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REVIEW

Sodium-Glucose Co-transporter-2 Inhibitors Induced Diabetic Ketoacidosis in Patients Undergoing Bariatric Surgery: a Systematic Review of Case Reports and Case Series

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Abstract

Sodium-glucose co-transporter-2 inhibitors (SGLT2i) are glucose-lowering agents being increasingly used for cardio-renal protection in patients with or without type 2 diabetes (T2DM). This systematic review identified the clinical risk factors and outcomes of diabetic ketoacidosis (DKA) in patients undergoing bariatric and metabolic surgery (BMS) on SGLT2i. We found 12 studies with a total of 16 patients (10 females; mean age of 51 years). Apart from one patient, all patients developed DKA in the post-operative period presenting at a median of 5 days after surgery. Most of the patients were euglycaemic on presentation with DKA. Patients undergoing BMS on SGLT2i are at increased risk of developing DKA that can mimic post-operative surgical complications causing diagnostic dilemmas, especially with the euglycaemic variant, and delaying treatment.

Keywords Sodium-glucose co-transport 2 inhibitors · Euglycaemic · Diabetic ketoacidosis · Bariatric and metabolic surgery

Key Points
- Patients with T2DM on SGLT2i undergoing BMS are at risk of EDKA perioperatively.
- The risk of EDKA appears to be small and diagnosis requires a high index of suspicion.
- There appears to be a good response to prompt emergency treatment.
- Incidence can be reduced by stopping SGLT2i 48 h before the perioperative diet.

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Introduction

Sodium-glucose co-transporter-2 inhibitors (SGLT2i) are a relatively new group of antihyperglycaemic medications that are often recommended as an add-on therapy for patients with type-2 diabetes mellitus (T2DM) [1]. These drugs inhibit glucose reabsorption in proximal convoluted tubules thereby causing glucosuria and lowering serum glucose levels. Through these effects, SGLT2i have been shown to help patients lose weight through the reduction of fat mass in patients with T2DM [2, 3], and could potentially replace metformin as first-line therapy in patients who are intolerant to metformin or with specific cardio-renal indications [3]. Apart from improving glycaemic control and reducing weight, SGLT2i have a favourable effect on blood pressure and improve cardio-renal outcomes associated with a reduction in cardiovascular mortality. Consequently, SGLT2i are increasingly used in patients with or without T2DM. The most prescribed medications in this group include canagliflozin, dapagliflozin, and empagliflozin, whereas ipragliflozin, luseogliflozin, ertugliflozin, and tofogliflozin are used less commonly in clinical practice.

Diabetic ketoacidosis (DKA) has been linked with the use of SGLT2i medications and reported as an adverse effect in the initial clinical trials [4, 5]. The United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have issued alerts on the risk of DKA associated with the use of SGLT2i medications [6]. DKA can be precipitated by insulin deficiency with a concomitant increase in counter-regulatory hormones such as cortisol, glucagon, and adrenaline, which can happen with the sudden omission of insulin, reduced food or fluid intake, or intercurrent events such as major surgery, infections, and trauma. The pathophysiology of SGLT2i-associated DKA however remains unclear but is thought to be associated with increased glucagon secretion, reduction in circulating glucose via renal excretion of glucose with subsequently reduced insulin secretion and reduced negatively charged ketone excretion due to increased tubular loss of positively charged sodium ions [25, 26]. This may pose a unique clinical presentation of DKA as the blood glucose level may be normal or only moderately increased up to 14 mmol/L (250 mg/dL). Such euglycaemic DKA (EDKA) may cause diagnostic dilemmas and delay the treatment of a medical emergency.

A few isolated cases of SGLT2i-associated DKA in perioperative patients have been reported and summarised by Thiruvenkatrajan et al. in the systematic review [7]. However, there is no published systematic review on SGLT2i-associated DKA in BMS patients. Patients undergoing bariatric and metabolic surgery (BMS) present a different problem compared to patients undergoing other types of operations. Firstly, patients undergoing BMS are far more likely to have T2DM and are being prescribed SGLT2i. Secondly, these patients remain on a low-calorie diet starting from a couple of weeks before the operation with some form of liver reduction diet to a few weeks to months postoperatively. These factors, together with the likely omission or reduction in the doses of insulin can create the perfect storm for the development of DKA in the perioperative period. We undertook this systematic review to summarise the current evidence on the clinical features, risk factors, and outcomes for SGLT2i-associated DKA in patients undergoing BMS and measures that can be taken to reduce such risk.

