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Stratified Preoperative A1c is not Significantly Associated With Clavien-Dindo Major Complications Following Bariatric Surgery in the MBSAQIP Database

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Abstract

Background: Type 2 Diabetes Mellitus (T2DM) is highly prevalent comorbidity in patients with morbid obesity. It is still unclear whether a cutoff value of preoperative A1c represents an increased risk for major postoperative complications following Roux-en-Y Gastric Bypass (RYGB) and Sleeve Gastrectomy (SG).

Methods: Retrospective MBSAQIP Participant Use File cohort for both years 2017 and 2018 were analyzed to evaluate the relationship between HbA1c in patients with morbid obesity and T2DM undergoing bariatric surgery, and the 30 days postoperative major complications by Clavien-Dindo classification (III/IV). We used an HbA1c cutoff of <7, > =7, and stratified by 1% increment for a total of 11 groups. We used univariate and multivariate logistic regression to analyze the outcome of the complications. Predicted probabilities were calculated for major complications. All statistical tests were two-sided with a *P*-value of less than .05 considered as a cut-off for statistical significance.

Results: Of 42,181 patients that met inclusion criteria, there were 20,955 identified with HbA1c <7%, and 21,226 patients with HbA1c >7%. Utilizing HbA1c <7% as a cutoff, we found no consistent statistical significance in the major postoperative complication in patients with HbA1c >7%, and when stratified with 1% increment between groups. We also found no significance between groups with risk adjustment.

Conclusions: Extensive analysis of the large MBSAQIP cohort didn't result in a clinically significant association between stratified HbA1c and 30-day Clavien-Dindo major complications (III/IV) following Roux-en-Y Gastric Bypass (RYGB) and (SG).

Keywords

bariatrics, endocrine, gastrointestinal, minimally invasive surgery, obesity

Introduction

Obesity and Type 2 Diabetes Mellitus (T2DM) are well-established leading global health concerns in the United States of America (USA). Among US adults with diagnosed diabetes, T2DM accounted for 91.2% of the diagnoses.[1] Type 2 Diabetes Mellitus is highly prevalent in patients with severe obesity. Approximately 90% of patients with T2DM have obesity or are overweight.[2] The 1991 National Institutes of Health Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity recommended bariatric surgery for patients with Body Mass Index (BMI) > 40 kg/m^2, or BMI >35 kg/m^2 with an obesity-associated medical problem including T2DM.[3] Several clinical trials and meta-analyses have shown significant and sustained

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weight loss in patients with severe obesity in addition to dramatic improvement or remission of the T2DM following bariatric surgery.[4-9] Although bariatric surgery is not exempt from complications, the rate of early postoperative major complications (eg anastomotic leaks, myocardial infarction, and pulmonary embolism) has been reported to be low (<1.6%), with subsequent mortality rate as consequence of these complications also low (<.7%).[10] However, little is known with respect to the effect of elevated preoperative Hemoglobin A1C (HbA1c) on the incidence of early postoperative Clavien-Dindo major complications following the most commonly performed bariatric procedures in patients with obesity with T2DM. Additionally, studies reporting the association of preoperative HbA1c with postoperative adverse events following bariatric surgery were conflicting.[11,12] This study aims to review the association between stratified preoperative HbA1c levels and 30 days postoperative Clavien-Dindo major complications, in an attempt to identify a cut-off that represents significantly worse outcomes following laparoscopic RYGB and Sleeve Gastrectomy (SG) in MBSIQIP database.

Methods

Data Source

We retrospectively analyzed the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) Participant Use Data File (PUF) for both the years 2017 and 2018. The MBSAQIP is a single unified National Accreditation Program for bariatric surgery Centers. All accredited centers from the USA and Canada report their bariatric surgical outcomes to the MBSAQIP database. The PUF is a Health Insurance Portability and Accountability Act (HIPAA)-compliant data file containing cases reported to the MBSAQIP Data Registry. The 2019 MBSAQIP PUF contains 206,570 cases submitted from 868 MBSAQIP-participating centers.

