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# Prevalence of Steroid Induced Hyperglycemia in Oncology Patients

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Prevalence of Steroid Induced Hyperglycemia in Oncology Patients

A DNP Project

Presented to the

Faculty of the Department of Nursing

West Chester University

West Chester, Pennsylvania

In Partial Fulfillment of the Requirements

for the Degree of

Doctor of Nursing Practice

By

Dawn Hornberger, MSN, AGPCNP- BC

May 2022

## Dedication

To my husband, Brian, for your love, support, and patience during this education journey.

To my mom and dad, for your unwavering support, encouragement, and prayers. Thank you all for encouraging me to pursue my dreams and follow God's direction.

### Acknowledgements

Thank you to all the faculty of West Chester's Doctor of Nursing program for your guidance and support over the past three years. Thank you to my mentor, Dr. Veronica Wilbur for all your help and encouragement over the past. I would not have completed this project without you. I cherish our friendship. Thank you to my professional external mentor, Dr. Jodie Reider for all your support and kindness. You have a heart of gold and an inspiration for many. Thank you to all my stakeholders who helped to make this project possible! Thank you to my family and friends for the encouragement and support. Above all, I thank God for this opportunity to further my education and continue to help others. May I continue to follow in His will.

## Abstract

Glucocorticoids (steroids) are an integral part of chemotherapy treatment; however, steroids can cause hyperglycemia. There is no established protocol for the identification and treatment of steroid induced hyperglycemia in the literature. Literature does show steroid induced hyperglycemia is best identified by checking glucoses throughout the day following steroid administration. Furthermore, the best treatment for steroid induced hyperglycemia is basal/bolus insulin therapy. The prevalence of steroid induced hyperglycemia needs to be established to support the implementation of a steroid induced hyperglycemia protocol in oncology patients. A retrospective chart review of all patients 18 years and older admitted to Hematology and Hematopoietic Stem Cell Transplant services over a three-month period was conducted to determine the prevalence of steroid induced hyperglycemia at a rural tertiary hospital. Results: Prevalence of steroid induced hyperglycemia was 37.9%. However, only 16.1% were ordered glucose monitoring throughout the day and only 18.6% received any antidiabetic medications during hospitalization.

*Keywords:* steroid induced hyperglycemia, steroids, chemotherapy, hospitalization, oncology, hyperglycemia

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## Chapter 1 - Introduction

### Background/Problem

Glucocorticoids (steroids) are medications used to treat various conditions during hospitalization, including inflammation and immunosuppression. Glucocorticoids are prescribed for oncology patients treated for cancer as part of chemotherapy treatment. The therapeutic effects of glucocorticoids with chemotherapy include controlling chemotherapy induced nausea and vomiting, preventing an allergic reaction to blood transfusion products or medications, increasing appetite, reducing inflammation, treating pain, treating dyspnea, and killing cancer cells and shrinking tumors as part of chemotherapy (Carter, 2020). A negative side effect of glucocorticoids is hyperglycemia or elevated blood glucose levels. Glucocorticoids cause hyperglycemia by augmentation of hepatic gluconeogenesis, alteration of receptor and post-receptor functions, and inhibition of glucose uptake in adipose tissue (Saag & Furst, 2021). Hyperglycemia leads to adverse patient outcomes including higher mortality rates, increased hospital length of stay, more likely to require admission to ICU, more likely to require transitional care or nursing home placement at discharge (Umpierrez et al., 2002).

Hyperglycemia caused by steroids is called steroid induced hyperglycemia (SIH) and is also associated with poor clinical outcomes and treatment related morbidities (Umpierrez et al., 2002). Since oncology patients being treated for cancer are often prescribed steroids as part of chemotherapy treatment, they are one of the most affected populations of SIH. Detection of hyperglycemia can be found with daily lab work or blood glucose monitoring via fingerstick glucose. However, blood glucose monitoring is often not ordered in this population. In addition, there is no specific protocol for a hospital to follow to identify and manage steroid induced

hyperglycemia. Unidentified hyperglycemia often results in a variability of treatment, suboptimal glycemic control, and a gap in the timeliness of therapy.

A study by Umpierrez et al. (2002), looked at the prevalence of diabetes and hyperglycemia in hospitalized patients to determine the effects of newly diagnosed hyperglycemia on survival and functional outcome after adjusting for known prognostic factors. The results showed that in-hospital hyperglycemia is a common finding and is an important marker of poor clinical outcomes and mortality in patients with and without a history of diabetes (Umpierrez et al., 2002). Therefore, identification and management of steroid induced hyperglycemia in oncology patients treated with steroids is imperative.

### **Conceptual Framework**

Donabedian's Quality Framework evaluates the quality of care by assessing structure, process, and outcomes (McDonald et al., 2007, Chapter 5). The structure looks at the setting in which health care is provided while the process assesses the care delivery and care coordination. Structure and process lead to health outcomes. Steroid induced hyperglycemia leads to negative health outcomes; therefore, it is imperative to look at structure and process to improve care and thus improve health outcomes and decrease costs to health care organizations and insurance companies.

### **Cost of Hyperglycemia**

The cost of steroid induced hyperglycemia has not been specifically identified in any literature; however, the cost of diabetes has been established. Patients with steroid induced hyperglycemia may have a history of diabetes or the hyperglycemia is new onset and related to steroid effect. For those with a history of diabetes, the estimated total annual cost of diagnosed diabetes in 2017 was \$372 billion, with inpatient hospital care comprising 30% of the total cost

(American Diabetes Association [ADA], 2018). Pennsylvania is equally affected by diabetes, with an estimated \$9.3 billion spent on direct medical expenses in 2017 for those diagnosed with diabetes (American Diabetes Association [ADA], 2021b). Uncontrolled hyperglycemia, including prolonged steroid induced hyperglycemia, can lead to the diagnosis of diabetes. Diabetes is a leading metabolic disorder affecting an estimated 10.5% of the total United States (U.S.) population and 13% of U.S. adults aged 18 years and older, and another estimated 2.8% of the adult U.S. population has undiagnosed diabetes (Centers for Disease Control and Prevention [CDC], 2020). Diabetes was the seventh leading cause of death in 2017 (ADA, 2018). Therefore, identification and management of steroid induced hyperglycemia is essential.