Methods

Information Sources and Search Strategy

A systematic search was performed on the PubMed, MEDLINE, Embase, and ScienceDirect databases by two authors independently. The last search was on the 7th of May 2022. There were no restrictions on the publication year or status. Only full-text articles published in English were included. A combination of the following search terms was used. "SGLT2 inhibitors" or "sodium-glucose co-transporter 2 inhibitors" or "empagliflozin" or "canagliflozin" or "dapagliflozin" or "ertugliflozin" and "bariatric surgery" and "ketoacidosis" or "DKA." The following types of studies were searched: "clinical study," "clinical trial," or "randomised controlled trial." Original articles, case reports, and case series published in the English language were included. Review articles, conference abstracts, and articles not relevant to bariatric surgery were excluded. We have adopted the strategies suggested by Nambiema et.al., [27, 28] for study selection and quality of synthesis assessment.

Study Selection and Data Extraction

BM and NB independently screened the titles and abstracts to assess their potential relevance for a full review. The full text of potentially relevant articles was retrieved and screened. Any discrepancies were resolved through mutual discussion. The reference lists of all the relevant studies were also screened. Figure 1 depicts the flow diagram to report the study process as per the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. The inclusion criteria were clinical studies that reported the occurrence of DKA in patients undergoing BMS who were prescribed any of the SGLT2i medications. The exclusion criteria were non-clinical studies and clinical studies on patients who did not undergo BMS or were not prescribed SGLT2i medications or did not develop DKA. Data were extracted by BM and NV using a piloted modified worksheet including the type of the study, year of publication, baseline patient demographics such as age, sex, body mass index (BMI), comorbidities, type of SGLT2i used, the preoperative onset of DKA, days before surgery the SGLT2i was stopped, type of bariatric surgery, the postoperative onset of DKA, symptoms and laboratory findings, management of DKA, and associated morbidity and mortality.

Quality of Synthesis Assessment

We used a validated tool for assessing the methodological quality of the included studies [8]. This tool consisted of five questions about the study. A score of 5 would grade the report as strong, a score of 4 would be moderate and 3 or less would be low. As seen in Table 1, individual studies were rated as weak, moderate, or strong by two reviewers independently. Amongst the case series, two studies were graded as moderate, and another two studies were strong. Amongst the case reports, three were graded as moderate and five were strong.

