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COMPARISON OF SHORT-TERM AND LONG-TERM USE OF CORTICOSTEROIDS IN A TERTIARY CARE HOSPITAL – CROSS-SECTIONAL STUDY

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ABSTRACT

Background: Corticosteroids are powerful anti-inflammatory drugs that have been used to treat a variety of diseases for over seven decades, the administration of corticosteroids may have possible hazards, ranging from minor adverse medication reactions to more serious considerations, among the more serious side effects noted with systemic corticosteroid therapy, particularly when used at high doses for prolonged periods. Therefore, educational interventions among healthcare professionals and patients are required to enhance rational drug use

Objective: To assess the safety and efficacy of long term and short-term use of corticosteroids

Materials and methods: The Cross-sectional study was conducted in the Mallige Medical Centre and included a total case of 539 in which patients receiving corticosteroids during the study period of six months. The study data was collected through the pretested and validated questionnaires that included the demographic details, past medical history, past medication history, presenting complaints, corticosteroid duration etc.

Results: In a total of 539 patients with prescribed corticosteroids for In-patient and Out-patient, 205 (38%) were male and 334 (62%) were female. The study findings concluded that Short Term Corticosteroid use is most widely prescribed, 487 (90.4%) and efficient than of long-term Corticosteroid therapy, 52 (9.6%). 298(55%) patients were found to have drug interaction. The

majority non-corticosteroid drugs interacting with corticosteroid were Pantoprazole 174 (32.3%) followed by Fosaprepitant 17 (3.2%).

Conclusion: The study findings concluded that Short Term Corticosteroid use is most widely prescribed about 487(90.4%) and efficient than of long-term Corticosteroid therapy 52 (9.6%) out of 539 patients in the study population.

Keywords: Corticosteroids, glucocorticoids, mineralocorticoids, ADR, drug interaction, HPA- axis, short-term and long-term duration

INTRODUCTION:

The adrenal cortex naturally produces corticosteroids, which have a variety of functions in the body **[1]**. Corticosteroids are categorized into two main classes according to their functions: mineralocorticoids and glucocorticoids **[2-3]**. Corticosteroids are among the most effective commonly used treatments for diverse autoimmune and inflammatory disorders **[4]**. These conditions include multiple sclerosis (MS); inflammatory bowel disease (IBD) (like ulcerative colitis and Crohn's disease); painful and inflamed joints, tendons, and muscles; polymyalgia rheumatica; giant cell arteritis; urticaria (hives); hay fever; allergic rhinitis; chronic obstructive pulmonary disease (COPD); asthma; lupus; and atopic eczema **[5]**.

Yet long term use of corticosteroids is generally avoided, as it is having risks of causing serious acute complications such as infection, venous thromboembolism, avascular necrosis, and fracture, as well as chronic diseases such as diabetes mellitus, hypertension, osteoporosis, and other features of iatrogenic Cushing's syndrome **[6-7]**. Indeed, corticosteroids are one of the most common reasons for admission to hospital for drug related adverse events, and optimizing their long-term use has been a major focus for clinical guidelines across diverse specialties for many years **[8-9]**.

In contrast the risk and complications of long term and short-term use of corticosteroids is much less understood, and evidence is generally insufficient to guide clinicians **[10]**. In the hospital setting, brief courses of oral corticosteroids are often used to treat conditions with clearly defined inflammatory pathophysiology for which there is clinical consensus for efficacy, such as asthma, chronic obstructive lung disease, rheumatoid arthritis, and inflammatory bowel disease **[11-12]**. Yet anecdotally corticosteroids are also used often in the short term to treat many other prevalent conditions where evidence is lacking, such as non-specific musculoskeletal pain and rashes **[13]**. Despite such pervasive indications for use of oral corticosteroids, there is little information is known for prescribing the corticosteroids in the general

adult population, or their potential harm **[14]**.

In this study we aimed to create a deeper evaluation and understanding in the way CORT are prescribed for all types of cases ranging with infections to autoimmune diseases in various demographical patients. The essence of the study lies in the fact that the focus of CORT drugs, CORT regimes, and therapy was studied by comparing the duration of treatment, specifically short-term and long-term.

