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A PROSPECTIVE STUDY ON CORTICOSTEROID USAGE AND INCIDENCE OF CORTICOSTEROID-INDUCED HYPERGLYCEMIA IN A TERTIARY CARE HOSPITAL

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Keywords:

Steroids, Steroid Induced Hyperglycemia (SIH), Incidence, Risk factors, management

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ABSTRACT: Corticosteroids are a widely used class of drugs for respiratory, autoimmune, gastrointestinal, and dermatological conditions. Despite the efficacy of steroids, they have a wide variety of side effects. However, SIH remains the most misdiagnosed side effect. Undiagnosed SIH will precipitate DM, increases the morbidity and length of hospital stay, especially when pre-existing risk factors are present. Steroids may cause glucose control to deteriorate if administered to those who already have diabetes. The primary aim of the study was to review the corticosteroid usage and to assess the incidence of steroid-induced hyperglycemia. The patients were enrolled based on the inclusion and exclusion criteria. They were categorized into diabetic (HbA1c <6.5%) and non-diabetic population, and their blood glucose levels were assessed. The Incidence of Corticosteroid Induced Hyperglycemia was found to be 45.8%. The potential risk factors for SIH were older age, history of diabetes mellitus, higher BMI, duration of therapy, and drug interaction. Insulin and combination therapy (CT) of insulin & OHA was the most frequently prescribed treatment for SIH, which showed an increased efficacy compared to others.

INTRODUCTION: Corticosteroids are a class of steroid hormones produced by the adrenal cortex which mimic the action of cortisol. They are involved in a wide range of physiological processes, including stress response, immune response, and regulation of inflammation, electrolyte balance, and so forth [1]. The most commonly used glucocorticoids are prednisolone, hydrocortisone, dexamethasone, methyl-predni-solone, budesonide, and deflazacort.

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Though many new drugs and biologics are discovered, glucocorticoids remain the main therapy for many conditions [2]. Steroids are most commonly used for respiratory, autoimmune, and dermatological conditions. Glucocorticoids affect many physiological processes, including fat, carbohydrate, protein metabolism, and have effects including anti-inflammatory, anti-proliferative, vasoconstrictive and immuno-suppressive actions [1].

Despite their therapeutic efficacy, glucocorticoids have a wide variety of side effects, including Cushing syndrome, hyperglycemia, weight gain, osteopenia with subsequent osteoporosis, dyslipidemia (DLP), avascular necrosis, cataracts, and open-angle glaucoma [2, 3, 4]. However, steroid-induced hyperglycemia (SIH) remains the most underrated side effect [5, 6]. Studies about gluco-

corticoids suggest that during corticosteroid therapy, almost all patients with a history of diabetes will experience worsening of diabetic control leading to a prolonged hospital stay that eventually affects the quality of life, and those patients without diabetes can develop hyper-glycemia [2, 3]. Undiagnosed SIH will precipitate diabetes mellitus (DM). American Diabetes Association (ADA) defines SIH as serum fasting glucose levels of 126 mg/dl or random glucose levels of 200 mg/dl in at least two separate measurements. Multiple mechanisms are believed to be involved in the development of Glucocorticoid-induced hyper-glycemia, such as the increase in hepatic glucose production, decreased b-cell function and inhibition glucose up take in to the muscle and adipose tissue [2]. Skeletal muscle represents the largest reserve of glycogen in the body as it stores 80% of postprandial glucose and its storage depends on the presence of insulin and the glucose transporter type 4 (GLUT4) glucose transporters availability. The predominant mechanism responsible for glucose intolerance after administration of glucocorticoids is reduced insulin sensitivity [7]. Steroids induce insulin resistance by directly interfering with signaling cascades, mainly the GLUT4 transporter. Insulin resistance may resolve in the case of low dose steroid therapy, whereas it may lead to diabetes in moderate to high dose steroid therapies.

In a hospital setting, there was evidence that more than half of the patients receiving high-dose steroids developed hyperglycemia, with an incidence of 86% of at least one episode of hyperglycemia. The incidence of glucocorticoid-induced hyperglycemia in an elderly population treated with glucocorticoids has been reported to be 12%. Almost 94% of hyperglycemic cases develop within 1-2 days of initiation of steroid therapy in non-diabetic patients.

