

# Bariatric surgery and the perioperative management of type 2 diabetes: Practical guidelines

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#### **TITLE PAGE**

#### **English title:**

Bariatric surgery and the perioperative management of type 2 diabetes: practical guidelines.

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T2D: perioperative management

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Bariatric surgery and the perioperative management of type 2 diabetes: practical guidelines

#### Summary

*Background*: Metabolic surgery is now considered as a therapeutic option in type 2 diabetes (T2D). However, few data are available regarding perioperative management of T2D.

Objectives: To assess current practice among bariatric teams regarding perioperative management of T2D in order to propose guidelines.

Methods: A two-round Delphi method using online surveys was employed among bariatric teams experts (surgeons, diabetologists, anesthetists, nutritionists): first round, 63 questions covering 6 topics (characteristics of experts/teams, characteristics of patients, operative technique, pre/postoperative management, diabetes remission); second round, 44 items needing clarification. They were discussed within national congress of corresponding learned societies. Consensus was defined as ≥ 66 % agreement.

#### Results:

A total of 170 experts participated. Experts favored gastric bypass to achieve remission (76.7 %). Screening for retinopathy, cardiac ultrasound, and reaching an HbA1c < 8 % are required in the pre-operative period for 67 %, 75.3 % and 56.7 % of experts, respectively. After surgery, insulin pump should not be stopped, basal insulin should be halved, and bolus insulin should be stopped except if severe hyperglycemia. DPP-IV inhibitors and metformin are preferred after surgery. Patients should be seen by a diabetologist within one month if on oral antidiabetic agents (71.8 % of experts), 2 weeks if on injectable treatments (77.1 % of

experts), and immediately after surgery if on insulin pump (93.5 % of experts). Long-term monitoring of HbA1c is necessary even if diabetes remission (100 %).

# Conclusion:

Rapid postoperative modifications of blood glucose require a close monitoring and a prompt adjustment of diabetes medications.

Key words:
Metabolic surgery
Diabetes
Guidelines
Bariatric surgery
Key points:
Management of type 2 diabetes before and after bariatric surgery requires the following:
Recent ophthalmoscopy and cardiac ultrasound before surgery
Monitoring of glucose capillary levels in the immediate postoperative period
Adjustment of insulin treatment made by diabetologist
Use of metformin and DPP-4 inhibitors if a non-insulin glucose lowering treatment is
required
HbA1c tested every 6 months even in case of diabetes remission

#### Introduction

evolution from bariatric surgery to metabolic surgery [1, 2]. Recent randomized control trials have demonstrated its metabolic efficiency in Type 2 Diabetes (T2D)[3], and surgery now aims not only to achieve weight loss, but also to improve glycemic control in this population. Metabolic surgery is now considered as a new therapeutic option in T2D severe obese patients with poor glycemic control. Accordingly, following the Diabetes Surgery Summit II, Rubino et al published in 2016 a joint statement endorsed by International Professional Societies regarding metabolic surgery in the treatment algorithm for T2D[4]. In spite of the increasing number of bariatric procedures among patients with type 2 diabetes, there are no specific recommendations concerning the perioperative management of these patients. In 2013, the American Association of Clinical Endocrinologists in association with the American Society for Metabolic and bariatric Surgery published clinical practice guidelines for the perioperative nutritional, metabolic and nonsurgical support of bariatric surgery patients. Nevertheless, their recommendations regarding management of T2D treatments immediately after bariatric surgery were rather vague[5]. In 2015, Machnica et al. issued recommendations about glycemic control for inpatients and post-discharge diabetic patients benefiting from bariatric surgery, but other aspects of patients' care were not addressed [6]. In 2016, the French anesthetist scientific society (SFAR), in association with the Francophone Diabetes Society (SFD) published guidelines regarding perioperative management of patients with diabetes[7]. However these guidelines do not consider the specificities of bariatric surgery. In the practical recommendations issued by the Task Force of the European Association for the Study of Obesity in 2017, pre-surgery assessment of

We have been witnessing a paradigm shift in the surgical treatment of obesity, with an

diabetes complications is not addressed and no specific recommendations according to the surgical technique are made.[8]

Undoubtedly, bariatric surgery in T2D patients raises several specific concerns. Glycemic homeostasis is rapidly and profoundly modified following bariatric surgery. These changes occur early, in the first days following surgery, especially after gastric bypass[9]. In addition, management of diabetes medications in the post-operative period must take into account the important inter and intra individual variations of postoperative evolution of glycemia. Finally, the rapid shift towards lower glycemic values can worsen microvascular complications[10, 11].