Given that corticosteroids are readily available and cost-effective treatment choices in developed nations, it is essential to assess the general awareness of these medications in such countries **[15]**. Thus, our study aimed to comprehensively assess levels of public awareness concerning corticosteroid use, side effects, and predictors of its use.

METHODS:

I. Study design and population:

This is a cross-sectional observational study to assess the safety and efficacy as well as compare short-term and long-term CORT.

II. Data Collection:

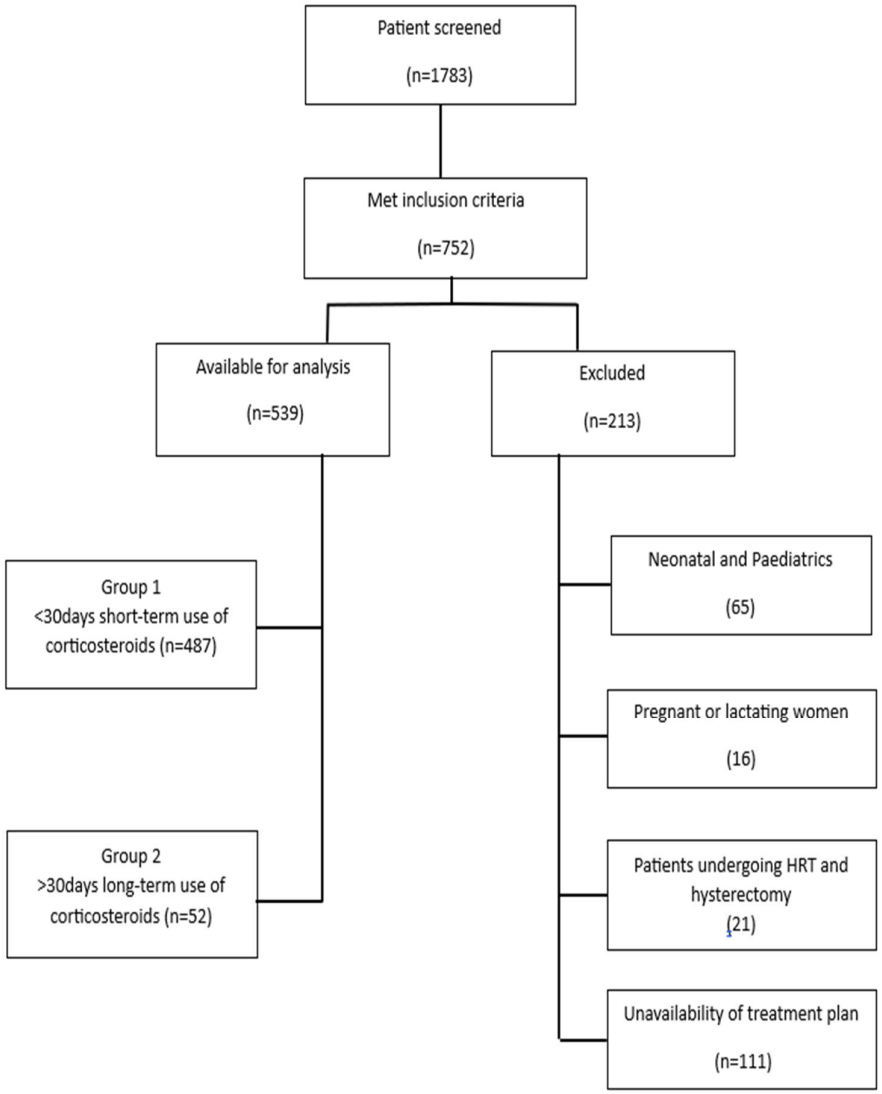
The primary end point is to assess and compare the safety as well as efficacy of long-term and short-term CORT regime prescribed to patients of all diagnoses, gender, age-group, and racial demographics. Patients who were prescribed with CORT in IPD and OPD were selected. The purpose of the study was fully explained and they were asked to sign the informed consent form.