Since, hyperglycemia in hospitalized patients would increase mortality and morbidity as there is a relationship between hyperglycemia and cardiovascular risk, the primary objective of this study was to determine the incidence of hyperglycemia that occurred due to corticosteroid therapy and to find the usage of glucocorticoids in various disease conditions.

Also, this study assessed the risk factors for SIH and also the effective management for hyperglycemia that occurred due to steroid therapy.

MATERIALS AND METHODS: This study was conducted in the departments of General medicine, Dermatology, Nephrology in a tertiary care multispecialty teaching hospital in Coimbatore, Tamil Nadu, India, from February 2019 to July 2019 (6 months). This study was a Prospective Observational study with a sample size of 200. The Ethical clearance for this study protocol was obtained from the Institutional Human Ethics Committee (IHEC No: 19/003), PSGIMSR, Coimbatore, Tamil Nadu.

The study population included patients who were on Glucocorticoids. Both the gender who were above the age of 18 irrespective of their diabetic history (diabetic and non-diabetic patients) were included in the study. Furthermore, for diabetic patients, HbA1C was assessed before including them in the study. If the diabetic patient had HbA1C greater than 6.5%, they were excluded from the study due to their uncontrolled diabetes. Patients who are not willing to participate in the study were also excluded.

The patient's random blood sugar levels of pre-corticosteroid therapy and post-corticosteroid therapy were recorded. In addition to this, the patient's FBS, PPG, evening blood sugar, and post-dinner blood sugar levels for 5 days were collected from the patient's medical record file and were followed throughout their hospital stay to identify the incidence of steroid-induced hyperglycemia. The incidence of hyperglycemia was determined using the definition as per the American Diabetes Association (ADA). ADA defined SIH as serum fasting glucose levels of 126 mg/dl or random glucose levels of 200 mg/dl in at least two separate measurements. This study also included the assessment of risk factors for the incidence and management of SIH.

Statistics: We used frequency, percentage, mean ± standard deviation, graph, and pie charts for descriptive statistics and to present the study results. Paired student T-Test was used to evaluate the significant difference between the pre-and post-steroid blood sugar levels and also to identify the

effective management. The odds ratio (OR) and Chi-square test were used to assess the risk factors for SIH.P<0.05 was considered statistically significant. Statistical analysis was performed using SPSS Version 20.0, and Microsoft excels 2016.

RESULTS AND DISCUSSION: Demographic details of 200 patients who were commenced with steroids were obtained, and steroid usage was estimated in these patients. We found that 28.5% of steroids were indicated for respiratory problems, 27% for auto-immune disorders, 19% for dermatological problems, 11.5% for renal problems, and 4% for gastroenterological problems. Similarly, in a study conducted by Ashley. C. fong *et al.*, eight were assessed for various indications of steroids, in which 55 subjects were treated with steroids for respiratory diseases, 5 for rheumatic conditions and 2 for gastroenterological diseases. 12% of the patients were administered steroids which were indicated for other diseases like Sjogren's syndrome, multiple myeloma, facial nerve palsy, Wegener's granulomatosis, multiple myeloma, primary sclerosing cholangitis and optic neuritis.