To tackle these issues, the French Society of Bariatric and Metabolic Surgery (SOFFCO-MM) and the SFD jointly sought to describe current expert practices in the management of T2D patients, candidates for bariatric surgery, before and after the bariatric procedure. The aim was to lead to a consensus of experts in the field, regarding adequate preoperative evaluation, diabetes treatment management and long-term follow-up modalities of these patients.

#### **Methods**

A Delphi method[12] was employed among a panel of bariatric teams experts (surgeons, diabetologists, anesthetists, nutritionists) selected within and without the SOFFCO-MM and the SFD. Were considered expert bariatric teams those who had the label of the French National Authority for Health (HAS) as well as bariatric teams performing more than 100 procedures per year.

Two online anonymous surveys were created using *Survey Monkey®* tool. The first round was made of 63 closed questions divided into 6 topics: *characteristics of the experts and their bariatric team, characteristics of operated patients, choice of the operative technique for T2D patients, pre/postoperative T2D management and diabetes remission. Detailed questions are reported in tables 1-4. Experts had one month to answer the online questionnaire and data were collected at the beginning of May 2017. In accordance with the Delphi method, the survey was presented to the attendees of the 2017 national congress of the SOFFCO, who were submitted the same questions, with anonymous electronic voting with instantly visible answers during an interactive session.* 

The second survey was adapted from the first one (detailed questions reported in tables 1-4). Questions with agreement over 66 % and no commentaries were no longer open to voting from the experts; questions with balanced answers or which elicited commentaries were rephrased in order to obtain a clarified input. The new set of questions was made of 44 selected items divided into 5 of the 6 first topics (remission of T2D treatments had been satisfactorily answered after the first round). Again, experts had one month to answer the online questionnaire and data were collected at the beginning of March 2018. This round was presented to the attendees of the 2018 national congress SFD, who were submitted selected questions, with anonymous electronic similar to the previous round.

Data are reported as percentage of usable responses. Consensus was defined as > 66 % agreement among responders[13].

#### **Results**

Characteristics of the experts and their bariatric teams (Table 1)

A total of 170 experts completed the online questionnaires (first round: 106, second round: 64) and 353 congress attendees participated in the electronic votings (first voting: 132, second voting: 221). The fields of the experts (bariatric surgeons, diabetologists, anesthetists and others) and their characteristics are presented in Table 1. Sixty one percent of the teams performed more than 100 procedures per year and 80.6 % have 2 or more bariatric surgeons in the team.

# Characteristics of operated patients (Table 2)

Mean preoperative BMI was over 40 kg/m² for a vast majority of expert teams (96.1 %). T2D patients represented more than 20 % of the recruitment for 47.6 % of the teams. Experts considered that poorly controlled and insulin resistant diabetes (94.6 %) but also recent diabetes (89.9 %) can benefit from metabolic surgery.

#### Choice of operative technique (Table 2)

Experts favored Roux-en-Y gastric bypass (RYGB) over sleeve gastrectomy in order to obtain T2D remission (76.7 %). However, the benefit/risk ratio of sleeve gastrectomy vs gastric bypass was considered acceptable for only 57.8 % of the experts.

#### Pre-operative management (Table 2)

In the preoperative period, more than two third of the experts endorsed that screening for retinopathy (67 %) and cardiac ultrasound (75.3 %) should be performed, while exercise test did not reach consensus (54.7 %). Only 65.4 % of the experts consider that a predetermined level of HbA1c value should contra-indicate surgery. There was no consensus concerning which HbA1c threshold should be set. In particular, 43.3 % considered acceptable to operate patients with HbA1c values above 10 %.

