



Type 2 Diabetes Mellitus and Preoperative HbA1c Level Have no Consequence on Outcomes after Laparoscopic Sleeve Gastrectomy—a Cohort Study

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Abstract

Introduction Available clinical data on the influence of baseline HbA_{1c} postoperative morbidity and readmission after laparoscopic sleeve gastrectomy is scarce. This prompted us to conduct a multicenter retrospective study evaluating the influence of chronic hyperglycemia on postoperative course among patients undergoing laparoscopic sleeve gastrectomy (SG). We aimed to investigate the influence of baseline HbA_{1c} levels on postoperative outcomes in patients after SG.

Material and Methods We conducted a multicenter retrospective cohort study of consecutive patients who underwent SG from March 2017 to March 2018 in seven referral centers for bariatric surgery. Exclusion criteria were revision surgeries, different bariatric interventions, SG combined with other procedures, and lack of necessary data. Patients were divided into three groups depending on their preoperative glycated hemoglobin level (HbA_{1c}) < 5.7%, 5.7–6.4%, and ≥ 6.5%. Primary endpoints were influence of HbA_{1c} on early and late postoperative morbidity, impact on prolonged length of hospital stay (LOS), and readmission rate.

Results The HbA_{1c} < 5.7% group comprised 842 (49%) patients, HbA_{1c} 5.7–6.4% comprised 587 (34%), and HbA_{1c} ≥ 6.5% comprised 289 (17%). Overall morbidity was 6.23%; this did not differ among groups ($p = 0.571$). Three patients died postoperatively. Late postoperative morbidity was comparable among groups ($p = 0.312$). The ratio of prolonged LOS and readmission did not differ among groups ($p = 0.363$ and 0.571). ROC analysis revealed that HbA_{1c} > 7.3% increased OR for hospital readmission ($p = 0.007$).

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Conclusion Preoperative HbA_{1c} does not affect postoperative morbidity and prolonged LOS after SG. Patients with HbA_{1c} > 7.3% have an increased chance of hospital readmission.

Keywords Laparoscopic sleeve gastrectomy · Glycated hemoglobin · Postoperative morbidity · Postoperative mortality · Length of hospital stay · Readmission

Introduction

It is believed that almost every surgical procedure induces a stress response that may be responsible for morbidity and mortality [1]. Patients with diabetes mellitus type 2 (DM2) and chronic hyperglycemia, reflected by elevated glycated hemoglobin level (HbA_{1c}), may be particularly exposed to perioperative morbidity from diabetes-related complications [2, 3]. DM2 and increased mortality and morbidity in cardiac surgery are connected [4, 5]. This association is less clearly documented in other surgical fields [6–10].

HbA_{1c} has been proposed as a reliable indicator of glycemic status in the preoperative period because it is unaffected by fasting status. Furthermore, it is less affected by stress hyperglycemia than glycemic status [11, 12]. It has therefore been accepted as an appropriate method for diagnosing and monitoring DM2 [13, 14]. A meta-analysis investigating the association between HbA_{1c} and surgical outcomes in different branches of surgery has shown conflicting results and did not include bariatric surgery [15]. We found scarce clinical data regarding the influence of baseline HbA_{1c} on postoperative morbidity and readmission after laparoscopic sleeve gastrectomy. This prompted us to conduct this multicenter retrospective study, evaluating the influence of chronic hyperglycemia on postoperative course among patients undergoing laparoscopic sleeve gastrectomy (SG). To the best of our knowledge, this problem has not yet been investigated [16–20].

Aim of the Study

The aim of this study was to assess the influence of baseline HbA_{1c} levels on postoperative outcomes in patients undergoing laparoscopic sleeve gastrectomy.

Material and Methods

Methods

A retrospective cohort study was used to analyze consecutive patients who underwent surgical treatment for morbid obesity in seven referral bariatric centers in Poland from March 2017 to March 2018. Each participating center provided specific data, which were processed and used in the overall analysis.

The study was designed and described according to the STROBE guidelines for observational studies [21]. The included patients underwent laparoscopic sleeve gastrectomy. Each patient qualified for surgical treatment in accordance with the Polish Guidelines for Metabolic and Bariatric Surgery [22]. Exclusion criteria were revision surgeries, different bariatric operations, sleeve gastrectomy combined with other procedures, and lack of necessary data (only patients with complete follow-up were included). All procedures were performed laparoscopically using comparable surgical techniques, and perioperative care was based on standardized protocols, which ensured reliable data comparison. HbA_{1c} was measured on the day of hospital admission. Patients were divided into three groups depending on their preoperative glycated hemoglobin level (HbA_{1c}): HbA_{1c} < 5.7%, HbA_{1c} 5.7–6.4%, and HbA_{1c} ≥ 6.5%. These values equate to the American Diabetes Association definitions of normal HbA_{1c}, prediabetes, and diabetes mellitus [13]. Baseline characteristics were sex, age, body mass index (BMI), and relevant comorbidities.