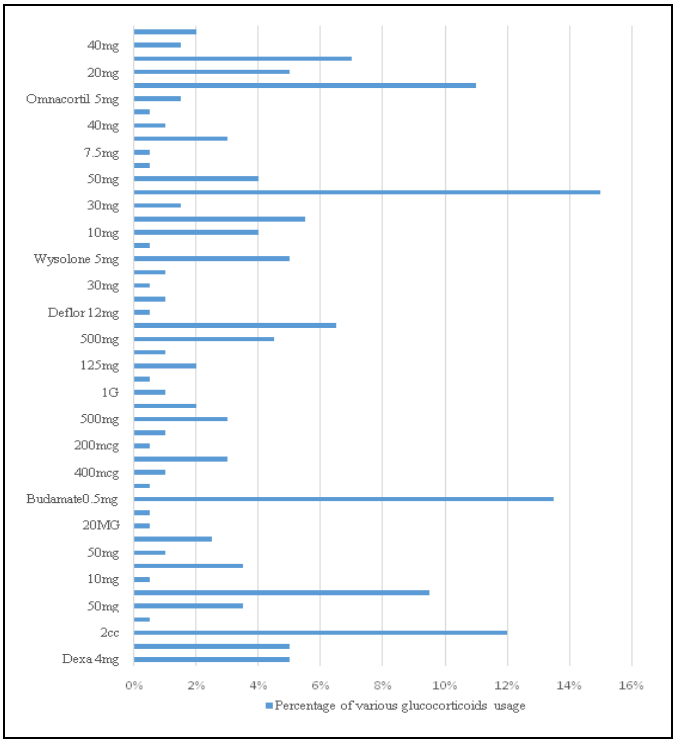

FIG. 1: USAGE OF CORTICOSTEROIDS IN STUDY POPULATION

Prednisolone was the most common form of oral steroids prescribed whereas dexamethasone was the most frequent parenteral form administered.

This result is similar to the Ashley. C. fong *et al.*, study where they concluded prednisolone to be the most common oral form of corticosteroids prescribed [8]. When various brands for prednisolone were evaluated, we inferred that the most frequently prescribed brand and administered dose of prednisolone were wysolone (35.5%) and 40 mg (15%), respectively. However, the usage of steroids varies accordingly with different hospital setups, the prevalence of the disease condition in that hospital and brands of steroids used depends on the choice of the physician, drug formulary of the hospital. The wide range of indications and uses of steroids is attributed to their anti-inflammatory and immunosuppressive properties.

Patients (n=67) who had no blood glucose monitoring were excluded from the study as they were considered to have a lesser chance of developing hyperglycemia by the physician. To determine the incidence rate of SIH, patients (n= 133) who had blood glucose monitoring with at least four measurements per day were only included. The incidence rate of SIH in this study was found to be 45.8%. Similar studies carried out by Jose Gerardo Gonzalez *et al.*, and G.B Cansu *et al.*, showed an increased incidence rate of 46% and 75%, respectively [9, 10]. The higher incidence in the latter study may be due to their limited sample size. This study also found that males had a higher incidence of SIH (52.1%) than females (38.7%).

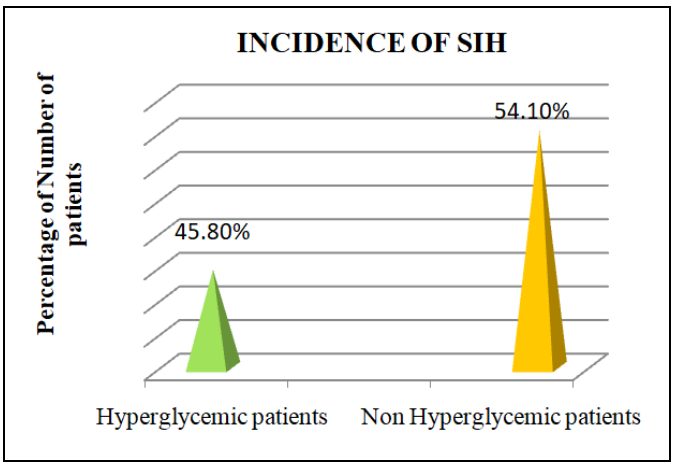

FIG. 2: INCIDENCE OF SIH

The study also focused on the incidence rate for individual steroid drugs. Out of 23 patients administered methylprednisolone, 12 (52.1%) of them developed SIH followed by dexamethasone, where out of 34, 13(48.1%) of them developed it.

Down the list, 84 patients prescribed with prednisolone, 40 (47.6%) of them developed hyperglycemia, 16 (47.1%) of them showed hyperglycemic status among 34 patients prescribed with dexamethasone whereas 5(20%) out of 25 patients prescribed with budesonide developed SIH. Among all the steroids administered, deflazacort showed a higher incidence where with a total of 4 patients, 3 developed SIH and the incidence rate was found to be 75% which is due to its limited usage in the hospital. There is no evidence to show that a particular steroid can have a higher potential to induce hyperglycemia when compared to others. Further studies are required to determine steroid with a higher risk of developing hyperglycemia.