There was a large consensus between the experts and the SFAR/SFD recommendations concerning the management of hypoglycemic compounds in the pre-operative state. Metformin is stopped earlier than other oral hypoglycemic compounds: 48 hours or 24 hours before surgery for 26.4 and 36.3 % of experts, respectively. Other oral hypoglycemic compounds are stopped the morning of the surgery for 67.4 % of experts. The experts stopped Glucagon-like peptide-1 (GLP-1) receptor agonists 24 hours before the surgery (45%) or the day of the surgery (25%). Fast-acting insulin and long-acting insulin are stopped in the morning of the surgery for respectively 60% and 45% of the experts. Answers of experts concerning the management of sub-cutaneous insulin pump therapy did not reach consensus.

#### Postoperative management (Table 3)

Survey 1 showed that for 90.6 % of experts, patients should be addressed to a diabetologist no later than the 1rst post-operative month (44.3 % before discharge, 12.3 % within 2 weeks and 34 % within 1 month). Survey 2 clarified the delay according to diabetes treatment: less than one month if on oral antidiabetic agents (71.8 %) and less that 2 weeks if on injectable treatments (77.1 %). In both surveys, there was a very high consensus for seeing a diabetologist immediately after surgery in case of insulin pump therapy (93.5 %).

For 97.2 % of the experts, patients can be addressed to their general practitioners instead of a diabetologist in case of mild diabetes. Self-monitoring of blood glucose (SMBG) should be performed in the postoperative period but no consensus was reached about the duration of this monitoring.

Concerning postoperative management of T2D treatments, there was a high consensus in the followings: insulin pumps should not be stopped, basal insulin should be halved, and prandial insulin should be stopped except in case of severe hyperglycemia.

For non-insulin treatments, the first round showed a consensus in stopping sulfonylureas in the immediate post-operative period (93.6 %), but balanced responses about maintaining metformin and incretin mimetics. Therefore questions were clarified in the second round by 1) specifying how long after surgery treatments could be resumed 2) asking separate questions for dipeptidyl peptidase-4 (DPP-4) inhibitors and GLP-1 receptor agonists within the incretin mimetics class and 3) asking separate questions for sleeve gastrectomy and bypass (Figure 1). This second round showed a consensus to resume metformin (> 95 % both for sleeve gastrectomy and bypass) and DPP-4 inhibitors (> 80 % both for sleeve gastrectomy and bypass), but balanced responses as to when. Concerning sulfonylureas and GLP-1 receptor agonists, there is no consensus to recommend these treatments after surgery; however, experts endorsed that if they are to be prescribed, it is only in case of elevated HbA1c at 2-3 months after surgery.

## Diabetes remission (Table 4)

Most experts (90.4 %) considered that T2D is a lifelong disease and that long-term monitoring of HbA1c is necessary even in case of diabetes remission (100 %), with testing performed every 6 months (72.7 %).

#### Discussion

Management of T2D patients undergoing bariatric surgery is not limited to glycemic control but involves a coordinated utilization of healthcare resources. Our recommendations, based

on two consecutive experts' surveys, address T2D patient's management from the preoperative period to long-term follow-up after metabolic surgery, and aim at ensuring patients' short and long-term security.

Patients treated for diabetes represented 11.5 % of all bariatric surgery patients in France in 2013, and our recommendations are limited to patients with T2D, who represent the majority of patients with diabetes considering metabolic surgery[14]. Bariatric teams must identify patients with type 1 diabetes, in whom management is different, as they must never be discontinued insulin treatment. The categorization of diabetes, i.e. type 2 or type 1 diabetes, was not discussed in our survey.

Strength of our work is the use of a rigorous, iterative and inclusive approach to identify consensus among a multidisciplinary group of surgeons and endocrinologists, all largely involved either in bariatric surgery per se or in perioperative T2D patients' care. Questions to the experts concerned five aspects of patients' care: characteristics of operated patients, choice of the operative technique for T2D patients, pre/postoperative management and diabetes remission. There was a very close agreement between answers of both surveys. This two-step approach allowed us to clarify aspects that had initially been insufficiently questioned. In particular, several expert comments during the first round led us to wonder whether it was necessary to divide the questions according to the technique: sleeve or bypass. The second round showed that answers remained very close for both procedures, and that most clinicians considered that the same caution is needed whatever the technique employed.