All assessments were performed at baseline and rationality of prescribed drugs, any adverse drug effects that occurred, potential drug interactions and CORT prescribed frequency was recorded throughout the study. The ethical approval for the study was granted by the Mallige Hospital, Bangalore (Approval No: MCP/RRB/014/23-24). After the approval from IEC, voluntary written informed consent was obtained from the subject(s) and their legal representative before the start of the enrolment.

In the duration of 6 months, this study considered IPD, OPD, MRD, and electronic medical records that were used to access patient documents. The data extracted from the patient case forms dataset of socioeconomic and demographic details, medical histories, laboratory investigations, current diagnoses, treatment inclusive of CORT drugs and all other details from patient interview & counselling forms relevant to the prescribed regime of CORT were utilized. All collected data were put through forms and later transferred and corroborated to match expected treatment

regimens and prescribed therapeutic cycles.

A total of 1783 patients reports were collected and evaluated with which 752 met inclusion criteria. 213 were disbarred according to the set study exclusion criteria, specifically neonatal, pediatrics, pregnant and lactating women, HRT and hysterectomy, and patients unavailable of treatment plan. 539 patients were ultimately taken forward for the purpose of the study. From the total of these patients, 487 patients had undergone short-term CORT therapy while 52 of out 539 patients were on long-term CORT regime, including OPD patients.



Data Analysis

Data obtained from study was analyzed using version 27 of SPSS software. Qualitative data obtained is represented through various graphs and figures giving major importance to the parameters essential to the study to correlate therapeutic benefits of CORT drugs.

RESULTS:

The data was analyzed from the corroborated data collection of complete totals of 539 patients. **Table 1** shows the demographic characteristics of the study population, in proportion to the patients on short-term or long-term CORT depicting the correlation of both in terms of drug safety and efficacy.

For this study, a search carried out over 102 unique references and screening of more than 1783 patient showed no emphasis on the safety of the use of CORT drugs. There is proof enough on the ADR and DI of CORT drugs but none emphasize on the method of optimizing it for maximum therapeutic efficacy and minimize unwanted effects.

Table 1:Demographic characteristics of the study population

All patients		n (%)	CORT Monotherapy	CORT Combination Therapy	Drug Interactions	Adverse Drug Reactions
		539 (100%)	450(83.4%)	89(16.5%)	249(46.1%)	188(34.8%)
Sex	Female	334 (62%)	287(53.2%)	47(8.7%)	179(33.2%)	110(20.4%)
	Male	205 (38%)	163(30.24%)	42(7.7%)	75(14%)	78(14.8%)
Age, years	>12 years	9 (1.7%)	8(1.8%)	1(0.18%)	5(0.92%)	1(0.18%)
	21-30 years	33 (6.1%)	30(5.5%)	3(0.55%)	16(2.9%)	4(07%)
	31-40 years	43 (8%)	36(6.67%)	7(1.29%)	23(4.2%)	9(1.6%)
	41-50 years	57 (10.6%)	50(902%)	7(1.29%)	25(4.6%)	19(3.5%)
	51-60 years	105 (19.5%)	89(15.2%)	16(2.9%)	59(10.9%)	34(6.3%)
	61-70 years	134 (24.9%)	118(24.8%)	16(2.9%)	71(13.1%)	49(9.1%)
	>70 years	158(29.3%)	119(22%)	39(7.2%)	50(9.2%)	72(13.3%)
Duration of Hospital Stay	1-4 days	404(74.9%)	358(66.6%)	47(8.7%)	232(43%)	117(21.7%)
	4-6 days	82(15.2%)	59(10.9%)	19(3.5%)	13(2.4%)	43(7.9%)
	6-10 days	41(7.6%)	24(4.4%)	14(2.6%)	3(0.55%)	23(4.2%)
	Above 10 days	12(2.2%)	9(1.6%)	3(0.55%)	1(0.18%)	5(0.9%)
Duration of CORT	Short-term	487(81.4%)	412(76.4%)	69(12.8%)	235(43.6%)	148(27.4%)
	Long-term	52(9.6%)	32(5.9%)	20(3.17%)	14(2.6%)	40(7.42%)

Based on **Table 1**, it can be concluded that long term CORT therapy carried the most amount of ADRs and DIs. Utilizing the qualitative data obtained, the ratio of ADRs occurring for short term therapy was 0.304 while for long term therapy was 0.769. This data is clear proof for short term being safer.