When the average blood glucose levels of pre and post steroid therapy were plotted on a graph, it depicts that the glucose levels of post steroid therapy were higher, indicating SIH. The mean RBS values before and after steroid therapy among SIH patients were found to be statistically significant (P<0.05) **Table 1**.

TABLE 1: AVERAGE BLOOD GLUCOSE LEVELS BEFORE AND AFETR THERAPY

Study population		Random Blood Sugar Level		P-Value
		Before therapy (Mean ± SD)	After therapy (Mean ± SD)	
SIH patients	Diabetes Patients	131.12±25.16	268.45±42.6	
	Non-diabetic patients	119.42±19.7	243.9±25.9	0.000*
Non-SIH patients		65.31±56.05	71.65±71.83	0.086

Statistically, a significant difference was seen among SIH patients when P<0.05 using paired Student T-test.

Upon obtaining 4-point measurements (FBS, post-lunch, evening, post-dinner) of 61 patients who developed SIH, hyperglycemia was observed in most of the patients on the third day after initiation of steroid therapy. Hector Eloy Tamez *et al.,* [11] study proposed that SIH occurred within 1-2 days of initiation of steroid therapy in 94% of patients while G.B Cansu *et al.,* [10] showed SIH incidence was higher on 3rd day of steroid therapy. Similarly, 4-point measurements (FBS, post-lunch, evening, post-dinner) were used to detect the effect of glucose levels of steroid therapy at different time points, the abnormal levels were seen at post-lunch. It is in line with the work done by GB Cansu *et al.,* [10,] which predicted that at post-lunch and post-dinner periods, hyperglycemia incidence was high. D.H. Van Raalte *et al.,* [12] proposed that skeletal muscle is responsible for insulin-mediated capture of postprandial glucose. As corticosteroids cause insulin resistance by directly interfering with the insulin signaling cascade, it results in the increased postprandial glucose levels. So, we suggest that measuring the post-lunch glucose level is ideal for detecting hyperglycemia in steroid-administered patients. A previous prospective study by Yuen KC *et al.,* [13] showed that a medium dose of glucocorticoids induced postprandial hyperglycemia from mid-day to midnight, whereas fasting plasma glucose remains unchanged. Therefore, the timing and frequency of measuring the blood glucose level play a crucial role in detecting SIH.

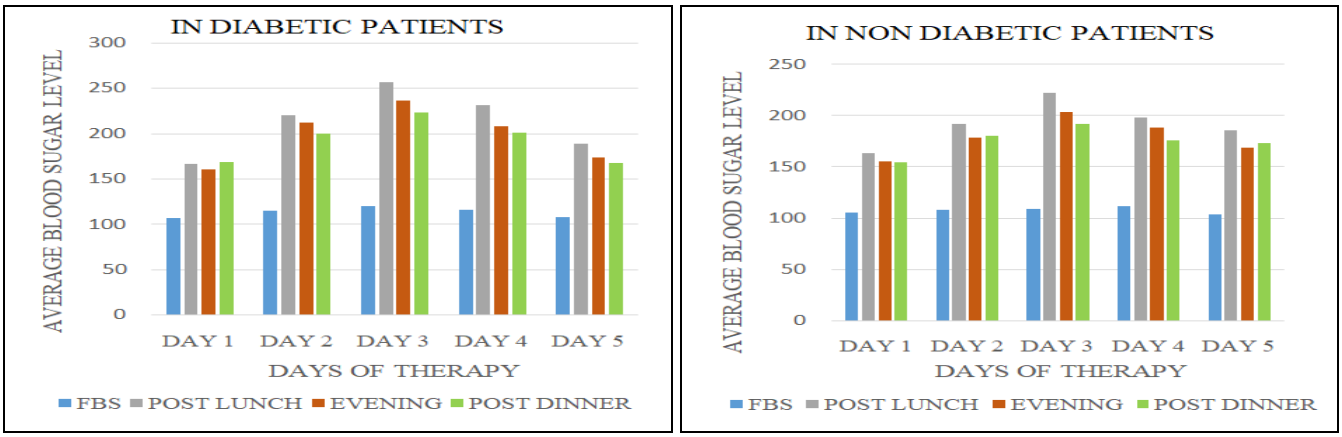

FIG. 3: DISTRIBUTION OF PATIENTS WITH GLUCOSE MEASUREMENTS ACCORDING TO DAY AND MEAL TIME IN DIABETIC AND NON-DIABETIC PATIENTS

FBS and PPG levels of both diabetic and non-diabetic populations were plotted separately. FBS and PPG levels of SIH patients were compared with non-SIH patients.

