The Impact of Laparoscopic Gastric Sleeve on blood glucose and HbA1c: A Retrospective Cohort Study

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Abstract

Statement of the problem: The efficiency of bariatric procedures for attenuating the development of obesity and diabetes mellitus and therefore improving the patient's general health status is wildly debatable when compared with conventional pharmacotherapy methods. The current retrospective study aims to examine the effect of the laparoscopic gastric sleeve (LGS) operation on circulating blood HbA1c and fast blood sugar in patients with obesity and with or without diabetes mellitus. **Methods**: Circulating blood HbA1c and FBS of eight hundred sixty-three (n=863) patients with obesity were evaluated before (baseline) and less than 3 months, 3 to 6 months, 6 to 12 months, 1 to 2 years, and 2 to 5 years of operation. **Results**: The results show a positive effect on the time-varying effect of LGS on the profile of FBS and HbA1c for patients with obesity who underwent this procedure. There was an improvement in the mean value of FBS from 111.79 mg/dl at the baseline point before an operation, to 86.49 mg/dl after over 2 to 5 years of operation ($P < 0.05$). Whereas HbA1c was also improved by decreasing from 6.54 mg/dl to 5.27 mg/dl ($P < 0.05$) in the same period. **Conclusion**: In both diabetic and non-diabetic patients with obesity, the current study found that LGS is an efficient approach for helping to reduce fasting blood glucose levels and HbA1c over the course of the 5-year evaluation period.

Keywords: Laparoscopic Gastric Sleeve (LGS), Fast Blood Sugar (FBS), Glycated hemoglobin (HbA1c), obesity, diabetes mellitus (DM).

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1. Introduction

Obesity is a worldwide epidemic [1]. In Gulf Cooperative Council (GCC) countries, especially Qatar where it is reported that around 33% of the adult population is obese, morbid obesity is becoming a serious clinical problem [2]. Studies showed that morbid obesity (body mass index that is higher than 40 kg/m^2 or 35 kg/m^2 with comorbidities) is the precursor of several chronic disorders such as metabolic syndrome, endocrinal, clinical obesity, diabetes, etc. [3]

In addition, it was reported that about 415 million people worldwide are diabetics, and this number is predicted to be 642 million by 2040 [4]. In GCC

countries, data shows a remarkable elevation in diabetic patients through the last two decades and 73% of deaths are due to non-communicable diseases such as cancer, cardiovascular, and diabetes. In Qatar, studies indicate that 10.8% of the female population was diagnosed with type 2 diabetes mellitus (T2DM) [4]. It is also estimated that the prevalence of diabetes may reach 24% of adult Qataris in 2050, meanwhile, efforts are underway to reduce the cases of diabetes by 10% in 2022, by reducing the rate of obesity [4]. It is estimated that the cost of medical treatment for diabetic patients between the ages of 20 and 79 years may reach 825 billion dollars in 2030 worldwide, which presents a heavy burden [4]. In Qatar, unhealthy diet habits and the lack of regular physical activity, in association with the high temperature and humidity of the country, are all factors that contribute to increasing the percentage rate of obesity. Searching for an effective way to solve the obesity problem is a menace that has been worrying scientists for a long time.

There is a clear association between obesity and T2DM [5]. Forty-four percent of T2DM incidence worldwide is because of overweight or obesity [6, 1]. Successful treatment of T2DM is mainly based on weight loss. In both cases, obesity and diabetes mellitus are difficult to control by conventional pharmacotherapy *per se*, or by using other lifestyle interventions including dietary management and behavioral modification [7, 8, 9, 10, 11]. Only a trivial number of patients may achieve an efficient control for both cases by lifestyle interventions on a long-term basis [12].

Recently, bariatric surgeries were considered to be common and effective methods for treating obesity [13, 14, 15, 16, 17], and its comorbid diseases. However, although LGS is a popular bariatric procedure worldwide, [18], no studies so far have examined its effect on diabetes mellitus patients who undergo LGS.