Inclusion Criteria

All patients with T2DM who underwent Laparoscopic or Robotic SG, and RYGB, by the Current Procedure Terminology (CPT) codes of 43644, 43645, 43775, with documented preoperative HbA1c, were included in the study. We excluded patients without diabetes, patients with Type 1 Diabetes Mellitus (T1DM), and those with age younger than 18 years old.

Outcome and Statistical Analysis

The primary outcome of our study was 30-day postoperative Major Complication defined by Clavien-Dindo Classification III and IV. The Clavien-Dindo Classification was initiated in 1992 and it is based on the type of therapy required to correct the complication.[13] With respect to our study, the complications graded as Clavien-Dindo III were postoperative organ/space infections, wound disruption, and postoperative sepsis. Grade IV complications were defined as the following: unplanned admission to the critical care unit within 30 days, pulmonary embolism, respiratory ventilator requirement over 48 hours, intraoperative or postoperative myocardial infection, intraoperative or postoperative cardiac arrest requiring cardiopulmonary resuscitation, stroke, coma for over 24 hours, unplanned intubation, progressive or acute renal failure and postoperative septic shock. We divided our sample into 2 groups determined by preoperative HbA1c levels. Patients with HbA1c of less than 7% were assigned to the controlled diabetes group, whereas patients with HbA1c equal to or above 7% were assigned to the uncontrolled diabetes group. For all patients assigned to the uncontrolled diabetes group, we stratified the HbA1c by a 1% increment for a total of 10 sub-groups, to analyze the primary outcome.

We utilized adjusted logistic regression to analyze the primary outcome. Logistic model results were used to calculate predicted probabilities for major complications in the adjusted stratified subgroups for each incremental increase in the HbA1c level. Categorical variables were compared using chi-square analysis, continuous variables were compared using 2-sided t-tests, non-normal data was analyzed utilizing Wilcoxon Rank Sum tests. Data analysis was performed using a SAS Enterprise Guide 8.3. All statistical tests were two-sided with a *P*-value of less than .05 considered as a cut-off for statistical significance.

Results

A total of 42,181 patients met our inclusion criteria. As represented in Table 1, 20,955 had baseline HbA1c <7%, (controlled diabetes group), whereas 21,226 patients had baseline HbA1c ≥7% (uncontrolled diabetes group). The mean age and BMI were respectively, 49 years and 45.6 kg/m^2 for the controlled diabetes group, compared to 50.2 years and 44.6 kg/m^2 for the uncontrolled diabetes group ($P < .001$). The controlled diabetes group had a higher proportion of females to males within the group sample when compared to the uncontrolled diabetes group (75.8% and 24.2% vs 69.6% and 30.4%, respectively, $P < .001$). Insulin dependence differed significantly between the 2 groups, with the uncontrolled group having a higher proportion of patients with insulin-dependent type 2 diabetes and a lower proportion of patients with non-insulin dependent diabetes when compared to the controlled group (10,553 and 10,673 vs 3838 and 17,117 patients respectively, $P < .001$). Four-hundred and eighty-seven patients had a preoperative history of chronic use of steroids and/or immunosuppressants in the group with

Table 1. Preoperative Univariate Comparison Between the Patients with HbA1c < 7% (controlled diabetes) vs Patients With Preoperative HbA1c >7% (Uncontrolled Diabetes).