### **Glucose Monitoring**

Identification of steroid induced hyperglycemia in oncology patients is achieved with blood glucose monitoring and should be initiated on all hospitalized patients receiving steroids. Based on the metabolic effects of steroids, postprandial glucose monitoring offers the greatest diagnostic sensitivity for identifying hyperglycemia. Testing four times per day, before meals, will help identify any hyperglycemia caused by the steroids. Fasting glucose monitoring is not a reliable diagnostic method for identifying steroid induced hyperglycemia and testing fasting glucose only could result in underdiagnosed steroid induced hyperglycemia.

### **Identification and Treatment of Steroid Induced Hyperglycemia**

The American Diabetes Association does not provide specific guidelines for the identification or management of steroid induced hyperglycemia, nor does any other professional diabetes/endocrinology organization. Providers prescribing chemotherapy focus on the effects of chemotherapy on treating the illness, not necessarily secondary consequences such as hyperglycemia from steroids.

**PICOT Statement**

Are hospitalized oncology patients who have received steroids compared to those who have not received steroids at increased risk of hyperglycemia? We will also examine the frequency of blood glucose monitoring, determine average fasting glucose and average overall glucose during the hospital stay, and the use of any antidiabetic medications.

**Methodology**

Three months of retrospective data will be collected from the electronic health record. A list of patients meeting the inclusion criteria will be de-identified and given a unique number. Demographic data collected will include age, self-identified gender, race, and ethnicity. Additional data collected will include the status of hyperglycemia (glucose  $\geq$  200 mg/dL), frequency of glucose monitoring, use of antidiabetic medications, average fasting glucose, and average glucose. Data will be analyzed to determine if there is a statistically significant association between the reception of steroids and the presence of hyperglycemia.

## Chapter 2- Literature Review

### Overview

The literature review covers the topics of prevalence, health outcomes, glucose monitoring, treatment with basal and bolus insulin, treatment with basal insulin only, treatment with bolus insulin only, treatment with metformin, and education regarding identification and management of steroid induced hyperglycemia in hospitalized patients.

### The Review of the Literature

The literature review process started with searching the following electronic databases: PubMed, CINAHL and Cochrane. Keywords and phrases searched were chemotherapy, hospitalized, inpatient, hyperglycemia, drug therapy, cancer treatment, pharmacotherapy, insulin therapy, non-insulin therapy, hyperglycemia therapy, hyperglycemia drug therapy, steroid induced hyperglycemia, glucocorticoid, steroid induced diabetes, chemically induced hyperglycemia, and chemically induced diabetes mellitus. The terms were used as both keywords and MeSH terms. Initial filters applied included English language, Adult (18+years), and publication date from 2016-2021. A total of 42 articles were reviewed, but only eight articles were appropriate for the literature review. These eight articles all had the keywords: steroid, chemotherapy, hospitalization, and hyperglycemia. Reference lists of articles were reviewed for any relevant studies not obtained through original search in the database. Three additional articles were identified with the keywords: steroid, chemotherapy, and hyperglycemia – a total of 11 articles utilized for this literature review.

The negative health outcomes of steroid induced hyperglycemia have been established in the literature; however, there is limited research on the prevalence of steroid induced hyperglycemia in the inpatient setting (Umpierrez et al., 2002). There is also a lack of consensus

regarding the most effective management option for steroid induced hyperglycemia, particularly for patients hospitalized for cancer. Most of the articles were retrospective chart reviews.

### **Prevalence of Steroid Induced Hyperglycemia**

The retrospective review by Donihi et al. (2006) reported that 66 out of 617 patients admitted to a general medicine service received high dose corticosteroids, but only 50 out of the 66 had glucose measurement. Hyperglycemia was recorded in 64% of the 50 patients (Donihi et al., 2006). In a retrospective review by Healy et al. (2017), the prevalence of steroid induced hyperglycemia was 39% of 168 patients in an inpatient, hematologic setting. Healy et al. (2017) analyzed hospitalized patients admitted to specific hematology/bone marrow transplant services, while Donihi et al. (2006) analyzed hospitalized patients admitted to a general medical service where steroids could have been utilized for a condition unrelated to an oncology diagnosis. Fong & Cheung (2013) also looked at the prevalence of steroid induced hyperglycemia in non-diabetic hospital patients where a protocol for glucose monitoring was implemented previously. In this study, 48% of the 80 patients developed steroid induced hyperglycemia (Fong & Cheung, 2013). In a more extensive retrospective study of hospitalized patients, 33.5% or 812 out of 2525 patients developed steroid induced hyperglycemia (Delfs et al., 2020).

### **Health Outcomes with Steroid Induced Hyperglycemia**

Delfs et al. (2020) did a large forty-month retrospective study to assess the outcomes of hospitalized patients with glucocorticoid-induced hyperglycemia while looking at secondary endpoints of death, cardiovascular events, and infections. Mortality was not noted to be higher in patients with steroid induced hyperglycemia; however, secondary endpoints identified oncology patients receiving steroids as a significant covariable for hyperglycemia along with advanced age and endocrinology patients receiving steroids for treatment of adrenal insufficiency (Delfs et al.,

2020). Patients with steroid induced hyperglycemia had more cardiovascular events and the infection rate was higher (Delfs et al., 2020).

### **Glucose Monitoring**

In the retrospective analysis completed by Fong & Cheung (2013), only 38 of the 80 patients were started on glucose monitoring the same day steroids were initiated and 19 patients were started on glucose monitoring the following day. Of these patients, 57 patients who did have glucose monitoring within the first 48 hours, 94% developed hyperglycemia within 48 hours of starting on steroids. In another retrospective review, only 50 out of 66 patients documented glucose measurements while receiving high dose corticosteroids (Donihi et al., 2006). A retrospective review of 30 genitourinary (GU) cancer patients receiving corticosteroids as part of chemotherapy showed a mean incidence of blood glucose monitoring in 19% of the patients with diabetes and 76% in patients without diabetes (Rowbottom et al., 2015). Rowbottom et al. (2015) concluded that all patients should be monitored for elevated glucose levels to optimize patient care.

