 194 patients are non-smokers. Differentiation of a number of smokers and nonsmokers using particular steroids was shown in **Table 5**. Usually, drugs have side effects if the patient is a smoker, so monitoring is required. In this study, we tried to find out the association between steroid treatment and smoking habit shown in **Table 5**. We have done a statistical procedure (Pearson chi-square) in SPSS version 16 software and finally got a result of significance

0.018 which states that steroid treatment is dependent on smoking habit of patients **Table 6**.

TABLE 5: SMOKING ASSOCIATED WITH STEROID USE

Steroids are taken by Patient	Smoking habit		Total
	Nonsmoker	Smoker	
Dexamethasone	39	16	55
Prednisolone	33	9	42
Budesonide	67	54	121
Hydrocortisone	40	31	71
Methyl Prednisolone	10	4	14
Clobetasol	0	2	2
Deflazacort	1	0	1
Betamethasone	4	0	4
Total	194	116	310

Cross Tabulation of Smoking Habit vs. Steroid Taken by Patients :

TABLE 6: CHI-SQUARE TESTS

	Value	df	Asymp. (2-sided)
Pearson Chi-Square	16.885 ^a	7	.018
Likelihood Ratio	19.565	7	.007
Linear-by-Linear Association	1.298	1	.255
N of Valid Cases	310		

a. 6 cells (37.5%) have expected count less than 5. The minimum expected count is .37.

P value is less than LOS 0.05. So, the null hypothesis is rejected. This value of chi-square indicates that there is an association between the smoking and steroid treatment taken by the patient. That is steroid treatment dependent on smoking habit of patients⁹.

Alcohol Associated with Steroid Treatment: Out of 310 cases, the social history of each patient was collected and analyzed. We found that 118 patients are alcoholics and 192 patients are non-alcoholics. Differentiation of a number of alcoholics and nonalcoholics using particular steroids was shown in **Table 7**. Usually, many drugs have interactions with alcohol, so monitoring of drug levels should be done if required. In this study, we tried to find out the association between steroid treatment and Alcohol habit shown in **Table 7**. We have done a statistical procedure (Pearson chi-square) in SPSS version 16 software and finally got a result of significance 0.092 which states that steroid

System Involved vs. Steroid Taken by Patients:

TABLE 9: SYSTEM ASSOCIATED WITH STEROID USE

System involved	Steroids used								Total
	Dexamethasone	Prednisolone	Budesonide	Hydrocortisone	Methylprednisolone	Clobetasol	Deflazacort	Betamethasone	
Skeletal	3	4	4	1	3	0	0	0	15
Respiratory	8	9	23	24	1	0	0	0	65
Reproductive	0	0	0	1	0	0	0	1	2
Renal	1	4	6	3	1	0	0	0	15
Nervous	29	6	20	11	4	0	0	1	71
Muscular	3	1	3	0	2	0	0	0	9
Lymphatic	3	7	2	7	0	2	1	0	22
Digestive	2	2	33	13	1	0	0	0	51
Endocrine	2	0	6	0	0	0	0	1	9
Vascular	4	9	24	10	1	0	0	1	49
Total	55	42	121	71	14	2	1	4	310

treatment is independent on alcohol consumption of the patients **Table 8**.

Cross Tabulation of Alcohol vs. Steroid Taken by Patient:

TABLE 7: ALCOHOL ASSOCIATED WITH STEROID TREATMENT

Steroid took by the patient	Alcohol habit		Total
	Nonalcoholic	Alcoholic	
Dexamethasone	40	15	55
Prednisolone	31	11	42
Budesonide	65	56	121
Hydrocortisone	42	29	71
Methylprednisolone	8	6	14
Clobetasol	1	1	2
Deflazacort	1	0	1
Betamethasone	4	0	4
Total	192	118	310

TABLE 8: CHI-SQUARE TESTS

	Value	Df	Asymp. (2-sided)	Sig.
Pearson Chi-Square	12.257 ^a	7	.092	
Likelihood Ratio	14.158	7	.048	
Linear-by-Linear Association	1.121	1	.290	
N of Valid Cases	310			

a. 6 cells (37.5%) have expected count less than 5. The minimum expected count is .38.

