## CLINICAL REPORT

# Impact of Laparoscopic Sleeve Gastrectomy and Laparoscopic Gastric Bypass on HbA1c Blood Level and Pharmacological Treatment of Type 2 Diabetes Mellitus in Severe or Morbidly Obese Patients. Results of a Multicenter Prospective Study at 1 Year

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Abstract Gastric bypass (GBP) has proved its efficacy 30 years ago in the management of diabetes mellitus (T2DM) for severe obese patients. More recently, interesting results have been published after sleeve gastrectomy (SG) in the same indication. Between 2005 and 2008, three bariatric centers have prospectively collected the data of T2DM patients treated by laparoscopic gastric bypass (LGBP) or laparoscopic sleeve gastrectomy (LSG). Effects on hemoglobin A1c (HbA1c), pharmacological treatment and excess weight loss after 1 year of surgery have been analyzed. All patients (35 LGBP and 33 LSG) were treated with oral anti-diabetics (OAD) or insulin before surgery (32

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OAD and three insulin in LGBP group and 27 OAD and six insulin in LSG group). The average body mass index (BMI) in the LGBP group was 47.9 and 50.6 kg/m<sup>2</sup> in the LSG group. At 1 year after surgery, the average HbA1c lost was 2,537 in the GBP group and 2,175 in the SG group. T2DM had resolved (withdrawal of pharmacological treatment) in 60% of the LGBP group and 75.8% of the LSG group. Reduced use of pharmacological therapy was noted in 31.42% of the LGBP group and 15.15% of the LSG group. Percentage excess weight loss and BMI lost were 56.35% and 29.75% in the LGBP group and 60.11% and 29.80% in the LSG group, respectively. During short-term follow-up, the impact on regulation of HbA1c blood level of LGBP or LSG is important. At 1 year after surgery, LSG seems to be as effective as LGBP for the management of T2DM in severely obese patients.

## Background

Type 2 diabetes mellitus (T2DM) is a well-known disease linked to severe obesity. In France, around 20% of patients who have undergone bariatric procedures to treat morbid obesity suffer from T2DM [1]. The resolution or improvement of T2DM after bariatric procedures has been emphasized in many studies [2]. Gastric bypass (GBP) has proved its efficacy for 30 years in this respect [3]. More recently, sleeve gastrectomy (SG) has been validated as a sole restrictive bariatric procedure [4]. Excellent results have been presented in terms of excess weight loss and improvement of comorbidities linked to obesity in shortand medium-term follow-up. Rapid resolution or improvement of T2DM may be found in 65–85% of patients in short-term follow-up, even if a duodeno-jejunal shunt is not created during this procedure [5, 6]. The explanation of such a positive result remains unclear because it is not solely correlated to weight loss. It seems sensible to consider LSG as a restrictive and metabolic procedure. This French multicenter prospective study, carried out by three French expert bariatric teams, aims to compare the impact of laparoscopic gastric bypass (LGBP) and laparoscopic sleeve gastrectomy (LSG) on HB1Ac level and improvement of pharmacological treatment of T2DM patients.

## Methods

Between 2005 and 2008, three French expert bariatric centers prospectively collected data of T2DM patients with a body mass index (BMI) >35 kg/m<sup>2</sup>, who have undergone laparoscopic gastric bypass (35 patients) or laparoscopic sleeve gastrectomy (33 patients).

The indications for these procedures were:

 severe (BMI >35 kg/m<sup>2</sup>) or morbid (BMI >40 kg/m<sup>2</sup>) obese patients with type 2 diabetes mellitus (DM) who fulfilled the criteria of the NIH consensus for bariatric surgery.

The specific contra-indications for LSG were represented by severe inflammation of the esophagus (Barrett's disease) or of the stomach, and the presence of gastric ulcers or bowel disease for LGBP group. The choice of the procedure was made in agreement with the patients after consultation of the multidisciplinary staff. Written informed consent was obtained from all participants. Standard preoperative evaluations for these patients were performed by a multidisciplinary team (endocrinologist, nutritionist, psychologist, and anesthesiologist) 4-8 months prior to the procedure. During the consultation, blood tests were performed to check the level of hemoglobin A1c (HbA1c) and thus evaluate the efficacy of pharmacological treatment. After the procedure, all patients underwent medical follow-up during a 1 day hospitalization at 12 months to evaluate effectiveness of the procedure. The evaluation of weight, morbidity, HbA1c blood level, and evolution of pharmacological agents, was prospectively collected.