Variable	Level	Controlled diabetes: HbA1c < 7	Uncontrolled Diabetes: HbA1c > 7	*P* value
n		20955 (%)	21226 (%)	
Age		48.98 ± 11.75	50.22 ± 10.82	<.001
BMI		45.61 ± 8.29	44.61 ± 7.88	<.001
Sex	Female	15877 (75.8)	14781 (69.6)	<.001
	Male	5078 (24.2)	6445 (30.4)	
Race	White	15290 (73.0)	15014 (70.7)	<.001
	Black or African American	3665 (17.5)	4112 (19.4)	
	Other/Unknown	2000 (9.5)	2100 (9.9)	
Diabetes	Insulin	3838 (18.3)	10553 (49.7)	<.001
	Non-insulin	17117 (81.7)	10673 (50.3)	
Pre-op GERD requiring medication	Yes	7678 (36.6)	7414 (34.9)	<.001
Pre-op hypertension requiring medication	Yes	14520 (69.3)	16282 (76.7)	<.001
Pre-op hyperlipidemia	Yes	9654 (46.1)	11962 (56.4)	<.001
Pre-op obstructive sleep apnea	Yes	10763 (51.4)	10389 (48.9)	<.001
Pre-op history of COPD	Yes	650 (3.1)	620 (2.9)	.277
Pre-op oxygen dependent	Yes	351 (1.7)	312 (1.5)	.090
History of MI	Yes	418 (2.0)	733 (3.5)	<.001
Pre-op renal insufficiency	Yes	253 (1.2)	382 (1.8)	<.001
Pre-op steroid/Immunosuppressant use for chronic condition	Yes	487 (2.3)	448 (2.1)	.137
Previous obesity surgery/foregut surgery	Yes	1149 (5.5)	1245 (5.9)	.090
Current smoker within 1 year	Yes	1588 (7.6)	1771 (8.3)	.004
Patient's ambulation limited most or all of the time pre-op	Yes	574 (2.7)	583 (2.7)	.963
ASA class	1-No disturb	41 (.2)	50 (.2)	
	2-Mild disturb	2548 (12.2)	2158 (10.2)	
	3-Severe disturb	17198 (82.1)	17686 (83.3)	
	4-Life threat	1112 (5.3)	1276 (6.0)	
	5-Moribund	2 (.0)	3 (.0)	
Pre-op requiring or on dialysis	Yes	113 (.5)	180 (.8)	<.001
CPT principal operative procedure	43644	7183 (34.3)	8069 (38.0)	<.001
	43645	180 (.9)	250 (1.2)	
	43775	13592 (64.9)	12907 (60.8)	

controlled diabetes, compared to 448 in the group with uncontrolled diabetes, without any statistical significance ($P = .132$). A total of 15,682 patients underwent SG by CPT code 43775, whereas the remaining 26,499 patients underwent RYGB by CPT codes 43644 and 43645. Major complication was identified in 335 (1.6%) patients amongst the controlled group, significantly lower when compared to 477 (2.2%) in the uncontrolled group ($P < .001$) as demonstrated in Table 2. There was no difference in 30-day mortality between the groups (.1% vs .2%, controlled group, and uncontrolled group respectively, $P = .253$).

On multivariable analysis of stratified preoperative HbA1c of the uncontrolled diabetes group, adjusting the primary outcome for age, gender, BMI, insulin-dependence type 2 diabetes mellitus, preoperative gastroesophageal reflux disease (GERD) and hypertension requiring medication, preoperative hyperlipidemia and obstructive sleep apnea, preoperative renal insufficiency, history of myocardial infarction, history of tobacco use within 1 year, preoperative dialysis and CPT code, the risk of postoperative complications did not consistently increase with higher preoperative HbA1c. However, the risk appeared to be increased and maximized when baseline HbA1c was 9-10% but then the odds ratios fluctuated with HbA1c 10-11%. Again, we observed the risk increased with HbA1c 11-13%, then it was not significant with HbA1c >13% (Table 3). When treating HbA1c as a continuous covariate in the same model, we observed an odds ratio of 1.040, representing a 4% increased risk which every unit increase of preoperative HbA1c (*P*-value .044) (Table 4).

Table 2: Perioperative Outcomes Between the Patients With Preoperative Hba1c < 7% (Controlled Diabetes) vs Patients with Preoperative Hba1c >7% (Uncontrolled Diabetes).