Primary endpoints included the influence of the HbA_{1c} level on early postoperative morbidity (30 days) and late postoperative morbidity (12 months excluding the first 30 days), including mortality, influence on the rate of prolonged length of hospital stay (prolonged LOS), and readmission rate. Secondary endpoints were to determine HbA_{1c} cut-off points and when the odds ratio (OR) of primary endpoints significantly rose.

Definitions

Postoperative morbidity was defined as any deviation from the standard postoperative course that required additional measures to correct. LOS was defined as the period from surgery to discharge. Prolonged LOS was defined as > 4 days because the hospitalization for surgical bariatric treatment was planned for a maximum of 4 days. Readmissions were analyzed only if they occurred in the indexed hospitals.

Ethics

All procedures performed in the study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later

Table 1 General characteristics

<i>N</i> (%)	1718 (100%)
Males/females, <i>n</i> (%)	585/1133 (34%/66%)
Median age, years (IQR)	41 (35–51)
Median BMI, kg/m ² (IQR)	44.1 (40.3–48.77)
Arterial hypertension, <i>n</i> (%)	787 (45.8%)
Obstructive sleep apnea, <i>n</i> (%)	218 (12.69%)
Median operative time, min (IQR)	70 (55.5–90)

amendments or comparable ethical standards. Formal consent was not required for this study.

Statistical Analysis

Calculations were performed using Statistica 13.5 software (StatSoft®, Tulsa, OK, USA). Continuous values were presented as means with standard deviations or medians with interquartile ranges when appropriate. Quantitative variables were compared using the Kruskal-Wallis ANOVA with post hoc multiple comparisons of ranges. Qualitative variables were compared using the Pearson χ -square with or without Yates' correction. Receiver operating characteristic (ROC) curves were used to set HbA_{1c} cutoffs; then, univariate logistic regression models were built. Significant univariate logistic regression was adjusted for relevant intergroup baseline differences in multivariate analyses to calculate the OR with 95% confidence interval (CI). *P* values \leq 0.05 were considered statistically significant.

Material

The study group comprised 1718 patients from seven bariatric centers in Poland. The study population is characterized in Table 1.

Table 2 Group characteristics

	HbA _{1c} < 5.7%	HbA _{1c} 5.7–6.4%	HbA _{1c} \geq 6.5%	<i>p</i> value
<i>N</i> (% total)	842 (49%)	587 (34%)	289 (17%)	N/a
Diabetes mellitus type 2, <i>n</i> (%)	77 (8.95%)	132 (22.39%)	134 (46.37%)	< 0.001
No diagnosis of diabetes mellitus type 2, <i>n</i> (%)	765 (91.05%)	455 (77.61%)	155 (53.63%)	
Males/females, <i>n</i> (%)	243/599 (29%/71%)	205/382 (35%/65%)	137/152 (47%/53%)	< 0.001
Median age, years (IQR)	38 (32–47)	43 (35–53)	48 (40–57)	< 0.001
Median BMI, kg/m ² (IQR)	43 (40–48)	44 (40–49)	47 (42–52)	< 0.001
Arterial hypertension, <i>n</i> (%)	287 (34%)	309 (53%)	191 (66%)	< 0.001
Obstructive sleep apnea, <i>n</i> (%)	66 (8%)	89 (15%)	63 (22%)	< 0.001

Results

Group Characteristics

Group characteristics depending on the level of glycated hemoglobin are presented in Table 2. Median HbA_{1c} was 5.7% (5.3%–6.1%). Sex distribution significantly differed between HbA_{1c} groups, with an increasing prevalence of male patients from the HbA_{1c} < 5.7% to HbA_{1c} \geq 6.5% groups (29%, 35%, and 47%; *p* < 0.001). Multiple range comparisons in Kruskal-Wallis ANOVA showed a significant increase in age from the HbA_{1c} < 5.7% to HbA_{1c} \geq 6.5% groups (*p* < 0.001). This was also the same for patients' preoperative BMI.

Primary Outcomes

Table 3 presents postoperative outcomes of the whole study population.

