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ORIGINAL CONTRIBUTIONS

Five-Year Outcomes of Sleeve Gastrectomy in Patients with Class I Obesity and Type 2 Diabetes Mellitus

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Abstract

Background Several studies have reported short and medium-term outcomes of laparoscopic sleeve gastrectomy (LSG) in patients with class I obesity and type 2 diabetes mellitus (T2DM). However, literature on outcomes beyond three years is scarce. The present study discusses the 5-year results of a previously reported cohort of 20 patients with class I obesity and T2DM, who had undergone LSG between March 2012 and March 2015.

Materials and Methods Patients were followed up in the bariatric clinic at yearly intervals as per institute protocol. Primary outcome was proportion of patients with a glycated haemoglobin (HbA1c) level of 6.5% or less, 5 years after LSG. Secondary outcomes were percentage total weight loss (%TWL), excess weight loss (EWL), weight regain and complications.

Results Out of 20 patients, 9 (45%) were male and 11 (55%) were female. Mean age was 41.6 ± 9.5 years. Mean pre-operative weight and BMI were 94.8 ± 14.4 kg and 33.4 ± 1.2 kg/m^2, respectively. Median duration of diabetes was 42 months. Mean pre-operative fasting plasma glucose (FPG) and HbA1c were 171.1 ± 56.8 mg/dL and 8.7 ± 1.6%, respectively. Of the 17 patients available for follow-up at 5 years, 9 (52.9%) achieved HbA1c < 6.5% without medication, while 7 (41.2%) patients had improvement of their glycaemic status. One patient had recurrence of diabetes after initial remission. Mean %TWL and %EWL were 18% and 65.1%, respectively.

Conclusion Laparoscopic sleeve gastrectomy is a reasonable option as a metabolic procedure for patients with T2DM and class I obesity.

Keywords Bariatric surgery · Metabolic surgery · Non-severe obesity · Long-term outcomes · T2DM

Introduction

Metabolic and bariatric surgery (MBS) has been reported to be more effective than either standard or intensive medical treatment in patients with severe obesity and T2DM [1]. The impact of bariatric surgery on T2DM is impressive, with around 70–80% patients achieving remission or improvement [2]. This positive impact on diabetes can be seen in the early postoperative period,

Key Points

- The positive impact of sleeve gastrectomy on glycaemic control in patients with class I obesity and type 2 diabetes is sustained at five years after surgery.
- Mean HbA1c decreased from 8.7% to 6.6% at five years after sleeve gastrectomy.
- More than 70% patients achieved HbA1c less than 6.5% at five years.
- More than half the patients were off anti-diabetic medication.
- All patients on insulin before surgery were off insulin at five years.

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even when substantial weight loss has not been achieved [3, 4]. Further improvement in glucose tolerance occurs later due to weight loss [5]. The promising results of MBS has led to its use in patients with T2DM and class I obesity, with the primary objective of remission of diabetes. Metabolic surgery in these patients was popularised by DePaula et al. [6, 7] who reported good results with ileal interposition with sleeve gastrectomy (SGIT). However, SGIT is a technically complex procedure and is not considered as a standard metabolic procedure by most surgical societies. Sleeve gastrectomy, due to its technical simplicity and wide applicability, is the most popular bariatric procedure worldwide [8]. Several studies, including one from our centre, have reported satisfactory short and medium-term outcomes of LSG in patients with T2DM and class I obesity [3, 9–11]. However, there is a dearth of literature on glycaemic control beyond 3 years of LSG in this patient population. This report analyses the 5-year outcomes of LSG in patients with T2DM and class I obesity.

Materials and Methods

This is a follow-up study of a cohort of 20 patients with class I obesity with T2DM, who underwent LSG between March 2012 and March 2015, as part of a prospective study. The eligibility criteria and technique of LSG have been described earlier [3]. These patients were regularly followed up at yearly intervals as per the institute protocol. Parameters including fasting plasma glucose (FPG), glycated haemoglobin (HbA1c), weight, body mass index (BMI) and use of anti-diabetic medications were analysed. Primary outcome was proportion of patients with HbA1c level of 6.5% or less without any anti-diabetic medication, 5 years after LSG. Secondary outcomes were percentage total weight loss (%TWL), excess weight loss (EWL), weight regain and complications. Weight regain was defined as increase of more than 10 kg from nadir weight [12].