In spite of limited evidence in the long-term [3, 15], experts favor bypass over sleeve gastrectomy in order to achieve remission. This is consistent with French practice, where it

was shown that patients treated for diabetes are more frequently proposed a RYGB compared to those with no diabetes treatment[16]. Interestingly, experts considered that RYGP and sleeve gastrectomy were similar in terms of diabetes management. However, given that metformin absorption and bioavailability seem to be higher after gastric bypass[17], dose adjustments may be needed.

In order practical document, to propose Table 5 summarizes recommendations/position statement comprising the present consensus and the relevant SFAR/SFD position. All are simple and can easily be implemented in most bariatric surgery centers. Patients must be prepared for surgery with an assessment of diabetes complications, an evaluation of glycaemic control and a prescription of SMBG in the early postoperative period. In the postoperative period, hypoglycemic agents will be resumed according to pre-operative treatment and adjusted according to SMBG results. A consensus about the duration of this SMBG has not been reached, probably reflecting heterogeneity in T2D patient's recruitment.

Concerning the definition of an HbA1c value contra-indicating surgery, we chose to endorse the SFAR/SFD recommendation and include it although this question did not reach consensus in our survey. Indeed, the SFAR/SFD recommendations had not yet been published in a peer-reviewed journal when the first round was performed, and were made available online in Feb 2018, at the time of our second round. We believe that this endorsement is necessary to ensure both consistency between learned societies and clarity for medical teams. The publication of the SFAR/SFD recommendations in Feb 2018[7] was also the reason why questions about preoperative management of T2D treatments were removed of the second round, as there is no reason to consider that bariatric surgery T2D

patients should be managed differently from other T2D patients in this regard. We focused on the specificities of bariatric surgery, arising either from obesity itself as an additional risk factor or because of the consequences of rapid improvement of glucose control.

Finally, our survey emphasizes the need for a referring diabetologist in all teams that perform metabolic surgery.

#### Conclusion

The results of the French multidisciplinary Delphi process concerning metabolic surgery highlight that rapid improvement of postoperative glycaemia after metabolic surgery requires a close monitoring and a prompt adjustment of diabetes medications. HbA1c should be monitored in the long term even in case of postoperative diabetes remission. Bariatric teams should be supported by a dedicated diabetologist.

#### **Ethical statement**

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

#### Blinded conflict of interest disclosure statement

Authors 1, 2, 3, 4, 5, 6, 8, 10: report no conflict of interest

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 $\underline{\textbf{Table 1}} \textbf{:} \textbf{ Characteristics of the experts who completed the online surveys and their bariatric teams}$ 

		Round 1	Round 2	Total
		(N = 106)	(N = 64)	(N = 170)
Specialty	Bariatric surgeon	56.6	1.6	35.9
,	(%)			
	Diabetologist (%)	29.2	89.1	51.8
	Other (%)	14.2	9.4	12.4
Gender	(% male)	63.2	35.9	52.9
Age category, years	<35 (%)	3.8	4.7	4.1
	35-45 (%)	41.5	21.9	34.1
	46-55 (%)	26.4	25.0	25.9
	> 55 (%)	28.3	48.4	35.9
Modalities of exercise	Public practice		67.2	
	Private practice		31.3	
	Other		1.6	
Number of annual bariatric procedures	<50 (%)	3.8	9.4	5.9
	50-100 (%)	9.4	18.8	12.9
	100-150 (%)	15.1	10.9	13.5
	150-200 (%)	10.4	9.4	10.0
	>200 (%)	58.5	26.6	46.5
	No answer	2.8	25.0	11.2
Number on bariatric surgeons in the team	1 (%)	9.4	21.9	14.1
	2 (%)	38.7	35.9	37.6
	3 (%)	27.4	12.5	21.8
	> 3 (%)	24.5	15.6	21.2
	No answer (%)	0.0	14.1	5.3
Referring diabetologist in center?	Yes (%)	84.0		
	No (%)	11.3		
	No answer (%)	4.7		

