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High preoperative HbA1c does not affect early or late complication rates after bariatric surgery

Kamran Shah[1,2] · **Ismail Gögenur**[3,4] · **Hjörtur Gislason**[1,2]

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Abstract

Background Preoperative HbA1c has been associated with an increased incidence of postoperative morbidity and mortality after abdominal and cardiovascular surgery. The literature on bariatric surgery is inconclusive and guidelines recommend postponement of surgery when HbA1c is above an arbitrary threshold (≥ 8.5%). In this study, we sought to understand the impact of preoperative HbA1c on early and late postoperative complications.

Methods We performed a retrospective analysis of prospectively collected data on obese patients with diabetes who underwent laparoscopic bariatric surgery. Patients were categorized into three groups according to their preoperative HbA1c level: < 6.5% (group 1), 6.5–8.4% (group 2) and ≥ 8.5% (group 3). Primary outcomes were early and late postoperative complications (< and > 30 days, respectively) that were differentiated based on severity (major/minor). Secondary outcomes were length of stay (LOS), duration of surgery, and rate of readmission.

Results In total, 6798 patients underwent laparoscopic bariatric surgery from 2006 to 2016, of which 1021 (15%) patients had Type 2 Diabetes (T2D). Complete data with a median follow-up of 45 months (3–120) were available for 914 patients with HbA1c < 6.5% ($n = 227$, 24.9%), 6.5–8.4% ($n = 532$, 58.5%) and ≥ 8.5% ($n = 152$, 16.6%). Early major surgical complication rate was similar across the groups ranging from 2.6 to 3.3%. No associations between high preoperative HbA1c and late complications—medical as well as surgical—was observed. Groups 2 and 3 had statistically significant more pronounced inflammatory status. LOS (1.8–1.9 days), readmission rates (1.7–2.0%) and surgical time was similar across the three groups.

Conclusion Elevated HbA1c is not associated with more early or late postoperative complications, longer LOS, longer surgical time or higher rates of readmission.

Keywords Glycosylated hemoglobin · HbA1c · Type 2 diabetes · Bariatric surgery · Surgical outcomes · Complications · Inflammatory status

The association between diabetes mellitus and increased long-term morbidity and mortality after surgery is well-known [1, 2] especially chronic hyperglycemia reflected by elevated glycated hemoglobin level (HbA1c). Studies have shown that chronic hyperglycemia is associated with an increased incidence of adverse events and complications after surgery. Specifically, chronic hyperglycemia has been associated with higher rate of pneumonia, urinary tract infection, pleural effusion, postoperative ileus, anastomotic leakage, abscess after colorectal and abdominal surgery, acute kidney injury after cardiac surgery, and surgical wound infection after gastrointestinal surgery and orthopedic surgery [3–6].

Although there is insufficient evidence to recommend an upper limit for HbA1c before elective surgery, several authors advocate for postponing elective surgery until glycemic control has been achieved [7, 8]. The National Institute for Health and Care Excellence (NICE) along with the Association of Anaesthetists of Great Britain and Ireland advocate postponement of elective surgery and

✉ Kamran Shah
kamranshaah@gmail.com

1 Aleris Obesity Clinic and Department of Surgery, Aleris Hospital, Oslo, Norway

2 GB Obesitas, Metabolic and Bariatric Unit, Skeppsbron 11, 211 205 Malmö, Sweden

3 Department of Clinical Medicine, Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark

4 Department of Surgery, Center for Surgical Science, Zealand University Hospital, Køge, Denmark

referral to diabetes specialist teams when HbA1c is ≥ 8.5% (69 mmol/L) [9, 10], while the Society for Ambulatory Anesthesia (SAMBA) recommend a threshold HbA1c level of 7.0% (53 mmol/L)[11].

Similar guidelines have been implemented in bariatric surgery although the evidence suggests that an elevated HbA1c does not lead to increased postoperative morbidity or mortality in obese patients with diabetes. However, the majority of the studies to date are limited by a retrospective study design, small cohorts, or short-term follow-up [12–16]. Furthermore, bariatric surgery is unique from other kinds of surgeries as it carries an inherent metabolic effect that aims to ameliorate the negative effects of elevated HbA1c by ultimately causing remission of type 2 diabetes [17].

This study aimed to assess the impact of preoperative elevated HbA1c levels on medical and surgical complications, differentiated by early and late and by severity (major and minor) on peri- and postoperative outcomes after bariatric surgery with long-term follow-up in a large cohort of patients with obesity and diabetes.

Methods

This study was a retrospective analysis of prospectively collected data on patients with obesity and diabetes who underwent bariatric surgery from January 2006 to January 2016 at a high-volume bariatric center in Norway.