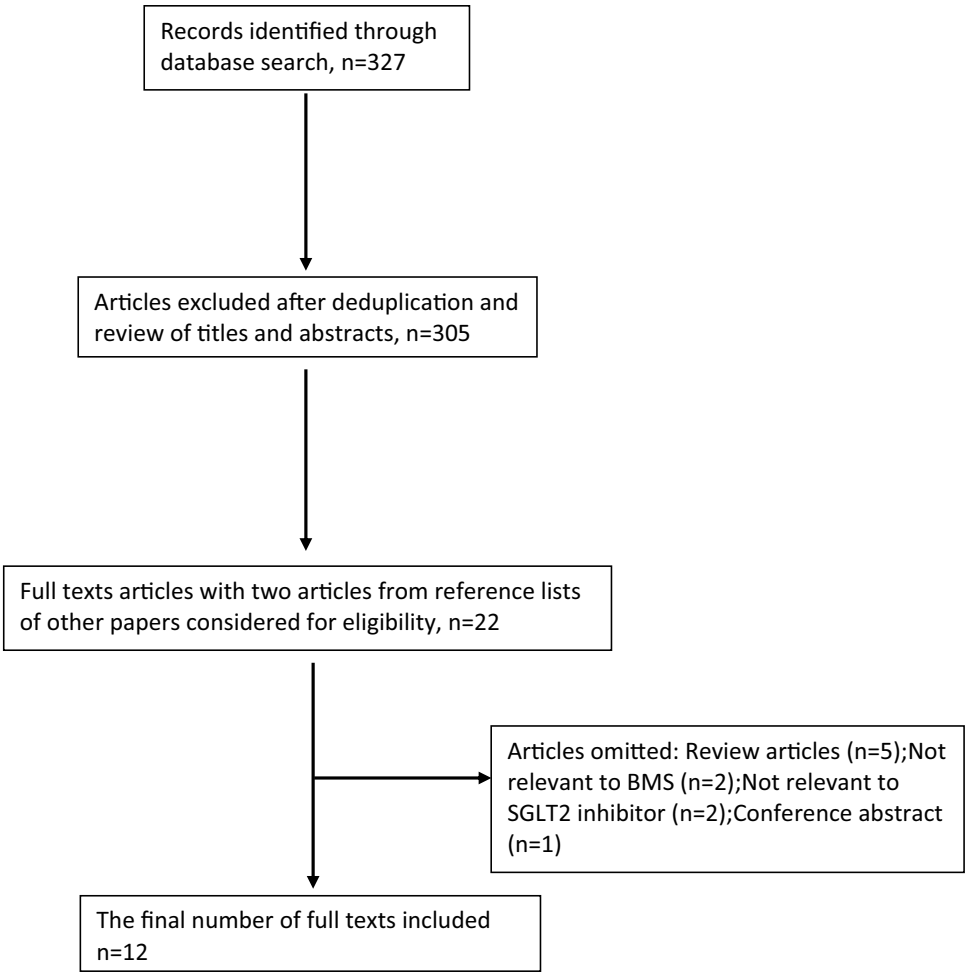

Fig. 1 Flow diagram of the selection process and literature search

Table 1 - Summary of the publications included

Study author	Year of publication	Which SGLTi medication preoperatively	No. of days before surgery medication stopped	Surgery	SGLT2 Stopped	Grade of case report/ series
Amianda [18]	2021	Canagliflozin	1 day	RYGB	Yes	Strong
		Empagliflozin	1 day	LSG	Yes	
Kapila [16]	2021	Canagliflozin	2 days	LSG	Yes	Moderate
Smith [17]	2021	Canagliflozin	2 days	Robotic SG	Yes	Moderate
Iqbal [3]	2020	Canagliflozin	Not mentioned	Band to RYGB	Yes	Moderate
		Dapagliflozin	Not mentioned	LSG	Yes	
		Canagliflozin	Not mentioned	Sleeve bypass	Yes	
Andalib [19]	2016	Canagliflozin	Not mentioned	LSG	Not mentioned	Strong
Bonanni [20]	2016	Canagliflozin	Not stopped	RYGB	Not mentioned	Strong
Brown [21]	2018	Dapagliflozin	Not mentioned	RYGB	Not mentioned	Moderate
Dizon [22]	2017	Canagliflozin	Not mentioned	RYGB	Yes	Moderate
		None	Not applicable	RYGB	Yes	
Banakh [23]	2019	Dapagliflozin	Not mentioned	LSG	Yes	Strong
van Niekerk [24]	2018	Canagliflozin	1 day	RYGB	Not mentioned	Strong
Rizo [25]	2019	Empagliflozin	Not mentioned	RYGB	Yes	Strong
Yared [9]	2020	Empagliflozin	1 day	RYGB	No	Strong

Statistics

Simple descriptive statistics are employed. Significant gaps in the reported data made it difficult to calculate accurate standard deviation, and hence continuous data are presented as mean (range) or median (range) as appropriate. Due to the heterogeneous nature of the studies included, no attempt was made to perform a meta-analysis.

Results

The initial literature search revealed 327 papers, of which 305 articles were excluded after deduplication and review of the titles and abstracts. Full texts of the remaining 22 articles were reviewed and further exclusions were done for five review articles, two articles were not relevant to BMS, further two were not relevant to the use of SGLT2i and another publication was a conference abstract. Finally, 12 studies were analysed, of which eight were case reports and four were case series published between 2016 and 2021. Figure 1 depicts the PRISMA flowchart with an overview of the search process. Table 1 summarises the articles included in this study.