Changes in physiological measurements, including biochemical measurements after LGS, can be monitored, and reported in many studies [19]. One of the biochemical measurements that are affected by LGS is fast blood sugar (FBS), and glycated hemoglobin (HbA1c) [20]. A study also shows that LGS surgery may lead to the remission of T2DM as one of the comorbidities and can be determined by this procedure. The American Diabetes Association (ADA) in 2011 considered bariatric surgery as an effective way to treat obesity and comorbidities [21], by enhancing weight loss because of the drop in food intake or its absorption [22, 23, 24, 25, 26]. As a result of weight loss by bariatric surgery, insulin sensitivity and β cell function, as well as blood glucose and glycated hemoglobin (HbA1c), will be improved [26].

Nowadays, the essential procedures in bariatric surgeries are Roux en Y gastric bypass (RYGB) and laparoscopic sleeve gastrectomy (LSG) [25, 27]. In the case of patients with obesity who were diagnosed as diabetic patients, RYGB is the basic option for bariatric surgery [28]. However, recently, the international trend appears to be raising LGS [25, 29]. There is no sufficient proof that (RYGB) is superior to (LGS) in remission of (T2DM) in patients with morbid obesity. [28, 30]. Although it is well known that LGS is linked with good long-term weight reduction results, 5% to 10% of patients cannot achieve the desired result of sufficiently losing weight after this procedure [28]. With the rising burden of obesity and diabetes mellitus, particularly in Qatar, the setting of the current study, and a parallel rise of LGS in the world, particularly in Qatar, the current study comes to show the effect of LGS on patients with obesity, with or without diabetes mellitus, by measuring glycated hemoglobin (HbA1c) and fast blood sugar (FBS) as an indicator of the level of blood sugar postoperatively. The current study aims to assess the effect of LGS of HbA1c and FBS on patients with obesity, with or without diabetes mellitus, after 3 months, 6 months, 1 to 2 years, and 2 to 5 years of LGS surgery.

2. Subjects

For choosing participants, the data of 863 patients with obesity, diabetic and non-diabetic, who underwent LGS was collected to study the effect of LGS on specific biochemical measurements, e.g., FBS, HbA1c.

3. Materials and Methods

During the period 2015 to 2020, extraction of data of unidentified hospital recorded data for

patients with obesity who underwent LGS operation with or without complaining about comorbidities, including diabetic Type I and II mellitus, were collected from the system at Alemadi Hospital in Qatar. Extracted data included sociodemographic data (gender, nationality, age), and biomedical measures for patients with obesity, including FBS and HbA1c, by using Siemens Dimension EXL 200 machines (for patients' characteristics, see Table 1).

These readings were collected before and after the operation for 3 months, 6 months, 1 year, 2 years, and 5 years after the operation. Data concerning medication is not included in Sage software, the software that is used to save the data for patients in Alemadi Hospital. As a result, distinguishing patients who complain about Type I or Type II diabetes mellitus was not possible. Confidentiality and anonymity were maintained during data collection. Only the diagnostic patients with diabetes mellitus had their readings of these diagnostic biomedical tests, as per the rules of insurance companies and hospitals that covered the costs of operation. We used all samples that had recorded data in the hospital's system. The sample consisted of 863 patients; their reliable data were collected retrospectively, including the follow-up period of up to five years after the needed LGS surgery. This method on collected data gives each sample an equal probability and an equal chance of being selected. The required ethical approvals for this retrospective, observational, cohort study design have been granted by the hospital, the Ministry of Public Health in Qatar (MoPH), and Management and Science University. As per the requirements of the ethical approval by the Ministry of Public Health in Qatar (MoPH) for this kind of retrospective study, and as per all data extracted by the system, with non-identification of the private data of patients, a consent form is not required, and informing patients is also not a must.

The current study was conducted to examine the effect of LGS on the level of HbA1c and FBS and whether LGS leads to participation in the resolving of diabetes mellitus as a comorbid disease among patients who underwent the surgery. According to the American Society for Metabolic and Bariatric Surgery (ASMBS), the criteria for diagnosing the condition of diabetes following surgery to be under the category of Complete Remission can be summarised in three combined statuses: 1. HbA1c should be less than 6% (or below 42mmol/mol), 2. Fast blood sugar (FBS) is less than 5.56 mmol/L, 3. The absence of taking antidiabetic medications. [31, 32].