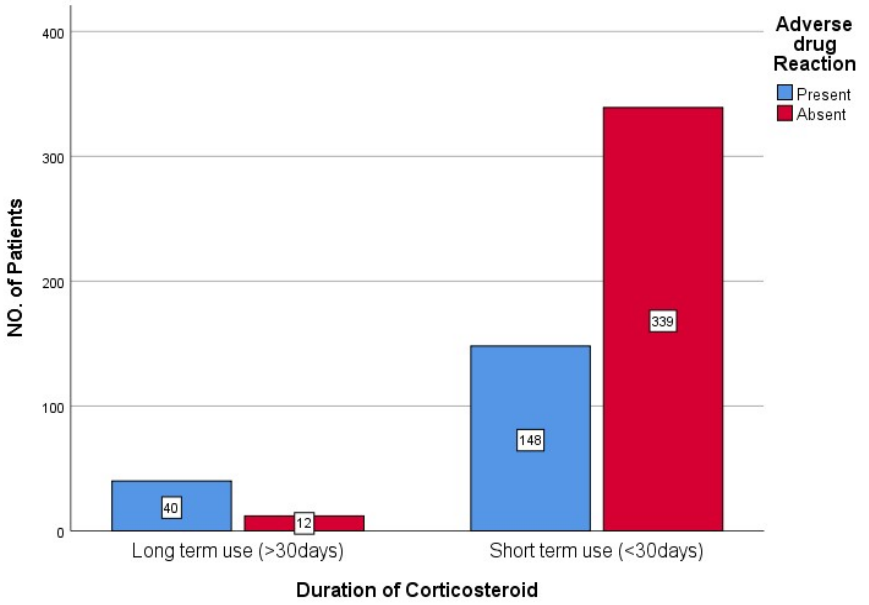


Figure 1: Number of patients based on ADR documented in respective to duration of therapy

Figure 1 carried the evidence for this statement. CORT drugs required sustained and longer duration of administration to result in adverse drug reactions. Patient on long-term therapy were diagnosed with chronic diseases like OSA, Acute exacerbation of asthma, COPD. Despite hyperglycemia being a major concern due to it's status as a primary ADR occurring in 126 patients (67%).

