



A PROSPECTIVE OBSERVATIONAL STUDY ON PRESCRIPTION PATTERN OF INSULIN IN STEROID – INDUCED HYPERGLYCEMIA AMONG DIABETIC PATIENTS WITH RESPIRATORY INFECTIONS - A PILOT STUDY

Ariya Krishna R. V^{*1}, Athira R. B¹, Afin A. R¹, Dr. Prasobh G. R²

Dr. Mahesh Sukumaran³, Dr. Nithin Manohar. R⁴, Dr. Padmesh P.R⁵

1. Fifth Year Students, Doctor of Pharmacy, Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram, Kerala, India.
2. Principal, Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram, Kerala, India.
3. Senior Consultant in General Medicine, SCE-Endocrinology & Diabetes, Cosmopolitan Hospital Post Graduate Institute Health Science & Research.
4. Professor and HOD, Department of Pharmacy Practice, Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram, Kerala, India.
5. Assistant Professor, Department of Pharmacy Practice, Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram, Kerala, India.

Corresponding Author

Ariya Krishna R.V

Fifth Year Student, Doctor of Pharmacy,
Sree Krishna College of Pharmacy and Research Centre, Parassala,
Thiruvananthapuram, Kerala, India.

Abstract: This prospective observational pilot study evaluated the prescription patterns of insulin in steroid induced hyperglycaemia among diabetic patients with respiratory infections, variations in glycaemic status before and after steroid therapy, and quality of life among 20 patients aged above 18 years receiving steroid therapy for respiratory infections who already diagnosed with type 2 Diabetes Mellitus. Patients were enrolled as per inclusion criteria. Prescription patterns and glycaemia status were assessed from case records, Knowledge, Attitude, Practice (KAP) was assessed before and after pharmacist-led counselling using Patient Information Leaflet (PIL), at discharge using a validated KAP questionnaire. Quality of life was evaluated using a modified World Health Organization Quality of Life -Brief Version (WHOQOL-BREF) questionnaire. Descriptive statistics were expressed as mean $\pm$ standard deviation (SD). The paired t-test was used to compare KAP scores. Among 20 patients, Basal-Bolus insulin was the most frequently prescribed insulin regimen (65%). Moderate hyperglycaemia was the predominant glycaemic status (60%) at admission. Pharmacist led

counselling significantly improved KAP scores ($p < 0.05$) and significantly enhanced quality of life in the study participants.

Keywords: Steroid induced hyperglycemia, Type 2 diabetes mellitus, Corticosteroids, Respiratory infections, Basal Bolus insulin.

I. INTRODUCTION

Glucocorticoids (GCs) are among the most commonly prescribed anti-inflammatory and immunosuppressive agents for the management of various acute and chronic inflammatory, autoimmune disorders and respiratory disorders. They are inexpensive, readily available, and accessible, yet they have frequent and dangerous side effects^[1]. The patients with pre-existing Diabetes Mellitus who undergo corticosteroid therapy for respiratory illness-including pneumonia, COPD, and LRTIs are more likely risk of steroid -induced hyperglycaemia.

1.1 STEROID INDUCED HYPERGLYCEMIA

SIHG is defined as abnormally elevated blood glucose associated with the use of GCs in patients with or without pre-existing DM. It occurs due to the diabetogenic effects of glucocorticoids, which increase insulin resistance, enhance hepatic glucose production, and impair pancreatic β -cell function^[8]. If left untreated, SIH can increase the risk of infections, delay wound healing, prolong hospitalization and contribute to poor clinical outcomes.

1.2 PATHOPHYSIOLOGY

Insulin resistance: Insulin resistance is the core pathophysiology of diabetes. This cascade could be accelerated following glucocorticoid administration. Glucocorticoid play an important role in adipogenesis and adipose tissue metabolism, increasing visceral rather than peripheral fat storage. They promote the differentiation of pre-adipocytes into mature adipocytes, increase visceral adiposity by selectively enhancing the affinity of lipoprotein lipase for visceral adipose tissue, and stimulate lipolysis to produce non-esterified fatty acids, which are not suppressed by insulin. The actions of various adipokines, including the upregulation of leptin and resistin due to an increase in white adipose tissue, contribute to insulin resistance. Interestingly, the appetite-suppressing effect of leptin is counteracted by glucocorticoids. In addition to adipose tissue, muscle contributes to the insulin resistance caused by glucocorticoids. Glucocorticoids further promote insulin resistance by decreasing the rate of protein synthesis and activating multiple protein degradation pathways, resulting in a reduction of skeletal muscle mass. Furthermore, glucocorticoids may contribute to insulin resistance in skeletal muscle by directly inhibiting the translocation of glucose transporter 4 to the cell membrane, there by interfering with insulin signalling and reducing glycogen synthesis kinase 3 phosphorylation^[10].

β -Cell dysfunction: Pronounced glucose intolerance due to insulin resistance leads to subsequent β -cell dysfunction. The suppressive effect on β -cells from acute glucocorticoid treatment within a few hours is counterbalanced by an increase in insulin secretion from healthy β -cells, which leads to subtle changes in blood glucose level^[10].

Liver: Glucocorticoids directly increase hepatic glucose production by altering the molecular regulation of gluconeogenic enzyme expression, including phosphoenolpyruvate carboxykinase and glucose-6-phosphatase^[10]

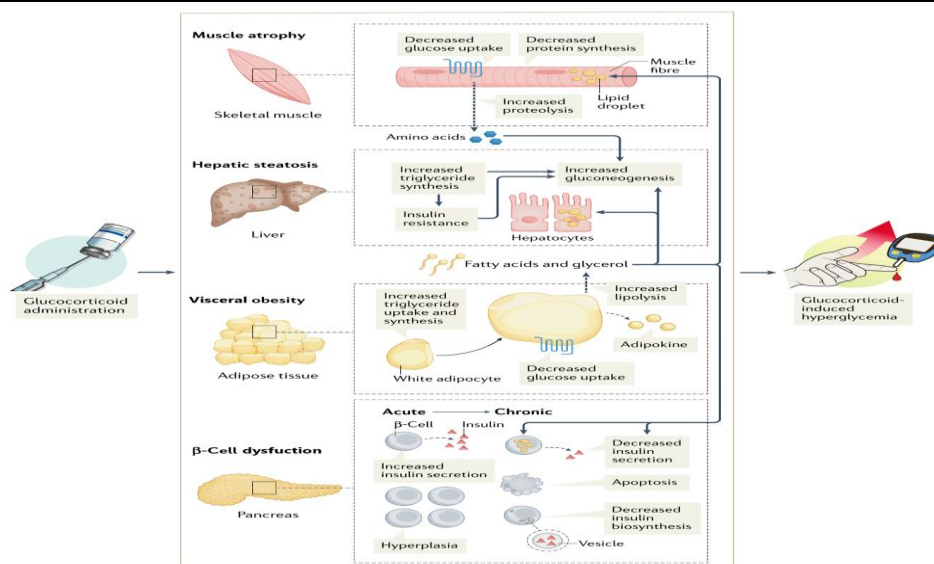


Fig 1: Pathophysiology of steroid induced Hyperglycaemia

1.3 DIABETES MELLITUS

Diabetes mellitus (DM) is a chronic metabolic disease characterized by elevated levels of blood glucose (hyperglycemia) resulting from defects in insulin secretion, insulin action or both. Persistent hyperglycemia can lead to long-term damage and dysfunction of various organs, particularly the heart, blood vessels, eyes, kidneys and nerves.

1.4 ROLE OF CORTICOSTEROID IN RESPIRATORY INFECTION

Systemic corticosteroids are frequently utilized in ambulatory medicine because of their anti-inflammatory qualities. The use of corticosteroids in the management of some severe illnesses, including hypoxia-related pneumocystosis, severe acute community-acquired pneumonia, LRTIs and several types of bacterial meningitis [2].

1.5 IMPACT OF CORTICOSTEROIDS IN DIABETES MELLITUS

Glucocorticoids are widely used in medical practice for their anti-inflammatory action, but lead to hyperglycaemia in 30% of cases, due to rapid reduction of insulin secretion and action.

As they are administered in the morning, glucocorticoids induce hyperglycemic excursion in the afternoon, and at this time screening can be performed by capillary glucose measurement. It is also critical to determine, on medical history and HbA1c assay, whether the patient had prior diabetes, sometimes overlooked, in which case diabetes will not resolve after glucocorticoid discontinuation, and poorly controlled diabetes will often require a basal-bolus insulin therapy in the meantime [3].