Variable	Level	Controlled Diabetes: HbA1c < 7	Uncontrolled Diabetes: HbA1c > 7	*P* value
n		20955 (%)	21226 (%)	
Surgical Approach	Conventional laparoscopy	18375 (87.7)	18615 (87.7)	.036
	Hand-assisted	3 (.0)	6 (.0)	
	Laparoscopic assisted	595 (2.8)	669 (3.2)	
	Robotic assisted	1944 (9.3)	1915 (9.0)	
	Single incision	38 (.2)	21 (.1)	
Procedure converted to another approach	Yes	48 (.2)	54 (.3)	.596
Operative time		82.00 [57.00, 119.00]	83.00 [59.00, 120.00]	<.001
Postop LOS		1.00 [1.00, 2.00]	1.00 [1.00, 2.00]	<.001
30-day readmission (%)	Yes	861 (4.1)	1039 (4.9)	<.001
30-day reoperation (%)	Yes	291 (1.4)	335 (1.6)	.107
30-day intervention (%)	Yes	273 (1.3)	301 (1.4)	.307
Minor complication (%)	Yes	542 (2.6)	626 (2.9)	.023
Major complication (%)	Yes	335 (1.6)	477 (2.2)	<.001
Any complication (%)	Yes	775 (3.7)	974 (4.6)	<.001
30-day mortality (%)	Yes	24 (.1)	33 (.2)	.253

Discussion

There are conflicting data with respect to the association of preoperative HbA1c with early postoperative complications following bariatric surgery. The purpose of this investigation was to analyze the relationship between preoperative HbA1c and 30-day postoperative complications in the MBSAQIP dataset. Hart et al collected data from the MBSAQIP PUF for 2017. The authors conducted a multivariable logistic regression and reported that elevated HbA1c >7% was significantly associated with increased odds of having an adverse postoperative outcome following bariatric surgery.[12] Meister et al conducted a single-institution retrospective study to assess the clinical significance of peri-operative hyperglycemia on patients undergoing bariatric surgery and found perioperative hyperglycemia to be associated with higher composite infectious complications in patients with diabetes and non-diabetes.[14] On the other hand, Rawlins et al performed a single-institution retrospective analysis of 342 patients with T2DM undergoing bariatric surgery and found no difference in combined complication rates when comparing groups with HbA1c < 7% with HbA1c > 7%.[11]

Elevated HbA1c has been reported to be associated with worse postoperative outcomes in other surgical fields. O'Sullivan et al reported a significantly higher incidence of overall 30-day morbidity in patients with and without diabetes, with perioperative HbA1c >7% and >6% respectively, undergoing emergent and elective vascular surgery procedures.[15] Gustafsson et al[16] studied 120 patients and found that postoperative complications were more common in patients with a high HbA1c level (>6%) after major colorectal surgery.[16] Similarly, Halkos et al found among 3201 prospectively followed patients, that higher HbA1c treated as a continuous variable was associated with reduced long-term survival for each unit increase in HbA1c after coronary artery bypass surgery.[17] This contrasts with what we found in our study, perhaps, due to the direct effect of bariatric surgery on glucose control compared to other non-metabolic surgeries.

In this study, on univariate analysis, we found a positive association with complications with HbA1c stratified by an increment of 1%, from levels >7 to 10. The association then fell off with HbA1c 10-11, was demonstrated again from 11-12, and consistently disappeared with HbA1c >13. After multivariable adjustment to all the variables that differed between the 2 groups of patients with T2DM, we did not identify a consistent cut-off that represented a significant increase in complication rates in our stratified patients. This may suggest that the more consistent association with complications observed in the non-adjusted analysis was due to those variables other than preoperative HbA1c itself. Furthermore, when treating HbA1c as a continuous covariable in the adjusted model, we found a mild positive association with early postoperative complications, with a statistically significant *P*-value. Despite representing a statistically significant increased risk for complications demonstrated by the *P*-value of .044, the overall trend of risk of postoperative

Table 3. Adjusted Multivariate Analysis of Sub-Group with HbA1c >7% for Major Complications by Clavien Dindo (III/IV).