The American Diabetes Association (ADA) presents a very comparable determination of complete remission of diabetes following the surgery, which includes the same statuses of HbA1c and FBS, and no requirement for antidiabetic medications for at least one year [33]. Due to the incapability of medication record extraction by Sage Software, the time criterion for medication was absent. Therefore, the evaluation of the status of diabetic patients who underwent LGS will be based on the differentiation between the reading of HbA1c and FBS before and after the surgery, within the first 5 years postoperatively. The inclusion criteria in this study included 863 patients with obesity who underwent LGS for the first time from 2015 to 2020, with or without a high level of FBS and HbA1c. Their age starts at 18 years old and above.

Regarding the inclusion and exclusion variables in this study, these variables are affected by the study's outcome:

A. Included variables: A.1. patient's characteristics: sex, age, nationality.

A.2. (FBS, HbA1c) readings before and after surgery.

B. Excluded variables

1) patient's characteristics: body weight, excess weight before the operation, and excess weight loss after the operation.
2) patients categorize as Type I or Type II diabetic mellitus.
3) smoking history.
4) how long the duration of DM is.
5) antidiabetic treatment records before and after the surgery.
6) complications of DM, even before or after surgery.
7) how much the resected part from the stomach and the rest of the gastric volume.

8) end-stage cardiac disease, end-stage renal disease, or end-stage cancer.
9) patients who repeated LGS twice.

4. Results

4.1 Sociodemographic Information

As can be seen below, Table 1 provides the sociodemographic characteristics of the participants.

Table 1. Sociodemographic characteristics of the sample

Total	
N=863	
Age (years)	32.7 (10.7)
Age (years)	
18-25	236 (27.3%)
26-40	432 (50.1%)
41-60	187 (21.7%)
60+	8 (0.9%)
Gender	
Men	285 (33.0%)
Women	578 (67.0%)
Nationality	
Non-Qatari	201 (23.3%)
Qatari	662 (76.7%)

4.2 Descriptive Statistics

Data are expressed as the mean and standard error (SE). All statistical analyses, with a value of $P \leq 0.05$, were considered statistically significant. Statistical analyses were performed using the STATA (version 17). After performing the data extraction, coded, and entered into STATA software for data analysis has been done. Generalized linear mixed models (GLMMs) were used in this study. One reason for using these models was that the current data were not normally distributed and involves repeated measures since GLMMs can model autocorrelation.

This part provides descriptive statistics on a patient's diabetes mellitus (DM) profile, including FBS and HbA1c. GLMMs were used in this study.

From the finding of the current study, and according to Table 2, it is observed that the average value of serum **FBS** before surgery was 111.79 mg/dl, then the mean value decreased to 87.54 mg/dl in the first three months of operation. Again, it decreased to reach 84.91 mg/dl from 3 to 6 months. After 6 months, 1 year, and 2 years postoperatively, mean values kept declining to reach (86.47, 84.67, 86.49) mg/dl respectively, compared with the mean value of baseline on the operation day. It is observed that the average value of serum FBS has decreased during the first 2 years. After over 2 years of operation, the average value of serum FBS was slightly increased compared with the first 2 years, but still lower than the first reading of the baseline value.

Similarly, according to Table 2, it is observed that the average value of serum **HbA1c** before surgery was 6.54%, and the mean value decreased to 5.79% during the first three months of operation. It decreased again to 5.05% from 3 to 6 months. After 6 months to 12 months of operation, the mean value slightly increased to 5.63% compared with the previous reading, but still less than the baseline value. From 1 to 2 years, 2 to 5 years postoperatively, mean values declined at a consistent level up to 5 years to reach (5.26, 5.27) % respectively, as compared with the mean value of baseline.

Table 2 Mean values (SE) of blood glucose and HbA1c among patients who underwent Laparoscopic Gastric Surgery, and P values.