1.6 EPIDEMIOLOGY

- Estimating the risk of SIDM and SIH remains difficult due to differences in steroid formulations, treatment duration and dosing regimens. Moreover, studies that evaluate only fasting glycaemia may underestimate the true magnitude of the disease [4].
- The risk increases with higher steroid doses, longer treatment duration, and more potent glucocorticoids.
- SIH can occur in individuals with or without pre-existing diabetes but more probable to pre-existing diabetes mellitus [4].
- Individuals with risk factors such as older age, obesity, family history of diabetes, impaired glucose tolerance or pre-existing diabetes are more likely to develop SIH [4].
- Hospitalized patients, particularly those receiving high-dose steroids for inflammatory, autoimmune, or oncologic conditions, have a higher incidence of SIH.

1.7 SIGNS AND SYMPTOMS

Many patients with SIH are initially asymptomatic, especially when hyperglycaemia is mild. When symptoms occur, they are similar to those seen in other forms of hyperglycaemia. Hyperglycaemia often develops after initiation of glucocorticoid therapy and may be more pronounced in the afternoon and evening, especially with morning administration.

- Polyuria (frequent urination)
- Polydipsia (excessive thirst)
- Polyphagia (increased hunger)
- Fatigue and weakness
- Blurred vision
- Unexplained weight loss (more common in severe hyperglycemia)
- Dry mouth
- Headache

1.8 DIAGNOSIS

The diagnostic criteria for SIHG do not differ from other types of diabetes and include a confirmed fasting blood glucose ≥ 7 mmol/L (≥ 126 mg/dL), a glucose level of ≥ 11.1 mmol/L (≥ 200 mg/dL) at 2hrs following ingestion of 75g glucose in an oral glucose tolerance test (OGTT), an HbA1c $\geq 6.5\%$ (≥ 48 mmol/mol) or a random blood glucose ≥ 11.1 mmol/L (≥ 200 mg/dL). However, in patients with SIHG diagnosis can be more challenging, fasting blood glucose might be normal especially when short-acting or intermediate-acting GCs are administered in single morning doses.

Determination of HbA1c can be useful to evaluate glycemic control in patients who are on long-term GC therapy or to distinguish between new-onset diabetes and pre-existing DM in a situation of hyperglycemia after GC initiation. Due to the mentioned limitations of the usual diagnostic approach to detect SIHG, it is recommended to perform frequent (capillary) glucose monitoring in those who receive high doses of GCs (defined as >20 mg prednisolone or equivalent). This approach is particularly recommended in people with a high risk to develop SIHG (e.g., advanced age, higher BMI, previously present impaired glucose tolerance, prediabetes or family history of diabetes). Then a random glucose value ≥ 11.1 mmol/L (≥ 200 mg/dL) can be utilized to establish the diagnosis of SIHG^[9].

1.9 RISK FACTORS FOR STEROID-INDUCED HYPERGLYCEMIA

Medical conditions directly causing kidney damage.^[8]

Patient related risk factors include^[5]:

- Idiopathic interstitial pneumonitis was more common (79.4% vs 49.7%, $P = 0.001$), and endobronchial tuberculosis was less common (5.9% vs 29.4%, $P = 0.004$)
- Elderly age
- Family history of diabetes mellitus
- Pre-existing diabetes mellitus
- History of gestational diabetes
- Sedentary lifestyle
- Metabolic syndrome

Treatment related risk factors:

- High-dose glucocorticoid therapy
- Prolonged duration of steroid treatment
- Multiple daily doses of steroids^[12]

1.10 COMPLICATIONS

Steroid -induced Hyperglycaemia complications include:

- Fluid and electrolyte imbalances
- Osteoporosis
- Uremia
- Anemia
- Cardiovascular disease
- Mineral and bone disorders
- Malnutrition

Acid-base imbalance

- Persistent hyperglycaemia (poor blood glucose control)
- Increased risk of bacterial, viral, and fungal infections
- Delayed wound healing
- Hyper osmolar Hyperglycaemic State (HHS)
- Diabetic Ketoacidosis (DKA), especially in susceptible patients
- Dehydration due to osmotic diuresis
- Electrolyte imbalance (e.g.: hyponatremia, hypokalaemia)
- Increased risk of acute kidney injury from dehydration
- Prolonged hospital stays
- Increased cardiovascular complications (e.g.: myocardial infarction, stroke)
- Increased morbidity and mortality in hospitalized and critically ill patients
- Unmasking or progression to overt diabetes mellitus
- Worsening of pre-existing diabetes mellitus
- Impaired immune function

Reduced quality of life due to symptoms such as polyuria, polydipsia, fatigue, and weight loss ^[6]

1.11 MANAGEMENT OF STEROID INDUCED HYPERGLYCEMIA

Insulin is the preferred treatment for managing **steroid-induced hyperglycaemia (SIHG)**, particularly in hospitalized patients and those with moderate to severe hyperglycemia.

INSULIN THERAPY

Basal human insulin may be administered in the morning as an insulin therapy for morning once-daily oral steroid-associated glucose excursion. Basal insulin analogues may be taken into consideration if hyperglycemia persists throughout the day until evening, and basal insulin injection in the morning is advised. The pharmacokinetic characteristics (particularly the amount and duration of action of the GC being used) and the pattern of hyperglycaemia should be taken into consideration when selecting an insulin formulation and regimen.

Hyperglycaemia is typically observed in the afternoon and evening for patients taking prednisolone once daily in the morning. In these situations, NPH insulin's glucose-lowering profile closely resembles the pattern of hyperglycaemia brought on by intermediate-acting GC. NPH given in the morning is therefore thought to be a wise decision. Meal time insulin can be added as needed in patients who still have severe hyperglycaemia. Hyperglycemia typically lasts for more than 24 hours in patients receiving long-acting GCs or repeated divided doses of intermediate-acting GCs. Consequently, the best option is a basal-bolus insulin treatment. As long as they are clinically stable and consuming a healthy diet, patients with pre-existing diabetes who are currently receiving oral or injectable medication can continue.

According to British guidelines, those without a pre-existing diabetes diagnosis should have their blood sugar checked at least once a day, ideally either before or one to two hours after lunch or dinner. Testing should be repeated once before or after lunch or dinner if the first blood glucose level is less than 216 mg/dL (12 mmol/L). Testing should be done four times a day (before meals and before bed) if the following blood glucose level is greater than 216 mg/dL (12 mmol/L). The steroid-induced diabetes treatment plan should be

implemented if capillary glucose is persistently more than 216 mg/dL (12 mmol/L) (i.e., twice in a 24-hour period).

2. METHODOLOGY

2.1 AIM OF THE STUDY

- To evaluate the prescription pattern of insulin regimens in managing steroid-induced hyperglycemia among diabetic patients with respiratory infections and to assess quality of life.

2.2 OBJECTIVES

- To evaluate the prescription pattern of insulin regimens in managing steroid-induced hyperglycemia among diabetic patients with respiratory infections and to assess quality of life.
- To assess the variations in glycaemic status before and after corticosteroid therapy.
- To educate patients through counselling by using Patient Information Leaflet and to assess their understanding using Knowledge, Attitude, Practice.
- To evaluate the quality of life using World Health Organization Quality of life –Brief Version.

2.3 STUDY DESIGN

A prospective observational study was conducted in 20 diabetic patients who develop steroid-induced hyperglycaemia during the treatment of respiratory infections. The study aims to evaluate the prescription pattern of insulin regimens used in the management of steroid-induced hyperglycaemia, assess variations in glycaemic status before and after corticosteroid therapy. Evaluate patient's quality of life and determine the impact of patient counselling on Knowledge, Attitude and Practice [KAP].

2.4 STUDY POPULATION

A pilot study was conducted involving a total of 20 diabetic patients with respiratory infection who develop steroid-induced hyperglycaemia following corticosteroid therapy. The study was conducted in the Department of General Medicine and Endocrinology at a multispecialty hospital in Thiruvananthapuram. The study protocol was approved by the Institutional Ethics Committee of Cosmopolitan Hospital, Thiruvananthapuram. In our study the patients were enrolled in the study based on the inclusion and exclusion criteria. A Written informed consent was obtained from each subject after a detailed explanation of the objectives and protocol of the study.

2.5 DATA SOURCE

All relevant information regarding the study was collected from case records and through direct interviews with patients after obtaining informed consent. Data were collected using pre-designed data collection forms or proformas. The study was approved by the Institutional Ethics Committee of Cosmopolitan Hospital, Thiruvananthapuram, Kerala, India.

Prescription patterns of Insulin were clinically studied among diabetic patients with respiratory infections receiving corticosteroid therapy. Glycaemic status will be evaluated based on fasting blood glucose [FBG], post prandial blood glucose [PPBG], Random blood glucose [RBG] and HbA1c levels before Corticosteroid therapy. The type of insulin prescribed, dosage, frequency, route of administration and insulin regimen will be recorded and analysed. Assessed their understanding using Knowledge, Attitude, Practice(KAP) and helps to improve their knowledge through patient counselling using patient information leaflet(PIL) and Quality of life using modified (WHOQOL -BREF VERSION).