It was found that there were fewer fluctuations in FBS levels when compared to the SIH and non-SIH groups. Instead, fluctuations were seen in PPG levels both in diabetic and non-diabetic patients.

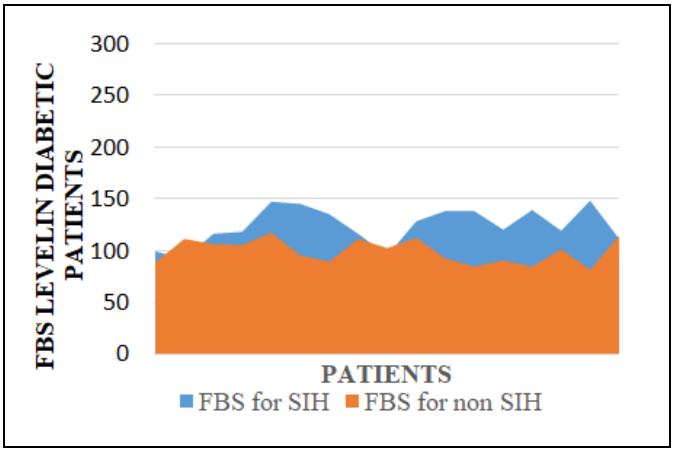

FIG. 4: EFFECT OF FBS IN DIABETIC PATIENT

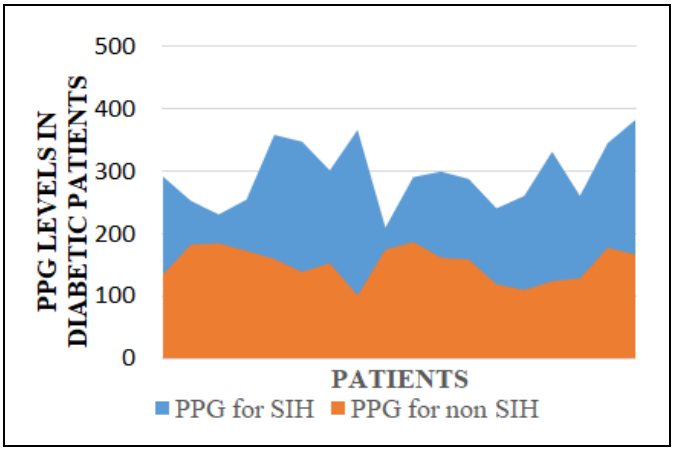

FIG. 5: EFFECT OF PPG IN DIABETIC PATIENTS

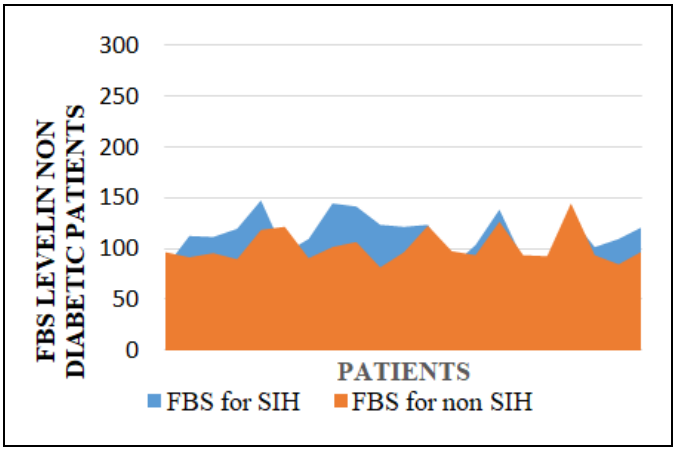

FIG. 6: EFFECT OF FBS IN NON-DIABETIC PATIENTS

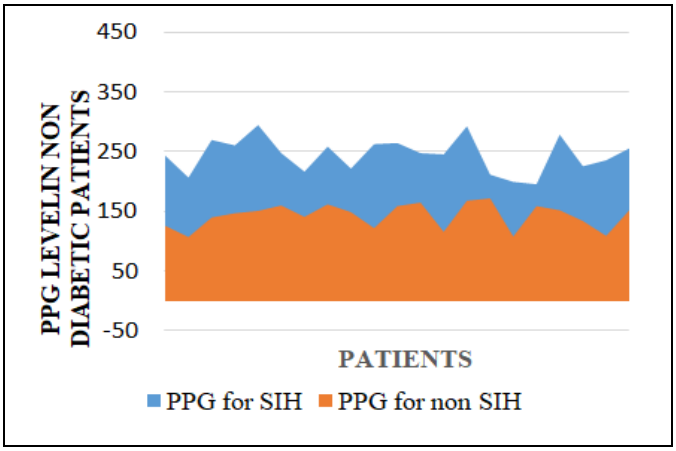

FIG. 7: EFFECT OF PPG IN NON-DIABETIC PATIENT

This study identified potential risk factors for SIH using the Chi-square test and OR. Older age, history of DM, BMI, duration of therapy, drug interaction are the risk factors that are identified for new onset of steroid-induced hyperglycemia. Similar risk factors like age (>40 years) and BMI (overweight, obese) were found in the study conducted by Katsyuma T *et al.*, [2].

When detecting the strength of association through the OR, we found that older age (>40 years) has an OR value of 5.95 which showed the strongest association to the risk factor and for developing SIH. A study conducted by Iwamoto T *et al.*, [14] also showed an older age to be the risk factor for developing SIH which is because glucose tolerance and beta-cell function decline with age, and it is reasonable that older age is a risk factor for SIH. While considering BMI, it showed an OR value of 4.02, which indicates a strong association for developing SIH, which indicated an independent risk factor. Uzu T *et al.