Technical Aspects of the Procedures

#### Laparoscopic Sleeve Gastrectomy

The LSG was standardized among the four different surgeons as described by our team. The first step of the procedure is the dissection of the gastro-colic ligament in vicinity of the stomach and as such to enter the lesser sac. The dissection along the greater curvature starts 6–8 cm from the pylorus and progresses towards the angle of His. A calibration tube of 36 French is placed trans-orally along the lesser curvature to perform a controlled vertical gastrectomy. The transection is parallel to the lesser curvature in contact to the calibration tube. It requires staplers (green or gold) capable of stapling the thick tissue of the stomach to prevent dehiscence of the stapling line. The stapling line is checked for leakage by injecting methylene blue through the gastric tube. All the patients received peri-operative deep vein thrombosis prophylaxis using low-molecular weight heparin.

Postoperative care: 2 days after the procedure, a barium swallow was performed to exclude fistulae on the staple line or stenosis. When the sleeve gastrectomy is confirmed watertight, the patient is commenced on a liquid diet for 1 week and semi-liquid for 1 month. The patient is mobilized on first postoperative day, initially to a chair.

## Laparoscopic Gastric Bypass

The LGBP was standardized among the four different surgeons. A vertical gastric pouch is created on the lesser curvature of the stomach (5 cm from the oesophago-gastric junction) with a linear stapler (Echelon Gold cartridges), then a Roux en Y limb is created 50 cm from the Angle of Treitz and put in an antecolic position. A side-to-side jejuno-jejunostomy is created using linear stapler (white cartridges) at 100 cm from the gasto-jejunostomy (side-to-side anastomosis using linear stapler) for patients with a BMI <50 kg/m<sup>2</sup> or 150 cm for those with a BMI >50 kg/m<sup>2</sup>. Closure of the mesenteric defects is performed at the end of the procedure.

#### Statistical Analysis

The baseline characteristics of patient are described in each group (Tables 1 and 2) and then compared between LGBP and LSG. At 1 year after surgery, the efficacy of these two surgical procedures was compared. For univariate analysis of categorical variables, chi-square and Fisher's exact tests were carried out. The Mann–Whitney U test was used for comparisons of continuous variables. The main criteria of efficacy was a composite criteria defined by a level of HbA1c <7 or improvement/withdrawal of pharmacological treatment (oral antidiabetic agent or insulin). The resolution of T2DM was defined by the stop of medical treatment and HbA1c level <7. Each of these three parameters was compared between the two groups. To identify if baseline characteristics as HbA1c level, age of patients, BMI

Table 1 Patients characteristics: LSG group

Variable	n	Mean	Min	Median	Max	P value
Age	33	46,490	23,200	47,180	64,890	SW, <i>p</i> =0.461
Preop weight	33	139,364	90,000	132,000	240,000	SW, <i>p</i> =0.025
Preop BMI	33	50,618	36,731	48,488	76,606	SW, <i>p</i> =0.062
Duration of T2DM (year)	33	6,727	0.000	6,000	31,000	SW, <i>p</i> <0.001
Preop HbA1c level	33	7,879	5,700	7,600	11,000	SW, <i>p</i> =0.059

duration of diabetes could predict the surgery efficacy, the relationship between withdrawal of diabetic treatment or the proportion of patients with HbA1c level <7 and these characteristics were also analyzed. In all the statistical tests, the level of significance alpha was 0.05. The SAS package version 8 was used (SAS Institute, Cary, NC, USA, 1989).

## Results

Baseline characteristics of the patients are presented in Tables 1 and 2.

Thirty-three patients with T2DM (63.6% women) with an average age of 46.49 years (23.2-64.89) underwent LSG and 35 patients with T2DM (80% women) with an average age of 47.51 years (29.9-67.7) underwent LGBP. Preoperative BMI was 50.618 kg/m<sup>2</sup> in the SG group (48.5% of superobese) and 47,921 kg/m<sup>2</sup> (25.7% of superobese) in the GBP group There were more superobese patients in the LSG group due to the possibility of two steps procedure (conversion to LGBP or LDS; p=0.051).