2.6 STATISTICAL ANALYSIS

Statistical analysis was performed using Microsoft Excel and SPSS. Descriptive statistics were used to summarize demographic and clinical characteristics, while prescribing patterns were expressed as frequencies and percentages. Continuous variables were presented as mean $\pm$ standard deviation (SD). Paired t-test was

used to compare medication adherence and WHOQOL-BREF questionnaire scores before and after counselling.

2.7 INCLUSION CRITERIA

- Patient age 18 years and above.
- Patients receiving corticosteroids therapy.
- Patients with type 2 DM.
- Patients admitted with respiratory infections.
- Patient developing hyperglycemia after steroid therapy.
- Inpatient who are willing to participate in the study.

2.8 EXCLUSION CRITERIA:

- Patients with gestational diabetes mellitus.
- Type 1 DM.
- Patients who are not willing to participate in the study.

2.9. RISULTS AND DISCUSSION

In this pilot study; 20 patients were enrolled in according to the inclusion and exclusion criteria .The results are as follows .

3 GENDER WISE DISTRIBUTION OF STUDY PARTICIPANTS (N=20)

Table 1 : Gender wise Distribution

GENDER	NUMBER[N=20]	PERCENTAGE(%)
FEMALE	11	55.0%
MALE	9	45.0%
TOTAL	20	100.0%

Out of 20 patients included in the study, 11were Females[55.0%] and 9 were Males[45.0%] indicating a slight female predominance among the study participants.

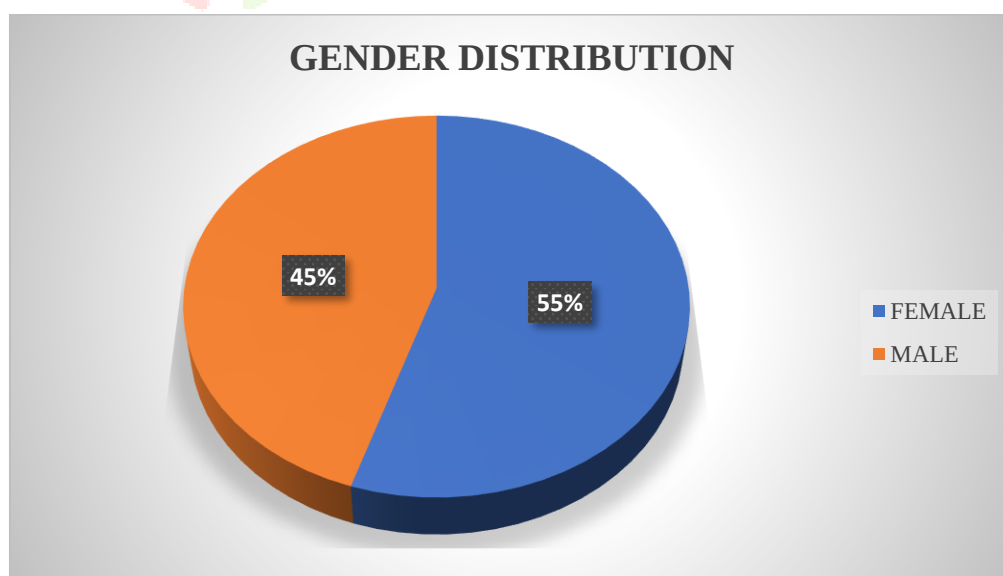


Fig 2 : Gender wise distribution

The slight variation in this gender distribution indicates the women with type 2 diabetes often exhibit greater susceptibility to steroid – induced hyperglycaemia due to differences in body fat distribution ,hormonal influences after menopause and a higher prevalence of obesity and insulin resistance in older women.

3.1 AGE WISE DISTRIBUTION OF STUDY PARTICIPANTS (N=20)

A total of 20 patients were included in the pilot study. The mean age of the participants was 66.0 years with a standard deviation of 9.23 years; the minimum age was 49 years and the maximum age was 81 years.

Table 2 : Categorization of Age

AGE GROUP	NUMBER OF PATIENTS[N=20]	PERCENTAGE
41-50	2	10%
51-60	3	15%
61-70	7	35%
71-80	7	35%
81-90	1	5%
TOTAL	20	100%

The majority of the patients belonged to the 61-70 years and 71-80 years age groups with 7 patients (35.0%) in each category. This was followed by the 51-60 years age group, comprising 3 patients (15.0%). Only 2 patients (10.0%) were aged 41-50 years, while 1 patient (5.0%) belonged to the 81-90 years age group. These findings indicate that steroid – induced hyperglycaemia among diabetic patients with respiratory infections was more commonly observed in older adults, particularly those aged 61-80 years.

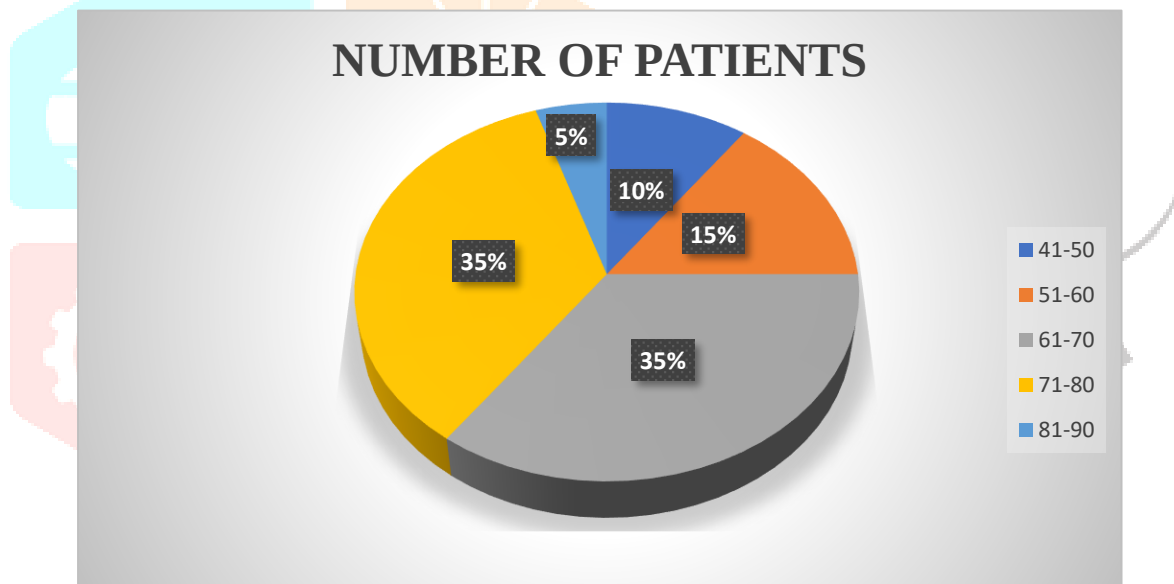


Fig 3 : pie Diagram showing the distribution of age

Most participants were aged 61-80 years, suggesting that older adults with type 2 diabetes are at greater risk of developing steroid -induced hyperglycaemia. Age related decline in beta cell function, increased insulin resistance may contribute to this higher susceptibility.

3.2 PRE – ADMISSION ANTI-DIABETIC MEDICATION PATTERNS

The ongoing antidiabetic medications administered to patients at the time of admission are presented below.

Table 3 : Distribution of Anti-Diabetic Medications

ANTIDIABETIC MEDICATION	PATIENT COUNT[N=20]	PERCENTAGE
SITAGLIPTIN+METFORMIN	9	45%
METFORMIN	4	20%
METFORMIN+GLIMIPIRIDE	2	10%
VILDAGLIPTIN+METFORMIN	1	5%
GLICLAZIDE+METFORMIN	2	10%
METFORMIN+LINAGLIPTIN	2	10%

Among the 20 patients included in the study, Sitagliptin+ Metformin was the most frequently prescribed previous anti – diabetic medication, accounting for 9 patients (45%). Metformin monotherapy was the second most common regimen, prescribed to 4 patients (20%). Metformin+Glimepiride, Gliclazide+Metformin and Metformin+Linagliptin were each prescribed to 2 patients (10%), Vildagliptin+ Metformin was prescribed to 1 patient (5%).