Variable	OR	95% CI		*P* value
a1c				
< 7	Ref	Ref	Ref	
≥ 7 and < 8	1.110	.923	1.335	.2677
≥ 8 and < 9	1.114	.890	1.394	.3476
≥ 9 and < 10	1.354	1.034	1.774	.0276
≥ 10 and < 11	1.105	.744	1.639	.6208
≥ 11 and < 12	1.618	1.052	2.489	.0284
≥ 12 and < 13	1.868	1.159	3.012	.0103
≥ 13 and < 14	1.011	.533	1.920	.9727
≥ 14 and < 15	.795	.326	1.942	.6155
≥ 15 and < 16	.603	.148	2.451	.4795
≥ 16	1.957	.593	6.463	.2706
Age	1.014	1.007	1.022	.0002
BMI	1.017	1.008	1.026	.0001
Sex: Male	1.426	1.224	1.662	<.0001
Race				
White	Ref	Ref	Ref	
Black or African American	1.304	1.090	1.561	.0038
Other/Unknown	.884	.671	1.164	.3781
Diabetes				
Insulin	Ref	Ref	Ref	
Non-insulin	.665	.568	.778	<.0001
Pre-op GERD requiring medication	1.477	1.279	1.705	<.0001
Pre-op hypertension requiring medication	1.187	.972	1.451	.0931
Pre-op hyperlipidemia	.998	.854	1.168	.9836
Pre-op obstructive sleep apnea	1.188	1.019	1.385	.0280
Pre-op oxygen dependent	1.802	1.285	2.527	.0006
History of MI	1.862	1.409	2.461	<.0001
Pre-op renal insufficiency	1.613	1.107	2.351	.0129
Pre-op steroid/Immunosuppressant use for chronic condition	1.485	1.027	2.148	.0358
Previous obesity surgery/foregut surgery	1.524	1.184	1.961	.0011
Current smoker within 1 year	1.180	.920	1.513	.1932
Patient's ambulation limited most or all of the time pre-op	1.588	1.189	2.121	.0017
ASA class				
1-No disturb	1.123	.272	4.642	.8731
2-Mild disturb	.835	.621	1.122	.2321
3-Severe disturb	Ref	Ref	Ref	
4-Life threat	1.721	1.376	2.153	<.0001
5-Moribund	<.001	<.001	>999	.9649
6-Unknown	2.311	.841	6.346	.1042
Pre-op requiring or on dialysis	1.123	.616	2.046	.7060
CPT				
43775	Ref	Ref	Ref	
43644	1.603	1.387	1.852	<.0001
43645	2.240	1.338	3.752	.0022

Clavien-Dindo major complications was very low, and in our interpretation, this was not clinically meaningful. Providing further logic to the latter statement, with an odds ratio of 1.040 on the analysis of HbA1c as a continuous covariable, for every unit percentage increase in HbA1c level, the risk increased by 4%. Furthermore, we calculated the predicted probabilities to further translate the increased risk. For instance, an HbA1c that increases 1 unit from 7 to 8 has a predicted probability of major complications increasing from 1.204% to 1.252% (a .048% increase). Additionally, an increase on HbA1c of 5 units from 7 to 12 has a predicted probability of major

Table 4. Adjusted Analysis of HbA1c as a Continuous Covariate for Major Complications by Clavien Dindo (III/IV).

Variable	OR	95% CI		*P* value
HbA1c	1.040	1.001	1.081	.0444
Age	1.014	1.006	1.021	.0003
BMI	1.017	1.008	1.026	.0001
Sex: Male	1.418	1.217	1.652	<.0001
Race				
White	Ref	Ref	Ref	
Black or African American	1.320	1.103	1.578	.0024
Other/Unknown	.892	.678	1.175	.4174
Diabetes				
Insulin	Ref	Ref	Ref	
Non-insulin	.644	.554	.749	<.0001
Pre-op GERD requiring medication	1.472	1.275	1.699	<.0001
Pre-op hypertension requiring medication	1.193	.976	1.458	.0843
Pre-op hyperlipidemia	1.005	.859	1.175	.9539
Pre-op obstructive sleep apnea	1.182	1.014	1.378	.0330
Pre-op oxygen dependent	1.806	1.288	2.532	.0006
History of MI	1.872	1.417	2.474	<.0001
Pre-op renal insufficiency	1.600	1.099	2.331	.0143
Pre-op steroid/Immunosuppressant use for chronic condition	1.481	1.024	2.143	.0368
Previous obesity surgery/foregut surgery	1.532	1.190	1.971	.0009
Current smoker within 1 year	1.185	.924	1.519	.1811
Patient's ambulation limited most or all of the time pre-op	1.587	1.189	2.119	.0017
ASA class				
1-No disturb	1.111	.269	4.582	.8846
2-Mild disturb	.836	.622	1.123	.2349
3-Severe disturb	Ref	Ref	Ref	
4-Life threat	1.732	1.385	2.166	<.0001
5-Moribund	<.001	<.001	>999	.9650
6-Unknown	2.314	.843	6.353	.1034
Pre-op requiring or on dialysis	1.114	.611	2.031	.7241
CPT				
43775	Ref	Ref	Ref	
43644	1.605	1.389	1.854	<.0001
43645	2.206	1.319	3.692	.0026