Statistical analysis was performed using Stata version 14 (StataCorp LLC, Texas). Continuous variables were described using mean and standard deviation, or median (range), as appropriate. Categorical data was expressed as frequency. Repeated measure ANOVA was used to check the trends of continuous variables over a period of time followed by Bonferroni correction for multiple comparison test. Independent *t* test or rank sum test was used to compare continuous variables between two categories, as appropriate. Significance was set at 5% level, and *p* value less than 0.05 was considered significant.

Table 1 Baseline characteristics of the study cohort

Variable	
Male/female	9/11
Age in years, mean ± SD (range)	41.6 ± 9.5 (21–60)
Pre-operative weight in kg, mean ± SD (range)	94.8 ± 14.5 (75.8–119.5)
Pre-operative BMI in kg/m^2, mean ± SD (range)	33.4 ± 1.2 (30.9–34.9)
Excess weight in kg, mean ± SD (range)	23.9 ± 5.2 (14.4–30.7)
Median duration of diabetes in months (IQR)	42 (16–78)
HbA1c (%), mean ± SD	8.7 ± 1.6
Fasting plasma glucose in mg/dl, mean ± SD	171.1 ± 56.8

SD standard deviation, *IQR* interquartile range

Results

Out of 20 patients in the initial cohort, 9 (45%) were male, and 11 (55%) were female. Mean age was 41.6 ± 9.5 (range 21–60) years. Pre-operative weight and BMI were 94.8 ± 14.5 (range 75.8–119.5) kg and 33.4 ± 1.2 (range 30.9–34.8) kg/m^2 respectively (Table 1). Mean excess weight was 23.9 ± 5.2 (range 14.4–30.7) kg. Median duration of diabetes was 42 months (IQR 16–78). Mean pre-operative HbA1c and FPG were 8.7 ± 1.6% and 176.4 ± 56.8 mg/dL, respectively. Seventeen (85%) patients were available for 5-year follow-up. There were no leaks or mortality.

Impact of LSG on T2DM

Mean HbA1c at 12, 24, 36, 48 and 60 months were 7 ± 1%, 6.7 ± 1%, 6.8 ± 1.2%, 6.7 ± 0.8% and 6.6 ± 0.7%, respectively. Mean FBG at 12, 24, 36, 48 and 60 months were 131.2 ± 28.2 mg/dL, 127.5 ± 32.3 mg/dL, 128.9 ± 39.6 mg/dL, 118.8 ± 22.3 mg/dL and 116.1 ± 21.3 mg/dL, respectively (Table 2). At 5-year follow-up, 12 (70.6%) patients achieved HbA1c < 6.5%, of which 9 (52.9%) were off anti-diabetic medication, and three were taking single OHA. Four (23.5%) patients had achieved HbA1c level of less than 6%. As per the definition of remission recommended by the American Society for Metabolic and Bariatric Surgery [13], nine (52.9%) patients had partial remission, and 7 (41.2%) had improvement (Table 3). Patients who had remission had shorter duration of diabetes and lower baseline FPG compared to those who did not. However, baseline serum insulin and C-peptide levels were comparable between these two groups. Baseline HbA1c was lower

Table 2 Impact of sleeve gastrectomy on weight, BMI, % EWL, HbA1c, FBS at 1-year, 2-year, 3-year, 4-year, and 5-year follow-up