The overall morbidity rate was 6.23% (107 patients); this did not differ among groups (*p* = 0.571). Neither the early nor late postoperative morbidity rate differed among groups (68 patients, *p* = 0.445 and 39 patients, *p* = 0.312 respectively). Details of clinical outcomes in each group are presented in Table 4. There were three early postoperative deaths (0.17%); these were due to urosepsis (HbA_{1c} = 6.7%), gastric leak (HbA_{1c} = 7.8%), and gastric leak and pancreatitis (HbA_{1c} = 5.2%). There were no deaths in the late postoperative period. The ratio of prolonged LOS did not differ among groups (*p* = 0.363). The readmission rate did not differ significantly among groups (*p* = 0.571). Patients with no preoperative diagnosis of DM2 who were in the HbA_{1c} \geq 6.5% group did not have increased ORs for early postoperative (OR 0.62, 95%CI 0.22–1.73, *p* = 0.361) or late postoperative complications (1.87, 95%CI 0.77–4.53, *p* = 0.167). Those patients also did not have increased ORs for prolonged LOS (OR 1.42, 95%CI 0.65–3.08, *p* = 0.379) or hospital readmission (OR 0.38 (0.05–2.85, *p* = 0.349).

Table 3 Postoperative outcomes

Median LOS, days (IQR)	3 (3–4)
Prolonged LOS, <i>n</i> (%)	94 (5.47%)
Overall morbidity, <i>n</i> (%)	107 (6.23%)
Early postoperative morbidity, <i>n</i> (%)	68 (3.96%)
Early postoperative mortality, <i>n</i> (%)	3 (0.17%)
Late postoperative morbidity (excluding 1st postoperative month), <i>n</i> (%)	39 (2.27%)
Readmissions, <i>n</i> (%)	27 (1.57%)

Secondary Outcomes

Surprisingly, analyses of the ROC curves did not reveal any HbA_{1c} cutoff point that would significantly increase ORs for primary endpoints. The only significant finding was that patients in the HbA_{1c} > 7.3% group had a higher likelihood of hospital readmission, as shown in Table 5. In multivariate logistic regression analysis, HbA_{1c} remained the only significant factor for readmissions (OR 4.59, 95%CI 1.61–13.06, *p* = 0.004).

Discussion

This is the first study to investigate the influence of preoperative HbA_{1c} levels on postoperative outcomes after laparoscopic sleeve gastrectomy. Our literature search revealed that the available information in the literature regarding this subject is limited. Previous studies predominantly analyzed patients after gastric bypass surgery. No studies investigating laparoscopic sleeve gastrectomy were found. Our study showed that baseline HbA_{1c} levels did not increase the likelihood of early and late postoperative morbidity or prolonged LOS. Further analysis revealed that patients with baseline HbA_{1c} > 7.3% had increased OR for hospital readmission.

The influence of baseline preoperative glycated hemoglobin HbA_{1c} levels on surgical morbidity has not been clearly determined, as presented in a systematic review by Rollins et al. [15]. HbA_{1c} was validated as an appropriate method for diagnosing

DM2 by diabetes specialist consensus [3, 13]. However, in the Polish Guidelines on the management of diabetic patients, HbA_{1c} is not recommended for diagnosing DM2 [23]. DM2 is diagnosed based on the fasting blood glucose level and/or fasting oral glucose tolerance test. In our study, 155 patients were in the HbA_{1c} ≥ 6.5% group. Although they should have been diagnosed and treated for DM2, the routine preoperative assessment did not diagnose them with DM2. Despite this, the early and late postoperative morbidity did not increase.

The available literature analyzed the influence of HbA_{1c} on postoperative outcomes after laparoscopic Roux-en-Y gastric bypass (LRYGB). Perna et al. published a study comprising 468 patients who underwent gastric bypass for morbid obesity [18]. They divided patients into three groups depending on their HbA_{1c} level HbA_{1c} < 6.5%, 6.5–7.9%, and ≥ 8.0%. They found no difference in overall complications or mortality. A year later, Rawlins et al. published a study analyzing the results of surgical treatment of 342 morbidly obese patients with DM2 who underwent LRYGB [19]. They found no significant increase in 1-year postoperative morbidity in patients with > 7% HbA_{1c} [19]. Crujisen et al. designed a single-center observational study involving 85 DM2 patients with a BMI ≥ 35 kg/m² who were scheduled for LRYGB [17]. Preoperative glycemic control was comparable in patients with and without surgical complications because HbA_{1c} levels were comparable in both groups [17]. In our study, patients' early postoperative morbidity was comparable among groups. Similar findings were also true for late postoperative morbidity. Neither did we find differences in the HbA_{1c} levels in the case of patients with and without prolonged LOS. Chuah et al. designed GLUCOSURG-pre RCT in which he divided DM2 patients to directly undergo LRYGB or to receive intensive preoperative DM2 treatment to preoperatively normalize HbA_{1c} levels [16]. Shockingly, neither LOS, nor 30-day perioperative complications differed among groups.