Biochemical Parameters of Blood Sugar	Before Operation	<3 months	3-6 months	6-12 month	2 years	>=3 years
FBS	111.79	87.54	84.91	86.47	84.67	86.49
	(1.77)	(6.41)	(6.02)	(6.09)	(5.27)	(5.19)
P value		<0.001	<0.001	<0.001	<0.001	<0.001

	Before Operation	<3 months	3-6 months	6-12 month	2 years	>=3 years
HbA1c	6.54	5.79	5.05	5.63	5.26	5.27
	(0.09)	(0.24)	(0.25)	(0.24)	(0.25)	(0.23)
P value		<0.002	<0.001	<0.001	<0.001	<0.001

To answer the research question:

What is the effect of LGS on the patients' DM profile after the surgery?

As shown in Table 3, according to GLMMs used in this study, the results of GLMMs of serum FBS on operation time show a reduction of serum **FBS** by 24.28 mg/dl in the first three months of operation as compared to the operation day level. This reduction is **statistically significant** at 5%, as (P value <0.001). In the periods after (3 months, 6 months, 12 months, 2 years, 2 to 5 years), the readings declined at a consistent level up to 5 years to reduce them by 26.89, 25.33, 27.12, 25, 30, respectively, after comparing with the baseline value. These differences were **statistically significant** as P values < 0.001, < 0.001, < 0.001, and < 0.001, respectively.

Findings of the current study show a reduction of serum **HbA1c** by 0.75 mg/dl in the first three months of operation as compared to the baseline value. This reduction is **statistically significant** (expressed as ß=0.75. P value = 0.002). In the periods after 3 months, 6 months, 12 months, 2 years, and 2 to 5 years, postoperatively, the readings declined at a consistent level up to 5 years, which was reduced by 1.50, 0.91, 1.28, and 1.27, respectively, in comparison with the operation day. These differences were **statistically significant** and presented as P values < 0.001, < 0.001, < 0.001, and < 0.001, respectively. Overall, the results of GLMMs on the **time-varying effects** of LGS on a patient's DM profile are positive. After LGS, both patients' FBS and HbA1c have been reduced with passaging time in over 2 years.

Table 3 Regression coefficients for HbA1c and Glucose by time since operation adjusting for age and gender

	HbA1c		Glucose	
Time since operation	β (95%CI)	P value	β (95%CI)	P value
Operation	0.00		0.00	
3 months	-0.75 (-1.22--0.29)	0.002	-24.28 (-36.98--11.57)	<0.001
6 months	-1.50 (-1.99--1.00)	<0.001	-26.89 (-38.81--14.96)	<0.001
12 months	-0.91 (-1.40--0.43)	<0.001	-25.33 (-37.48--13.17)	<0.001
2 years	-1.28 (-1.78--0.78)	<0.001	-27.12 (-37.65--16.59)	<0.001
>=3 years	-1.27 (-1.73--0.81)	<0.001	-25.30 (-35.68--14.92)	<0.001
Age (years)	0.03 (0.02-0.05)	<0.001	0.95 (0.65-1.25)	<0.001
Gender				
Men	0.00		0.00	
Women	-0.32 (-0.65-0.01)	0.055	-9.01 (-15.68--2.35)	0.008
Intercept		<0.001		<0.001

According to **Table 3**, the relationship between **gender** and **FBS** is **significant** (ß= -9.01, P value = <0.008). Whereas the relationship between **gender** and **HbA1c** is insignificant (ß= -0.32, P value = 0.055). The results showed a **positive relationship** between participants' **age** and both FBS and HbA1c levels, (ß=0.95, P value = <0.001), (ß=0.03, P value = <0.001), respectively.