All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

A multidisciplinary approach, lifestyle modification courses, and ERAS protocols were applied as previously described [18]. Pre- and postoperative clinical data along with routine blood tests, metabolic status, and nutritional status were registered prospectively as a part of a routine patient record system approved by The Norwegian Data Protection Authority. Amongst the preoperative measures, patients with diabetes were either accepted for surgery or postponed with the purpose of achieving glycemic control assessed from preoperative HbA1c. Patients with poorly regulated diabetes, who within the first 6 months failed to achieve optimal glycemic control despite interventions—such as an increase of peroral medication and/or insulin therapy—eventually underwent bariatric surgery. According to the last preoperative HbA1c value, patients were categorized into three groups:

1. Group 1: optimal control of diabetes with HbA1c < 6.5%
2. Group 2: acceptable control of diabetes with HbA1c 6.5–8.4%
3. Group 3: Poor control of diabetes with HbA1c ≥ 8.5%.

Our null hypothesis stated that there was no relationship between baseline HbA1c and postoperative complications in obese patients with diabetes. Therefore, it was not deemed necessary to have a matched control group of patients without diabetes, as our focus of interest was outcomes after poorly regulated diabetes compared with optimal glycemic control following bariatric surgery.

Possible associations between preoperative HbA1c and surgical outcomes were evaluated. Primary endpoints included the influence of preoperative HbA1c on overall complication rate differentiated by medical and surgical complications, both early and late, as well as major and minor as defined by the American Society for Metabolic and Bariatric Surgery (ASMBS) [19]. Thus, the threshold for early versus late complications was 30 days. Major complications "…include any complication that resulted in a prolonged hospital stay (beyond 7 days), administration of an anticoagulant, reintervention, or reoperation" in addition to death (within 7 days), myocardial infarction, cerebrovascular accident, and renal failure requiring dialysis among others. Minor complications include those which are not included under major complications.

Secondary endpoints were surgical time, length of stay (LOS), and readmission rate. In addition, we wanted to assess the association between preoperative HbA1c and inflammatory status as assessed by C-reactive protein (CRP, normal range < 10 mg/L) and white blood cell count (WBC, normal range 4.0–10.5 × 10^9/L) before surgery and at follow-up. A pronounced/elevated inflammatory status was defined as elevated CRP and WBC. Inflammatory status was compared across the three groups. Type 2 diabetes was defined according to ASMBS guidelines [19].

Statistical methods

Statistical analyses were performed using SPSS for Windows, version 29.0, and Microsoft Excel for Windows version 2209 with Analysis ToolPak. Values were reported as mean ± standard deviation or median with range based on whether the data were normally distributed. Shapiro–Wilk's test was used to test the normality of the continuous variables. Comparison between groups was made with 1-way ANOVA (Analysis of Variance), t-test or Chi-square test. P value < 0.05 was considered statistically significant. To assess the variation between each potential dependent variable and the binary outcomes, we performed a univariate analysis. If variables in outcomes had a P value < 0.2 on the univariate analysis, a multivariate logistic regression model with control for confounders was applied in which case p

values were considered significant when they were < 0.05. Patients with optimal glycemic control (group 1) acted as baseline reference when comparing the outcomes in patients with acceptable glycemic control (group 2) and poor glycemic control (group 3), respectively.

Results

Demographics

Overall, 6,798 patients underwent laparoscopic bariatric surgery from 2006 to 2016 at a single bariatric center, of which 1,021 (15%) had T2D. Complete data for assessment of primary and secondary endpoints were available for 914 patients (90%, Table 1): Group 1, HbA1c < 6.5% ($n = 227$, mean 5.8); group 2, HbA1c 6.5–8.4% ($n = 535$, mean 7.2) and group 3, HbA1c ≥ 8.5% ($n = 152$, mean 9.9).

All patients were receiving medical treatment for diabetes prior to surgery. Fifty-four patients (54/914; 5.9%) were treated with insulin in addition to oral antidiabetic medication. In group 1, patients only required oral antidiabetic medication (metformin hydrochloride, sitagliptin, glimepiride, a combination of biguanides and sitagliptin/rosiglitazone maleate, or similar). Additionally, in groups 2 and 3, 6.4% (34/535) and 13.2% (20/152) were treated with insulin, respectively.

The mean age ranged from 46.6 to 50.1 years across the groups and was higher in group 2. The male sex was more prevalent in groups with higher HbA1c. Groups 2 and 3 had a higher mean preoperative weight (125 kg) compared to group 1 (119 kg) and a higher waist circumference (132 and 131 cm, respectively, vs 127 cm). The mean preoperative BMI (range, 41.2–42.1) and median follow-up (range, 3–144 months) was higher in group 1 (51.1, 3–141 months) and 2 (44.1, 3–144 months) compared to group 3 (33.6, 3–131 months).