Our study improves the current knowledge of the influence of preoperative glucose metabolic state on postoperative SG outcomes. The HbA_{1c} level represents median blood glucose concentrations in the past 4 months, which should be the period

Table 4 Clinical outcomes

	HbA _{1c} < 5.7%	HbA _{1c} 5.7–6.4%	HbA _{1c} ≥ 6.5%	<i>p</i> value
<i>N</i> (% total)	842 (49%)	587 (34%)	289 (17%)	N/a
Overall morbidity, <i>n</i> (%)	47 (5.58%)	39 (6.64%)	21 (7.27%)	0.571
Early postoperative morbidity, <i>n</i> (%)	29 (3.44%)	28 (4.77%)	11 (3.81%)	0.445
Early postoperative mortality, <i>n</i> (%)	1 (0.12%)	0	2 (0.69%)	0.124
Late postoperative morbidity, <i>n</i> (%)	18 (2.14%)	11 (1.87%)	10 (3.46%)	0.312
Prolonged LOS, <i>n</i> (%)	40 (4.75%)	31 (5.28%)	21 (7.28%)	0.363
Prolonged LOS > 3 days	281 (33.37%)	150 (25.56%)	103 (35.64%)	0.017
Prolonged LOS > 5 days	13 (1.54%)	18 (3.07%)	10 (3.46%)	0.196
Readmissions, <i>n</i> (%)	47 (5.58%)	37 (6.30%)	21 (7.28%)	0.571

Table 5 Cutoff points of HbA_{1c} for clinical outcomes

	Cutoff for HbA _{1c}	AUC (95% CI)	OR (95% CI)	<i>p</i> value
Overall morbidity	5.9%	0.54 (0.48–0.60)	0.94 (0.61–1.44)	0.777
Early postoperative morbidity	5.9%	0.55 (0.49–0.62)	1.10 (0.66–1.84)	0.702
Early postoperative mortality	6.7%	0.67 (0.26–1.00)	3.66 (0.33–40.64)	0.290
Late postoperative morbidity	5.9%	0.52 (0.42–0.63)	0.64 (0.30–1.36)	0.244
Prolonged LOS	5.5%	0.54 (0.46–0.62)	1.37 (0.76–2.46)	0.293
Readmissions	7.3%	0.55 (0.42–0.67)	3.95 (1.46–10.68)	0.007

of intensive preoperative preparations. There were patients whose fasting glucose level was either normal or who would be diagnosed with glucose intolerance; however, according to HbA_{1c}, they would have been diagnosed with DM2. Fortunately, this did not translate into postoperative morbidity and mortality. Patients with high preoperative HbA_{1c} levels who underwent SG were at increased risk of hospital readmission. Further studies such as RCT similar to GLUCOSURG that focuses on patients with DM2 undergoing SG are required to extensively assess this subject. Additional data on the influence of gut hormone changes, stress response, variability of glucose concentrations, and preoperative glucose metabolic state would be useful to build a comprehensive answer to the question of the significance of preoperative glycemic control improvement for postoperative safety [12, 25, 26]. [24]

Limitations

The results of our study are limited by several aspects typical for observational multicenter reports. This was a non-randomized analysis and our groups were demographically heterogeneous and differed in preoperative factors. Furthermore, as the data were collected separately from seven bariatric centers using different electronic systems, some necessary information were lacking in our initial population, so we had to exclude some patients. We did not record postoperative events that occurred outside the indexed hospitals. Follow-up was complete in 86% of patients. The end of the study was in March 2018 and follow-up of 14% of patients was limited to 9 months. We did not analyze perioperative care protocols or operative techniques in each hospital. Another limitation is the fact that we have not investigated diabetes remission and bariatric effects 1 year after surgery.

Conclusions

HbA_{1c} ≥ 6.5% is common among patients undergoing SG (17%). Preoperative HbA_{1c} level is not associated with postoperative outcomes after laparoscopic sleeve gastrectomy, including postoperative morbidity and prolonged LOS. Patients with HbA_{1c} > 7.3% have a higher risk of hospital readmission.

Compliance with Ethical Standards

Conflict of Interest All authors declare no conflicts of interest.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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