Variable	Pre-operative ($N=20$)	1st year ($n=20$)	2nd year ($n=20$)	3rd year ($n=20$)	4th year ($n=17$)	5th year ($n=17$)	p Value*
Weight (kg) (Mean ± SD)	94.82 ± 14.49	80.0 ± 14.63	76.75 ± 12.68	75.02 ± 12.28	75.47 ± 12.79	76.88 ± 11.92	< 0.001
BMI (kg/m^2) (Mean ± SD)	33.46 ± 1.23	28.22 3.14	27.11 ± 2.41	26.49 ± 2.33	26.91 ± 2.93	27.44 ± 2.71	< 0.001
FBS (Mean ± SD)	176.45 ± 54.89	131.25 ± 28.20	127.5 ± 32.27	128.95 ± 39.57	118.83 ± 22.35	116.12 ± 21.31	< 0.001
HbA1c (Mean ± SD)	8.70 ± 1.61	6.96 ± 0.99	6.75 ± 1.02	6.79 ± 1.17	6.69 ± 0.76	6.59 ± 0.70	0.0001
% Excess weight loss (Mean ± SD)		63.21 ± 35.82	76.60 ± 26.01	83.92 ± 25.15	79.06 ± 31.64	73.01 ± 28.51	< 0.001

BMI body mass index, *EWL* excess weight loss, *FBS* fasting blood sugar, *SD* standard deviation

*Pre-operative vs 5-year outcomes

Table 3 Impact of sleeve gastrectomy on diabetic profile at successive follow-up to 5 years

Variable		Preoperative (N=20)	1st year (N=20)	2nd year (N=20)	3rd year (N=20)	4th year (N=17)	5th year (N=17)
T2DM	No change		2 (10%)	1 (5%)	1 (5%)		
	Improved		18 (90%)	14 (70%)	10 (50%)	7 (41.2%)	7 (41.2%)
	Remission			5 (25%)	9 (45%)	9 (52.9%)	9 (52.9%)
	Recurrence					1 (5.9%)	1 (5.9%)
Number of OHA	0		15 (75%)	12 (60%)	12 (60%)	11 (64.7%)	11 (64.7%)
	1	9 (45%)	5 (25%)	12 (60%)	8 (40%)	6 (35.3%)	6 (35.3%)
	2	9 (45%)					
	3	2 (10%)					
On insulin		6 (30%)	0	0	0	0	0
Weight regain		0	0	0	0	0	1 (5.9%)

T2DM type 2 diabetes mellitus, *OHA* oral hypoglycemic agents

in patients who had remission, but the difference did not reach statistical significance ($p=0.08$) (Table 4).

Before surgery, 6 out of 20 (30%) patients were on insulin, but after surgery, all patients were off insulin at 5-year follow-up. Before surgery, all patients were on oral hypoglycaemic agents (OHA); 9 (45%) were on single OHA, 9 (45%) on two OHAs and 2 (10%) on three OHAs. Requirement of OHA decreased significantly at successive follow-up. At 5 years, 11 (64.7%) patients were off OHA, while 6 (35.3%) were on single OHA. One patient aged 40 years had recurrence of T2DM 4 years after LSG. She had T2DM for 5 years, and her HbA1c before LSG was 9.1% on OHAs. After LSG, she had partial remission of diabetes till 3-year follow-up, but her disease recurred at 4 years, despite a good EWL of 74.5%.

Table 4 Comparison of baseline variables related to T2DM between patients with and without remission

Variable	Remission ($n=9$)	Non-remission ($n=8$)	p Value
Median duration of T2DM (months)	18	54	0.03
Mean fasting plasma glucose (mg/dL)	140	214	0.03
Mean body mass index (kg/m^2)	33.5	34.1	0.80
Mean HbA1c (%)	7.6	9.3	0.08
Mean C-peptide (ng/mL)	3.6	3.5	0.99
Mean insulin level (mIU/L)	18.8	19.3	0.96

T2DM type 2 diabetes mellitus

Impact on weight

Mean %TWL (SD) at 12, 24, 36, 48 and 60 months were 15.7 ± 8.7, 19 ± 6.2, 20.8 ± 5.9, 19.5 ± 7.8 and 18 ± 6.7%, respectively. Mean EWL at these times points were 63.2 ± 35.8%, 76.6 ± 26%, 83.9 ± 25.1%, 79.1 ± 31.6% and 73 ± 28.5%, respectively. Mean BMI at 12, 24, 36, 48 and 60 months were 28.2 ± 3.1, 27.1 ± 2.4, 26.5 ± 2.3, 26.9 ± 2.9 and 27.4 ± 2.7 kg/m^2, respectively (Table 2). One patient (5.9%) had weight regain after 3 years.