Groups 2 and 3 had statistically significant higher levels of CRP (9.2 [0–60, $P = 0.003$] and 10.3 [0.5–60, $P = 0.0003$], respectively) and WBC (7.8 [4.1–16.3, $P = 0.003$] and 9.0 [4–13.4, $P < 0.001$] respectively) compared to group 1 (6.9 [0–43] and 7.3 [3.3–18.4], respectively). No statistically significant difference was noted in smoking status across the three groups (Table 1).

From the cohort, 80% (728 patients) underwent Roux-en-Y gastric bypass (RYGB) and 15.5% (142 patients) had a

Table 1 Patient factors and procedures by preoperative hemoglobin A_{1c}, ($n = 914$)

	Preoperative HbA1c, %				
	Group 1 ($n = 227$)	Group 2 ($n = 535$)	*P* value	Group 3 ($n = 152$)	*P* value
	< 6.5	6.5–8.4		≥ 8.5	
Patient factors					
Age, year[a]	46.6 (20–72, 11.0)	50.1 (21–76, 10.4)	< 0.001	47.6 (18–71, 10.5)	0.2387
Sex, female/male, ratio[c]	178/49	340/195	< 0.001	83/69	< 0.001
Waist circumference, cm[a]	127 (89–190, 15.3)	132 (94–210, 15.1)	0.0019	131 (105–174, 14.3)	0.0108
Weight, kg[a]	119 (80–216, 23.3)	125 (72–231, 25.3)	0.0022	125 (75–208, 24.4)	0.0164
Preoperative BMI, kg/m^{2a}	41.2 (28.5–64.8, 6.6)	42.1 (29.2–71, 6.8)	0.0929	41.2 (31–60.1, 6.0)	1
HbA1c[a]	5.8 (4.7–6.4, 0.4)	7.2 (6.5–8.4, 0.5)	< 0.001	9.9 (8.5–17.7, 1.3)	< 0.001
C-reactive protein[a]	6.9 (0–43, 7.2)	9.2 (0–60, 8.9)	0.0025	10.3 (0.5–60, 10.2)	0.0003
White blood cell count[a]	7.31 (3.3–18.4, 2.0)	7.77 (4.1–16.3, 2.0)	0.0033	9.0197 (4–13.4, 2.1)	< 0.001
Smoker/non-smoker[c]	7/46 (15.2%)	21/119 (17.6%)	0.8230	6/33 (18.1%)	0.7714
Duration of diabetes, months[b]	31 (0–338)	48 (0–548)	< 0.001	101 (3–542)	< 0.001
Type of surgery					
RYGB[c]	183 (80.6%)	422 (78.9%)	0.6252	123 (80.9%)	1
Sleeve gastrectomy[c]	38 (16.7%)	80 (15.0%)	0.5842	24 (15.8%)	0.8876
SASI-bypass[c]	0 (0%)	14 (2.6%)	0.0141	2 (1.3%)	0.1602
BPD[c]	3 (1.3%)	9 (1.7%)	1	0 (0%)	0.2775
DRYGB[c]	3 (1.3%)	10 (1.9%)	0.7645	3 (2.0%)	0.6875

BMI Body mass index, *SASI-bypass* Single Anastomosis Sleeve Ileal Bypass, *BPD* Biliopancreatic Diversion, *DRYGB* Distal Roux-en-Y Gastric Bypass, *RYGB* Roux-en-Y Gastric Bypass

[a]Mean (± standard deviation)

[b]Median (range)

[c]Number (percentage)

sleeve gastrectomy (SG). The procedures were equally distributed among the three groups (Table 1). In the remaining 4.8% (44 patients), other procedures were performed (biliopancreatic diversion (BPD), distal RYGB (DRYGB), and Single anastomosis Sleeve Ileal bypass (SASI-bypass)).

Primary outcomes

The overall mean complication rate (early and late, medical and surgical) was 20.7% (189/914) and did not differ across the groups (Table 2): Group 1, 19.4% (44/227, $P=0.559$); group 2, 21.5% (115/535, $P=0.695$); and group 3, 19.7% (30/152, $P=1.00$). Multivariate regression analysis did not show any statistically significant difference between the three groups of procedures (RYGB, SG, and others such as BPD, DRYGB and SASI-bypass) when 'Overall Complication Rate' was chosen as the independent variable.

