

Diabetes in Focus

UGA College of Pharmacy Student Diabetes Club

Keeping pharmacy students informed on current and pertinent diabetes information!

Glycemic Control in Cancer Patients

Written by: Diana Figueroa Allgood, 3rd Year Pharm.D. Candidate

In 2018, the American Diabetes Association (ADA) released an update to current clinical practice guidelines for diabetes care. New ADA standards recommend that nonpregnant adult patients with type 2 diabetes target an HbA1c goal <7% in addition to fasting blood glucose levels between 80–130 mg/dL and 2-h postprandial blood glucose values <180 mg/dL.¹ Although each glycemic target must be individualized to the needs of the patient and his or her disease factors, current recommendations by the ADA for glycemic goals are optimal targets supported by extensive clinical research. Furthermore, patients achieving ADA-recommended glycemic goals can minimize short and long-term complications of diabetes. Glycemic control is the cornerstone of diabetes management and therapy is tailored to each patient in order to achieve the individualized glucose goals.

Although numerous aspects must be considered when setting glycemic targets, comorbid conditions is one of many patient-specific factors that should be taken into account when creating a proposed treatment plan. Often, cancer is identified as a comorbidity in diabetic patients and can present prior to being diagnosed with diabetes or even after the patient has been living with diabetes for many years. In either scenario, glycemic control remains of utmost importance for proper diabetes management. Maintaining glycemic control in the presence of cancer may be challenging for many patients. However, this creates a great opportunity for the pharmacist to aid in developing a new treatment plan or adjusting a preexisting diabetes regimen that is appropriate for the patient in the presence of both disease states.

When cancer presents in patients with an existing diabetes diagnosis, the focus of diabetes management shifts from prevention of long-term complications to prevention of acute outcomes such as dehydration, polyuria, hyperosmolar nonketotic states (HNK), and diabetic ketoacidosis (DKA). Of note, the most common acute outcome is asymptomatic hyperglycemia. Of note, patients

should perform self-monitoring of blood glucose (SMBG) more frequently in order to best assess the efficacy and safety of treatment and further prevent deleterious complications. In most cases, patients will be converted to basal-bolus insulin regimens as blood glucose levels can vary erratically during chemotherapy.² Additionally, chemotherapy can worsen kidney function requiring renal dose adjustments of all oral antidiabetics (OADs). This can be sufficient cause for discontinuation of OADs, but other contributing factors include chemotherapy induced nausea and vomiting (CINV) or other undesirable side effects such as weight loss or gastrointestinal discomfort.³

CANCER AND DIABETES



When cancer patients are later diagnosed with diabetes, clinicians must initiate appropriate diabetes therapy that does not interfere with the cancer chemotherapy regimen. Unfortunately, many chemotherapy agents come with an increased risk of developing type 2 diabetes. Some examples of these chemotherapies include: platinum-based medications, 5-fluorouracil, mTOR and ABL kinase inhibitors. Glucocorticoids, often a component of chemotherapy regimens, are known to induce hyperglycemia leading to steroid-induced hyperglycemia (SIHG). This can be ameliorated by dividing the total daily dose of glucocorticoids into more frequent, smaller doses throughout the day or slowing the IV infusion rate. Patients at high risk for developing diabetes may benefit from SMBG during glucocorticoid therapy. If the chemotherapy regimen is cyclic in nature, patients may benefit from the intermittent use of antidiabetic agents as the best option for prevention of hyperglycemia.³

With no dedicated clinical practice guideline for glycemic control in cancer patients, an interdisciplinary healthcare team is vital for this

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Glycemic Control in Cancer Patients Cont.

special population in order to provide the best care in every aspect. Pharmacists play a crucial role in weighing the risks versus benefits of various glycemic control methods and providing appropriate recommendations in patients with complex comorbidities. Not only does this include drug therapies, but also, patient education on correct SMBG techniques and beneficial lifestyle modifications. Providing diabetic patients with the necessary education and support during cancer treatment allows clinicians to create an individualized treatment plan that strives to improve patient's overall quality of life.