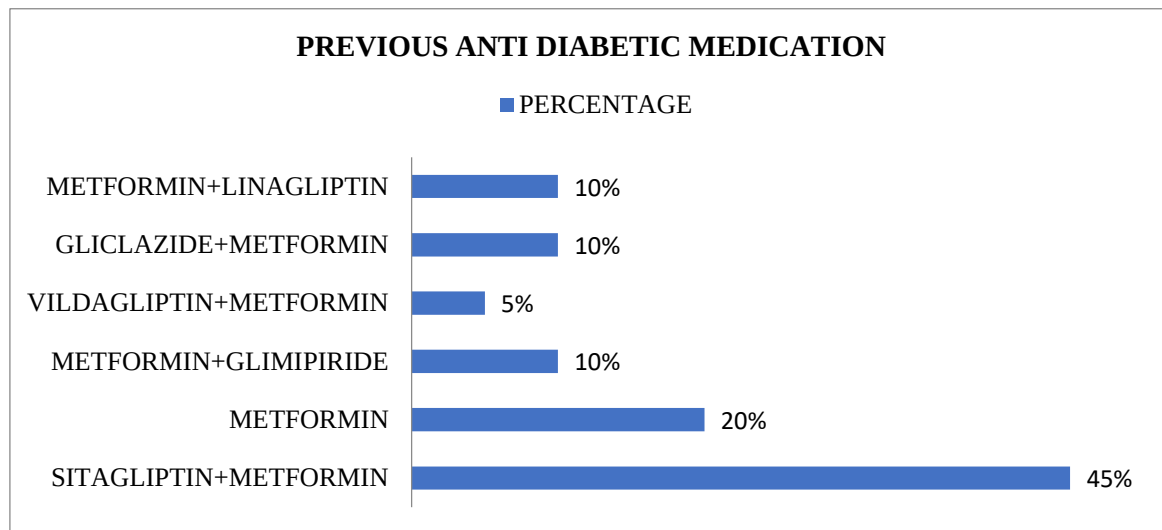


Fig 4: previous anti-diabetic medications

The predominance of metformin - based combination therapy reflects current treatment recommendations for type 2 diabetes mellitus, where metformin remains the first-line agent and DPP-4 inhibitors such as sitagliptin are commonly added to improve glycaemic control with a low risk of hypoglycaemia.

3.3 DISTRIBUTION OF RESPIRATORY INFECTION

Table 4 : Distribution of Respiratory Infection

RESPIRATORY INFECTION	FREQUENCY [N=20]	PERCENTAGE[%]
PNEUMONIA	11	55%
PNEUMONITIS	4	20%
COPD	4	20%
RESPIRATORYDISTRESS SYNDROME	1	5%

Among 20 study participants, pneumonia was the most common respiratory infection, affecting 11 patients (55%) followed by pneumonitis and COPD , each reported in 4 patients (20%). Respiratory distress syndrome was the least common diagnosis, observed in 1 patient (5%).

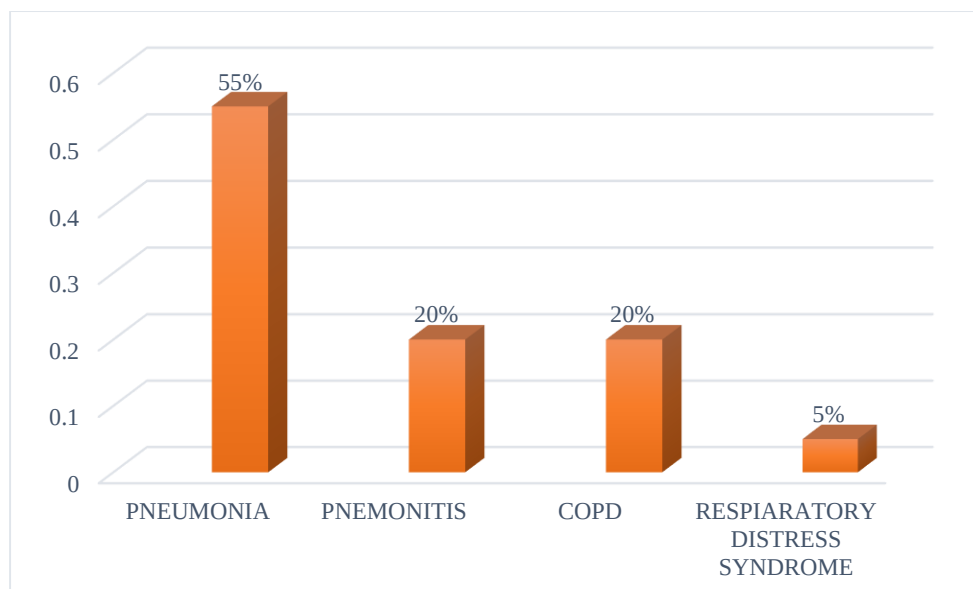


Fig 5 : Bar Diagram showing Distribution of Respiratory Infection

The high prevalence of pneumonia is consistent with the increased susceptibility of patients with type 2 diabetes mellitus to lower respiratory tract infections due to impaired immune function and chronic hyperglycemia.

3.4 PRESCRIPTION PATTERN

3.4.1 STEROID THERAPY DISTRIBUTION

Table 5 : Initial Steroid Therapy

STEROID MEDICATION	INITIAL DOSAGE	NUMBER[N=20]	PERCENTAGE
METHYLPREDNISOLONE	40mg	18	90%
HYDROCORTISONE	100 mg	1	5%
DEXAMETHAZONE	6mg	1	5%

Methylprednisolone 40mg was the most frequently prescribed initial corticosteroid, used in 90%[n=18] of patients. Hydrocortisone 100mg and Dexamethasone 6mg were each prescribed in 5% [n=1] of patients, indicating a clear preference for methylprednisolone as the initial steroid therapy in the study population.

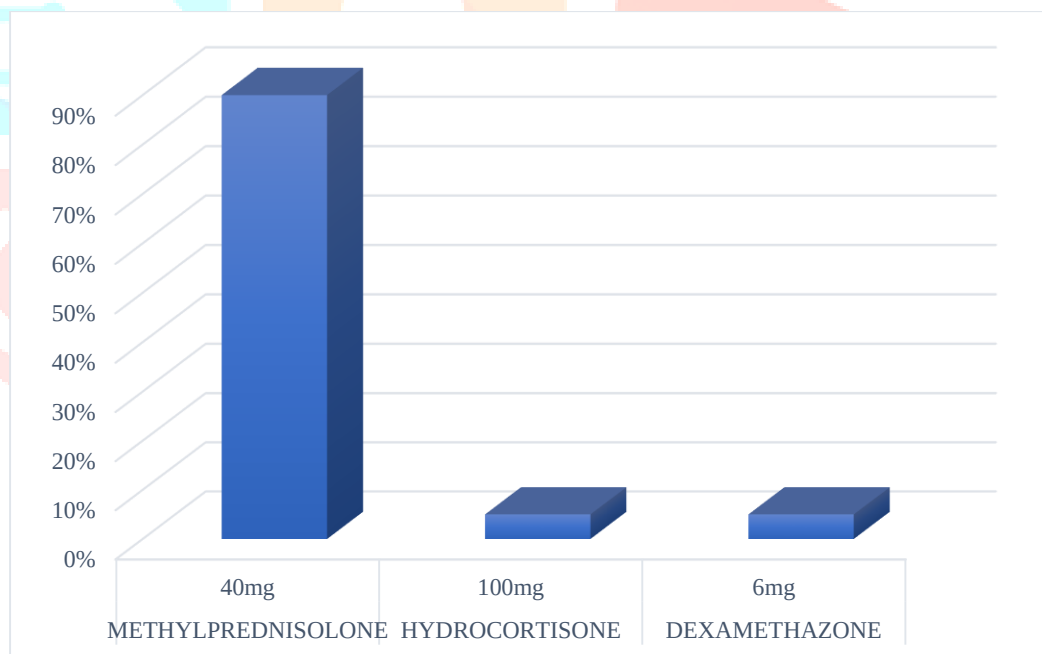


Fig 6: Diagram showing Initial Steroid therapy

Methylprednisolone was the most frequently prescribed corticosteroid due to its potent anti-inflammatory activity, excellent penetration into lung tissue, rapid onset of action and intermediate duration of action, making it the preferred corticosteroid for hospitalized patients with severe respiratory infections. Compared with dexamethasone and hydrocortisone, methylprednisolone allows flexible dose adjustment and gradual tapering to oral medication which reduce the risk of adrenal suppression while maintaining disease control.