The overall early complication rate (< 30 days) was 5.3% (48/914) for the whole cohort, without any significant statistical difference between the three groups (4.4%, 5.6%, and 5.3%). Early major medical complications included three patients in group 2 (1 patient with portal vein thrombosis, one pulmonary embolism and one ketoacidosis) and one patient in group 3 with diabetic coma. The patient with portal vein thrombosis underwent SG while the other three patients underwent RYBG. The early major surgical complication rate was 2.8% (26 patients), similar in all three groups (2.6%, 2.8%, and 3.3%). Eight patients experienced intra-abdominal bleeding (0.9%), four of whom needed re-operation and six (0.7%) were re-operated due to leaks.

The most common late surgical major complication was internal hernia. Of 728 patients that underwent RYGB, 39 (5.4%) were operated on for internal hernia and 16 (1.8%) for bowel obstruction due to other causes. The most common late medical major complication was hypoglycemia (1.1%, 10/914), which occurred after RYGB in all cases except in one patient who underwent SG. The incidence of hypoglycemia was 2.2% in group 1 and 0.7% in groups 2 and 3. A total of 71 (7.8%) patients needed re-operation in the median follow-up period of 45 months. No statistically significant differences were found between the three groups in early and late complications, major and minor, surgical and medical (Table 2). Stratifying the patients with HbA1c ≥ 8.5% in further sub-groups (8.5–9.9%, 10–11.9%, and > 12%) did not show any statistically significant difference between the groups nor when compared to the patients with HbA1c < 8.5%.

Multivariate linear regression analysis was first performed with "Early Major Complications" as an independent variable. There was no statistical significance regarding age ($P=0.6444$), sex ($P=0.1268$), waist circumference ($P=0.0923$) and preoperative weight ($P=0.6985$). When the independent variable was changed to "Early Minor Complications", no statistical significance on the abovementioned covariates was noted. There was no early (< 30 days) postoperative mortality.

Secondary outcomes

The mean length of hospital stay (LOS) was 1.8–1.9 days and mean readmission rates were 1.7–2.0%, similar for all three groups. Mean surgical time was similar for all three groups (Table 3).

Table 2 Complications by preoperative HbA1c

	No. (%)				
	Preoperative HbA1c, %				
	Group 1 ($n=227$)	Group 2 ($n=535$)	*P* value	Group 3 ($n=152$)	*P* value
	< 6.5	6.5–8.4		≥ 8.5	
Complications					
None	183 (80.6)	420 (78.5)	–	122 (80.3)	–
Early major medical	0 (0%)	3 (0.6%)	0.5585	1 (0.7%)	0.4011
Early minor medical	2 (0.9%)	9 (1.7%)	0.5207	1 (0.7%)	1.000
Early major surgical	6 (2.6%)	15 (2.8%)	1.000	5 (3.3%)	0.7608
Early minor surgical	2 (0.9%)	3 (0.6%)	0.6374	1 (0.7%)	1.000
Late major medical	6 (2.6%)	13 (2.4%)	0.805	3 (2.0%)	0.7458
Late minor medical	3 (1.3%)	14 (2.6%)	0.4209	3 (2.0%)	0.6875
Late major surgical	20 (8.8%)	44 (8.2%)	0.7767	12 (7.9%)	0.8514
Late minor surgical	5 (2.2%)	11 (2.1%)	1.000	3 (2.0%)	1.000
Total No of Complications	44 (19.3%)	112 (20.9%)	0.6948	29 (19.1%)	1.000

Standardized reporting of complications according to recommendations from the American Society for Bariatric and Metabolic Surgery (ASMBS). Further sub-classification in medical versus surgical complications

Table 3 Secondary outcomes by preoperative hemoglobin A_{1c}

	Preoperative HbA1c, %				
	Group 1 ($n=227$)	Group 2 ($n=535$)	*P* value	Group 3 ($n=152$)	*P* value
	< 6.5	6.5–8.4		≥ 8.5	
Surgical time, min[a]	45 (15–133)	47 (15–232)	0.2672	44 (19–229)	0.6507
Length of stay, days[a]	1.8 (0–6, 0.7)	1.8 (1–8, 0.9)	1.0	1.9 (1–8, 1.0)	0.2591
Readmissions[b]	4 (1.8%)	9 (1.7%)	1.0	3 (2.0%)	1.0

BMI Body mass index, *EWL* Excess weight loss, *TWL* Total weight loss

[a]Mean (range, standard deviation)

[b]Number (percentage)

No association was observed between early major/ minor complications and pre-operative CRP and WBC upon performing multivariate regression analysis.