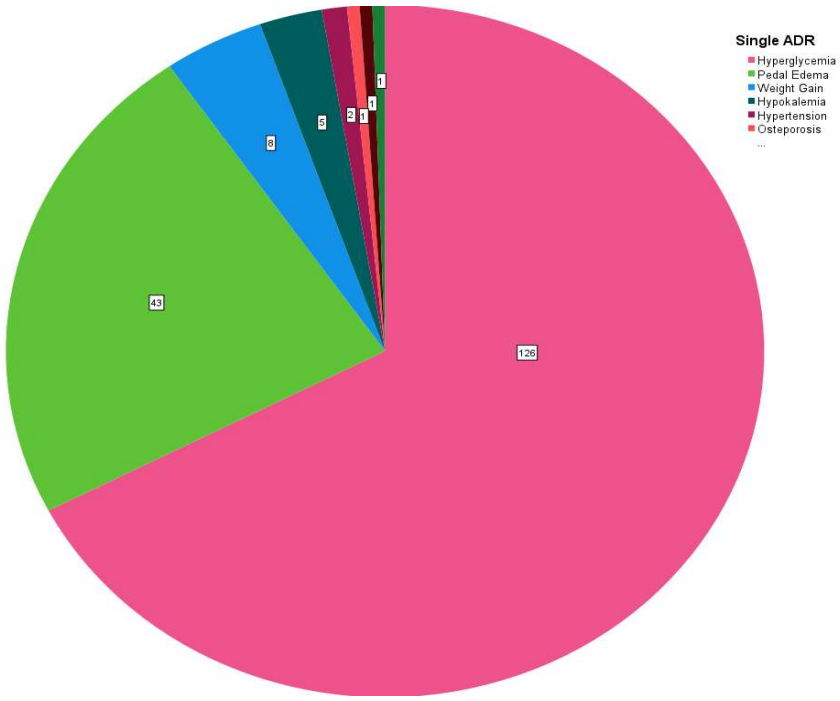


Figure 2: ADR caused by corticosteroids

In which majority of ADR consist of Hyperglycemia 126 (67%) followed by 43 (22%) patient showed pedal edema, 8 (4.2%) patients had weight gain, 5 (2.67%) of patients had Hypokalemia after corticosteroid use, 2 (1.06%) of patients had Hypertension after corticosteroid use, 1(1.06%) of patients had Hirsutism after corticosteroid use,1 (1.06%) of patient had Hypernatremia after corticosteroid use, 1 (1.06%) of patient had Osteoporosis after corticosteroid use.

Table 2: Corticosteroids used for monotherapy

Corticosteroid Used	No. of Patients	Population percentage
Dexamethasone	249	55%
Budesonide	129	28%
Methyl prednisolone	32	7.1%
Hydrocortisone	19	4.2%
Prednisolone	16	3.5%
Fludrocortisone	4	0.88%
Deflazacort	1	0.22%

Corticosteroids used in monotherapy	Short-Term Duration		Long-Term Duration	
Corticosteroids Used in Monotherapy	Number of Patients	Percentage of Patients	Number of Patients	Percentage of Patients
Budesonide	113	20.9%	15	2.7%
Dexamethasone	239	44.3%	10	1.8%
Fludrocortisone	1	0.18%	3	0.55%
Hydrocortisone	19	3.5%	0	0%
Methyl Prednisolone	31	5.7%	1	0.18%
Prednisolone	16	2.9%	2	0.37%
Deflazacort	0	0%	1	0.18%

Carcinoma being a major indication for CORT monotherapy, it deemed as most efficacious as 55% of patients underwent Monotherapy with Dexamethasone IV adjuvant chemotherapy under short0term regimen and had the least amount of hospital stay. The same cannot said about Budesonide as many patients were given inhaler/nebulizer with 15(2.7%) patients from OPD being long-term users. Budesonide Neb in IPD patients admitted for 1-4 days hospital stay showed more acute ADR in comparison to the long-term users.