Impact on hypertension

At 5 years, 4 out of 8 (50%) hypertensive patients had complete remission, 3 (37.5%) had improvement, while one had no change in blood pressure.

Discussion

In our previously published report of sleeve gastrectomy in 20 patients with class I obesity and T2DM, at a mean follow-up of 18 months, 50% patients had achieved FPG < 126 mg/dL and HbA1c level < 6.5% without any anti-diabetic drug, while the remaining had improvement of their glycaemic status [3]. This follow-up study shows that the positive impact of LSG on glycaemic control is sustained at 5 years and even beyond. At 5-year follow-up, more than half of the cohort still maintained HbA1c level < 6.5% without any hypoglycaemic agent. All but one of the remaining patients had improvement of their pre-operative glycaemic status.

Several studies have shown LSG to be effective in the treatment of T2DM in patients with class I obesity in the short or medium term(Table 5). In a randomised controlled trial (RCT) by Yang et al. [14], patients with BMI 28–35 kg/m^2 and T2DM were randomised to receive LSG or RYGB. At 3 years, remission of T2DM was noted in 78.6% patients receiving LSG and 85.2% patients receiving RYGB ($p = 0.525$). Changes in HbA1c, FPG and C peptide were comparable between the two groups.

Studies on long-term outcomes of LSG in patients with class I obesity and T2DM are scarce in the literature. Lee et al. [15] compared outcomes of LSG and one anastomosis gastric bypass (OAGB) in a RCT of 60 patients with BMI of 25–35 kg/m^2 and T2DM. At 5 years, 60% patients who underwent OAGB had HbA1C less than 6.5% without glycaemic therapy, compared to 30% patients undergoing LSG.

Table 5 Studies showing impact of sleeve gastrectomy on weight loss and diabetic profile in class I obese patients

Study and design	Lee et al. (14) 2010 Retrospective	Kakoulidis et al. (23) 2009 Prospective	Abbatini et al. 2012 (13) Prospective	Park et al. (18) 2015 Retrospective	Berry et al (24) 2018 Retrospective	Wu et al. (25) 2020 Retrospective	Our study 2020 Retrospective
Sample size	20	23	9	49	252	26	20
Follow-up duration and attrition rate	12 months	6 months	12 months	24 months	36 months At 3 years 144/252 (57%) lost to follow-up	12 months	60 months At 5 year 3/20 (15%) lost to follow-up
Mean pre-op BMI (kg/m^2)	31.0 ± 2.9		32.7	32.7 ± 1.6		32.20 ± 1.43	33.4 ± 1.217
Mean pre-op HbA1c	10.1 ± 2.2		8.1 .07	8	≤ 7	8.04 ± 1.30	8.7 ± 1.61
Mean FBS	240.1 + 80.9		139.5 3.5				171.1 ± 56.8
Change in BMI	31.1 to 24.6	33.8 to 25.0	32.7 to 21.1	32.7 to 24.5	32.3 to 25.1	32.2 to 23.5	33.4 to 27.4
%EWL at 1 year	70.4 ± 18.5				98.42	94.61 ± 13.27	63.21
%EWL at 2 years				86.1 ± 30.6			76.60
%EWL at 3 years					75.79%		83.92
%EWL at 5 years							73.01
Diabetic remission rate	At 1 year 10/20 (50%)		At 1 year 8/9 (88%)	At 2 years 9/11 (82%)	At 3 years 60%	At 1 yr 88.55	At 5 years 9/17 (52.94%)
Weight regain							1/17 (5.88%)