<u>Table 2</u>: Characteristics of operated patients, choice of operative technique and preoperative management

		Round 1	Round	Total
		N=106	2 N=64	(n=170)
What is the mean BMI of patients in	< 40.0 (%)	1.0	9.3	3.9
your center?	40.0-44.9 (%)	69.7	72.2	70.6
	45.0-49.9 (%)	29.3	18.5	25.5
	≥50.0 (%)	0.0	0.0	0.0
What is the percentage of T2D	<10 (%)	4.3	11.5	6.9
operated among your bariatric	10-19 (%)	50.5	36.5	45.5
surgery patients	20-30 (%)	31.2	26.9	29.7
	>30 (%)	14.0	25.0	17.9
Is it legitimate to operate recent T protect b-cell function? (% yes)	2D patients in order to	89.9		
Is it legitimate to operate poorly resistant T2D patients? (% yes)	controlled and insulin-	94.6		
What is the technique that best	RYGB (%)	81.1		
achieves diabetes remission?	Minibypass (%)	12.3		
	Sleeve gastrectomy (%)	2.8		
	Lap band (%)	0.0		
	Other (%)	3.8		
In the absence of contra-indication,	Yes (%)	82.3	66.7	76.7
is it justified to favor bypass over	No (%)	17.7	33.3	23.3
sleeve in order to achieve T2D remission?				
Do you consider that the benefit/risk	Yes (%)		57.8	
ratio of sleeve gastrectomy can be	No (%)		42.2	
better than that of bypass?				
What do you consider necessary	Screening for	62.5	73.4	66.7
before surgery? (% yes)	retinopathy			
	Cardiac ultrasound	73.1	79.3	75.3
	Exercise test	55.8	52.6	54.7
Is there an HbA1c value that should	Yes (%)	64.4	67.2	65.4
contra-indicate surgery?	No (%)	35.6	32.8	34.6
If yes, which value?	7 %	16.9	2.6	11.5
	8 %	46.2	43.6	45.2
	10 %	29.2	53.8	38.5
	12 %	7.7	0	4.8
When do you stop metformin before	The morning of surgery	29.7		
surgery?	24h before surgery	36.3		
	48h before surgery	26.4		
	Do not stop this	7.7		
	treatment			

When do you stop other OADs	The morning of surgery	67.4
before surgery?	24h before surgery	22.5
zerore surgery.	48h before surgery	4.5
	Do not stop this	5
	treatment	5.6
When do you stop GLP-1 receptor	The morning of surgery	63.9
agonists before surgery?	24h before surgery	23.6
agonists before surgery:	48h before surgery	2.8
	Do not stop this	2.0
	treatment	9.7
When do you stop basal insulin	The morning of surgery	51.2
before surgery?	24h before surgery	14.3
	48h before surgery	0.0
	Do not stop this	
	treatment	34.5
When do you stop prandial insulin	The morning of surgery	78.0
before surgery?	24h before surgery	4.9
	48h before surgery	1.2
	Do not stop this	
	treatment	15.9
When do you stop insulin pumps	The morning of surgery	36.8
before surgery?	24h before surgery	11.8
	Do not stop this	
	treatment	51.3

T2D: Type 2 diabetes; RYGB: Roux-en-Y gastric bypass; OADs: oral antidiabetic drugs; GLP-1: Glucagon-like peptide-1.