*, [4] concluded that BMI to be the risk factor for SIH. This is because, in obese individuals, the levels of NEFA, glycerol, hormones, cytokines, pro-inflammatory substances, and other substances that are involved in the development of insulin resistance are increased.

When the OR was determined for the duration of therapy, the OR value was found to be 2.1, which showed that a longer duration of steroid therapy may affect the glucose levels 2-fold greater than the shorter duration therapies. This result is similar to the study worked by Gonzalez- Gonzalez JG et al., [9] where they found that a continuous glucocorticoid regimen was an independent risk factor for the development of GC-HG. This is because the longer duration of steroid therapy may result in the

accumulation of steroid, and this causes insulin resistance and beta-cell dysfunction. Apart from the above-mentioned risk factors, history of diabetes was also considered to be the risk factor for SIH as it showed an OR value of 2.06. 65.9% of patients with DI developed hyper-glycemia, which indicates a risk factor. The interacting drugs with steroids that cause a risk to develop hyperglycemia include atorvastatin, tacrolimus, Aldactone, metronidazole, loratadine, fluconazole, and ciprofloxacin. DI was found to be a risk factor since the mechanism for all the interacting drugs was due to an increase in the level or effect of steroids by P-glycoprotein efflux transporter inhibition. We found no studies regarding diabetic history and drug interactions as risk factors for SIH.