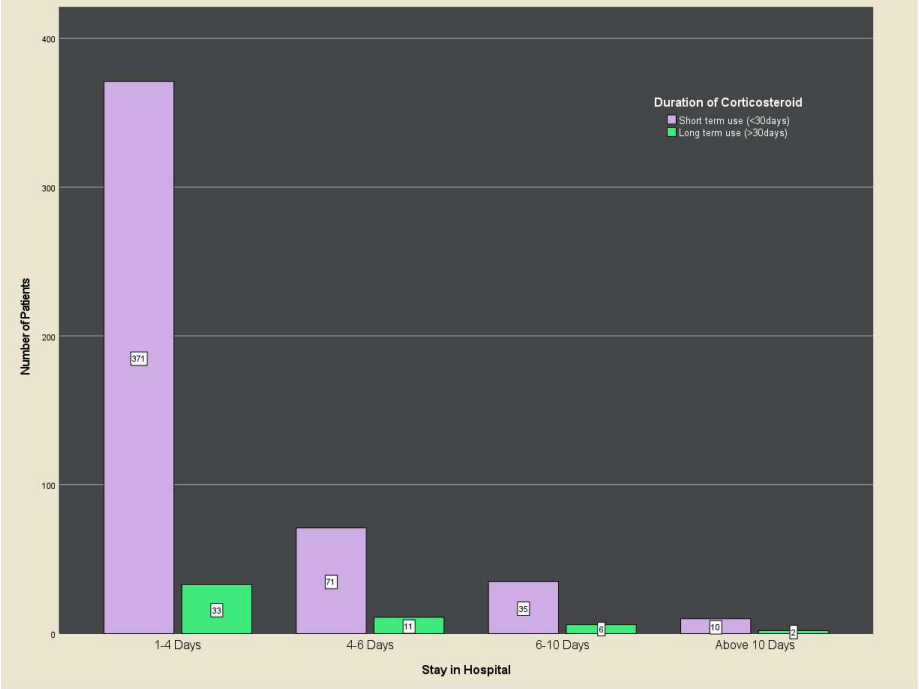


Figure 3: Number of patients intended for corticosteroids treatment based on duration of therapy

In the study population of 539 patients majority of patients were prescribed Short term corticosteroids 487 (90.4%) out of which 371 (84%) patients were released from the hospital within 1-4 days and 33 (6.1%) patients were prescribed long term corticosteroid therapy , 71 (13.17%) patients were released within 4-6 days were prescribed short term Corticosteroids and 11(2.04%) patients were prescribed Long term corticosteroid Therapy , 35 (6.4%) patients were released within 6-10 days were prescribed Short term corticosteroid therapy and 6 (1.11%) patents were prescribed long Term Corticosteroid therapy, 10 (1.85%) patients were released from the hospital above 10 days were prescribed short term Corticosteroid therapy and 2 (0.3%) patients were prescribed Long term corticosteroid therapy.

Cancer of different etiologies were also considered in this study, for which corticosteroids were more commonly prescribed. 178 (33.02%) women and 71(13.17%) men were prescribed Dexamethasone for short-term duration adjuvant to their chemotherapy cycles. This group was followed by Budesonide, used in all chronic inflammatory disease in 70(12%) women and 59(10.9%) men over long-term yielded more ADR in these patients compared to the Cancer patient group. Short-term resulted more benefit than long-term in cancer and as well as chronic inflammation diseases.

Adverse Drug Reaction	Number of Patients	Population Percentage
Hyperglycemia	126	67%
Pedal Edema	43	22%
Weight gain	8	4.2%
Hypokalemia	5	2.67%
Hypertension	2	1.06%
Hirsutism	1	1.06%
Hypernatremia	1	1.06%
Osteoporosis	1	1.06%
TOTAL:	187	34.69%

Naranjo Scale was also utilized to understand the extent of the ADR and which reaction occurred more commonly. Table 3 gave the statistics, stating that 126(67%) of patients ended up with hyperglycemia in both short-term and long-term. Diabetic, CKD, AKI patients developed hyperglycemia much faster than long-term patient using Budesonide nebulization for Asthma, COPD, OSA and recurrent respiratory infections.

In summary, using multiple parameters in this study is confounded that short-term regimes deemed more benefits for treatment in patients of all disease categories.

DISCUSSION:

We aimed to create a deeper evaluation and understanding in the way CORT are prescribed for all types of cases ranging with infections to autoimmune diseases in various demographical patients. The essence of the study lies in the fact that the focus of CORT drugs, CORT regimes, and therapy was studied by comparing the duration of treatment, specifically short-term and long-term.

Several cross-sectional studies estimates that CORT ranging from 0.5% to 1.2% over various study periods **[16-17]**. An analysis of the National Health and Nutrition Examination Survey described self-reported use of drugs taken within the previous 30 days. Its findings indicated a mean duration of corticosteroid use exceeding four years among users—thus capturing a larger proportion of chronic treatment but potentially underreporting short-term use. Furthermore, although the analyses were weighted, the actual sample of corticosteroid users included only 356 people. In our longitudinal analysis of 1.5 million insured Americans, the incidence was approximately 7% for short term oral corticosteroid use on a yearly basis.