3.4.2 STEROID TAPERING REGIMEN

Table 6 : Steroid Tapering Regimens

INSULIN STEROID THERAPY	TAPERING REGIMEN	NO: OF PATIENTS[N=20]	PERCENTAGE
METHYPREDNISOLONE 40mg TDS	40mg BD - DEFLAZACORT 6mg TDS	18	90
HYDROCORTISONE 100mg TDS	50mg TDS - PREDNISOLONE 20mg OD	1	5
DEXAMETHASONE 6mg	NOT TAPERED	1	5

Among the 20 patients included in the study ,18 patients [90%] who were initially treated with methylprednisolone 40mg three times daily [TDS] underwent a stepwise tapering regimen, where the dose was reduced to 40 mg twice daily [BD] and subsequently switched to Deflazacort 6mg TDS. This indicates that methylprednisolone was the predominant corticosteroid used and was generally tapered in a structured manner due to its intermediate duration of action and allows flexible dose adjustment to minimize the risk of adrenal suppression and to maintain disease control.

Only 1 patient [5%] receiving hydrocortisone 100 mg TDS was tapered by reducing the dose to 50 mg TDS , following by conversion to prednisolone 20 mg once daily [OD]. 5[%] dexamethasone 6 mg not had undergone tapering. Overall steroid tapering was performed in 95% of patients, indicating that gradual dose reduction was the standard practice in this study.

3.4.3 PRESCRIPTION PATTERN OF INSULIN IN STEROID -INDUCED HYPERGLYCEMIA

Table 7: Prescription of insulin pattern

INSULIN TYPE	NUMBER [N=20]	PERCENTAGE[%]
Human Insulin Regular	6	30.00%
Human Insulin Regular+Insulin Glargine	11	55.00%
Insulin Aspart + Insulin Degludec	1	5.00%
Premixed	1	5.00%
Insulatard + Novorapid	1	5.00%
TOTAL	20	100%

The majority of patients received Human Insulin Regular + Insulin Glargine 55%[n=11], followed by Human Insulin Regular monotherapy 30% [n=6]. InsulinAspart+Insulin Degludec, Premixed Insulin and Insulatrad +Novorapid were each prescribed to 5% [n=1] of patients .

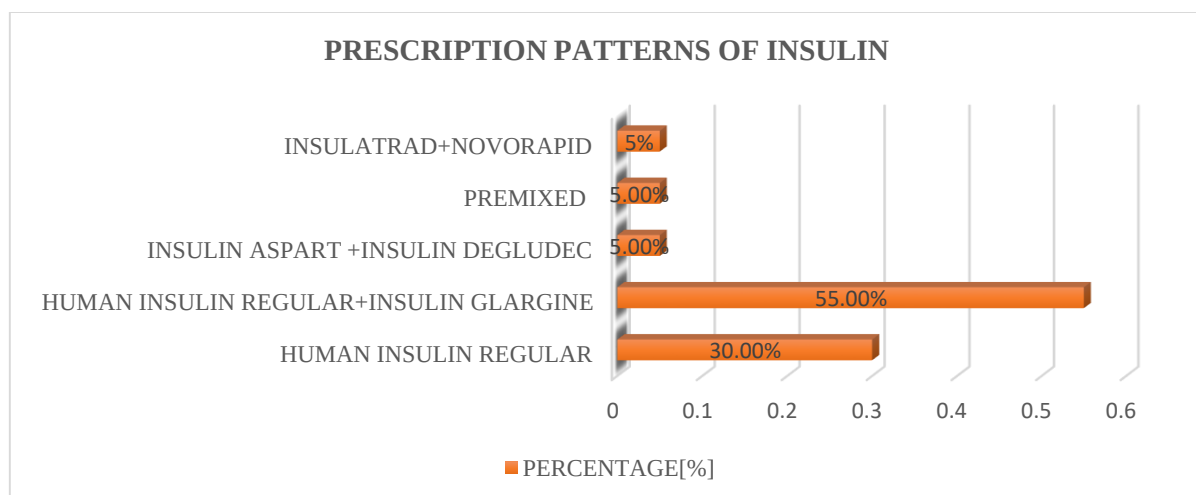


Fig 7 : Bar Chart Representing Prescribing Pattern Of insulin

The predominance of the combination of human insulin regular and insulin glargine is because of the basal-bolus approach closely mimics physiological insulin secretion ,with insulin glargine providing consistent basal insulin coverage and regular insulin controlling steroid-induced postprandial glucose excursions.

3.4.4 DISTRIBUTION OF INSULIN REGIMEN

Table 8 : Insulin regimens

REGIMEN CATEGORY	COUNT[N=20]	PERCENTAGE [%]
SLIDING SCALE	6	30.00%
BASAL -BOLUS REGIMEN	13	65.0%
PREMIXED INSULIN	1	5.0%
TOTAL	20	100%

Basal- Bolus Regimen was the most frequently prescribed insulin regimen, accounting for 65% [n=13] of patients, followed by sliding -scale insulin 30% [n=6]. Premixed insulin was prescribed to only 5%[n=1] of the study population.

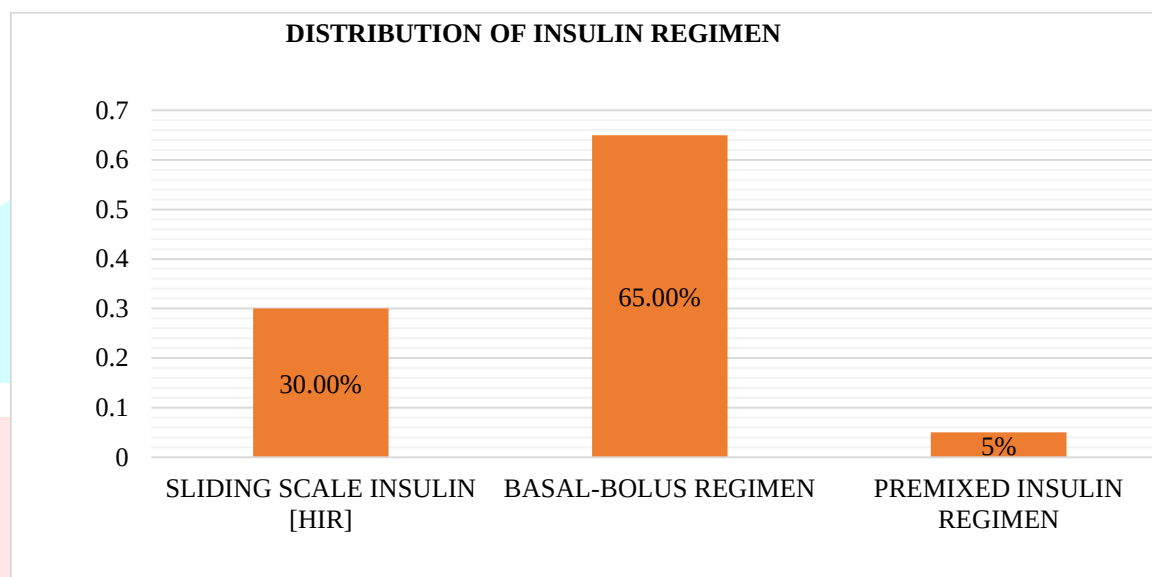


Fig 8 ; Distribution of Insulin Regimen

The predominance of the basal-bolus regimen suggests that clinicians preferred a physiological insulin replacement strategy for managing steroid-induced hyperglycaemia. Basal – Bolus therapy provides continuous basal insulin to control postprandial glucose excursions, making it more effective for the fluctuating blood glucose levels commonly seen with corticosteroid therapy. This prescribing trend reflects current recommendations, which suggest basal – bolus therapy provides superior glycaemic control in hospitalized patients receiving systemic corticosteroids. The predominance of basal-bolus therapy observed in the present study is consistent with the recommendations by Aberer et al. (2021), who advocated basal-bolus insulin as the preferred regimen for hospitalized patients receiving systemic corticosteroids.

3.5 GLYCEMIC STATUS BEFORE STEROID THERAPY

Table 9 : Glycemic status before steroid initiation

GLYCEMIC STATUS	RANGE [mg/dl]	FREQUENCY[N=20]	PERCENTAGE[%]
CONTROLLED/MILD HYPERGLYCEMIA	<200	4	20.00%
MODERATE HYPERGLYCEMIA	200-299	12	60.00%
SEVERE HYPERGLYCEMIA	≥300	4	20.00%

At admission the majority of patients 60%[n=12] had moderate hyperglycaemia [200-299mg/dl] ,controlled /mild hyperglycaemia [<200mg/dl] and severe hyperglycaemia [≥300mg/dl] were each observed in 20% [n=4] of patients .