All procedures were performed under laparoscopic approach in the SG group; but in one case of the LGBP group, a conversion in laparotomy was performed due to technical difficulties. The average length of hospital stay was 4.875 days in LSG group and 5.314 days in the LGBP group (Table 3).

There was no mortality in this series, for either group. The peri-operative morbidity rate was 2.9% in the LSG group and 5.8% in the LGBP group. One patient in the LSG group (2.9%) was reoperated for the management of a gastric leakage diagnosed at day 2 after surgery. A reinforcement of the staple line (sutures) and abdominal drainage was performed by laparotomy. In the LGBP group, there was one case of gastric leakage treated by radiological drainage, and one case of jejuno-jejunostomy stenosis which was reoperated at day 3 (Table 4).

At 1 year after surgery, the excess weight loss following LSG (60.12%) was comparable to that following LGBP (56.35%). The percentage of BMI lost was 29.75% in the LGBP group and 29.80% in the LSG group.

All patients were treated with OAD or insulin before surgery (32 OAD and three insulin in LGBP group and 27 ADO and six insulin in LSG group). The Hb1ac level was <7 in 30.7% of patients of the LSG group and 31.4% of the LGBP group. Duration of DM was 6.27 years (>1 year for 63.6% of the patients) in LSG group and 7.71 years in the LGBP group (>1 year for 97.1% of the patients). Arterial hypertension was diagnosed in 54.5% of LSG subjects and 44.1% of LGBP subjects. The clinical and biological characteristics of patients were compared for BMI level, T2DM duration, Hb1Ac level, and T2DM treatment. No significant difference was been found between the two groups (Table 5).

At 1 year after surgery, there was no lost to follow-up of patients. Efficacy of surgery (withdrawal or diminution of medical drugs or HbA1c level <7) was found in 100% of GB group and 93.94% (31/33 patients) of the SG group (p=0.23). T2DM had resolved (withdrawal of the medical treatment) in 21 patients (60%) of the GBP group and 25 patients (75.8%) for the SG group. The mean of HbA1c decrease was 2,537 in the GBP group and 2,175 in the SG group. The number of patients who had an HbA1c level >7 move from 24 to four in the GBP group and from 23 to four in the SG group. No statistical differences were found between the type of surgery in terms of efficacy on HbA1c level (p=0.552) and upon evolution of the pharmacological treatment (p=0.231). The preoperative level of HbA1c has been found to be correlated to withdrawal of treatment. Better results were found for patients that had an HbA1c level <7 with pharmacological

Table 2Patients characteristics:LGBP group	Variable	п	Mean	Min	Median	Max	P value
	Age	35	47,519	29,900	47,810	67,700	SW, <i>p</i> =0.927
	Preop weight	35	131,400	90,000	130,000	174,000	SW, <i>p</i> =0.860
	Preop BMI	35	47,921	37,461	48,199	63,692	SW, <i>p</i> =0.191
	Duration of T2DM (year)	35	7,771	0.000	6,000	29,000	SW, <i>p</i> <0.001
	Preop HbA1c level	35	8,186	5,900	7,700	13,300	SW, <i>p</i> =0.001

**Table 3** Evolution of HbA1Clevel 1 year after surgery

Variable	Type_of surgery	п	Mean	Min	Max	P value
HbA1c postop	LGBP LSG	35 33	5,649 5,704	4,800 3,900	9,100 9,900	0.918
HbA1c unit decrease	LGBP LSG	35 33	-2,537 -2,175	-6,300 -4,600	-0,400 -0,700	0.552

agent before surgery (p=0.037), though no difference was found with regard to age, gender, BMI, or duration of diabetes. Furthermore, no correlation was noted between EWL and unit of HbA1c lost (p=0.681). Specific evaluation of patients who were not treated by insulin before surgery is described in Table 6. Same conclusions are emphasized (p=0.457).