Discussion

In our study, we found that a high preoperative HbA1c was neither associated with a more difficult operation—as estimated from surgical time—nor with a higher frequency of complications. This is in accordance with other studies investigating possible associations between preoperative HbA1c and outcomes after SG [20] and RYGB [14, 15]. There was no increase in morbidity or mortality, which has been shown by others as well [21].

To date, this is the largest single-center study conducted on obese patients with type 2 diabetes focusing on the impact of HbA1c on complications in bariatric surgery. Several large registry studies from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) have been published, whereof some are limited by their 30 days follow-ups, and have slightly different conclusions depending upon the aim of the study and the methodology employed for data analysis. Thus, one study shows no direct relationship between HbA1c and early postoperative complications within the first 30 days but only when adjusting for underlying comorbidities [22], while another study shows no difference in postoperative complications when comparing those with HbA1c below 8% versus those with HbA1c > 8% [23]. However, the latter study found more complications in those with a higher preoperative HbA1c when they instead changed the HbA1c threshold to above and below 10%. Another study from MBSAQIP looked at 30-day Clavien–Dindo III/IV complications and found no consistent statistical significance in major postoperative complications [24].

Samuel et al. [25] included 440 patients with type 2 diabetes in their study and showed no association between elevated preoperative glycosylated hemoglobin and 30-days readmissions and no difference in surgical complications within the first 30 days. In our study, we additionally showed no association between HbA1c levels and surgical and medical complications when differentiating them based on late and early stage as well as severity (minor/major).

Amongst the major medical complications in our study, two were acute diabetic complications (one ketoacidosis in group 2 and one diabetic coma in group 3). It could be argued that they could have been avoided by optimal glycemic control preoperatively, but even when optimal glycemic control is achieved, the risk is still present. It is known that diabetic ketoacidosis may occur after bariatric surgery in type 2 diabetes with an incidence rate of 0.2%, and is considered "uncommon and usually mild" [26].

Besides preoperative hyperglycemia, diabetic ketoacidosis has been attributed to other predisposing factors such as anesthesia, surgical stress, poor peri-operative insulin adjustment, postoperative infection, and poor oral intake/ dehydration after surgery [27]. Therefore, it is important that if bariatric surgery is decided upon in a patient with preoperative elevated HbA1c, sufficient measures should be taken peri-operatively and postoperatively to minimize the risk of medical complications. In particular, it seems that abrupt withdrawal of insulin therapy in the first postoperative period could be among the precipitating causes of diabetic ketoacidosis even after even purely restrictive procedures and with HbA1c levels below the recommended threshold of 8.5% from NICE [28–30]. The two patients in this study with diabetic ketoacidosis that had a long duration of diabetes (> 10 years) were dependent upon insulin treatment and had an abrupt withdrawal of their medication without proper consultation.

In concordance with other studies showing an association between low-grade inflammation and diabetes [31] and obesity [32], we found that elevated HbA1c was associated with a low-grade inflammatory response, measured by elevated CRP and WBC count. However, this did not affect complication rates as no confounding effect was found on multivariate analysis, which is in line with other studies that have shown a resolution of low-grade inflammatory response after bariatric surgery [33, 34].

Albeit our study findings are convincing, one must be cautious in interpreting the results, as possible confounders may be present. Among these, we know both from clinical practice and reported literature [35] that a higher preoperative HbA1c is associated with more frequent capillary glucose concentration measurements and a lower threshold for starting intravenous insulin infusion. Thus, patients with poor glycemic control are compensated by more vigilant observation and treatment pre-, peri-, and postoperatively. Although this may hypothetically account for a possible reduction in perioperative and immediate postoperative medical complications, surgical complications are probably not affected by temporary glycemic control.

Amongst other possible limitations, we found that due to the retrospective nature of the study, the data was arranged in such a way, that it was not possible to distinguish between HbA1c at the initial evaluation and HbA1c at the time of surgery as the latest value taken preoperatively replaced any previous values prior taken. As such, it is difficult to assess whether the preoperative attempts at achieving glycemic control in patients with a HbA1c $\geq$ 8.5% is what contributed to the lack of statistically significant differences in complication rates across the groups or not. However, we assume that this would have a low impact given the inherent metabolic properties of the surgery as well as the low number of complications.

Conclusion

High levels of preoperative HbA1c are not associated with a higher rate of either early or late postoperative complications or longer hospital stay after bariatric surgery. As such, delaying or even denying bariatric surgery on grounds of a high preoperative HbA1c may not be warranted, in particular when bariatric surgery is unique in that is a metabolic surgery targeted at type 2 diabetes and inherently leads to glycemic control.

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Data availability All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

Declarations

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