P value is more than the LOS 0.05. Therefore we fail to reject the null hypothesis. This value of chi-square indicates that there is no association between the alcohol and steroid treatment taken by the patient. This indicates that steroid treatment is independent of the alcohol consumption of the patients.

System Associated with Steroid use: In this study, patients with the disorder in different systems were enrolled. Out of 310 cases, 71 patients with disorder in nervous system use steroids and 65 patients with Respiratory disorder use steroids and 51 patients are with digestive system disorder, and 49 patients are with vascular system disorder and 22 patients are with lymphatic system disorder and

15 patients each from both skeletal and renal system disorders and 9 patients each from both muscular and endocrine system disorder and 2 patients from reproductive system disorder use steroids. Differentiation of particular steroid used in disorder of a particular system was shown in **Table 9**.

Steroid vs. Diagnosis Cross Tabulation:

TABLE 10: DIAGNOSIS ASSOCIATED STEROID USE

Steroids	Diagnosis - Department in the hospital									Total
	Cardiology	Neurology	GM	Orthopedics	Gynecology	Gastroenterology	Pediatrics	Pulmonology	Nephrology	
Dexamethasone	2	22	6	6	0	1	13	4	1	55
Prednisolone	3	4	11	6	1	2	9	5	1	42
Budesonide	17	18	28	3	1	30	2	18	4	121
Hydrocortisone	7	11	13	1	2	13	2	22	0	71
Methyl Prednisolone	0	3	4	3	1	0	2	0	0	14
Clobetasol	0	0	2	0	0	0	0	0	0	2
Deflazacort	0	0	0	0	1	0	0	0	0	1
Betamethasone	0	0	1	0	3	0	0	0	0	4
Total	29	58	65	19	9	46	28	49	6	310

Diagnosis Associated Steroid use: In this study, after analyzing 310 prescriptions with corticosteroids we found that 29 patients are from the cardiology department, 58 patients are from the neurology department, 65 patients are from General Medicine, 19 patients are from the Orthopaedics department, 9 patients are from the Gynaecology department, 46 patients are from the Gastroenterology department, 28 patients are from the paediatrics department, 49 patients are from Pulmonology department and 6 patients are from the Nephrology department. Here, we also found the association between diagnosis and steroid treatment by performing pearson chi-square statistical method in SPSS version 16 software. We got a result shown in the **Table 11** that steroid treatment is dependent on the department of its use.

TABLE 11: CHI-SQUARE TESTS

	Value	Df	Asymp. (2-sided)	Sig.
Pearson Chi-Square	2.545E2 ^a	63	.000	
Likelihood Ratio	162.919	63	.000	
Linear-by-Linear Association	.269	1	.604	
N of Valid Cases	310			

a. 58 cells (72.5%) have expected count less than 5. The minimum expected count is .0.

P-value is less than 0.05. So, Null hypothesis is rejected. The chi-square value indicates that steroid treatment is dependent on the department of its use.

Co-Morbidities of Patients Under Steroid Treatment:

A total of 310 prescriptions were analyzed during the study period, and details of comorbidities of each case were also noted, and the results showed that out of 310 cases using steroids 124 have Hypertension, 114 cases have Diabetes, 46 have COPD, 35 have heart diseases, 26 have kidney diseases, 17 have CVD, 12 cases have liver disease, and 9 have arthritis and 8 have thyroid disorders. We found that the major comorbidity in most of the cases as Hypertension and next major was Diabetes, as these both may lead to further complications steroids should be used carefully to prevent any side effects. The dose and use of steroids should be carefully monitored in patients with comorbidities. Differentiation of use of Steroid in different comorbidities of patients was shown in **Table 12**.