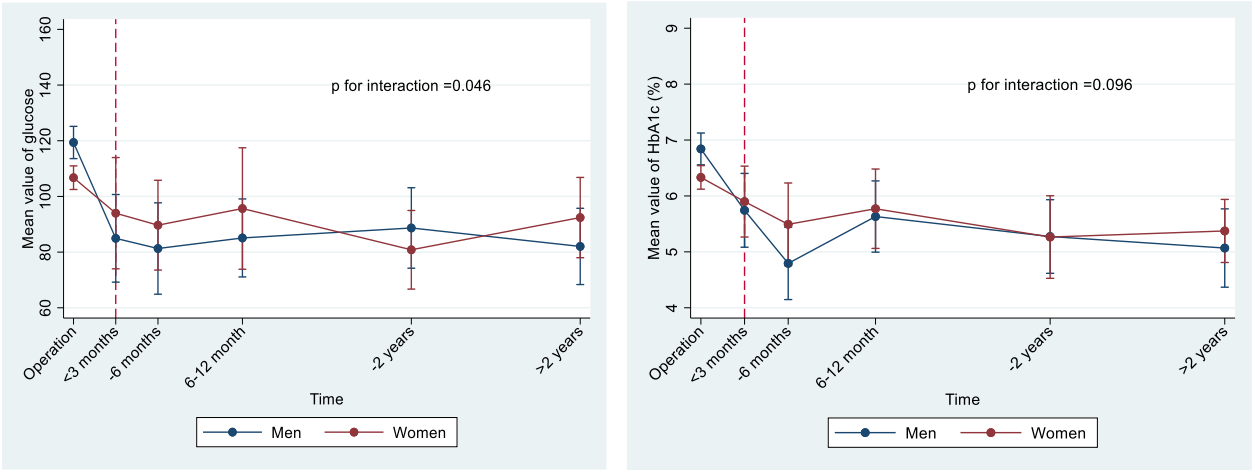
Table 4 provides the blood Sugar profile level for FBS and HbA1c at different times concerning participants' **gender and age group**.

	Before Operation	<3 months	3-6 months	6-12 month	2 years	>=3 years
All sample	111.79	87.54	84.91	86.47	84.67	86.49
FBS	(1.77)	(6.41)	(6.02)	(6.09)	(5.27)	(5.19)
Gender						
Men	119.38	84.95	81.29	85.09	88.67	82.05
	(2.95)	(8.03)	(8.37)	(7.15)	(7.38)	(6.99)
Women	106.74	93.98	89.67	95.66	80.83	92.41
	(2.16)	(0.12)	(8.22)	(11.13)	(7.2)	(7.36)
Age						
<35 years	112.98	84.93	92.85	88.02	91.02	94.45
	(3.00)	(10.70)	(11.16)	(10.44)	(8.79)	(8.39)
>=35 years	110.47	88.41	80.10	85.34	80.44	81.11
	(3.2)	(8.13)	(7.37)	(7.65)	(6.78)	(6.96)

	Before Operation	<3 months	3-6 months	6-12 month	2 years	>=3 years
All sample	6.54	5.79	5.05	5.63	5.26	5.27
HbA1c	(0.09)	(0.24)	(0.25)	(0.24)	(0.25)	(0.23)
Gender						
Men	6.84	5.74	4.79	5.63	5.27	5.07
	(0.15)	(0.34)	(0.33)	(0.33)	(0.34)	(0.36)
Women	6.33	5.9	5.49	5.77	5.77	5.37
	(0.11)	(0.23)	(0.38)	(0.36)	(0.38)	(0.29)
Age						
<35 years	6.28	5.47	5.10	5.15	4.92	5.20
	(0.11)	(0.31)	(0.43)	(0.38)	(0.41)	(0.36)
>=35 years	6.79	6.04	5.14	6.05	5.64	5.53
	(0.13)	(0.36)	(0.30)	(0.32)	(0.31)	(0.29)

Figure 1 shows the relationship between gender and time for the blood sugar profile. The curve showed the value between male and female mean values of FBS and HbA1c, portraying that there is an **interaction effect** between gender and time for FBS (P value =0.046). Whereas the curve of HbA1c shows that there is **no interaction effect** between gender and time for HbA1c (P value =0.96).

Figure 1. Interaction between gender and time for the blood sugar profile.



Answer to the research question:

Does LGS lead to resolving comorbidities and DM problems among patients who undergo the surgery?

Table 2 describes biochemical parameters and P value among patients who underwent laparoscopic gastric sleeve, and changes in their mean values, compared with the operation day.