Baseline Characteristics

There was a total of 16 patients which included 10 female and 6 male patients. The mean age was 51 years (range 30 to 64 years), and the mean BMI was 45.5 kg/m^2 (range 38 to 56.4 kg/m^2). In five patients the only co-morbidity was T2DM, whereas the other 11 patients had more than one co-morbidity along with T2DM with hyperlipidaemia ($N=10$) and hypertension ($N=9$) being the most common. The other co-morbidities included gastro-oesophageal reflux disease (GORD) in five patients, and asthma, chronic kidney disease (CKD), and obstructive sleep apnoea (OSA) in one patient each.

SGLT2i and Other Diabetic Medications

All patients were on multiple diabetic medications that included oral hypoglycaemic agents and insulin. Canagliflozin was the most common SGLT2i medication used ($N=9$), followed by empagliflozin and dapagliflozin in three patients each, whereas one patient was commenced on canagliflozin postoperatively. One patient developed preoperative DKA [9] and the rest of the patients developed DKA in the postoperative period. All patients were put on a very low-calorie diet before BMS. In four patients, the SGLT2i was stopped 1 day before BMS; in two patients, it was stopped 2 days before whereas in one patient, it was not stopped at all. In eight patients, the authors did not specify whether the SGLT2i was stopped or not pre-operatively. Ten patients underwent Roux-en-Y Gastric Bypass (RYGB) and further six patients underwent Sleeve gastrectomy (SG). None of the patients had any post-operative complications from the surgery per se.

DKA Presentation and Management

Patients presented with DKA after a median duration of 5 days (range 1 to 60 days) after surgery. The most common symptoms were lethargy seen in seven patients and shortness of breath seen in five patients. Other symptoms included a combination of generalised weakness, cold extremities, polydipsia, polyuria, nausea, vomiting, diarrhoea, and abdominal pain. Thirteen patients were reported to have EDKA with raised anion gap. One patient was reported to have hyperglycaemic ketoacidosis [13]. The glycaemic status at the time of ketoacidosis was not mentioned in the two patients. Ten out of 16 patients underwent computed tomography (CT) scan of the abdomen and pelvis to rule out any surgical complications. One patient was subjected to an upper gastrointestinal (GI) contrast series to rule out an anastomotic leak. Another patient underwent diagnostic laparoscopy which was normal. All patients received treatment with intravenous fluids and insulin. No mortality was reported. All the patients were managed in the intensive care unit or the high-dependency unit. The mean length of hospital stay with DKA was 4 days (range 1 to 8 days, $N=10$).

Discussion

This systematic review highlights the importance of awareness of potential harm from SGLT2i in patients undergoing BMS. Although we found only 12 publications with a total of 16 patients who developed DKA after BMS associated with the use of SGLT2i, we suspect this may be under-reported. The most common type of SGLT2i associated with DKA was canagliflozin. The pre-operative plan to omit SGLT2i was not specified in over half of the patients. Despite all patients being on the low-calorie diet pre-operatively, most patients developed DKA in the postoperative period after both RYGB and SG. Clinical presentation can be non-specific and variable, often mimicking post-operative surgical complications leading to unnecessary radiological investigations as well as diagnostic laparoscopy in at least one patient. Most patients presented with DKA after a median duration of about 5 days. Management of DKA required admission to critical care or high dependency unit in all patients with an average length of stay (LOS) of 4 days. There was no reported mortality.

The diagnosis of EDKA is usually confirmed by the presence of metabolic acidosis, ketosis, serum bicarbonate less

Table 2 - Recommendations for perioperative planning for patients on SGLT2i undergoing BMS (reproduced with permission) [11]

1	Stop SGLT2i 48 h before starting low calorie preoperative (liver-reducing) diet
2	Stop SGLT2i 48 h before bariatric and metabolic surgery even if no preoperative diet is recommended
3	Do not restart SGLT2i after BMS without a full discussion of the pros and cons and other treatment options with the patient
4	The risk of DKA due to SGLT2i in patients without type 2 diabetes mellitus is very rare. However, initiation of these agents for their cardio-renal benefits in patients who have had bariatric and metabolic surgery should only be done after a full discussion of the pros and cons
5	Consider withholding SGLT2i in any patient hospitalised for major surgery or acute serious illness
6	Ketone levels should be monitored daily in all patients on SGLT2i hospitalised with an acute serious illness
7	SGLT2i should only be restarted once the clinical condition has stabilised, and normal oral intake established