3.5.1 ADMISSION HbA1c LEVEL

Table 10: Admission HbA1c level

BASELINE HBA1c	HBA1c RANGE	PATIENT COUNT[N=20]	HbA1c[%]mean±SD
OPTIMIZED CONTROL	7.0%	10	6.29% ±0.27%
SUBOPTIMIZED CONTROL	7.1%-8.5%	2	8.15%±0.21%
POOR CONTROL	>8.5%	8	9.13±0.60%

Baseline HbA1c assessment showed that 50% [n=10] of patients had optimized glycemic control [$\leq 7.0\%$], while 40% [n=8] had poor glycemic control [$>8.5\%$]. Only 10% [n=2] had suboptimal control [7.1-8.5%] indicating that a considerable long term glycaemic control before hospitalization.

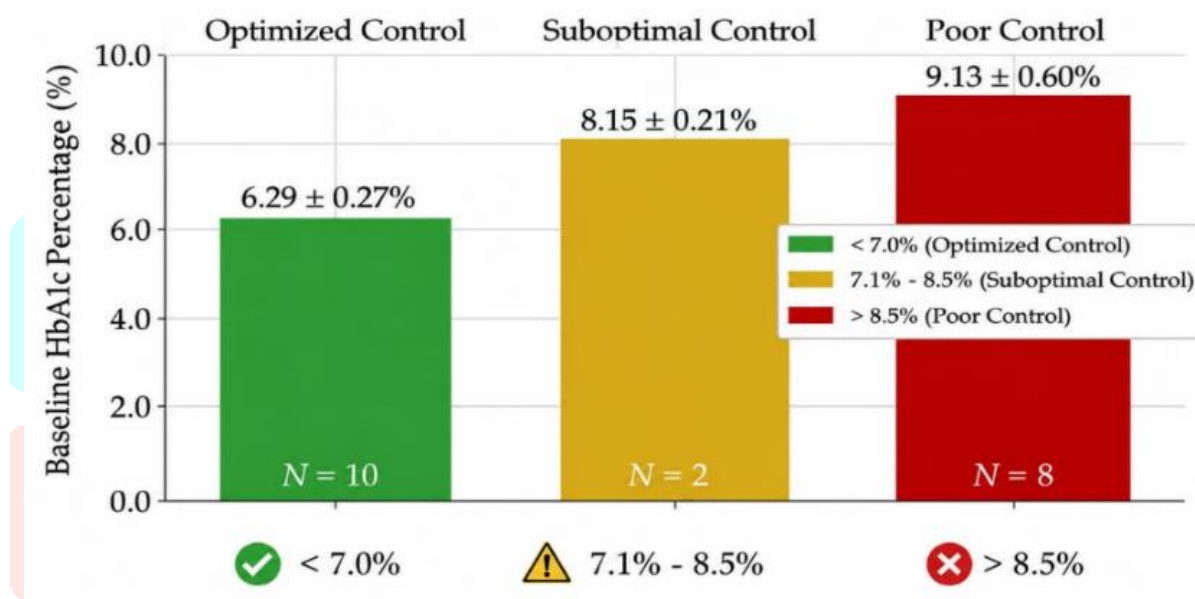


Fig 9 : Baseline HbA1c stratification in study population

Baseline HbA1C assessment showed that 50% of patients had acceptable long term glycaemic control prior to hospitalization, whereas 40% exhibited poor glycaemic control before hospitalization. This suggests that corticosteroid therapy may further aggravate pre-existing dysglycaemia, emphasizing the need for individualized insulin adjustment in diabetic patients receiving steroids.

3.5.2 GLYCEMIC PEAK AFTER STEROID THERAPY

Table 11 : Glycaemic peak After steroid Therapy

TIME OF GLYCEMIC PEAK AFTER STEROID THERAPY INITIATION	NUMBER OF PATIENTS	PERCENTAGE
DAY 1 [within 24 hours]	8	40%
DAY 2[24-48]	12	60%
TOTAL	20	100%

Following steroid therapy initiation, glycaemic peak occurred on Day 2 in 12[60%] patients, whereas 8 [40%] patients experienced peak blood glucose on Day 1.

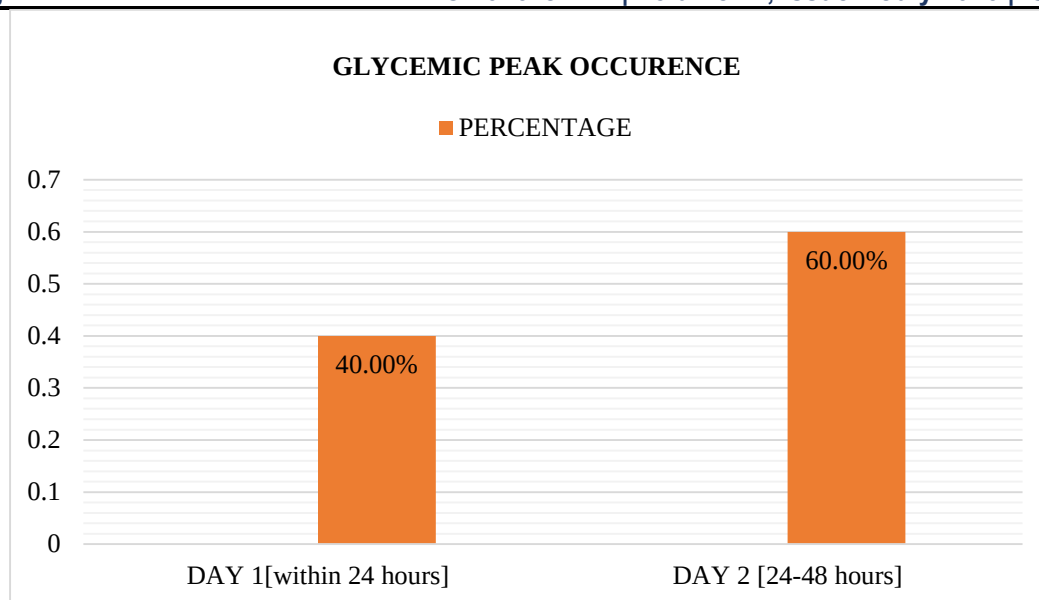


Fig 10 : Diagram showing Glycaemic peak occurrence after steroid initiation

Glycaemic peak occurred on Day 2 in 12[60%] patients, whereas 8 [40%] patients experienced peak blood glucose on Day 1. The most likely reason is the corticosteroid gradually increase insulin resistance and stimulate hepatic glucose production, while simultaneously reducing peripheral glucose uptake. With steroid administration, these metabolic effects become more pronounced, leading to greater rise in blood glucose levels within 24-48 hours. This suggests that most patients developed maximum hyperglycaemia within 24-48 hours after initiation of Corticosteroid therapy.

3.6 COMPARISON OF KNOWLEDGE ATTITUDE AND PRACTICE SCORES BEFORE AND AFTER INTERVENTION

3.6.1 KNOWLEDGE ATTITUDE AND PRACTICE BEFORE COUNSELLING

Table 12 : : Knowledge Attitude and Practice Before score

KAP BEFORE	MEAN SCORE	STANDARD DEVIATION
KNOWLEDGE BEFORE	3.55	1.19
ATTITUDE BEFORE	3.85	0.88
PRACTICE BEFORE	4	0.86

The mean knowledge score before counselling was 3.55 ± 1.19 , indicating that patients had only moderate knowledge regarding their disease and treatment.

The mean attitude score was 3.85 ± 0.88 , suggesting a moderately positive attitude toward disease management before counselling.

The mean practice score was 4.00 ± 0.86 , indicating that patients followed some appropriate self-care practices.

3.6.2 KNOWLEDGE ATTITUDE AND PRACTICE AFTER COUNSELLING

Table 13: Knowledge Attitude and Practice After Score

KAP AFTER	MEAN SCORE	STANDARD DEVIATION
KNOWELEDGE	5	0
ATTITUDE	4.8	0.7
PRACTICE	5	0

After pharmacist counselling , the knowledge score increased to 5.00 with a standard deviation of 0 , indicating that all participants achieved the maximum knowledge score .The attitude and practice score also improved after counselling ,demonstrating a positive impact of the educational intervention on patient 's understanding .

3.6.3 KAP BEFORE AND AFFTER

Table 14 : Knowledge Attitude and Practice scores Before and After Intervention

CATOGORY	MEAN[BEFORE]	MEAN[AFTER]	T-STATISTICS	P VALUE
KNOWLEDGE	3.55	5.00	-5.44	<0.0001
ATTITUDE	3.85	4.8	-3.71	0.0015
PRACTICE	4	5	-5.21	<0.0001

The mean knowledge, attitude and practice (KAP) scores improved following the intervention. The increases in knowledge (3.55 to 5.00) , attitude (3.85 to 4.80) , and practice (4.00 to 5.00) scores were statistically significant ($p < 0.05$), indicating that the educational intervention effectively improved patient's knowledge, attitude and practice.