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New Drug Spotlight: SOLIQUA™ 100/33

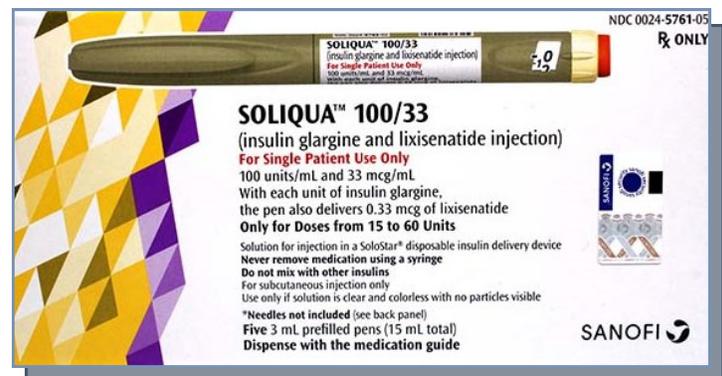
Written by: Sydney Finder, 3rd Year Pharm.D. Candidate

Gaining FDA approval in November 2016, once-daily SOLIQUA™ 100/33 (insulin glargine and lixisenatide injection) is a combination of a long-acting insulin analog, insulin glargine, and a glucagon-like peptide-1 (GLP-1) receptor agonist, lixisenatide. SOLIQUA™ 100/33 is indicated for adult patients with type 2 diabetes mellitus who are inadequately controlled on less than 60 units daily of basal insulin or lixisenatide. Insulins lower blood glucose through various mechanisms such as stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and decreasing hepatic glucose production. GLP-1 receptor agonists increase glucose-dependent insulin release, decrease glucagon secretion, and slow gastric emptying.¹ Supplied as 3 mL disposable, prefilled pen-injectors, SOLIQUA™ 100/33 utilizes SoloStar® technology to combine 100 units/mL of insulin glargine and 33 mcg/mL of lixisenatide for subcutaneous use.¹ The two components in this combination product are available individually as Lantus® (insulin glargine) and Adlyxin™ (lixisenatide).²

In preparation for SOLIQUA™ initiation, patients must discontinue all basal insulin and lixisenatide therapy. For patients inadequately controlled on less than 30 units of basal insulin or on lixisenatide alone, recommended initial dosage is 15 units subcutaneously once daily delivering 15 units of insulin glargine and 5 mcg of lixisenatide in a single dose. For patients inadequately controlled on 30 to 60 units of basal insulin, recommended initial dosage is 30 units subcutaneously once daily delivering 30 units of insulin glargine and 10 mcg of lixisenatide in a single dose. Based on patient-specific blood glucose levels, titrate the daily dose up or down by 2 to 4 units weekly until the goal fasting blood glucose level is achieved.¹

FDA approval for SOLIQUA™ was largely based on two trials, the LixiLan-L and LixiLan-O trials. First, LixiLan-L demonstrated the effectiveness of SOLIQUA™, formerly known as iGlarLixi in the study, in patients uncontrolled on insulin glargine after a 6-week

titration period. Following the 6-week titration period, patients were found to have a mean HbA1c of 8.1% and then randomized to receive either SOLIQUA™ or insulin glargine alone for 24 weeks. At the end of the trial period, patients receiving SOLIQUA™ had greater mean reductions in HbA1c (-1.1% vs. 0.6%, $P<0.0001$) reaching an average HbA1c of 6.9% in patients on SOLIQUA™ compared to 7.5% in patients on insulin glargine alone. Of note, mean body weight among patients decreased by 0.7 kg in the SOLIQUA™ arm versus an increase of 0.7 kg in the insulin glargine arm ($P<0.0001$).² The LixiLan-O trial further confirmed the original research results by comparing 1,170 patients on SOLIQUA™ to patients either on insulin glargine or lixisenatide alone. SOLIQUA™ patients reported a mean decrease in HbA1c of 1.6% compared to insulin glargine patients with a HbA1c decrease of 1.3% and lixisenatide patients with a HbA1c decrease of only 0.9%.³



Reprint from Drugs.com, March 2018:

Using injectable combination therapies will reduce the number of injections and potentially increase patient adherence, however, patients must be made aware of certain risks when switching to SOLIQUA™. If the patient was previously using insulin glargine or lixisenatide, it is necessary to confirm the patient has discontinued use of all monotherapy products. Additionally, providers must instruct patients not to administer other GLP-1 agonists concomitantly with SOLIQUA™ as this increases the risk for adverse drug reactions or result in overdose of the lixisenatide component. Patients should be counseled on the signs and symptoms of hypoglycemia including sweating, dizziness, and fainting. GLP-1 agonists have been correlated with an increased risk of pancreatitis, and patient should be instructed to call their doctor if they experience persistent severe abdominal pain that radiates to the back with or without vomiting.¹ More frequently at the start of SOLIQUA™ therapy, patients may experience gastrointestinal side effects including nausea, diarrhea, vomiting, constipation, dyspepsia, gastritis, abdominal pain or distension, flatulence, and decreased appetite.² However, patients should be made aware that the agents alone carry the same risks, and SOLIQUA™ has shown no increase in any adverse events compared to other agents in the same pharmacologic class. The most common adverse effect seen with SOLIQUA™ compared to insulin glargine alone is mild to moderate gastrointestinal distress, which in clinical trials led to treatment discontinuation in a small number of patients (1.1%).²