than 15 mmol/L, and a blood glucose level that is usually less than 11 mmol/L [3]. In contrast, in hyperglycaemic DKA, the blood glucose is abnormally elevated and is usually > 15 mmol/L. We found that EDKA was much more common than the hyperglycaemic variant. The identification of EDKA can be difficult due to the variable and vague clinical presentation and especially as the blood sugar levels are not elevated. We found that in patients presenting with DKA after BMS, the most common symptom was lethargy and weakness around 5 days postoperatively. However, the presentation can be highly variable and a delayed presentation up to 60 days after BMS has also been reported. The occurrence of DKA associated with the use of SGLT2i has been reported in the initial clinical trials as well as alerts have been raised by both FDA and EMA [6]. Measuring blood ketone levels along with serum glucose is crucial to identifying EDKA and should routinely be implemented within peri-operative care. SGLT2i-related DKA, however, is largely preventable. The National Institute for Health and Care Excellence, United Kingdom (NICE, UK) recommends checking whether the patient may be at increased risk of DKA, for example on a very low carbohydrate or ketogenic diet, before starting an SGLT2i [10]. British Obesity and Metabolic Surgery Society, United Kingdom (BOMSS, UK) has issued an alert on the use of SGLT2i in patients undergoing BMS and recommended a set of precautions (Table 2) [11]. The American Academy of Clinical Endocrinologists currently recommends that SGLT2i should be withheld for at least 24 h before elective surgery and until patients can tolerate a normal diet [12]. However, patients undergoing BMS can pose different challenges and may have to stop the SGLT2i well before their surgery.

Patients scheduled for BMS are advised to commence a low-calorie liver-reducing diet two or more weeks before the surgery. For many patients, this will be a sudden and significant reduction in their usual carbohydrate intake. Moreover, in the first few weeks after BMS, most patients will be consuming only around 600kcals per day and some struggle to meet their fluid requirements. As a result, patients undergoing BMS are at a higher risk of developing DKA (both euglycaemic and hyperglycaemic) than other surgical and non-surgical patients who are on SGLT2i. Euglycaemic DKA has been reported after the most common BMS procedures such as sleeve gastrectomy, gastric band, and Roux-en-Y gastric bypass [7]. As BMS significantly alters the glycaemic control in the postoperative period, SGLT2i medications must be stopped for at least 48 h before commencing the liver-reducing diet or before surgery if the liver-reducing diet is not indicated to reduce the risk of developing DKA in the perioperative period. Postoperatively, SGLT2i should not be recommenced till the patient is well established on their oral diet which often takes up to 6 weeks after BMS. Since BMS can be curative for T2DM or improve glycaemic control for many patients [14, 15] and they are likely to remain on reduced calorie intake for the rest of their lives, the indication to restart SGLT2i after BMS may need to be reassessed after a thorough review and discussion with the patient and metabolic physician. Although canagliflozin was the commonest medication associated with DKA in our review, precautions need to be exercised with any of the SGLT2i medications.

The management of DKA involves intravenous fluids, insulin infusion, and correction of serum electrolyte abnormalities especially potassium [7]. Complete resolution of DKA was seen in all patients and there was no mortality reported in our review. However, admission to the critical care unit is often required as the patients can be critically ill at the initial presentation. In addition, diagnosis may not be very clear at the initial presentation and investigations may be required to rule out surgical complications. Nonetheless, it is important for bariatric surgeons and their teams to be aware of this clinical entity of EDKA and maintain a high index of clinical suspicion in a patient who has been on any SGLT2i group of medications in the preoperative period and develops metabolic acidosis with vague symptoms such as lethargy and weakness and near normal blood glucose levels. It is also important to highlight that most cases of EDKA are preventable with the correct perioperative management of SGLT2i in a patient undergoing BMS. These recommendations are based on Level IV evidence.

Author Contribution BM and NB: independently screened the titles and abstracts to assess for a full review. BM and NV: data extraction and study rating. MS and NV: review of literature and discussion. BM and KM: initial concept and independent review. RS: independent review. II: review of literature.

Declarations

Conflict of Interest The authors declare no competing interests.

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