Results show that the problem of DM, measured through FBS and HbA1c, had a resolution tendency after LGS surgery as the mean value of FBS at the time of operation was 111.79 mg/dl, but decreased with passaging time for both males and females after over two years of LGS surgery to reach 86.49 mg/dl. These differences in the

mean values of FBS were statistically significant during all periods. In the same way, the mean value of HbA1c at the time of operation was 6.54%, and it decreased with passaging time for both males and females after over two years of LGS surgery to reach 5.27%. Also. these differences in mean values of HbA1c were statistically significant during all periods. So, the decreasing mean value of individuals over time shows that LGS surgery has a tendency to resolve the problem of DM.

5. Discussion

The current cohort retrospective study explores the effect of LGS on FBS and HbA1c as a main biochemical measurement of DM, and how far this procedure plays a role in overcoming DM problems. Eight hundred and sixty-three (n=863) LGS patients were included in the current study. The assessment shows that the resolution tendency of DM following LGS significantly improved the mean of FBS and HbA1c for patients with obesity who underwent this surgery in the period of 5 years postoperatively.

In a case study reported by Signorini *et al.* (2021), descriptive statistics were used to evaluate the outcome of LGS in patients who complained of type 2 diabetes mellitus (T2D) and had undergone LGS throughout 8 years of follow-up by comparing the reading preoperative (baseline T1), and the reading after one year postoperative (T2). The first year postoperative was characterized by rapid improvement for all patients; 79% of all patients achieved complete remission with an improvement in metabolic control by 21%. After 7.7 years to 12 years, with an average of 8 years, 54% of diabetic patients with initial control experienced a relapse. The patients who experienced higher weight loss maintenance had a greater remission or improvement of T2D. The study concluded that LGS improved diabetes control significantly, even after passing of long time, which may reach up to 8 years [34]. This result is in general agreement with the findings of the current study by achieving the maximum improvement in the medical status of diabetic patients during the first year of operation. Whereas, the result of the current study does not support the result of Signorini et al. regarding the rest of the study. The current study is keeping a consistent level of improvement during the rest of the study period. On the contrary, the result of Signorini et al. and his colleagues showed that there was a deterioration in a specific percentage of patients' outcomes at the end of the study period that reached 12 years. The scientific explanation of these contradictory results might be the difference in the longer duration of the Signorini et al. study, which was for 10 years, compared with the current study, which was only 5 years. This could give us a conclusion of the higher efficiency of LGS during the first years, which becomes lower with passing time.

6. Strength of the study

The present study was built on a wide number of cases during a moderate duration of time, reaching up to 5 years, which gave the opportunity to estimate the results and gave a clear interpretation. This study included cases of patients with similar profiles (patients eligible to undergo LGS), and this is expressed in the poor heterogeneity among the studies. This is chosen for all data accessible in medical records. We can exclude the prospect bias.

7. Conclusion

In this analysis, the effect of LGS was explored in terms of certain biochemical measurements, including FBS and HbA1c. In addition, the study explored the effect of LGS in treating certain conditions of comorbidities, including Diabetes Miletus. The study discovered that post-LGS improves blood sugar profiles by lowering FBS and HbA1c in a specific time frame. In conclusion, it is reasonable to expect an improvement in comorbidities with remarkable weight loss because of LGS. Further long-term studies are recommended.

8. Limitation of the study

1. The recorded data in Sage software is not included in the diagnosis of each case. The patients who had readings before the surgery under the category of high risk in the biochemical measurements of their blood sugar profile will be diagnosed as diabetic patients.

2. The recorded data in Sage is not included in the information about stopping or continuing any medication after LGS related to the studied cases.

3. The recorded data in Sage software could not include further information to distinguish between patients who had a normal range of studied parameters before the operation because of the regular use of medication, which kept their condition under control, or because of their health status without comorbidities.

5. Economic factors are not included.

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11. Declaration

- ll required ethical approvals are explained in the method section.
- The authors declare that all experiments on human subjects were conducted in accordance with the Declaration of Helsinki.

12. Conflict of Interest

The Authors declare that they have no conflict of interests.

13. Abbreviations

LGS: Laparoscopic Gastric Sleeve, FBS: Fast Blood Sugar, HbA1c: Glycated Hemoglobin, diabetes mellitus: DM

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