In conclusion, SOLIQUA™ 100/33 is an effective combination

New Drug Spotlight: SOLIQUA™ Cont.

therapy for adults age 18 years or older with uncontrolled type 2 diabetes striving to improve glycemic control in conjunction with healthy diet and exercise. In clinical trials, not only did the drug show favorable effects on HbA1c lowering, but also, potential for significant weight loss in patients. Besides SOLIQUA™ 100/33, only one other fixed ration basal insulin and GLP-1 agonist product is available on the market, XULTOPHY® 100/3.6 (insulin degludec and liraglutide) manufactured by Novo Nordisk.⁴

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Management of Hypoglycemia: Sulfonylurea or Insulin Overdose

Written by: Sonam Patel, 3rd Year Pharm.D. Candidate

With over 6,000 insulin and 3,000 sulfonylurea overdoses reported to the U.S. National Poison Data System in 2013 alone, these medications have been regarded for their link to increased numbers of ER visits and hospitalizations annually.¹ Hypoglycemia, also known as low blood sugar, has made its mark as the most common and life-threatening complication implicated with the use of certain oral antidiabetic agents (glipizide, glyburide, and glimepiride). Hypoglycemia management is an intricate process and crucial for patient survival. Management may transcend from the outpatient setting into the inpatient setting when patient presentation necessitates medical referral. Treatment modalities vary based on the patient setting and shall be explored here further.

Hypoglycemia, defined as having a blood glucose less than or equal to 70 mg/dL, follows a patient-specific presentation. However, common signs and symptoms of low blood sugar include sweating, confusion, palpitations, dizziness, blurred vision, and fatigue. Electrolyte disturbances, such as hypokalemia and hypomagnesemia, are also common and require close monitoring

and adjunctive treatment.¹ Unintentional overdoses of insulin or sulfonylureas, such as those resulting from therapeutic errors, may be managed in the outpatient setting.¹ When an adult patient presents with a blood glucose less than 70 mg/dL and exhibits symptoms of low blood sugar, the “15-15 Rule” should be utilized. Under this rule, the patient is instructed to consume 15 grams of carbohydrates, which may come in the form of glucose tablets, glucose gel, one tablespoon of sugar or honey, or a one-half cup of orange juice. Care must be taken to ensure that the chosen item does not contain fats and complex carbohydrates due to delayed glucose absorption. The patient must then recheck their blood glucose after 15 minutes. If the blood glucose level remains below 70 mg/dL, the patient may repeat the process no more than three times, after which the patient should seek medical care. If the patient’s blood glucose cannot be effectively managed by the “15-15 Rule”, such as in altered mental status, a glucagon injection may be considered as an alternative outpatient treatment option until appropriate medical care can be obtained.²

For hypoglycemia resulting from sulfonylurea ingestion by children or intentional sulfonylurea or insulin overdose by adults, inpatient treatment is warranted. In the event of a sulfonylurea overdose, activated charcoal may be administered to patients with a protected airway within 2 hours of sulfonylurea ingestion in order to impede further drug absorption. Patients who are alert and able to tolerate oral intake should be provided with enteral feeding. However, patients presenting with altered mental status should be given intravenous (IV) dextrose initially. Inpatient treatment of hypoglycemia is initiated with a 1 g/kg bolus of 50% dextrose (D50W) for adults or 25% dextrose (D25W) for children. If hypoglycemia is due to an insulin overdose, the dextrose bolus should be followed with a 10-50% dextrose infusion in order to maintain euglycemia, defined as blood glucose levels between 90 and 180 mg/dL.¹

In the event of a sulfonylurea overdose, an extended dextrose infusion should not be administered following the IV dextrose bolus. These patients tend to have retained pancreatic function. Therefore, high levels of dextrose will stimulate insulin release and lead to recurrent episodes of hypoglycemia in these patients. Octreotide is a synthetic somatostatin analogue that binds to receptors on pancreatic beta cells and inhibits insulin secretion.¹

How to Treat Low Blood Sugar (Hypoglycemia)

1.  **Eat/Drink 15 g Carbs**
2.  **Wait 15 Minutes**
3.  **Check Blood**
4.  **Less than 70 mg/dl? Repeat Steps 1-4**

Management of Sulfonylurea or Insulin Overdose Cont.