EWL excess weight loss, *BMI* body mass index, *FBS* fasting blood sugar

Percentage of weight loss was similar in the two groups, but mean HbA1c at 5 years was lower in patients undergoing OAGB (6.1 ± 0.7%) compared to those having LSG (7.1 ± 1.2%). Significant higher percentages of patients were on OHA 5 years after LSG (62.5%) compared to OAGB (16.7%). Insulin resistance, measured by homeostasis model assessment (HOMA) index, was significantly lower in both groups compared to baseline and comparable between the two groups at 5 years. Although better glycaemic control and higher incretin effect were observed after OAGB, serum iron levels were significantly lower in these patients compared to those who underwent LSG. The authors have suggested that LSG may be considered in the subset of patients who have good islet cell preservation and high C-peptide levels. Notably, mean HbA1c level at 5 years in our study was 6.6 ± 0.7%, lower than that in the LSG group in this study. Almost 53% patients in our study had HbA1C less than 6.5% at 5 years, compared to 30% in the study by Lee et al.

In the STAMPEDE trial [16], 150 patients with BMI 27–43 kg/m^2 (36% had BMI 27–34 kg/m^2) were randomised in a 1:1:1 ratio to three groups—intensive medical therapy (IMT) alone, IMT + RYGB and IMT + sleeve gastrectomy (SG). Of the patients who completed the 5-year follow-up, HbA1c < 6% was achieved in 14 of 49 (29%) patients in RYGB and 11 of 47 (23%) patients in SG group; the difference was not significant. Reduction in HbA1c was similar among patients with class I obesity and those with higher BMI. However, the percentage of patients off OHA/insulin was significantly higher in the RYGB group compared to SG group.

Seki et al. [17] have published 5-year outcomes of 118 Japanese patients who underwent LSG for class I obesity. Of these, 41 (34.7%) patients had T2DM before surgery. T2DM remission (HbA1c < 6.5% without medication) was seen in 91% patients at 1 year, 93% at 3 years and 60% at 5 years. However, this was a retrospective study, and follow-up was only 38.6% at 5 years. Nine (22%) patients were diagnosed to have T2DM during pre-operative evaluation, and 15 (37%) had only mild diabetes, which was being managed with dietary restriction. Thus, these results need to be interpreted with caution.

In a meta-analysis of four RCTs comprising 296 patients with T2DM and non-severe obesity, Sha et al. [18] found comparable T2DM remission rates after LSG (56.7%) and RYGB (54%). Mean FPG and HbA1c after these two procedures were comparable. However, the studies were heterogeneous with follow-up varying from 24 to 60 months, and both partial and complete remission were considered for the meta-analysis, due to varying definitions of remission in the individual studies.

In a meta-analysis of 13 studies, Li et al. [19] studied the metabolic effects of bariatric surgery in 357 patients with T2DM and class I obesity. Bariatric surgery led to reduction of mean BMI by 5.2 kg/m^2, of mean HbA1c by 2.6% and of mean FPG by 4.8 mmol/L (86.4 mg/dL). HbA1c below 6% was achieved in 66% of patients, which is higher compared to our study. In our study, although mean BMI reduction was 6 kg/m^2, decreases in HbA1c and FPG were lower—2.1% and 60 mg/dL, respectively—at 5 years. This difference can be explained by the fact that majority of the patients included in this meta-analysis underwent diversional procedures including bilio-pancreatic diversion, duodeno-jejunal bypass and one anastomosis gastric bypass, which have their own long-term nutritional complications. Notably, the meta-analysis included 69 patients from a study by De Paula et al. [7] who underwent diverted sleeve gastrectomy with ileal interposition. Mean HbA1c reduction in these patients was 2.8%, which was comparable to the overall mean HbA1c reduction.