#### Discussion

LGB and LSG are two bariatric procedures approved for the management of morbidly obese patient [1]. Both procedures are effective in terms of weight loss in shortand mid-term follow up. They can reach an average of 50-80% excess weight loss [1]. In the long term, results are less successful for LGB (60%) [1, 7] and still unknown for the LSG due to the lack of data. In France, around 20% of obese patients who undergo bariatric procedures present with T2DM before surgery [1]. Not surprisingly, improvement or resolution of this complication has been emphasized in many international studies [1, 4, 5, 8–15]. The impact of LGB on T2DM has been first reported by Pories many years ago [3]. In its comparative trial, SOS Study has confirmed the impact of bariatric procedures in the improvement of T2DM [4]. However, mechanisms of action are still unknown. The variation in incretins level, may potentially be explained by several mechanisms: duodenopancreatic shunt, exclusion of the fundus to the alimentary tract that decrease, in the short term, ghrelin secretion or rapid arrival of the meal in the distal part of the ileum that leads to an increase of the GLP1secretion [14, 15]. These incretin variations promote a decrease of insulin resistance and increase insulin secretion. The LSG is a more recent procedure that consists of removing 2/3 of the stomach by longitudinal partial gastrectomy. This operation

Table 4Percentage of patient with HbA1c level <7 before and after</th>surgery

	Hb1Ac	LGBP (%)	LSG (%)	P value
Preop HbA1c	HbA1c <7 HbA1c >7	31.43 68.57	30.30 69.70	0.920
Postop HbA1c	HbA1c <7 HbA1c >7	88.57 11.43	87.88 12.12	1.000

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has been approved by the French Health Ministry since the H.A.S report in 2008 as a sole restrictive procedure [5]. Though an intestinal shunt is not created during this procedure, hormonal variations (ghrelin, GLP1, PYY) have been described and may explain the impact of LSG on glucose regulation [15, 16]. Fundus resection (location of ghrelin secretion) and more rapid gastric emptying may be explanations for this finding. However, the current most efficient procedure to treat T2DM in morbidly obese patient is still biliopancreatic diversion, with or without duodenal switch (BPD/DS). BPD is not popular due to higher rates of mortality and morbidity, but all the trials emphasized its efficacy in this indication [1, 2]. The LAGB is the less invasive procedure, but is less efficacious in terms of resolution of T2DM. Using publications from 1990 to 2006 for his recent meta-analysis, Buchwald observes a T2DM cure for 56.7% of patients who underwent LAGB, stable for a long time (55% before 2 years of treatment and 58.3% after 2 years) [2]. These results are not as good as those of the GBP (80.3%) or of the BPD/DS (95.1%). Results concerning the LSG have not been described due to only recent use of this procedure for this indication. Surprisingly, Dixon [17], in his prospective randomized study described a higher rate of resolution of T2DM with LAGB, compared to medical therapy. Seventy-three percent of cases in surgical group after 2 years and only 13% in the drug treatment group had resolution of T2DM in this study. However, the preoperative level of HbA1c was low compared to other studies (average, 7.8% in the surgery group). Our study has reported the correlation between the level of HbA1c and the T2DM resolution (better results was found for patients that had an HbA1c level <7 before surgery; p=0.037). This point may be the explanation of good results in the above trial. Intermediate results were reported by Parikh after bariatric surgery in 282 diabetic patients (218 LAGB, 53 LGBP, and 11 DBP/DS). The percentage of excess weight loss was 43% and 50% after 1

Table 5 Resolution of T2DM at 1 year of surgery

Resolution of T2DM (stop medical treatment)	LGBP (%)	LSG (%)	P value
No	31.5 (1/3 insulin)	28 (3/6 insulin)	0.3876
Yes	68.5	72	

 Table 6
 Evolution at 1 year of the medical treatment, in non insulin patients

	LGBP (32 patients; %)	LSG (28 patients; %)	P value
Stop of the treatment	21 (65.69)	22 (81.48)	0.313
Decrease of treatment	9 (28.13)	3 (11.11)	
No change	2 (6.25)	2 (7.41)	