TABLE 12: CO MORBIDITIES OF PATIENTS UNDER STEROID TREATMENT

Comorbidities	Steroids are taken by the patient				
	Dexamethasone	Prednisolone	Budesonide	Hydrocortisone	Methylprednisolone
Diabetes	10	10	65	25	4
Hyper tension	19	12	59	29	5
Heart diseases	2	3	18	10	2
Kidney disease	4	1	14	6	1
Liver disease	1	0	10	1	0
CVD	4	2	4	4	3
COPD	1	2	18	24	1
Thyroid disorder	0	0	6	2	0
Arthritis	1	2	5	1	0

Drug Interactions with Steroids:

TABLE 13: DRUG INTERACTIONS WITH STEROIDS

Groups	Steroids	No. of patients	No. of DDI	% of DDI found
A	Dexamethasone	53	69	17.82
B	Prednisolone	42	58	14.98
C	Budesonide	121	145	37.46
D	Hydrocortisone	71	102	26.35
E	Methyl Prednisolone	14	13	3.35

Drug Interactions with Steroids: In this Drug Utilisation Review (DUR), 310 prescriptions with steroids were analyzed. In the studied cases and drugs analyzed in the prescriptions, we found DDI (Drug-Drug Interactions). Out of 121 patients using budesonide, we found 145 DDI and 71 patients use

Hydrocortisone we found 102 DDI, 53 patients using Dexamethasone we found 69 DDI, 42 patients using Prednisolone we found 58 DDI, 14 patients using Methyl Prednisolone we found 13 DDI. Percentage of Drug-Drug Interactions (%DDI) was shown in **Table 13**.

Steroid Drug Interaction Based on Severity:

TABLE 14: STEROID-DRUG INTERACTIONS BASED ON SEVERITY

Groups	Steroids	Major interactions	Moderate interactions	Minor interactions
A	Dexamethasone	15	43	11
B	Prednisolone	5	44	9
C	Budesonide	2	111	32
D	Hydrocortisone	23	71	8
E	Methyl prednisolone	-	10	3
F	Clobetasol	-	-	-
G	Deflazacort	-	1	-
H	betamethasone	-	4	-

Steroid - Drug Interactions based on Severity: Differentiating incidence of DDI according to severity is presented in **Table 14**. In this study total incidence of major interactions are 45 (15 interactions with Dexamethasone, 5 interactions with Prednisolone, 2 interactions with Budesonide, 23 interactions with Hydrocortisone) and total incidence of moderate interactions are 284 (43 interactions with Dexamethasone, 44 interactions with Prednisolone, 111 interactions with Budesonide, 71 interactions with Hydrocortisone, 10 interactions with Methyl Prednisolone, 1 interaction with Deflazacort, 4 interactions with

Betamethasone) and total incidence of minor interactions are 63 (11 interactions with Dexamethasone, 9 interactions with Prednisolone, 32 interactions with Budesonide, 8 interactions with Hydrocortisone and 3 interactions with Methyl Prednisolone) were found from a total Drug interactions of 392 as shown in the **Table 14**. These values show the comparative incidence of more significant drug-drug interactions, which tells that monitoring is required and change in therapy needed according to their significant level. In our study, we did not find any toxic or adverse effects of the steroids.

One way ANOVA for Treatments: In this study, the statistical procedure of One way ANOVA was done in SPSS version 16 software, to find out whether there is any difference between the Treatments. We got a result of significance 0.00

which was less than our Level of Significance (LOS) 0.05, indicating that there was a significant difference between the steroid treatments. The results of the test were shown in **Table 15**.

TABLE 15: ONE WAY ANOVA FOR TREATMENTS

Treatments	Sum of squares	D.f	Mean squares	F	Significance
Between groups	66.963	6	11.161		
With in groups	454.330	303	1.499	7.443	.000
Total	521.294	309			

Sig 0.00 < LOS 0.05 which indicates that there is a significant difference between treatments.

