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ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Enhancing medication safety for bariatric surgery patients

Problem: Bariatric surgery involves structurally modifying the gastrointestinal tract to reduce caloric consumption or absorption to help patients with obesity lose weight and improve control of metabolic disorders including type 2 diabetes, hypertension, and dyslipidemia.[1] The two most common procedures performed include the vertical sleeve gastrectomy (VSG), a restrictive procedure that reduces stomach size,[2] and the Roux-en-Y gastric bypass (RYGB), a malabsorptive procedure that involves creating a small pouch from the stomach and connecting the newly created pouch directly to the small intestine.[3] These physical alterations result in changes to the gastrointestinal (GI) tract that can affect medication absorption and pharmacokinetics, such as pH changes and a decrease in enzymatic first-pass metabolism.[4]

The pharmacokinetic changes may put patients at increased risk of making therapies more or less effective and/or causing adverse drug reactions (ADRs), such as hypoglycemia, dehydration, and hypotension. In addition, patients with obesity often have other serious health comorbidities and require medications to treat chronic diseases, which may need modifications pre- and post-bariatric surgery. However, some organizations may not have practitioners with expertise in caring for patients after bariatric surgery, such as appropriate drug formulation changes and monitoring to prevent medication-related harm. For example, when swallowed whole, large medication tablets may get stuck at the surgical site within the gastric pouch, especially in the first few months after the surgery.

Another challenge is that most standard multivitamin supplements do not provide the proper amount of nutrients and minerals for patients who have undergone bariatric surgery. That is because the gastric lining inadequately absorbs these supplements post-surgery. Copper is an example of a micronutrient that is commonly deficient in this population. Although the mechanism underlying neurological damage due to copper deficiency is unclear, the enzymes and pathways that require copper are well-known. The *American Society for Metabolic and Bariatric Surgery (ASMBS) Integrated Health Nutritional Guidelines for the Surgical Weight Loss Patient* recommend at least annual screenings of copper levels in post-RYGB patients, even in the absence of clinical signs or symptoms of deficiency.[5] Also, bariatric surgery patients require higher than standard dosing or more frequent administration of micronutrients (e.g., thiamine; vitamins B1 and B12; folate; iron; vitamins A, D, E, and K; calcium; zinc; copper).[5] To further complicate this issue, commercially available multivitamin products vary in micronutrient content and recommended daily dosage, so practitioners may struggle with ensuring adequate supplementation.

Errors Reported to ISMP

ISMP has received medication error reports involving patients post-bariatric surgery. Two examples involving errors with post-surgery nutritional support are presented below.

A prescriber entered an order in the electronic health record (EHR) for ***FLINTSTONES COMPLETE*** *(chewable) multivitamin for a patient who had undergone bariatric surgery. This multivitamin formulation was not on the hospital's formulary, so the pharmacist changed the product to a generic multivitamin capsule during order verification. The nurse administered the generic multivitamin to the patient for 3 days, until the prescriber notified the pharmacist and the nurse that the generic*

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Regadenoson glass syringes may be incompatible with needleless connectors. A prescriber ordered an intravenous (IV) regadenoson 0.4 mg/5 mL injection, a diagnostic agent used during myocardial perfusion imaging, for a patient in a cardiac catheterization laboratory. A nurse attached a regadenoson glass syringe (Accord, National Drug Code [NDC] 16729-477-31, lot number M2206499, expiration date 3/25) to a needleless connector for IV administration. When the nurse tried to inject the medication, a protrusion from the tip of the syringe (**Figure 1**) punctured the patient's IV line causing the medication to leak. The nurse also reported that the luer syringe connector dislodged from the syringe when she tried to tighten it to the needless connector, causing the medication to leak more since the connection would not maintain a seal. The nurse had to administer the dose from a new syringe at a second IV site. The organization has returned this product to their wholesaler and is now purchasing this medication from a different manufacturer.

Figure 1. Accord's regadenoson syringe with a protrusion from the tip of the syringe and a disconnected luer syringe connector.