As a result, IV octreotide 50-150 mcg every 6 hours remains the mainstay of treatment following IV dextrose bolus in these patients. For patients receiving inpatient treatment for an unintentional sulfonylurea overdose from therapeutic use, IV octreotide is only initiated if hypoglycemia persists after initial management with oral food intake and IV dextrose. Glucagon injection may be considered for use in the inpatient setting as well, but it is reserved for cases where IV access is not attainable.³ During inpatient management, blood glucose should initially be monitored hourly and then every 2-6 hours once stable. Following discontinuation of IV dextrose or octreotide, patients must be observed for at least 12 hours to rule out recurrent hypoglycemia.¹

Insulin and sulfonylurea overdose is a widespread public health concern that necessitates immediate action. Overdose-associated hypoglycemia is both severe and life-threatening, resulting in many preventable complications. However, with appropriate recognition and outpatient or inpatient treatment, euglycemia may be achieved and maintained in patients. Improvements in the management of hypoglycemia in the healthcare setting have continued to contribute to a decline in overdose-related deaths and an improvement in patient outcomes worldwide.

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Zynquista™: New Option for Type 1 Diabetes Patients?

Written by: Samuel Menasie, 3rd Year Pharm.D. Candidate

Type 1 diabetes is estimated to affect over 1.25 million Americans, and more than two-thirds of these patients have reported inadequately controlling their blood glucose levels.¹ Along with consistently monitoring blood sugar, insulin therapy is one of the only approved options for type 1 diabetes patients and is associated with side effects such as weight gain and hypoglycemia. With limited treatment options and the high cost of insulin, type 1 diabetes can be a difficult disease state to manage and avoid serious complications such as diabetic retinopathy, neuropathy, reduced kidney function, and cardiovascular disease.

Zynquista™ (sotagliflozin) is an exciting new drug that has recently been FDA approved for investigational treatment in conjunction with insulin therapy for type-1 diabetes patients.⁴ Zynquista™ works by inhibiting both sodium-glucose co-transporters (SGLT) 1 and 2, thus reducing glucose absorption in both the intestinal tract (SGLT1) and the kidneys (SGLT2). As a result, patients will experience delayed postprandial hyperglycemia and increased glucose excretion in the urine.² This once-daily oral medication has potential to be the first agent

FDA-approved for use in combination with insulin for type-1 diabetes treatment and would provide patients with an innovative way to manage their blood sugar.²

Examining the inTandem3 clinical trial, Zynquista™ was assessed for glycemic control, defined as hemoglobin A1c (HbA1c) levels less than 7.0%, and the incidence of severe hypoglycemia and diabetic ketoacidosis in insulin-receiving type 1 diabetes patients.² In this phase 3, multicenter, double-blind trial, approximately 1400 patients were monitored for 24 weeks on either once-daily Zynquista™ 400 mg or placebo. When compared to placebo, significantly more patients receiving Zynquista™ achieved HbA1c levels lower than 7.0% in addition to having no incidence of severe hypoglycemia or diabetic ketoacidosis.² The Zynquista™ group also had significant decreases in HbA1c levels, fasting plasma glucose levels, insulin dose, weight, and systolic blood pressure.² However, these patients had higher rates of serious adverse effects such as hypoglycemia compared to the placebo group. Among those who had post-treatment HbA1c levels greater than or equal to 7%, rates of diabetic ketoacidosis were significantly higher in those who received Zynquista™ than those who did not.²

In a 2015 randomized, double-blind clinical trial, Zynquista™ therapy was assessed for safety and efficacy in 33 insulin-receiving patients with poor control of type 1 diabetes. Over about a month, patients who were treated with once-daily 400 mg Zynquista™ experienced lower HbA1c and daily glucose levels along with lower bolus insulin dose requirements, demonstrating improvement in glycemic control without hypoglycemic events.³ This smaller study also reported that patients on Zynquista™ had lower systolic blood pressure readings, a higher percentage of time between goal glucose ranges (70-180 mg/dL), and more instances of weight loss than placebo.³ Reported side effects included nausea and diabetic ketoacidosis with no instances of severe hypoglycemia.

While monitoring for hypoglycemia and diabetic ketoacidosis remains a concern, oral Zynquista™, in addition to insulin, shows promise as a beneficial treatment option for adults with type 1 diabetes. As of May 2018, the FDA has accepted Sanofi's regulatory filing for this drug and the anticipated target FDA action date for approval is March 22, 2019.⁴ If approved, patients with uncontrolled HbA1c levels who add Zynquista™ to their insulin therapy will potentially be able to achieve glycemic control and lower their insulin dose, opening the door to new adjunctive agents being introduced in the future.