Two way ANOVA for Gender vs. Treatment: In this study, we performed a statistical procedure of Two way ANOVA among the two variables Gender and Steroid Treatment using SPSS version 16 software and the result showed that variability is observed in the gender groups with treatment with regard to steroids is due to chance and it cannot be attributed to effects of gender or the effect of

Treatment. The results of the test were shown in **Table 16**. F table values for d.f (4,4) and (1,4) are 16 and 21.2 respectively. So, $F_{cal} < F_{tab}$ this proves that variability is observed in the gender groups with treatment about steroids is due to chance, and it cannot be attributed to effects of gender or the effect of treatment.

TABLE 16: TWO WAY ANOVA FOR GENDER vs. TREATMENT

Source of Variation	D.f	Sum of squares	Mean sum of squares	F
Treatments	4	3152.6	788.15	15.8
Gender	1	260.1	260.1	5.22
Error	4	199.3	49.8	
Total	9	3612		

Steroid Treatment: Table 17 shows the means and standard error of Steroid treatment at the level of 95% confidence interval.

TABLE 17: DEPENDENT VARIABLE: GENDER

Steroids	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Dexamethasone	1.309	.066	1.180	1.439
Prednisolone	1.452	.075	1.304	1.601
Budesonide	1.397	.044	1.309	1.484
Hydrocortisone	1.465	.058	1.351	1.579
Methyl prednisolone	1.357	.130	1.100	1.614

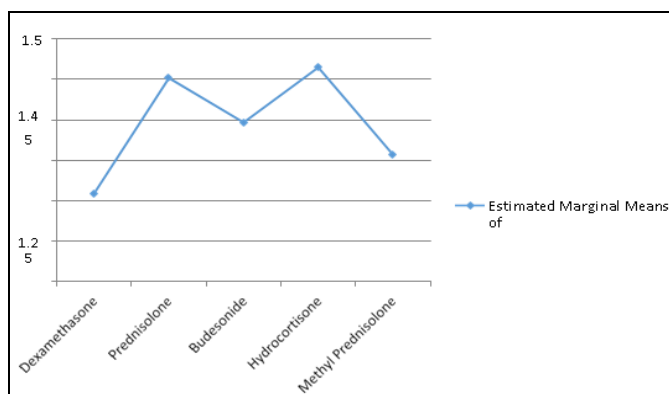


FIG. 1: SHOWS THE GRAPHICAL REPRESENTATION OF ESTIMATED MARGINAL MEANS OF GENDER USING DIFFERENT STEROIDS

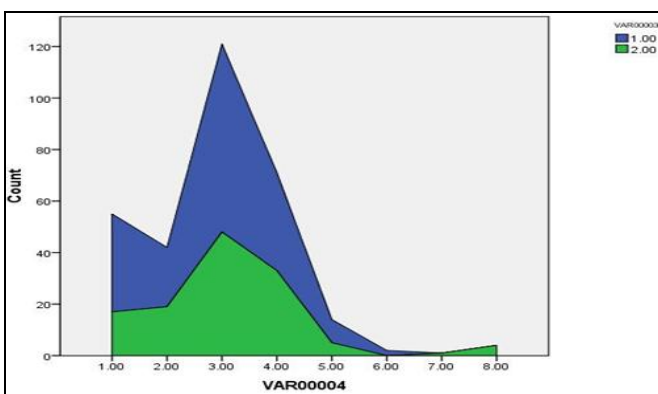


FIG. 2: SHOWS THE STACKED GRAPHICAL REPRESENTATION OF GENDER DISTRIBUTION OF MALE AND FEMALE PATIENTS ON STEROID TREATMENT

This graph represents the steroids taken by gender-wise distribution. The blue graph indicates male; green indicates female. VAR00004 indicates steroid drugs like Dexamethasone, Prednisolone, Budesonide, Hydrocortisone, Methylprednisolone, Clobetasol, Deflazacort, Betamethasone.