A second hospital reported a similar concern with both the Accord product mentioned above and Eugia's regadenoson 0.4 mg/5 mL injection (NDC 55150-443-01), which also comes in a glass syringe. In this case, a nuclear medicine technician tried to connect Eugia's

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multivitamin capsule did not contain the essential vitamins that are in the Flintstones Complete (chewable) and needed for this post-bariatric surgery patient. The pharmacist and the nurse were not aware of the differences in multivitamin formulations. The pharmacy purchased the non-formulary Flintstones Complete product, which the nurse administered to the patient for future doses.

A prescriber ordered two Bariatric Fusion ***MULTIVITAMIN*** *soft chews for a patient to take twice a day post-bariatric surgery. After taking the multivitamin for several days at home, the patient noticed skin changes and contacted their dietitian. The dietitian discovered that the pharmacy had substituted and dispensed a different product, ProCare Health* ***BARIATRIC MULTIVITAMINS WITH 45 MG IRON*** *(multivitamin with iron), which should only be taken as one tablet per day. The dietitian notified the prescriber who contacted the pharmacist to clarify the order. The pharmacist ran a report of recent multivitamin prescriptions which revealed similar dispensing errors that reached more than forty patients who had undergone bariatric surgery. The pharmacy staff was unaware of the difference in dose between the multivitamin formulations.*

Pharmacist-Led Bariatric Surgery Clinic Program[6]

We sought insights from experts in the field on how to improve medication safety in a bariatric surgery clinic program. The University of California, San Francisco (UCSF) Health, a 600-bed tertiary medical center, has integrated clinical pharmacist specialists into their interdisciplinary bariatric surgery care team, to provide patient education and pharmacotherapy management through consultations. Highlights of the pharmacist-led program include:

- Facilitating comprehensive medication reconciliation
- Therapeutic planning, dosage adjustments, and monitoring for all home medications including pre- and post-surgery instructions
- Risk assessment for adverse surgical outcomes (e.g., venous thromboembolism [VTE])
- Education on nutritional supplementation and monitoring to prevent deficiencies
- Medication education to prevent adverse outcomes post-surgery (e.g., estrogen may increase the risk of VTE, nonsteroidal anti-inflammatory drugs [NSAIDs] could cause ulcers and bleeding)
- Collaborating with outpatient providers to communicate the medication plan

The following case demonstrates the impact that pharmacist-led therapeutic planning can have on medication safety:

A patient with obesity and diabetes was planning to undergo bariatric surgery (VSG). The patient was receiving multiple diabetes medications, including **OZEMPIC** (semaglutide injection), insulin glargine injection, glipi**ZIDE** tablets, **JARDIANCE** (empagliflozin) tablets, and met**FORMIN** extended-release tablets. Prior to surgery, the patient had well-controlled glucose values (under 130 mg/dL when fasting) without excessive spikes with meals.

The pharmacist-led medication plan pre- and post-bariatric surgery included:

1) Hold semaglutide for one week before surgery due to aspiration risk and delayed gastric emptying.[7]
2) Discontinue semaglutide post-surgery due to excessive glucagon-like peptide-1 (GLP-1) exposure redundancy.[8,9]
3) Decrease insulin glargine dose by 20% (or more based on blood glucose levels) before surgery while on a protein shake diet to prevent hypoglycemia; monitor blood glucose levels closely and treat accordingly.

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regadenoson syringe to the patient's IV tubing, but the syringe would not attach and fell to the floor. The Eugia carton states, "Syringes may require needle or blunt" (**Figure 2**); however, practitioners may overlook this warning because it is in small font on the side of the carton.

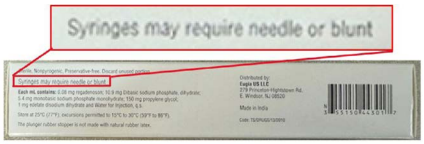

Figure 2. Eugia's regadenoson carton states, "Syringes may require needle or blunt" in a small-sized font on the carton's side.