and 2 years for LAGB, respectively. After 1 and 2 years, the rate of patients still using antidiabetic agent were 39% and 34% for the LAGB. After 1 and 2 years, the rate of patients treated by insulin was 14% and 18% for the LAGB. LAGB seems to be a less-efficient procedure to treat T2DM in obese patient [18]. Furthermore, no variation of incretin levels has been described with this procedure. Concerning LSG, mid-term studies have been published about the effect of this procedure on T2DM resolution. In his comparative study with LGBP (39 LSG/52LGBP), Vidal found a similar effectiveness between both procedures at 1 year (84.6% T2DM cure) [7]. Moreover, Silecchia has described T2DM resolution in 69.2% and an improvement in 15.4% at 12 months and 76.9% and 15.4% at 18 months in superobese patients after LSG [13]. The bariatric center of Montpellier Hospital has prospectively collected the data of T2DM patients that underwent LSG or LGBP. The comparison of the two groups of patients in terms of HbA1c blood level and treatment of type 2 diabetes mellitus has found the same results of Vidal, Sillechia and Abbatini [6, 7, 13]. LSG seems to be a very effective procedure to withdraw or enhance the pharmacological treatment of T2DM patients at 1 year. Moreover, no statistical difference was found between the type of surgery in terms of HbA1c level state change (p=0.552) and evolution of the pharmacological treatment (p=0.231) No difference was found if we analyze the age, gender, BMI, and duration of diabetes. Furthermore, no correlation has been found between the EWL and the unit of HbA1c lost (p=0.681), which emphasizes the impact of hormonal effect in glucose regulation. Moreover, in his retrospective study, Rosenthal presents the results at 2 and 6 months of 30 patients with T2DM who had undergone LSG [9]. Twentytwo patients (73%) had been taking medications for T2DM preoperatively. Resolution of T2DM was observed in 27% at 2 months and 63% at 6 months of follow-up. Glycosylated hemoglobin decreased from  $6.36\pm0.82$  (n=14) preoperatively to  $6.02\pm0.57$  (*n*=11) at 2 months and to  $5.92\pm0.33$  (*n*= 12) at 6 months after surgery. Patients with a shorter duration of DM (<5 years) and better weight loss after surgery achieved greater resolution rates. These points have not been found in our study. A comparative study between LAGB with partial gastrectomy (27), LSG (53), and LAGB (100) has been carried out by Frezza [10]. At 12 and 18 months. LSG had higher EWL (P < 0.05) and lower blood glucose level (P < 0.05) than either type of LAGB. The conclusion was that LSG provides better weight loss and glucose control at 1 and 1.5 years after surgery than LAGB, suggesting that gastric fundus resection plays an important, though not yet well-defined, role. Shah [11] has evaluated the impact of LSG on glycemic control in obese Indians patients with T2DM. Rapid resolution of T2DM has been noted. At 1 month after surgery, 81.2% of patients have stopped their antidiabetics medications. 100% of improvement and 96.2% of resolution are reported at 1 year. The rapid resolution of T2DM seems to be due to many changes in incretin hormonal regulation. In his randomized, prospective, parallel group study, Peterli has evaluated the effects of laparoscopic Roux-en-Y gastric bypass and LSG on fasting, and meal-stimulated insulin, glucose, and glucagon-like peptide-1 (GLP-1) levels. Body weight and body mass index decreased markedly (P < 0.002) and comparably after either procedure. Excess BMI loss was similar at 3 months (43.3± 12.1% vs. 39.4±9.4%, P>0.36). After surgery, patients had markedly increased postprandial plasma insulin and GLP-1 levels (P < 0.01) after both of these procedures, which favor improved glucose homeostasis. Compared with LSG, LGBP patients had early and augmented insulin responses as early as 1 week postoperative, potentially mediating improved early glycemic control. After 3 months, no significant difference was observed with respect to insulin and GLP-1 secretion between the two procedures. The author concluded that these results do not support the idea that the proximal small intestine mediates the improvement in glucose homeostasis [12]

## Conclusion

LSG and LGBP have demonstrated an unquestionable efficiency in the T2DM treatment of morbidly obese diabetic patients. The mechanism of action of these procedures remains unclear. However, even if weight loss is a part of the explanation, incretins seem to play a major role in the glucose homeostasis. BPD is the most efficient operation to treat T2DM, but LSG and LGBP lead to a lower rate of morbidity and mortality. This is a key point, and to choose the type of procedure after multidisciplinary discussion with the patient. After the analysis of our study, the three French bariatric teams have decided to propose LSG or LGBP, as the treatment of choice for the management of morbidly obese patients with T2DM. This is mainly due to the higher failure rate of LAGB with time, and excellent results of LSG and LGBP emphasized in many studies. However, the impact of LSG on glucose regulation has yet to be confirmed in long-term evaluation.

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