TABLE 2: IDENTIFYING RISK FACTORS USING CHI-SQUARE TEST AND ODDS RATIO

Risk factors	No. of patients developed hyperglycemia	No. of patients not developed hyperglycemia	Odds Ratio	P-value
Gender (male) Male(n=71) Female(n=62)	37(52.1%) 24(38.7%)	34(47.8%) 38(61.2%)	1.72	0.085
Age (>40) <40 years (n=30) >40 years (n=103)	4(13.3%) 57(55.3%)	26(86.7%) 46(44.7%)	5.95	0.00*
History of Diabetes Yes(n=58) No(n=75)	40(68.9%) 21(28%)	18(31.1%) 54(72%)	5.71	0.00*
Smoking Yes(n=32) No(n=101)	15(46.8%) 46(45.5%)	17(53.2%) 55(54.5%)	2.05	0.060
Alcohol Yes(n=20) No(n=113)	9(45%) 52(46%)	11(55%) 61(53.9%)	0.96	0.565
Physical Activity Yes(n=54) No(n=79)	17(31.4%) 44(55.6%)	37(68.5%) 35(44.3%)	0.36	0.005*
History of Steroid Therapy Yes (n=26) No(n=107)	14(53.8%) 47(43.9%)	12(46.2%) 60(56.1%)	1.48	0.244
Family history of Diabetes Yes (n=15) No(n=118)	7(46.7%) 54(45.8%)	8(53.3%) 64(54.2%)	1.03	0.58
BMI (overweight and obese) Normal (n=99) Overweight and obese(n=34)	37(37.3%) 24(70.5%)	62(62.6%) 10(29.4%)	4.02	0.01*
Hypertensive patients Yes (n=46) No(n=87)	24(52.2%) 37(42.5%)	22(47.8%) 50(57.5%)	1.47	0.19
Dyslipidaemia Yes(n=4) No(n=129)	3(75%) 58(45%)	1(25%) 71(55%)	3.67	0.25
Duration of Therapy (>15 day) <15 days(n=80) >15 days(n=53)	31(38.75%) 30(56.3%)	49(61.25%) 23(43.39%)	2.06	0.032*
Drug Interaction Yes(n=32) No (n=101	31(65.9%) 30(34.8%)	16(34%) 56(65.1%)	3.61	0.001*

These variables were statistically significant when P<0.05 using the Chi-square test. *Parameter is significantly associated with SIH.

Since postprandial hyperglycemia is the primary complication of SIH, treatment for SIH is not well established. In this study, Insulin was the most frequently prescribed treatment for SIH, which showed an increased efficacy compared to others which are followed by the combination therapy (CT) of insulin and oral hypoglycemic drugs (Glycomet). To support this result, Paired Student T-test was conducted to determine the efficacy of insulin before and after the management with insulin. It showed a significant difference in glucose levels before and after management with the insulin. Hector Eloy Tamez *et al.*, [11] suggested insulin to be the effective treatment for SIH, particularly NPH insulin. Joint British Diabetes Societies for Inpatient Care (JBDS-IP) recommended that an increased morning dose of insulin is effective in reducing SIH.

TABLE 3: STATISTICAL ANALYSIS OF MANAGEMENT FOR HYPERGLYCEMIA

Management	Mean glucose levels (Mean ± SD)	Difference (Mean ± SD)	P-value	Management
	Before Management	After Management		
Insulin therapy	266.55±46.08	148.34±27.9	118.21±40.09	0.000*
Combination therapy	247.14±34.9	130.57±22.11	116.57±34.9	0.000*
Glycomet	264.75±35.3	262.00±34.3	2.75±2.27	0.151
Route change	240±45.17	236.66±34.4	3.333±22.1	0.819
Dose reduction	260±41	258±39.5	2±1.41	0.295

CONCLUSION: Persistent and even short-term hyperglycemic conditions impair the immune function and increase the risk of infection and vascular events. So, regular monitoring of glucose levels and assessing the risk factors in patients who are on steroids should be considered as an important aspect in clinical practice.

Early assessment of risk factors (older age, history of diabetes mellitus, higher BMI, duration of therapy, and drug interaction) for developing SIH may reduce the episodes of hyperglycemia and also complications of SIH such as increased length of stay in the hospital, readmission to hospital, higher risk of infection, delayed wound healing, and higher mortality. This study detected that SIH was occurring commonly on the third day of steroid therapy. Hence, glucose monitoring should be performed during the first three days of steroid therapy, and also measuring the post-lunch glucose levels is ideal for detecting hyperglycemia in steroid administered patients. In this study, Insulin and combination therapy (CT) of insulin & OHA were the most frequently prescribed treatment for the subjects who developed SIH, which in turn showed an increased efficacy compared to others. Therefore, proper diagnosis and precise treatment for hyperglycemia may result in improved health and reduced health care cost.

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