### **Basal and Bolus Insulin**

The circadian pattern of hyperglycemia induced by steroids given daily in the morning predominantly causes hyperglycemia in the afternoon and evening, followed by normalization of glucose overnight with little to no effect on fasting glucose (Suh & Park, 2017). Radhakutty et al. (2017), Spanakis et al. (2014), and Burt et al. (2015) all assessed the use of basal-bolus insulin for the treatment of steroid induced hyperglycemia in hospitalized patients.

The randomized control study by Radhakutty et al. (2017) did not show any significant difference in efficacy or safety between isophane-based insulin regiment versus glargine-based insulin regimens. Spanakis et al. (2014) completed a retrospective chart review of 58 non-

critically ill hospitalized diabetic patients receiving steroids in which only 20 patients achieved normoglycemia during admission. The normoglycemia patients required a slightly higher total daily dose of insulin per kilogram bodyweight with a significantly higher percentage of nutritional insulin and a significantly lower percentage of correctional and basal insulin (Spanakis et al., 2014). Similarly, Burt et al. (2015) completed a cross-sectional study of 66 hospitalized diabetic patients, including 24 patients taking prednisone and 42 patients not on any steroids treated with a basal-bolus insulin protocol. The results showed that the patients taking prednisolone required a significantly higher total daily dose of insulin compared to control (Burt et al., 2015). The extra insulin requirements were at 1200 hours and 1700 hours, which corresponds to the circadian pattern of hyperglycemia with steroids.

In a retrospective study, Gosmanov et al. (2013) compared basal-bolus insulin with sliding scale insulin in treatment of forty patients with hematologic malignancies treated with high dose dexamethasone. The basal-bolus regimen resulted in an average blood glucose reduction of 52 +/- mg/dL during therapy, which was statistically significant compared to the sliding scale insulin regimen. In another study focusing on diabetic patients with steroid induced hyperglycemia during cancer treatment, patients were started on a basal-bolus insulin regimen with 25% basal insulin and 75% bolus (prandial) insulin (Brady et al., 2014). While the daily average blood glucose improved significantly for these patients as their insulin doses increased, glucoses remained above goal.

Currently, the Endocrine Society Clinical Practice Guidelines recommend starting insulin at 0.3-0.5 units/kg for hospitalized patients with hyperglycemia (Umpierrez et al., 2012). However, based on the studies above, patients with steroid induced hyperglycemia require significantly more insulin. Radhakutty et al. (2017) found that an initial daily insulin dose of 0.5



units/kg body weight is safe in hospitalized patients with prednisone-induced hyperglycemia. Patients who achieved normoglycemia in the Spanakis et al. (2014) study required 0.8 units/kg/day. The normoglycemia patients required a significantly higher percentage of nutritional insulin and a significantly lower percentage of correctional and basal insulin (Spanakis et al., 2014). The patients with steroid induced hyperglycemia in the Burt et al. (2015) required approximately 0.7 units/kg/day. Still, they had hyperglycemia in the afternoon and evening, indicating a higher dose is required to achieve euglycemia.

In the two studies focusing on steroid induced hyperglycemia in patients receiving cancer treatment, the total units/kg daily dose was higher. In the Gosmanov et al. (2013) study, patients receiving bolus-basal insulin regimens were started at an average daily dose of 0.66 units/kg. By the end of the study, they received a mean dose of 1.2 units/kg/day without any hypoglycemia. Similarly, patients in the Brady et al. (2014) required an average insulin dose of 1-1.3 units/kg. Despite the increased insulin requirements, the number of patients achieving euglycemia was not noted in these studies.

### **Basal only**

Basal-bolus insulin is the best treatment for steroid induced hyperglycemia; however, numerous basal insulins have varying pharmacodynamic properties. Neutral protamine Hagedorn (NPH) insulin onset is two to four hours, peaks four to twelve hours later, and is effective 12-18 hours. NPH mimics most steroids' onset, peak, and duration of most steroids, making it the preferred choice of basal insulin for steroid induced hyperglycemia based on pharmacodynamics. Dhital et al. (2012) specifically compared the effect of NPH versus glargine as the basal insulin used to manage steroid induced hyperglycemia in diabetic patients during hospitalization. The results showed NPH and glargine were equally effective; however, the NPH cohort required less

total daily dose of insulin. The NPH cohort required approximately 0.27 units/kg for basal insulin, while the glargine cohort required 0.34 units/kg. The NPH cohort also required less bolus insulin at 0.26 units/kg versus 0.36 units/kg for the glargine cohort. So overall, the NPH group required approximately 0.53 units/kg daily, while the glargine group required approximately 0.7 units/kg daily. As noted previously, in the Radhakutty et al. (2017) study, no difference was seen between the isophane based insulin regimen versus the glargine-based insulin regimen. A further breakdown of the total daily dose was not differentiated.

### **Sliding Scale Insulin**

Sliding scale insulin is usually part of the bolus part of a basal-bolus insulin regimen and provides guidance on the amount of insulin needed to treat hyperglycemia; however, sliding scale insulin can also be used solely for the treatment of hyperglycemia. Health care institutions use sliding scale insulin frequently as it is easy and convenient. However, it does not deliver insulin in a physiologic manner, leading to fluctuations in glycemic levels. Unfortunately, there is limited data to compare the use of basal/bolus insulin regimen versus sliding scale insulin.

Umpierrez et al. (2012) did a prospective randomized clinical trial to compare the efficacy and safety of basal-bolus insulin with that of sliding scale insulin in non-critically ill patients with type 2 diabetes. Based on the pharmacodynamics of insulin, sliding scale insulin treats hyperglycemia after it has already occurred instead of preventing the occurrence of hyperglycemia. The results did show that treatment with basal-bolus insulin regimen resulted in a significant improvement in glycemic control compared with that of sliding scale insulin only regimen.