Excellent long-term remission of T2DM after RYGB was reported by Cohen et al. [20]. The authors prospectively studied 66 patients with class I obesity for up to 6 years (median 5 years, range 1–6 years) following RYGB. Diabetes remission, defined as HbA1c < 6.5% without any anti-diabetic medication, was observed in 88% patients. Mean HbA1c decreased from 9.7 ± 1.5% to 5.9 ± 0.1%. Results from the prospective studies by Lee et al. and Cohen et al. suggest that gastric bypass (OAGB or RYGB) may have a more profound impact on diabetes remission than SG in patients with class I obesity. However, these procedures are known to have more long-term nutritional complications, higher risk of internal herniation and a greater need for stringent follow up [21, 22]. Sleeve gastrectomy has several advantages over gastric bypass. It is technically simpler and has a shorter learning curve, and long-term nutritional deficiency is rare as the integrity of the gastrointestinal tract is not disturbed [23]. Immediate postoperative complications are also less in SG compared to RYGB or OAGB. Feng et al. [24] collected data of primary bariatric procedures in patients with class I obesity from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program for 2015–2016. LSG was done in 6243 patients and RYGB in 1838 patients, highlighting the vast popularity of LSG. Composite morbidity (defined as presence of any of 24 pre-defined postoperative adverse events) was significantly less after LSG (2.9%) compared to RYGB (7.8%). Incidence of blood transfusion, unplanned ICU admission, 30-day reintervention, reoperation and readmission were all significantly lower after LSG than RYGB. Better safety profile of LSG makes it a more favoured procedure by many surgeons and patients. In a similar study, data of bariatric procedures performed on patients with T2DM and BMI of 25–35 kg/m^2 was collected from the American College of Surgeons National Surgical Quality Improvement Program. More patients had undergone RYGB ($n = 702$) compared to LSG ($n = 341$). Composite morbidity (presence of any of 16 pre-defined major adverse events) was 5.1% after RYGB versus 3.5% after LSG; however, the difference was

not significant. Thirty-day serious morbidity (Clavien Dindo grade 4/5) was also not significantly different between RYGB (0.7%) and LSG (0.3%).

Sleeve gastrectomy is primarily a resectional bariatric procedure. Although it does not involve any alteration of intestinal anatomy, it has been found to cause significant improvement of glycaemic status in the short term [25], which occurs by both weight-dependent and weight-independent mechanisms. In the immediate post-operative period, even before any significant weight loss, improvement in plasma glucose levels occurs because of increased insulin sensitivity and improved beta cell function, leading to marked improvement in the early phase of insulin release, which is usually defective in patients with T2DM [26, 27]. Sleeve gastrectomy also leads to marked increase in incretin levels like glucagon-like peptide-1 (GLP 1), peptide YY (PYY) and oxyntomodulin (OXM), with significant reduction of ghrelin and leptin levels [3]. However, variation in metabolic response is common among patients due to differences in baseline HbA1c and C-peptide levels, duration of diabetes and requirement of OHA/insulin, all of which have been known to affect impact of bariatric surgery on diabetes remission [8]. Duration of diabetes and pre-operative glycaemic control are important determinants for metabolic success of bariatric surgery [28]. In our study, patients with shorter duration of diabetes and lower baseline FPG had significant higher remission rates.

Our study is limited by a small sample size and the lack of any control arm. However, it has an impressive 5-year follow-up rate of 85% and would be a valuable addition to the scanty literature on long-term impact of sleeve gastrectomy on T2DM in patients with class I obesity. While RYGB or OAGB are more established as metabolic procedures in this subset of patients, our study shows that LSG may also lead to satisfactory glycaemic control in the long term, and can be a useful addition to the armamentarium of bariatric surgeons performing metabolic surgery in patients with non-severe obesity. The addition of LSG as a standard metabolic procedure will provide more options to patients with T2DM and class I obesity, who do not wish to undergo a diversional procedure. However, further studies with larger sample size and longer follow-up are needed to establish sleeve gastrectomy as a standard of care in these patients.

Conclusion

In patients with class I obesity and T2DM, LSG results in significant improvement in glycaemic control at 5 years.

Author Contributions Devender Singh - Acquisition and analysis of data, drafting and final approval of manuscript.

Aditya Baksi - Design of work, interpretation of data, drafting and final approval of manuscript.

Prasanna Ramana - Acquisition of data, drafting and final approval of manuscript.

Vitish Singla - Analysis of data, drafting and final approval of manuscript.

Sandeep Aggarwal - Conception and design of work, critical revision and final approval of manuscript.

Declarations

The study was undertaken after clearance from institutional ethical committee. There was no commission or omission of intervention for the study purpose, and all the interventions were done in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.
A written informed consent was taken from each patient for the surgical procedure.

Conflict of Interest The authors declare no competing interests.

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