<u>Table 3</u>: Postoperative management

		Round 1	Round 2		All
			Patient	Patient with	
			with OADs	Injections	
When should T2D patients	Before discharge	44.3	20.8	54.2	
have a diabetologist visit after	< 2 weeks (%)	12.3	5.7	22.9	
surgery?	< 1 month (%)	34.0	45.3	16.7	
	< 2 month (%)	6.6	28.3	6.3	
	> 2 month (%)	2.8	0.0	0.0	
In the immediate	Yes (%)	3.2	2	2.0	2.8
postoperative period, do you					
think that T2D can be	Only if mild	96.8	9	8.0	97.2
managed by GP instead of	diabetes (%)	30.0	3	0.0	37.2
diabetologist?					
			SG	RYGB	
Should SMBG be performed	No	1.1	1.9	1.9	
after surgery?	Yes. < 2 weeks (%)	53.7	51.9	50.9	
	Yes. > 2 weeks (%)	45.3	46.2	47.2	
Do patients treated by insulin pumps need to see a diabetologist immediately after surgery? (% yes)		92.9	94.4	94.4	93.5
Can insulin pumps be stopped in surgery? (% no)	nmediately after	88.9	75.7	68.3	
Should basal insulin dose be halved in the immediate postoperative period? (% yes)		89.2	93.6	93.8	
Should prandial insulin be discontinued in the					
immediate postoperative period except in case of		86.8	90.2	90.2	88.2
severe hyperglycemia? (% yes)					
After surgery, would you stop	Metformin (%)	64.2			
these treatments?	Sulfonylurea (%)	93.6			
	Incretin mimetics (%)	46.3			

T2D: Type 2 diabetes; OADs: oral antidiabetic drugs; GP: general practitioner; SMBG: self monitoring of blood glucose; SG: sleeve gastrectomy; RYGB: Roux-en-Y gastric bypass.

<u>Table 4</u>: Diabetes remission

	Round 1	
Do you consider that T2D is a lifelong disease? (% yes)		
Do you consider that long-term monitoring of HbA1c is necessary even if diabetes remission? (% yes)		
After diabetes remission, HbA1c should be 6 month	72.7	
monitored every 12 month	26.1	
2 years	0.0	
3 years	1.1	
> 3 years	0.0	

T2D: Type 2 diabetes;

# <u>Table 5</u>: Summary of key recommendations/consensus statement for metabolic surgery in patients with type 2 diabetes

For each recommendation, the level of consensus (% agreement among experts) or the reference is indicated, as appropriate.

**Statement 1:** In the preoperative state, in addition to clinical parameters, the assessment of diabetes complications shall include recent (< 3 months) ophthalmoscopy (66.7 %), cardiac ultrasound (75.3), ECG at rest[7], urinary albumin excretion rate[7], serum creatinine[7].

**Statement 2:** In the preoperative state, it is recommended to evaluate the HbA1c level with the following decisions[7]:

HbA1c 6-8 %: no surgery limitation

HbA1c 8-9 %: diabetologist counselling

HbA1c > 9 %: postpone surgery to improve glycemic control first

**Statement 3:** In the preoperative state, a) stop metformin the day before surgery b) all other diabetes medications should be stopped the morning of surgery (other oral hypoglycemic medications, GLP-1 receptor agonists, fast-and long-acting insulins)[7].

**Statement 4:** In the post-surgical state, monitor glucose capillary levels so as to adjust postoperative treatment (98.1 %).

**Statement 5:** In the post-surgical state, all patients with insulin pump therapy have to be evaluated by a diabetologist before discharge (93.5%).

**Statement 6:** In the early post-operative period:

Basal insulin dose has to be halved (89.2%)

Prandial insulin had to be discontinued except in case of severe hyperglycemia (86.8%)

**Statement 7:** After surgery, choose metformin (SG: 97.8%; RYGB: 95.4%) and DPP-4 inhibitors (SG: 87.8%; RYGB: 83.7%) if a non-insulin glucose lowering treatment is required

**Statement 8:** After surgery, a diabetologist visit is required

- a) Immediately if on sub-cutaneous insulin pump therapy (93.5%)
- b) Within 2 weeks if on injectable treatments (77.1%)
- c) Within 1 month if on oral hypoglycemic therapy (71.8%)

**Statement 9:** HbA1c should be tested every 6 months even in case of diabetes remission (72.7%)

# Legend to Figure 1

Clarifications concerning postoperative non-insulin treatments (second round).

SG: sleeve gastrectomy; RYGB: Roux-en-Y gastric bypass; DPP4-i: dipeptidyl peptidase-4 inhibitors; GLP1-agonist: Glucagon-like peptide-1 agonsit.

Figure 1