Though the long-term complications of chronic corticosteroid use are well known, there is a paucity of clinical data on the potential short term adverse effects of corticosteroid use, despite the existence of pathophysiological evidence suggesting possible early changes after drug initiation. For example, the impact of corticosteroids on the immune system has been widely

studied, and in randomized controlled trials of prednisone (versus placebo) in healthy adults there were effects on peripheral cell lines (eg, peripheral white blood cells) within the first day after drug ingestion that were noticeable with 10 mg, 25 mg, and 60 mg doses **[18-19]**. Rapid alteration in markers of bone metabolism has also been documented with the initiation of corticosteroid use; mean serum concentrations of osteocalcin and both serum propeptide of type I N-terminal and C-terminal procollagen were statistically significantly decreased in the early weeks after starting prednisone **[20]**. The mechanisms underlying the increase in venous thromboembolism are not fully known. However, infection is a common trigger of thrombosis **[21]**, suggesting that both venous thromboembolism and sepsis may be potentially mediated through changes in the immune system. Further work is needed to clarify whether and how our observations in this large population may be linked to potential causal pathways **[22]**.

The findings of this study suggest that short term CORT was more prevalent and commonly used and also have more efficacy than of Long-term CORT therapy. The most frequently appearing ADR due to CORT used was Hyperglycemia followed by Pedal Edema but most of the ADR were caused due to short term CORT use. The most used CORT was found to be dexamethasone followed by budesonide. And we also found that most common non-CORT drug interaction with CORT was with pantoprazole, Dexamethasone and followed by Fosaprepitant.

Our study findings highlight that short-term CORT therapy was the most commonly prescribed regimen, with 487 patients (90.4%) out of the 539 studied receiving this treatment. It was observed that short-term CORT therapy was more efficient than long-term therapy, as 371 patients (84%) were discharged from the hospital within 1 to 4 days and have less ADR, compared to only 33 patients (6.1%) on long-term therapy with more ADR. In total, 71 patients (13.17%) were discharged within 4 to 6 days, with 11 (2.04%) of them receiving long-term CORT therapy. Furthermore, 35 patients (6.4%) who were discharged within 6 to 10 days had been on short-term CORT therapy, while 6 patients (1.11%) had been on long-term therapy. Of the patients discharged after more than 10 days, 10 (1.85%) were on short-term therapy and 2 (0.3%) on long-term CORT therapy.

Adverse drug reactions (ADRs) were observed in 187 patients (34.69%), the majority of which were related to hyperglycemia (67%), followed by pedal edema (22%). Weight gain, hypokalemia, hypertension, hirsutism, hypernatremia, and osteoporosis were less frequently reported.

Dexamethasone was the most frequently prescribed corticosteroid for monotherapy, accounting for 249 cases (55%), followed by Budesonide (129 cases, 28%). Methylprednisolone, hydrocortisone, and prednisolone were prescribed in smaller proportions. Combination therapies primarily involved Methylprednisolone and Budesonide, prescribed to 29(32%) patients with other combinations, such as Hydrocortisone with Budesonide, showing lower prescription rates.

Drug interactions were reported in 298 patients (55%), with the most common interaction being between corticosteroids and Pantoprazole (32.3%), followed by Fosaprepitant and Paclitaxel.

Regarding gender distribution, respiratory disease and carcinoma were the most frequent indications for CORT therapy, with 13.5% of male patients and 32.3% of female patients diagnosed with carcinoma. Other conditions included infections, endocrine, and gastrointestinal disorders.

In summary, short-term CORT therapy was associated with fewer ADRs and faster hospital discharge times compared to long-term therapy. Among the patients receiving short-term therapy, 30% experienced ADRs, while 76% of those on long-term therapy reported ADRs, underscoring the higher risk profile of extended corticosteroid use.

This study clearly demonstrates that short-term CORT therapy is safer and more efficacious compared to long-term treatment for the studied population at Mallige Medical Centre.

CONCLUSION:

short-term corticosteroids are safer and more efficacious than long-term. Due to their mechanism of action, plasma half-life and valid indications in variety of disease category, short-term corticosteroid showed better rationality. The duration of corticosteroid use remains a controversy, and real clinical practice is different than the guideline recommendations. Further studies are recommended to assess the safety and efficacy of corticosteroids large population.

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NIL

CONFLICT OF INTEREST:

NIL

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