Gosmanov et al. (2013) conducted a retrospective chart review of diabetic patients with hematologic malignancies who received dexamethasone to determine whether a basal-bolus

insulin (BBI) regimen was superior to a sliding scale insulin regimen for management of hyperglycemia. This study showed that the basal-bolus regimen resulted in an average blood glucose reduction of  $52 \pm 82$  mg/dL during the study while the sliding scale insulin regimen resulted in an average blood glucose increase of  $128 \pm 77$  mg/dL, which was statistically significant (Gosmanov et al., 2013). Both studies confirm that the basal-bolus insulin regimen is safer and more effective in treating steroid induced hyperglycemia than sliding scale insulin alone.

### **Metformin**

First line therapy for patients diagnosed with type 2 diabetes or prediabetes, includes lifestyle modifications such as meal planning, weight loss, and exercising. The second line of treatment is with the medication metformin. Metformin lowers blood sugar levels by decreasing the amount of glucose produced by the liver and increasing insulin sensitivity to absorb glucose more readily. Based on pharmacodynamics, metformin could be an option to prevent steroid induced hyperglycemia. In a prospective randomized controlled trial, Ochola et al. (2020) assessed metformin's effectiveness in preventing steroid induced hyperglycemia among hematological cancer patients. In this study, non-hyperglycemic hematological cancer patients receiving prednisone-based chemotherapy were randomized to receive metformin 850 mg once then twice daily for two successive weeks or to the control group receiving standard care (Ochola et al., 2020). Fasting and 2-hour postprandial fingerstick glucose tests were drawn weekly for a total of four weeks. Eighteen out of 24 patients completed the study. Eight out of eleven patients developed prediabetes in the control group, while only one out of seven patients in the treatment group developed prediabetes (Ochola et al., 2020). The treatment group had a

statistically significant improvement in mean 2-hour postprandial blood sugar readings in weeks 2, 3, and 4 of the study (Ochola et al., 2020).

### **Education**

While treating steroid induced hyperglycemia is important, recognizing the need for monitoring blood glucose in patients and initiating proper treatment is equally important. Nurses can be proactive in screening patients for hyperglycemia, particularly in those with no known history of diabetes because these patients are often asymptomatic with hyperglycemia.

De Vos-Schmidt & Dilworth (2014) developed a protocol specifically for patients on corticosteroids during chemotherapy. All patients who received steroids as part of their day one treatment regimen were screened with a two-hour postprandial fingerstick glucose level on day two of the first chemotherapy cycle. No further intervention was indicated if the two-hour postprandial blood glucose was less than 140 mg/dL. If two-hour postprandial blood glucose was 140-200 mg/dL, patients were provided with an educational intervention. As part of the education, the patient was given a glucometer with one-on-one education on the use of the glucometer, advised to check blood glucose two hours after the largest meal of the day, and advised to limit carbohydrate consumption at one meal to 30 grams (De Vos-Schmidt & Dilworth, 2014).

If the two-hour postprandial blood glucose level was 201 mg/dL or higher, they were provided with the same educational intervention and started on a short acting insulin. The patients were instructed to check blood sugars before every meal and follow the insulin instructions provided (De Vos-Schmidt & Dilworth, 2014). The insulin regimen was based on a formula of one unit for every 10 grams of carbohydrate and one additional unit for every 40 points above the target glucose of 130 (De Vos-Schmidt & Dilworth, 2014). In this quality

improvement study of 30 patients, ten patients required intervention. Three patients only required educational intervention while the other seven required educational intervention and insulin (De Vos-Schmidt & Dilworth, 2014). Nine out of the ten patients requiring either intervention achieve glycemic control for the remainder of the cancer treatments. De Vos-Schmidt & Dilworth (2014) identified the importance of recognizing and managing hyperglycemia in patients with cancer receiving treatment using a nurse driven protocol.

In a study by Sinaga & de Koeijer (2018), an evidenced practice protocol was implemented to increase knowledge of both the nursing staff and patients on the importance of blood glucose management during chemotherapy. A baseline audit showed that the current standard of care was to notify the covering physician of any persistent hyperglycemia. However, there were no set guidelines for target glucose or what constituted persistent hyperglycemia (Sinaga & de Koeijer, 2018). Without an established protocol, insulin therapy was rarely utilized for treatment, and patients were usually advised to contact their primary care provider for diabetes management. Patients also did not receive any education regarding signs and symptoms of hyperglycemia, monitoring glucose, or treatment of hyperglycemia (Sinaga & de Koeijer, 2018).

This study highlighted the importance of education for nursing staff and patients in the identifying and treating steroid induced hyperglycemia. An evidenced based protocol for identification and management of steroid induced hyperglycemia was created and implemented. The nursing staff received education for identifying patients at increased risk of hyperglycemia, signs and symptoms of hyperglycemia, and best management strategies (Sinaga & de Koeijer, 2018). The staff was advised on the importance of clearly assessing and documenting a patient's glucose levels prior to and during chemotherapy, along with identifying any signs or symptoms

of hyperglycemia. Staff was encouraged to obtain a referral to a diabetes educator for patients who had uncontrolled glucoses (Sinaga & de Koeijer, 2018). Following the implementation of the evidenced based protocol, a repeat audit showed increased knowledge and awareness of both staff and patients on the sign & symptoms of hyperglycemia, the importance of blood glucose monitoring while receiving steroids, and the need to take appropriate action for treatment (Sinaga & de Koeijer, 2018) (Sinaga & de Koeijer, 2018).

### **Gaps in the Research**

Research regarding steroid induced hyperglycemia in hospitalized patients with cancer is limited. The literature shows steroid induced hyperglycemia is treated in various ways, but resultant glycemic control has not been clearly documented (Umpierrez et al., 2002). Most studies are retrospective, with no specific protocol for the identification and management of hyperglycemia. More prospective randomized controlled trials are needed.

### **Conclusion**

Steroid induced hyperglycemia appears in patients regardless of whether they have a prior history of diabetes, with a prevalence of 33.5-65% established in the literature (Umpierrez et al., 2002). Recognition of steroid induced hyperglycemia is the first step to managing hyperglycemia. The education of both staff and the patient is an integral part of the process. The literature does indicate insulin is the best treatment for steroid induced hyperglycemia and basal-bolus insulin regimen is the most effective for glucose management (Burt et al., 2015; Radhakutty et al., 2017; Spanakis et al., 2014). However, recommendations regarding the optimal dosing of basal-bolus insulin remain inconclusive. For non-diabetics, metformin can also be considered to prevent prediabetes while on steroids (Ochola et al., 2020). Each organization

should consider establishing a protocol that identifies steroid induced hyperglycemia and initiates basal-bolus insulin sooner to achieve and maintain euglycemia.