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ZYNQUISTA



Eversense®: The First Implantable 90-Day CGM

Written by: Emily Harden, 4th Year Pharm.D. Candidate

SDC Highlights

Presented on the basics of insulin and managing hypoglycemia at AU Medical Center's Diabetes Health Fair in Augusta

Fundraising opportunities this semester:

- College of Pharmacy Tumblers
- Halloween-Themed Bake Sale

Members Sydney Finder and Sonam Patel led a diabetes education class at Barney's Pharmacy in Augusta.

Continuous glucose monitoring (CGM) is a system that tracks blood glucose levels throughout the day. With traditional CGMs, a sensor is inserted transcutaneously on the abdomen or arm where it then assesses the interstitial glucose level every few minutes. A wireless transmitter sends this level to a monitor, which may be part of an insulin pump or a separate device, such as a smartphone or tablet.¹ While CGMs are used primarily in patients with type 1 diabetes, use is rising amongst type 2 diabetic patients with uncontrollable blood glucose.

In June 2018, the FDA approved Senseonics' Eversense® CGM system as the first implantable CGM for patients age 18 years and older. The system consists of a fluorescence-based implantable sensor, smart transmitter, and mobile application, which displays glucose values, trends and alerts for detection and prediction of hypo- and hyperglycemic episodes.² Eversense also offers on-body vibrations during these episodes even if the mobile device is out of range. The transmitter can also be taken off and on for times when patients do not want it to be visible. The fluorescent coating on the surface of the sensor generates a light signal in response to the amount of glucose in the interstitial fluid. This signal is converted to a glucose reading and transmitted to a mobile device every 5 minutes.² Due to Eversense being implanted in the subcutaneous tissue, insertion of the sensor is performed by a qualified physician. Once implanted, the sensor is viable for 90 days.² This is the longest-lasting sensor available to date, as traditional CGM systems, such as the Freestyle Libre and Dexcom G5/G6, require replacement every 7 – 14 days. Of note, Eversense requires two calibration sticks per day, unlike the Dexcom system.

In the PRECISE II trial, Eversense was assessed for safety and efficacy in 90 patients enrolled at 8 clinical sites. Each patient had the sensor implanted in the upper arm with a smaller subset of 15 patients having 2 sensors inserted bilaterally.³ Patients were blinded to the CGM glucose readings and asked to follow a calibration procedure twice daily in addition to wearing the transmitter at all times. Efficacy was assessed at four

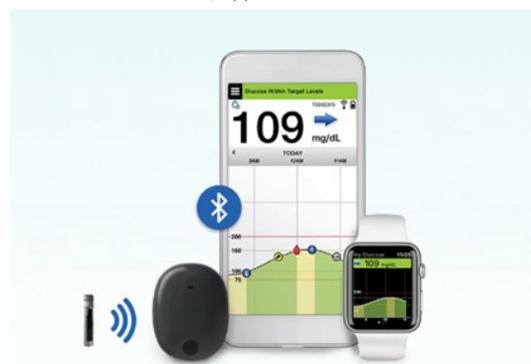
clinic visits where venous blood glucose was measured and compared to Eversense system readings. Analysis of readings showed that 93.3% of CGM values were within +/- 20 mg/dL of the reference venous glucose values.³ Demonstrated by the primary efficacy endpoint of the mean absolute relative difference (MARD) of 8.9%, Eversense was proven to be highly accurate when compared to the reference values. Safety was assessed by measuring the incidence of device-related or sensor-insertion/removal procedure-related adverse events.³ The incidence of serious adverse events related to insertion and/or removal of sensor was approximately 1%. The most common adverse event was pain and bruising at the insertion site.³

Primary care providers and pharmacists should be aware that certain medications could interfere with the Eversense system. When administered in high doses intravenously or as part of a peritoneal dialysis solution, mannitol and sorbitol may falsely elevate glucose readings.² Tetracycline antibiotics may decrease sensor glucose readings.

Despite Eversense recently gaining FDA approval, Senseonics is already looking toward the approval of the Eversense XL CGM, which lasts for 180 days and is already approved in Europe. Cost should be considered when recommending Eversense to patients, as it requires more doctor visits and procedures scheduled every 90 days. Eversense could be a good option for patients who desire a discrete transmitter and longer periods between insertions.

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