complication increase from 1.204% to 1.462% (a .258% increase). This, in our opinion, supports our findings on the stratification analysis, that the mild statistically significant increased risk demonstrated by the odds ratio is clinically insignificant. Hart et al[12] found that HbA1c >7% was associated with an increased risk of complications in the MBSAQIP database.[12] We hypothesize that the significant difference demonstrated by the authors in their study was due to the inclusion of patients without diabetes in their control group with HbA1c <7%. Hence, this subset of patients was healthier than their counterpart group with HbA1c >7%, resulting in a statistically significant association of preoperative HbA1c with complications when comparing both groups. We excluded all patients without diabetes from our study.

When clinically assessing patients with morbid obesity and elevated HbA1c above a Bariatric Program's cut-off for surgery, the rationale of the bariatric procedure being these patients' best chance for remission should be highly considered. Patients should and must undergo the best medical therapy to lower their preoperative HbA1c. Should the latter fail to be achieved, despite patients' compliance, we recommend not delaying the bariatric surgery.

The limitations of this study include coding errors in the setting that we utilized a large dataset. The data integrity of a large database depends on the accuracy and completeness of data entered by data extractors. Additionally, variables not reported in the dataset such as patient's socio-economic status, surgeon and center volume and experience, could all affect postoperative outcomes when assessing complications. Another limitation of the study was the sizable sample excluded due to the lack of preoperative HbA1c reported. This could have

empowered the results of our measurement of HbA1c as a continuous variable towards a significant finding one-way or the other. It has been shown previously by Still et al that patients with preoperative controlled diabetes had a higher probability of achieving early and late remission of T2DM following bariatric surgery.[9] However, long-term outcomes cannot be assessed utilizing this dataset as it only includes 30-day outcomes, representing another limitation of our study. And lastly, the MBSAQIP does not provide information concerning the timing in relation to the bariatric procedure, the preoperative HbA1c level was reported, constituting another limitation of this analysis.

Conclusion

In conclusion, following extensive analysis of stratified preoperative HbA1c, we identified a slightly increased risk of 30-day postoperative Clavien-Dindo major complications (III/IV) with high HbA1c, however not clinically significant. We did not find a cut-off level of preoperative HbA1c that could represent a target when attempting to lower the glucose levels prior to bariatric surgery to reduce complications. Nonetheless, this does not undermine the importance of aggressive preoperative control of glucose levels. We do recommend attempting the best medical treatment to achieve optimal HbA1c control prior to undergoing surgery. However, for morbidly obese patients with medically refractory T2DM despite best medical therapy, bariatric surgery should not be delayed for strict HbA1c control, given that these patients will benefit from the metabolic procedure itself, as it represents their best chance for remission. Further studies are warranted to assess whether stratified HbA1c is associated with other long-term outcomes, such as diabetes remission and the need for further bariatric procedure revision for any reason.

Key Points:

(1) What is the Preoperative HbA1c Level That is Associated With increased Perioperative Major Complications in Patients Undergoing Bariatric Surgery?
(2) Stratified HbA1c up to 16 is not consistently associated with an increased risk of early postoperative complications after Bariatric Surgery in T2DM patients.
(3) Bariatric surgery should not be delayed for patients with medically refractory T2DM despite optimal medical therapy.

Declaration of Conflicting Interests

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