## **Chapter 3 – Methods**

### **Retrospective Chart Review**

This project was designed as a retrospective chart review of hospital records over three months for all patients admitted to Hematology and Hematopoietic Stem Cell Transplantation services at a tertiary health care center. The primary intention of the retrospective chart review was to determine if hospitalized oncology patients who received steroids compared to those who have not received steroids are at increased risk of hyperglycemia. Inclusion criteria included all patients admitted to Hematology and Hematopoietic Stem Cell Transplantation service greater than or equal to 18 years of age.

The data was collected via manual chart review from the electronic health record using a pre-established database of patients meeting inclusion criteria obtained from the information technology team. The primary investigator completed data collection.

### **Internal Review Board**

Before collecting the data and for human subject protection, approvals were obtained by submission to the Internal Review Board (IRB) of the research committee of the tertiary hospital. This project coordinator also presented the proposal to the Nursing Research Committee (NRC) for approval. After approval from both the NRC and IRB at the tertiary hospital (Appendix A), an application and proposal were submitted to this project coordinator's university IRB for approval (Appendix B). Next, the primary investigator submitted an analytics intake request via information technology portal at tertiary hospital for a list of medical record numbers for patients meeting the inclusion criteria for this project. The turnaround time was approximately 30 days. In conjunction with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, the data was de-identified and given a unique number to mitigate privacy risk. The primary



investigator was the only person accessing the medical record number and could be matched to the unique identifying number. To minimize risk of external knowledge of the medical record number and the matched unique identifying number, the records were kept on a password-protected personal computer that is only in possession of the primary investigator. All information used for this project will be destroyed after three years in a confidential manner.

### **Measures**

Demographic data collected included age, self-identified gender, race, and ethnicity. Additional data collected included the status of hyperglycemia (glucose  $\geq$  200 mg/dL), frequency of glucose monitoring, use of antidiabetic medications, average fasting glucose, and average glucose.

The Centers for Medicare and Medicaid Services (CMS) measures inventory tool of hospital harm – severe hyperglycemia assesses “the number of inpatient hospital days with a hyperglycemia event (harm) per the total qualifying inpatient hospital stays for patients 18 years of age or older at admission” (The Centers for Medicare and Medicaid Services [CMS], 2021, p. 1). This inventory tool was used to establish and identify hyperglycemia when collecting the data for this study. Patients with one glucose reading  $>$  200 mg/dL were identified as having hyperglycemia. The charts were reviewed for whether the patient received any steroids during hospitalization, regardless of the dose, timing, or indication.

The primary outcome of the retrospective chart review was to evaluate the incidence of steroid induced hyperglycemia. The secondary outcomes from the chart review include a) average fasting glucose, b) average glucose, c) frequency of glucose testing, d) use of antidiabetic medication (e.g., insulin). The secondary outcomes were used to determine the

appropriate frequency of glucose testing and the type of intervention that may be most useful when developing a protocol for implementation in the future.

### **Analysis**

The data was analyzed using IBM SPSS Statistics (Version 27) predictive analytics software. The data was analyzed to determine if there is a statistically significant association between the reception of steroids and the presence of hyperglycemia. A hospitalized oncology patient either received steroids or did not received steroids. The reception of steroids is a nominal variable with two levels (yes vs. no). Based on the CMS definition, the patients with glucose readings  $> 200$  mg/dL was considered as having hyperglycemia. The status of hyperglycemia is a nominal variable with two (yes vs. no) levels. A nominal variable has two or more categories, but there is no intrinsic ordering to the categories (Stevens, 1946).

The data was also analyzed to look at the secondary outcome measures. Average fasting glucose and average glucose are ratio variables. A ratio variable is one where there is order and the difference between two values is meaningful and has a clear definition of 0 (Stevens, 1946). When the variable equals 0, there is none of that variable. The frequency of glucose testing is a nominal variable with two levels (daily vs. AC/HS). The use of an antidiabetic medication is a nominal variable with two levels (yes. vs. no). An examination of test assumptions was completed to assess for presence of multicollinearity that could affect analysis of data.

A univariate analysis was used for descriptive analysis of the data. Frequency tables summarize the data, including the primary measure, the secondary measures, the predictor, and the demographics. Next a bivariate analysis was completed to examine the relationship between the dependent variable and independent variable as well as the relationship between the dependent variable and the covariable. The chi-square test of independence was performed to

determine if there is a statistically significant association between reception of steroids and status of hyperglycemia, i.e., to determine if hospitalized oncology patients who have received steroids are at increased risk for hyperglycemia, compared to those who have not received steroids (Field, 2013). The chi-square test of independence was also performed to determine if there is a statistically significant association between frequency of glucose monitoring and reception of antidiabetic medication to the status of hyperglycemia during hospitalization. A multivariate analysis was completed to further assess the bivariate variables with statistical significance to determine which variable is the strongest predictor of the dependent variable hyperglycemia, which is the overall goal of this data analysis study. A binary logistics regression model was used for the multivariate analysis. For any tests, a  $p$ -value less than 0.05 was considered significant.

A priori power analysis based on the chi-square test of independence for determining if there is a statistically significant association between reception of steroids (a nominal variable with two levels: yes vs. no) and status of hyperglycemia (a nominal variable with two levels: yes vs. no) was conducted to determine the minimum sample size required for this study using G\*power 3.1.9.4 (Faul, Erdfelder, Buchner, & Lang, 2009). Assuming a medium effect size (Cohen's  $w = 0.3$ ) (Cohen, 1992) and a significance level of 0.05, the minimum sample size required to detect a significant effect with 80% power is 88. Thus, chart reviews for at least 44 hospitalized oncology patients who have received steroids and 44 hospitalized oncology patients who have not received steroids are required for this study. Figure 1 shows the results of power analysis using G\*power. Data was collected from 118 charts.