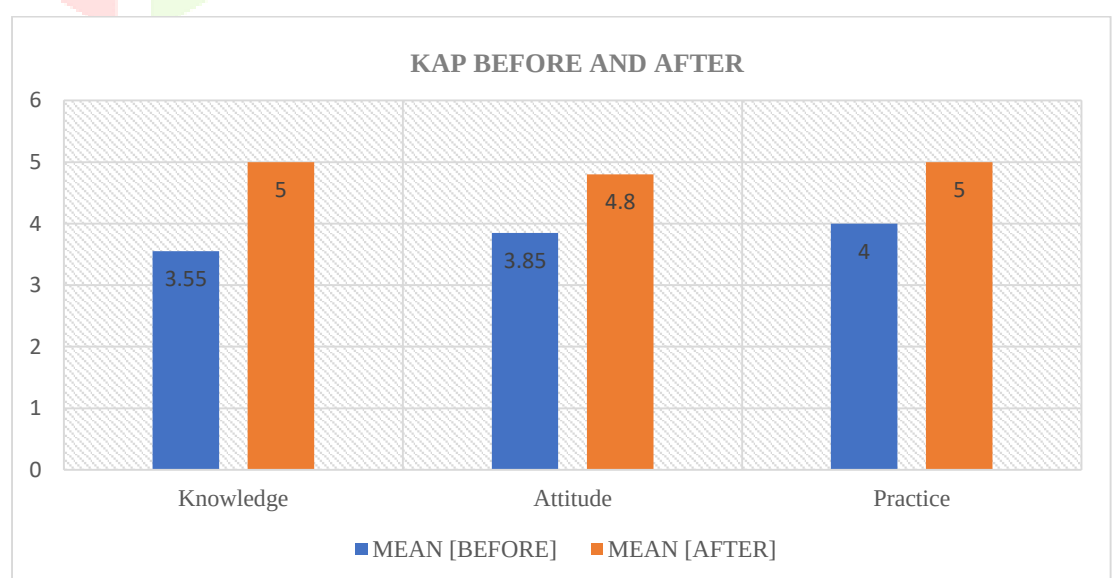


Fig 11: Comparison of Knowledge Attitude and Practice scores Before and after Intervention

Pharmacist – led counselling produced significant improvement in patient's knowledge, attitude and practice scores ($p < 0.05$) regarding diabetes management and steroid – induced hyperglycaemia. This statistically

significant improvement observed after counselling highlights the valuable role of clinical pharmacists in patient education and medication adherence.

3.7 COMPARISON OF QUALITY OF LIFE [WHOQOL BREF VERSION] ASSESSMENT SCORE BEFORE AND AFTER COUNSELLING

Table 15 : Quality Of Life scores before and after

DESCRIPTIVE STATISTICS					
		BEFORE		AFTER	
DOMAIN	N	MEAN	SD	MEAN	SD
PHYSICAL HEALTH	20	11.74	3.30	18.68	3.97
PSYCHOLOGICAL HEALTH	20	10.79	2.57	18.53	2.78
SOCIAL HEALTH	20	10.95	2.66	19.37	2.75
TREATMENT AND AND LIFESTYLE	20	10.95	2.66	18.37	2.85
IMPACT ON DAILY ACTIVITIES	20	12.25	2.07	18.15	2.18

The mean quality of life scores improved in all domains following patient counselling. The mean physical health score increased from 11.74 to 18.68, psychological health from 10.79 to 18.53, social health from 10.95 to 19.37, treatment and lifestyle from 10.95 to 18.37 and impact on daily activities from 12.25 to 18.15 indicating an overall improvement in quality of life after counselling.

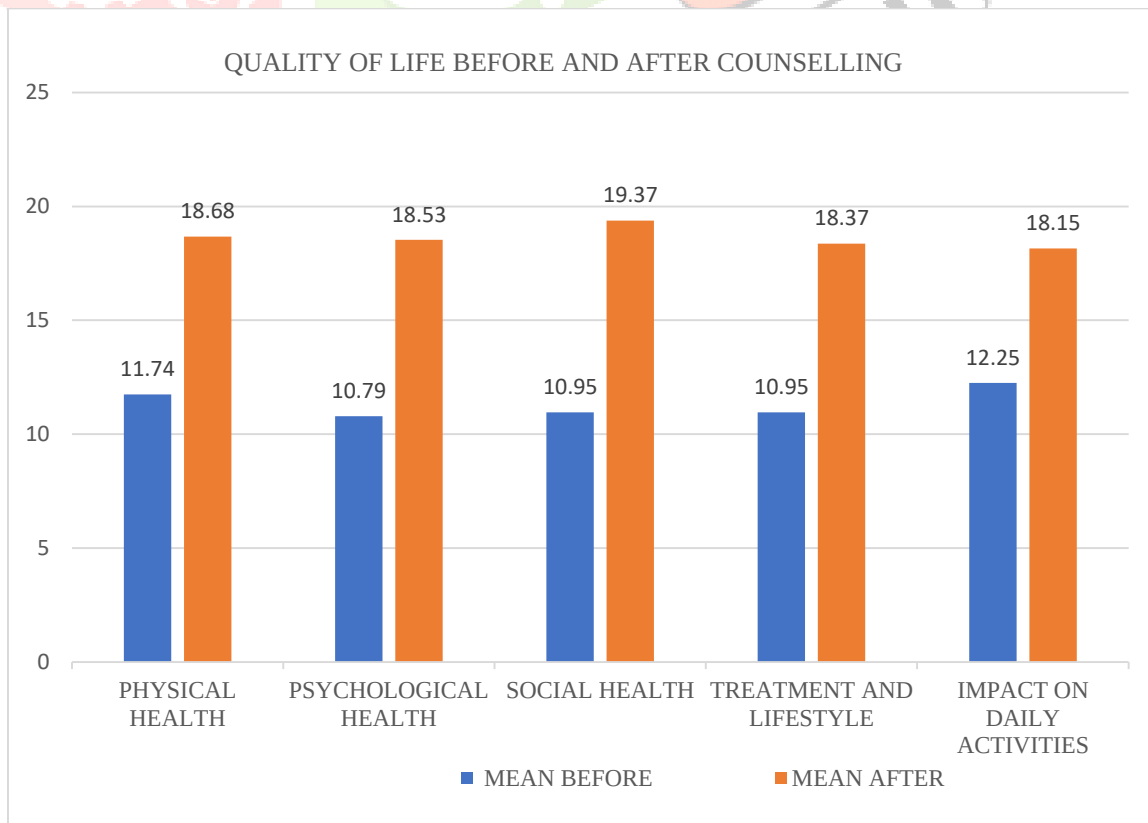


Fig 12 : Comparison of Quality of life scores before and after counselling

Quality of life assessment also demonstrated improvement following pharmacist – led counselling. Mean scores increased across all five study domains-physical health, psychological health, social health, treatment and lifestyle and impact on daily activities indicating better patient – perceived health status after the intervention.

3.8 SUMMARY

This prospective observational pilot study evaluated insulin prescription patterns, knowledge, attitude, practice (KAP) and quality of life among patients with type 2 diabetes mellitus who developed steroid-induced hyperglycaemia during treatment for respiratory infections. The findings demonstrated that basal- bolus insulin therapy was the most commonly prescribed regimen, accounting for 65% of all insulin prescriptions, followed by sliding scale insulin therapy. This prescribing trend reflects current recommendations, which suggest basal – bolus therapy provides superior glycaemic control in hospitalized patients receiving systemic corticosteroids. The predominance of basal-bolus therapy observed in the present study is consistent with the recommendations by Aberer et al. (2021), who advocated basal-bolus insulin as the preferred regimen for hospitalized patients receiving systemic corticosteroids. The predominance of metformin - based combination therapy in ongoing anti-diabetic therapy reflects current treatment recommendations for type 2 diabetes mellitus, where metformin remains the first-line agent and DPP-4 inhibitors such as sitagliptin are commonly added to improve glycaemic control with a low risk of hypoglycaemia. Despite receiving these therapies, patients developed steroid – induced hyperglycaemia requiring insulin during hospitalization, highlighting that oral antidiabetic agents alone may be insufficient to control corticosteroid -induced glucose excursions and that temporary insulin therapy is necessary.