We have contacted the US Food and Drug Administration (FDA) and the manufacturers to notify them of this concern. Organizations should review product packaging and prescribing information to determine if a prefilled syringe has any restrictions regarding its use with a connector or if it may require use with a needle. We have previously written about certain needlefree syringe connectors for IV lines, called luer-activated valve (LAV) connectors, which are incompatible with prefilled glass syringes, most recently in our December 1, 2022 article, *Prefilled glass syringes incompatible with certain needlefree connectors*. We shared that ISMP and FDA have received multiple reports from practitioners who have been unable to inject a medication into an IV line once the prefilled glass syringe has been connected to the needlefree system. In these cases, they reported that inserting the glass syringe tip caused the pin in the MicroClave needlefree access system to break off in the syringe tip, preventing delivery of the medication. In some events, a piece of plastic was found lodged inside the syringe tip, effectively blocking the flow of medication. After multiple reports sent to ISMP and FDA, FDA released an alert on November 22, 2022, regarding LAV internal pins breaking after practitioners attached prefilled glass syringes.

Incompatibility between syringes and connectors can delay therapy, particularly in emergent and urgent situations, and potentially result in serious harm. FDA has requested LAV connector manufacturers to update the labeling on their products to warn practitioners

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4) Post-bariatric surgery, decrease insulin glargine dose by up to 80% and continue to monitor for hypoglycemia.

5) Discontinue glipi**ZIDE** pre-surgery (and do not reinitiate post-surgery) to prevent hypoglycemia.

6) Discontinue empagliflozin three days before surgery due to the risk of euglycemic diabetic ketoacidosis. Post-surgery, monitor for dehydration, caloric intake, and current need when considering if it should be restarted.[10]

7) Switch met**FORMIN** extended-release tablets to met**FORMIN** immediate-release tablets which are safe to crush after surgery. Monitor for gastrointestinal upset and lactic acidosis.

8) Initiate once daily ProCare Health Bariatric Multivitamin with Iron.

9) Initiate calcium citrate-vitamin D supplementation.

Safe Practice Recommendations: Consider the following when treating bariatric surgery patients:

Ensure the formulary includes appropriate nutritional supplements. Review the multivitamins on your organization's formulary to ensure there is an appropriate formulation (e.g., avoid gummy multivitamins with high sugar content) for patients post-bariatric surgery who have an increased risk of nutrient deficiencies. Coordinate post-bariatric care with providers to select the appropriate combination of supplements and dosing to meet nutritional requirements. For additional recommendations, review the *Clinical practice guidelines for the perioperative nutrition, metabolic, and nonsurgical support of patients undergoing bariatric procedures—2019 update.*[11]

Develop bariatric surgery order sets. Build pre- and post-bariatric surgery medication order sets to guide prescribers in selecting appropriate medication doses, routes, frequencies, and formulations in accordance with the patient's clinical state (e.g., weight, comorbidities, nutritional requirements). For multivitamin selection, consider including the manufacturer's name (e.g., ProCare Health Bariatric Multivitamin, Bariatric Fusion) on medication ordering and verification screens to help differentiate them from other multivitamins. Automatically link products to the corresponding order sentences. Include laboratory monitoring (e.g., blood glucose, nutrient levels) in order sets, when applicable. Regularly review order sets and update as needed. Consider building "Do Not Substitute" designations in the order comments for inpatient orders, and indicate "Dispense as Written" for outpatient prescriptions so that the pharmacy does not provide automatic substitutions.

Use clinical decision support (CDS). Evaluate and/or implement interaction screening (i.e., drug-drug, drug-disease) and dose range checking. Ensure the body mass index (BMI) calculator is readily accessible to practitioners in the EHR, so they can monitor changes and adjust medication doses as needed.

Enhance medication reconciliation. Evaluate the medication reconciliation process as it relates to pre- and post-bariatric surgery medication orders and during transitions of care (e.g., admission, transfer, discharge). If you are using external medication history sources (e.g., outpatient fill data, bariatric clinic notes), verify the information with the patient or caregiver as prescribers may modify the doses based on laboratory results, and the patient's latest regimen may differ from the pharmacy fill data. Establish a formal process identifying the prescriber responsible for completing medication reconciliation during transitions of care. Consider modifications to the medication reconciliation screens that allow a prescriber to select either "Do Not Substitute" or "Dispense as Written." If this is not possible, consider organizational policy changes that require notification to prescribers of automatic substitutions to home medications that are continued on admission for this patient population. Collaborate with the patient and document their current home medication regimen.