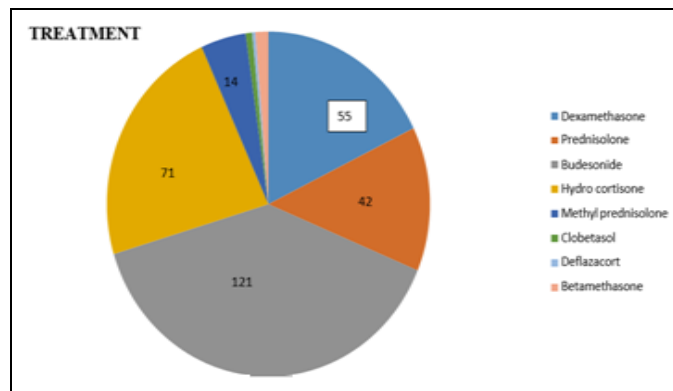


FIG. 3: THE PIE CHART OF STEROIDS USED FOR TREATMENT IN THE 310 CASES OF THIS STUDY. MAJOR PART OF THE PIE GRAPH WAS COVERED BY BUDESONIDE (121), FOLLOWED BY HYDROCORTISONE (71), DEXAMETHASONE (55), PREDNISOLONE (42), METHYLPREDNISOLONE (14), BETAMETHASONE (4), CLOBETASOL (2), DEFLAZACORT (1)

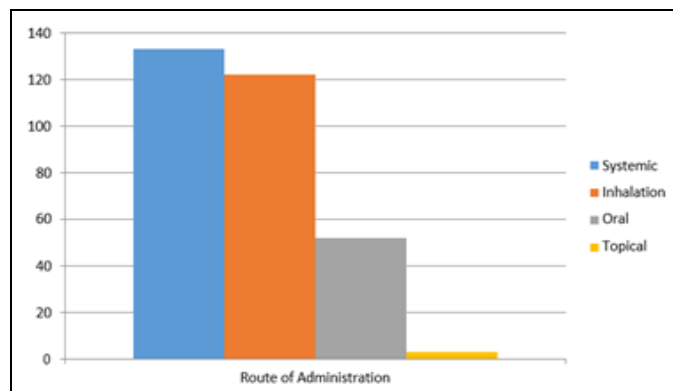


FIG. 4: SHOWS THE BAR GRAPH OF ROUTE OF ADMINISTRATION OF STEROIDS. MAJORITY OF STEROIDS WERE GIVEN THROUGH SYSTEMIC ROUTE (133) FOLLOWED BY INHALATION (122), ORAL (52), TOPICAL (3)

CONCLUSION: The irrational use of drugs (*e.g.*, inadequate dose or polypharmacy) may lead to failure of therapy or drug interactions/adverse reactions and increase the cost of therapy/mortality. This will increase the adverse effects and can lead to dependence on these medications. So, urgent steps are required to eliminate the root of this problem at the earliest. Periodic monitoring of the drug utilization pattern is one of the methods to analyze the rationality of the drug and has been an effective tool to constitute guidelines for improving the utilization pattern. This will not only

constitute a rational therapy but also lead to economic benefit and easy identification of the problem related to drug use like Polypharmacy, drug interactions, and adverse reactions.

One of the reason for the major causes of irrationality, in an Indian hospital is lack of clinical pharmacist involvement & encourage, in the clinical practice prescription monitoring. Clinical pharmacists interact directly with patients in several different ways. They use their knowledge of medication (including dosage, drug interactions, side effects, expense, effectiveness, *etc.*) to determine if a medication plan is appropriate for their patient. If it is not, the pharmacist will consult the primary physician to ensure that the patient is on the proper medication plan. The clinical pharmacist has a major role in promoting the steroids utilization rationally, by educating and promoting the evidence-based practice guidelines.

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