## Chapter 4 – Results

### Data and Analysis

This study was a retrospective chart review and data analysis to determine the prevalence of steroid induced hyperglycemia in patients admitted to a Hematology and Hematopoietic Stem Cell Transplantation services at a tertiary health care center over a three-month period. Inclusion criteria were all patients aged 18 years and older admitted to Hematology and Hematopoietic Stem Cell Transplantation services between 7/1/2021-9/30/2021. Data examined included demographics, administration of steroids, presence of hyperglycemia (glucose >200 ml/dL), frequency of glucose testing, average glucose, average fasting glucose, and use of any antidiabetic medications.

The IRB at both the medical center and education institution approved this project. The project had support from the Hematology and Hematopoietic Stem Cell Transplantation services, oncology pharmacist, endocrinology department director, and information technology.

### Demographic Analysis

A descriptive analysis of demographics is listed in Table 1. The age ranged from 18-91 years with a mean of 60.38. Gender was almost equally divided, 48.3% of the 118 were male while 51.7% were female. There was no variation in either race or ethnicity and all participants were 100% white and non-Hispanic or Latino. A descriptive analysis of the categorical variable's steroid received during hospitalization, hyperglycemia during hospitalization, frequency of glucose monitoring and reception of antidiabetic medication during hospitalization are listed in Table 2. More than half of patients received steroids during admission (n=66; 66%) while approximately a quarter of the patients developed hyperglycemia during admission (n=28; 23.7%). Most of the patients had fasting glucose monitoring (n=99; 83.9%) while the other

16.1% (n=19) had glucoses monitored before meals and at bedtime. Similarly, 81.4% (n=96) did not receive any antidiabetic medications during hospitalization while only 18.6% (n=22) received any antidiabetic medications during hospitalization.

Descriptive analysis of the variable's average fasting glucoses and average glucose before meals/bedtime (AC/HS) during admission are listed in Table 3. The average fasting glucose was 121.31 mg/dL (SD=26.248; MIN/MAX=68/252) and average AC/HS glucose was 152.30 mg/dL (SD=27.715; MIN/MAX=94/203).

### **Glucose Monitoring and Antidiabetic Medications**

Bivariate analysis of the categorical variable's steroid received frequency of glucose monitoring and reception of antidiabetic medications with the dependent variable hyperglycemia are listed in Table 4. Chi-square analysis indicated reception of steroids was associated with hyperglycemia,  $X(2)=16/568$ ,  $p<0.001$ . Chi-square analysis also indicated AC/HS glucose monitoring and reception of antidiabetic medications were also associated with hyperglycemia,  $X(2)=31.227$ ,  $p<0.01$  and  $X(2)=18.684$ ,  $p<0.01$ , respectively.

Bivariate analysis of the continuous variable average fasting glucose and AC/HS average glucose with the dependent variable hyperglycemia are listed in Table 5. An independent-samples t-test showed patients with fasting glucose monitoring who developed hyperglycemia had a mean average glucose (M=146.57, SD=32.012) which was statistically higher than those who did not develop hyperglycemia (M=113.46, SD=18.212),  $t(116)=-6.892$ ,  $p<0.001$ . Likewise, an independent samples t-test showed patients with AC/HS glucose monitoring who developed hyperglycemia had a mean average glucose (M=162.93, SD=18.839) that was statistically higher than those patients who did not develop hyperglycemia (M=120.40, SD=26.651),  $t(18) = -3.954$ ,  $p<0.001$ .

### **Indicator of Hyperglycemia Analysis**

A binary logistic regression analysis of the predictors to determine the strongest indicator of hyperglycemia during hospitalization is shown in Table 6. The data showed the statistical significance of the overall model  $X(3) = 46.814$ ,  $p < .001$ . The individual predictor, reception of steroids, showed those who received steroids during hospitalization were almost 21 times (OR=20.990, 95% CI=3.576-123.216) more likely to develop hyperglycemia,  $X(1, N=118) = 11.363$ ,  $p=0.001$ . Data also showed frequency of glucose monitoring was also statistically associated with hyperglycemia,  $X(1, N=118) = 7.023$ ,  $p=0.008$ .

## Chapter 5 - Discussion

For hospitalized oncology patients receiving steroids, there is limited data regarding the incidence of steroid induced hyperglycemia (Rowbottom et al., 2015). There are no established guidelines listed in the literature for the identification and management of steroid induced hyperglycemia (Umpierrez et al., 2012). The tertiary hospital where this chart review was completed also did not have any established guidelines for identification and treatment of steroid induced hyperglycemia. Glucoses are typically elevated the most a few hours after steroid administration; therefore, identification of steroid induced hyperglycemia is best identified by measuring glucoses throughout the day (Suh & Park, 2017). Steroid effect on glucoses often wears off in 24 hours, resulting in normal fasting glucoses when steroids are given in the mornings (Suh & Park, 2017).

The prevalence of steroid induced hyperglycemia from the literature review ranged from 33.5-64% of hospitalized patients. This retrospective chart review confirmed the prevalence of steroid induced hyperglycemia on one unit of hospitalized oncology patients at 37.9%, which is consistent with the literature. This also means 62.6% of patients who received steroids did not develop hyperglycemia during hospitalization. There were also three patients (5.8%) who developed hyperglycemia but did not receive any steroids during hospitalization. It is unknown what percentage of patients had underlying diabetes which could have contributed to hyperglycemia.

The frequency of glucose monitoring identified in the literature review ranged from 45.7-75.7%; however, the differentiation between fasting glucose monitoring versus glucose monitoring throughout the day was not specified. In this retrospective chart review, only 16.1% of the patients had glucose monitoring throughout the day, before meals and at bedtime. The

remaining patients only had fasting glucose readings available for review. The fasting glucoses were not specifically ordered, but part of a basic metabolic panel (BMP) drawn every morning for hospitalized patients. Due to the low percentage of patients having glucoses checked during the day, patients with steroid induced hyperglycemia may not have been identified.