Implement a pharmacist consultation. Consider implementing a clinic-based pharmacist visit for a comprehensive medication review as part of a pre-bariatric surgery evaluation. Pharmacists should evaluate medication regimens and collaborate with the care team to plan appropriate

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that connectors with an internal pin may not be compatible with prefilled glass syringes. Additional recommendations include:

- Stock medications that come in plastic prefilled syringes or vials, when possible, or purchase connectors that do not use an internal pin.
- Review the instructions on LAV connectors used within your organization to determine if they have an internal pin and/or contact the manufacturer to confirm.
- Establish and implement a plan to ensure the safe administration of these drugs if your facility uses LAV connectors with an internal pin and medications packaged in prefilled glass syringes.
- Inform staff that compatibility issues may occur when using prefilled glass syringes with LAV connectors with an internal pin.

Special Announcements

Impact of Hurricane Helene. In response to Hurricane Helene and the devastation it brought across southeastern United States, we join hands with all Americans to offer our deepest sympathies to those impacted. In addition, Baxter has communicated that there has been a disruption to their North Cove, NC facility due to the hurricane. The company has provided a list of product codes that have been impacted, including several intravenous (IV) fluids, along with Suggestions for Management and Conservation. We encourage organizations to evaluate their current inventory and clinical needs, optimize fluid management, and identify alternatives to use, when possible.

Webinar sponsored by National Action Alliance. Register now for the National Action Alliance's webinar, ***Leadership Strategies that Improve Workforce Safety and Well-being***. The webinar will be held on **October 8, 2024**, from 12:00 - 1:00 pm ET. To register, click here.

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adjustments for pre- and post-bariatric surgery. This may include recommendations to modify medications, formulations, and/or dosages. Assess patients at higher risk for VTE after bariatric surgery and the need for taking prophylactic anticoagulant medications after discharge.

Monitor patients using an interdisciplinary approach. Conduct interdisciplinary team rounding during which the team (e.g., prescribers, pharmacists, nurses, dietitians) discusses the medications for each bariatric surgery patient. Rounding with an interdisciplinary team to discuss the care of a patient in real-time can be a valuable tool that detects errors and improves safety. Encourage prescribers, pharmacists, and nurses to conduct a daily review of their patient's medication orders (including any substitutions that pharmacy may have made), laboratory results, and assess for ADRs. Hold interdisciplinary discussions about any barriers to discharge (e.g., new high-cost medications, inability to pick up discharge medications) and formulate alternative plans.

Educate practitioners. During orientation and annual competency assessments, educate practitioners about expected pharmacokinetic changes patients may experience post-bariatric surgery, the risk of nutritional deficiencies with the need for lifelong nutrient supplementation, along with common ADRs and monitoring recommendations. Ensure practitioners understand commonly reported errors (e.g., inappropriate multivitamin formulation) as well as the best workflow to reduce the risk of these types of errors. Educate prescribers to indicate "Dispense as Written" on outpatient multivitamin prescriptions.

Educate patients. Educate patients on perioperative medication management. In addition to asking about medications during the medication reconciliation process, educate patients to proactively maintain a current medication list that includes doses, routes, frequencies, and formulations for each drug. Teach patients what to do if they miss a dose, and the signs and symptoms of ADRs that they should report to their prescriber. Teach patients about the risks of medication substitutions and stress the need to query their pharmacists about any substitutions that may have been made. Advise patients to use one pharmacy to obtain all their medications, if possible. Encourage patients to attend bariatric support groups to enhance their knowledge and share their personal experiences with others.

Learn from errors. Review internally reported bariatric surgery-related errors as well as published external events, such as those described in this article. Encourage staff to report close calls and errors that have reached the patient.

We thank Nicole Yvonne Nguyen, PharmD, BCPS, Clinical Pharmacist at UCSF Health, for sharing a review of the UCSF bariatric program. Email ISMP (ismpinfo@ismp.org) with questions.

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