The present study also evaluated corticosteroid prescribing patterns and tapering practices among hospitalized diabetic patients with respiratory infections. Methylprednisolone was the most frequently prescribed corticosteroid in the present study, likely onset of action. It is recommended for the management of moderate to severe respiratory inflammatory conditions. Compared with dexamethasone and hydrocortisone, methylprednisolone provides effective control of pulmonary inflammation while allowing flexible dose adjustment and gradual tapering. Steroid tapering was performed in the majority of patients according to clinical response. Appropriate tapering facilitates gradual recovery of endogenous adrenal function and assists in reducing steroid-associated hyperglycaemia, thereby allowing timely adjustment of insulin therapy. These findings highlight the importance of individualized corticosteroid prescribing and tapering strategies, along with regular glucose monitoring. Most participants exhibited moderate hyperglycaemia at admission (60%), while 20% had severe hyperglycaemia. The glycaemic peak occurred predominantly within 24-48 hours following steroid initiation, emphasizing the need of close glucose monitoring during the early phase of corticosteroid therapy. These findings are in agreement with previous studies demonstrating that glucocorticoid – induced hyperglycaemia is most pronounced during the first two days of treatment. Baseline HbA1C assessment showed that 50% of patients had acceptable long term glycaemic control prior to hospitalization, whereas 40% exhibited poor glycaemic control before hospitalization. This suggests that corticosteroid therapy may further aggravate pre-existing dysglycemia, emphasizing the need for individualized insulin adjustment in diabetic patients receiving steroids. Pharmacist – led counselling produced significant improvement in patient's knowledge, attitude and practice scores ($p < 0.05$) regarding diabetes management and steroid – induced hyperglycaemia. This statistically significant improvement observed after counselling highlights the valuable role of clinical pharmacists in patient education and medication adherence. Quality of life assessment also demonstrated improvement following pharmacist – led counselling. Mean scores increased across all five study domains-physical health, psychological health, social health, treatment and lifestyle and impact on daily activities indicating better patient – perceived health status after the intervention. Overall, the findings suggest that basal – bolus therapy combined with structured patient education may improve the management of steroid – induced hyperglycaemia among hospitalized diabetic patients with respiratory infections. However, because of the small sample size and single – centre nature of this pilot study, larger multi centre studies are necessary to validate these observations and establish evidence-based treatment protocols.

3.9 . CONCLUSION

This prospective pilot study demonstrated that methylprednisolone was the most commonly prescribed corticosteroid and the steroid tapering was appropriately implemented in the majority of patients. Basal-bolus insulin therapy was the most frequently prescribed regimen for managing steroid – induced hyperglycaemia among patients with type 2 diabetes mellitus receiving corticosteroids for respiratory infections. Moderate hyperglycaemia was the most common glycaemic presentation, with peak glucose levels occurring predominantly within 24-48 hours after initiation of steroid therapy. Pharmacist- led counselling significantly improved patients' knowledge, attitude and practice regarding diabetes management.

Pharmacist – led counselling significantly improved patient's knowledge, attitude and practice regarding diabetes management and steroid – induced hyperglycaemia. In addition, quality of life improved across all five study domains-physical health, psychological health, social health, treatment and lifestyle and impact on daily activities following the educational intervention.

The findings suggests that importance of early glucose monitoring, individualized insulin therapy and multidisciplinary patient education in optimizing the management of steroid – induced hyperglycaemia. Nevertheless, the small sample size and single centre design limit the generalizability of these findings.

4. ROLE OF THE CLINICAL PHARMACIST IN STEROID-INDUCED HYPERGLYCEMIA[SIH]

Steroid – Induced Hyperglycaemia is a common complication of systemic corticosteroid therapy, particularly among patients with Type 2 DM receiving treatment for respiratory infections. Uncontrolled hyperglycaemia is associated with increased morbidity, delayed recover, increased in hospital stay. Despite its clinical significance, evidence regarding insulin prescription patterns and glycaemic management of SIHG is routine practice is limited.

ROLES INCLUDES:

- Clinical Pharmacist Identifying patients at risk for steroid-induced hyperglycaemia.
- Review corticosteroid and antidiabetic prescriptions for appropriate use.
- Monitor blood glucose levels and identify abnormal glucose trends.
- Assess glycemic status using FBG, PPBG, RBG, and HbA1c.
- Provide patient counselling on steroid-induced hyperglycemia and diabetes.
- Pharmacist in Educating patients on self-monitoring of blood glucose (SMBG).
- Improve medication adherence through pharmacist-led counselling.
- Provide lifestyle education, including diet and physical activity.
- Distribute and explain the Patient Information Leaflet (PIL).
- Assess Knowledge, Attitude, and Practice (KAP) before and after counselling
- Improve patients' quality of life through education and follow-up.
- Patient education regarding insulin use, blood glucose monitoring, lifestyle modification, medication adherence, lifestyle modification plays a crucial role in improving treatment outcomes.

The findings are expected to support evidence – based management strategies and highlight the role of clinical pharmacists in optimizing the care of patients with steroid -induced hyperglycemia.

REFERENCES

- [1] . Melani AS, Croce S, Cassai L, Montuori G, Fabbri G, Messina M, Viani M, Bargagli E. Systemic corticosteroids for treating respiratory diseases: less is better, but... when and how is it possible in real life?. *Pulmonary Therapy*. 2023 Sep;9(3):329-44.
2. Bru JP. The role of systemic corticosteroids when treating infections in adult primary care. *Infectious Diseases Now*. 2024 Jun 1;54(4):104925.
3. Descours M, Rigalleau V. Glucocorticoid-induced hyperglycemia and diabetes: Practical points. In *Annales d'Endocrinologie* 2023 May 1 (Vol. 84, No. 3, pp. 353-356). Elsevier Masson.
4. Bonaventura A, Montecucco F. Steroid-induced hyperglycemia: an underdiagnosed problem or clinical inertia? A narrative review. *Diabetes research and clinical practice*. 2018 May 1;139:203-20.
5. Kim SY, Yoo CG, Lee CT, Chung HS, Kim YW, Han SK, Shim YS, Yim JJ. Incidence and risk factors of steroid-induced diabetes in patients with respiratory disease. *Journal of Korean medical science*. 2011 Jan 24;26(2):264.
6. Umpierrez, G. E., Hellman, R., Korytkowski, M. T., et al. (2012). Management of hyperglycemia in hospitalized patients in non-critical care settings. *The Journal of Clinical Endocrinology & Metabolism*, 97(1), 16–38.
7. Casqueiro, J., Casqueiro, J., & Alves, C. (2012). Infections in patients with diabetes mellitus: A review of pathogenesis. *Indian Journal of Endocrinology and Metabolism*, 16(Suppl. 1), S27–S36.
8. Clore JN, Thurby-Hay L. Glucocorticoid-induced hyperglycemia. *EndocrPract*. 2009;15(5):469–474.
9. Aberer F, Hochfellner DA, Sourij H, Mader JK. A practical guide for the management of steroid induced hyperglycaemia in the hospital. *Journal of Clinical Medicine*. 2021 May 16;10(10):2154.
10. Cho JH, Suh S. Glucocorticoid-induced hyperglycemia: a neglected problem. *Endocrinology and Metabolism*. 2024 Apr 1;39(2):222-38.
11. Malik R, Batool R, Rehman MA, Ali MM, Shakeel Z, Tarique H. Evaluation of Blood Glucose Fluctuations in Diabetic Patients Receiving Corticosteroids. *Indus Journal of Bioscience Research*. 2025 Apr 24;3(4):465-70.
12. Tamez-Pérez HE, Quintanilla-Flores DL, Rodríguez-Gutiérrez R, González-González JG, Tamez-Peña AL. Steroid hyperglycemia: prevalence, early detection and therapeutic recommendations: a narrative review. *World journal of diabetes*. 2015 Jul 25;6(8):1073.
13. Badi S, Suliman SZ, Almahdi R, Aldomah MA, Elkheir HK, Ibrahim MI, Ahmed MH. The impact of the clinical pharmacist-led diabetes education on the knowledge and attitude of individuals with type II diabetes mellitus: an interventional study. *Pharmacy*. 2024 Sep 29;12(5):151.
14. Religioni U, Barrios-Rodríguez R, Requena P, Borowska M, Ostrowski J. Enhancing therapy adherence: impact on clinical outcomes, healthcare costs, and patient quality of life. *Medicina*. 2025 Jan 17;61(1):153.
15. Barker HL, Morrison D, Llano A, Sainsbury CA, Jones GC. Practical guide to glucocorticoid induced hyperglycaemia and diabetes. *Diabetes Therapy*. 2023 May;14(5):937-45.
16. Alex M, Sreedharan DP, Bhandari R, Kolar R. Retrospective analysis of Sliding Scale versus Basal Bolus Insulin in the treatment of uncontrolled hyperglycemia in patients with Type 2 diabetes mellitus and infections. *International Journal of Diabetes in Developing Countries*. 2025 Sep;45(3):661-9.
17. Pramanik S, Ray S, Biswas K, Bandyopadhyay T, Mukhopadhyay M. Management of Steroid-induced Hyperglycemia. *J India*