Additionally, only 18.6% of the patients received antidiabetic medications for treatment of hyperglycemia in this retrospective chart review. The type of medication used was not identified in this study; however, there were patients who had hyperglycemia, but no antidiabetic medications prescribed.

### **Limitations**

#### **Project Methodology**

This retrospective chart review did have some limitations. First, the sample size was small. While enough data was collected to identify statistical significance, a larger sample size would better identify the prevalence of steroid induced hyperglycemia. While a total of 118 charts were reviewed, patients may have been hospitalized more than once over the 3-month period reviewed which could affect the data analysis. Another limitation was the retrospective nature of this study. Retrospective studies have biases including selection and misclassification bias that can impact the data collected and analyzed. Finally, this retrospective chart review relied on the data inputted into the electronic medical records, which could lead to inaccurate data.

#### **Protocol Methodology**

This tertiary hospital did not have any specific protocol for glucose monitoring or hyperglycemia treatment in place which leads to the inconsistent ordering of both glucose monitoring and antidiabetic medications. Additionally, there was no specific order for fasting glucoses. The fasting glucose was just part of the daily basic metabolic panel ordered for the



patient which means providers were not necessarily interested in monitoring glucose levels. Since the steroid effect causes glucoses to peak 4-6 hours after administration, only monitoring fasting glucoses may not capture all patients who developed steroid induced hyperglycemia.

Another limitation was the lack of cultural diversity. All patients self-identified as white and non-Hispanic or Latino, which is most representative of the rural setting of this tertiary hospital. Therefore, the results cannot be generalized to other hospital settings with more cultural diversity.

### **Other Challenges**

There were some challenges completing this retrospective chart review. Due to contractual issues, data could not be collected or analyzed until ten days prior to the completion date of this study. The primary investigator personally completed the data collection and data analysis.

### **Future Recommendations**

Glucocorticoids are an important part of chemotherapy treatment; however, treating hyperglycemia during hospitalization is imperative to decrease mortality and poor clinical outcomes. Based on this retrospective chart review, this tertiary medical center would benefit from a protocol for identification and management of steroid induced hyperglycemia. A subsequent quality improvement (QI) project should involve educating the oncology providers, pharmacists, nursing staff and patients on the prevalence of steroid induced hyperglycemia, importance of treating steroid induced hyperglycemia, and the signs/symptoms of hyperglycemia. The protocol should include glucose monitoring and best practice treatment. As previously discussed in the literature review, it is best to check blood sugars before meals and throughout the day to identify steroid induced hyperglycemia (Suh & Park, 2017). Subsequently,

if a patient develops hyperglycemia, insulin therapy should be initiated promptly using basal/bolus insulin therapy as the best treatment option for steroid induced hyperglycemia (Burt et al., 2015)(Radhakutty et al., 2017)(Spanakis et al., 2014). The new protocol should have ongoing data collection and analysis using the parameters established from this retrospective chart review.

Additional data can be examined for secondary outcomes to provide more information regarding steroid induced hyperglycemia in the oncology population. These data points could include the type of cancer, type of steroid prescribed, the dose of steroid prescribed, frequency of steroid prescribed, type of insulin prescribed, preexisting diagnosis of diabetes, and which medical service managed diabetes during admission.

### **Conclusion**

This retrospective chart review identified the prevalence of steroid induced hyperglycemia in oncology patients admitted to Hematology and Hematopoietic Stem Cell Transplant services at a rural tertiary hospital over the three-month period. This study also identified the lack of glucose monitoring and the lack of antidiabetic medications administered during hospitalization. Establishing a protocol for identification and management of steroid induced hyperglycemia in this population would help improve health outcomes and decrease mortality.

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**Table 1***Descriptive Statistics of Demographics*

Variable	n	Minimum	Maximum	Mean
<b>Age</b>	118	18	91	60.38

Variable	n	%
<b>Gender</b>		
Male	57	48.3
Female	61	51.7
<b>Race</b>		
White	118	100
<b>Ethnicity</b>		
Non-Hispanic or Latino	118	100



**Table 2***Descriptive Analysis of Categorical Variables (N=118)*

Variable	n	%
<b>Steroid received during hospitalization</b>		
No	52	44.1
Yes	66	55.9
<b>Hyperglycemia (Glucose &gt;200) during hospitalization</b>		
No	90	76.3
Yes	28	23.7
<b>Frequency of glucose monitoring</b>		
Fasting	99	83.9
AC/HS*	19	16.1
<b>Receiving antidiabetic medication during hospitalization</b>		
No	96	81.4
Yes	22	18.6

*Note:* \*AC/HS = before meals and at bedtime.

**Table 3***Descriptive Analysis of the Continuous Variables*

Variable	M (SD)	MIN/MAX	Potential Scores
Average Fasting Glucose	121.31 (26.248)	68/252	n/a
Average AC/HS Glucose	152.30 (27.715)	94/203	n/a

*Note.* M = mean, SD = Standard deviation, Min = minimum, Max = maximum

**Table 4***Bivariate Analysis of Categorical/Categorical Variables – Chi-square (N=118)*

<b>Variable</b>	<b><u>Hyperglycemia (glucose &gt;200) during hospitalization</u></b>		<b>X2 (df)</b>
	<b><u>No</u></b> n (%)	<b><u>Yes</u></b> n (%)	
<b>Received Steroid</b>			16.568 (1) **
No	49 (94.2)	3 (5.8%)	
Yes	41 (62.2)	25 (37.9%)	
<b>Frequency of glucose monitoring</b>			31.227 (1) **
Fasting	85 (85.9)	14 (14.1)	
AC/HS	5 (26.3)	14 (73.7)	
<b>Received antidiabetic medications</b>			18.684 (1) **
No	81 (84.4)	15 (15.6)	
Yes	9 (40.9)	13 (59.1)	

*Note.* \*\* (p<0.01)

Table 5

*Bivariate Analysis of Categorical/Continuous Variables - Independent Samples t-test (n=118)*

<b><u>Hyperglycemia (glucose &gt;200) during hospitalization</u></b>			
<b>Variable</b>	<b><u>M (SD)</u></b>	<b><u>t (df)</u></b>	<b><u>p</u></b>
Average Fasting Glucose		-6.892 (116)	0.00
No	113.46 (18.212)		
Yes	146.57 (32.012)		
Average AC/HS glucoses		-3.954	0.01
No	120.40 (26.651)		
Yes	162.93 (18.839)		

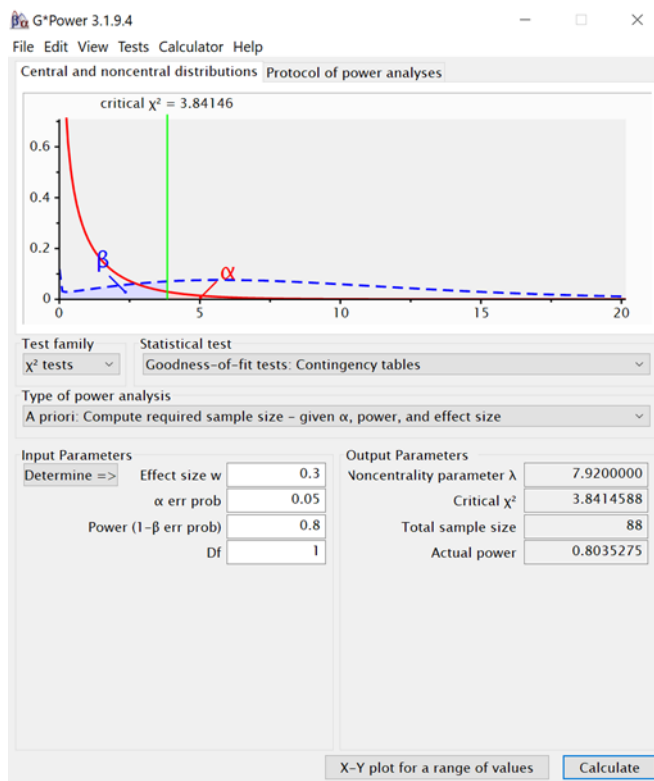
*Note:* (p<0.01 = statistically significant)

**Table 6***Binary Logistics Regression Analysis Examining Hyperglycemia*

Variable	B (SE)	(X <sup>2</sup> )	OR (95% CI)
<b>Steroid received during hospitalization</b>	3.044 (.903)	.001	20.990 (3.576-123.216) **
<b>Frequency of glucose monitoring</b>	2.720 (1.027)	.008	15.188 (2.031-113.586)
<b>Received antidiabetic medication during hospitalization</b>	.981 (.964)	.309	(.403-17.638)

*Note.* \*\* (p<0.01)

Figure 1

*Power Analysis Using G\*power*

## Appendix A

### Health Care Institution IRB approval

Geisinger Institutional Review Board (GIRB)  
FWA # 00000063 IRB# 00008343

Geisinger

100 N. Academy Avenue  
Denville, PA 17822-3069  
570-271-8663  
IRB@geisinger.edu

#### IRB Determination Notice Activity Does Not Meet the Definition "Research"

November 11, 2021

Dawn R Hornberger  
GMC - Endocrinology

IRB #: 2021-0890 (Steroid Induced Hyperglycemia), entitled Prevalence of hyperglycemia in Oncology patients receiving steroids

RE: Initial Review Submission Form, 11/05/2021 12:31:35 PM EDT

Dear Dawn R Hornberger:

The above proposal was reviewed on 11/11/2021 by Geisinger IRB staff/member(s).

From the information you have provided, the proposal does not meet the definition of *Research* as defined in 45 CFR 46.102(d): *a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*. Therefore, this proposal is not subject to human subjects research regulations and does not require oversight by Geisinger Institutional Review Board (GIRB). This means you do not need to submit your proposal to the IRB for further review/approval. However, this proposal may be subject to other non-research regulations, institutional policies or requirements.

If APPLICABLE: Case reports of 3 or less individuals are not research. However, Geisinger has other requirements that must be completed prior to submitting case report(s) for external presentation or publication:

- It is important to adhere to any applicable publication guidelines for informed consent.
- We recommend that you obtain permission from the patient(s) to use their information to generate your case report(s) using the [CONSENT FOR THE PUBLICATION OF MEDICAL IMAGES, RESULTS, AND CLINICAL INFORMATION IN A MEDICAL JOURNAL](#).
- You must also obtain HIPAA compliant authorization signed by the patient (or his/her legally authorized representative) to submit your case report for publication or presentation if it is not fully de-identified in compliance with Geisinger policies. If the publishing entity requires you to submit the signed patient consent, your case report is NOT de-identified and requires this signed patient authorization. Please note the authorization cannot be combined with any other form.



## Geisinger

- If you do not obtain written HIPAA authorization, your de-identified case report(s) must be submitted to the Privacy Office at [systemprivacyoffice@geisinger.edu](mailto:systemprivacyoffice@geisinger.edu) for review and approval.
  - Use the subject line: *Research Case Review*
  - Include where you wish to publish or present the case report(s).

If you have questions or need assistance, please contact Geisinger IRB at (570) 271-8663 or via email ([irb.geisinger.edu](mailto:irb.geisinger.edu)).

Sincerely,

Geisinger Institutional Review Board (IRB)



## Appendix B

### University IRB approval



Office of Research and Sponsored Programs | West Chester University | Ehinger Annex  
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Dec 3, 2021 10:55:58 AM EST

To: Dawn Hornberger  
Department: Academic Affairs, Nursing

Re: Exempt - Initial - IRB-FY2022-141 Prevalence of Hyperglycemia in Oncology Patients Receiving Steroids

Dear Dawn Hornberger:

Thank you for your submitted application to the WCUPA Institutional Review Board. We have had the opportunity to review your application and have rendered the decision below for Prevalence of Hyperglycemia in Oncology Patients Receiving Steroids.

Decision: Exempt

Selected Category: Category 4, Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- (i) The identifiable private information or identifiable biospecimens are publicly available;
- (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
- (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

If there are any questions, please don't hesitate to reach out to [irb@wcupa.edu](mailto:irb@wcupa.edu)

Sincerely,  
WCUPA Institutional Review Board

IORG#: IORG0004242  
IRB#: IRB00005030  
FWA#: FWA00014155