

Title	Metabolic surgery: surgical treatment of type 2 diabetes
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Aim

- Assess the benefit/risk balance of MS, which involves offering surgical treatment to a population currently only eligible for a pharmacological approach (administered orally and/or by injection).
- Determine the target population likely to benefit from metabolic surgery, as accurately as possible.

Conclusions and results

In this review, HAS assessed metabolic surgery – which up to now has only been accessible to Type 2 diabetes patients with Class 2 or 3 obesity via bariatric surgery indications – for T2DM patients with Class 1 obesity (BMI between 30 and 35 kg/m²) or overweight (BMI between 25 and 30 kg/m²).

The conclusions issued by HAS are as follows:

Metabolic surgery may be offered to type 2 diabetes patients with class 1 obesity (BMI of 30 to 35 kg/m²) when their individualised glycaemic targets have not been reached despite well-managed medical care, in particular diabetes treatment and nutritional measures, along with adapted physical activity, in accordance with current good practice guidelines, for at least twelve months.

The decision is taken with the patient following discussion at a multidisciplinary team meeting including a diabetes specialist.

Surgical techniques: laparoscopic adjustable gastric banding (LAGB), sleeve gastrectomy (SG), Roux-en-Y gastric bypass (RYGB) may be proposed.

At this stage there is no evidence making it possible to favour one of these three techniques over the others.

The contraindications for bariatric surgery and metabolic surgery are the same."

The development of bariatric surgery in the management of patients with class 2 or 3 obesity (severe or very severe) has resulted in the observation of favourable effects in terms of regulation of glucose metabolism with, in particular, type 2 diabetes (T2DM) remissions in certain patients. This has led to the emergence of the concept of surgical treatment of T2DM. The term "metabolic surgery" (MS) is used to differentiate this concept from "bariatric surgery", primarily aimed at weight loss.

In this work, the HAS carried out an assessment of MS - until now only accessible to type 2 diabetes patients with class 2 or 3 obesity via bariatric surgery indications - for

T2DM patients with class 1 obesity (BMI of 30 to 35 kg/m²) or overweight (BMI of 25 to 30 kg/m²).

The HAS reaches the following conclusions:

"Metabolic surgery may be offered to type 2 diabetes patients with class 1 obesity (BMI of 30 to 35 kg/m²) when their individualised glycaemic targets have not been reached despite well-managed medical care, in particular diabetes treatment and nutritional measures, along with adapted physical activity, in accordance with current good practice guidelines, for at least twelve months.

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The HAS bases these conclusions, firstly, on the published data having enabled it to carry out meta-analyses (MA) that all point to the superiority of MS compared to the conventional medical management of type 2 diabetes (T2DM), via medication without surgery, whether at 24, 36 or 60 months of follow-up, for type 2 diabetes patients with class 1 obesity. According to these meta-analyses, a patient with class 1 obesity and type 2 diabetes treated by MS is at least two to three times more likely to achieve remission of T2DM at 24 and 36 months, respectively, than a patient treated by conventional medical management.

As regards serious or non-serious adverse events reported in the trials selected and analysed, concerning patients with class 1 obesity having undergone MS, no particular safety signals were identified that would differentiate MS from bariatric surgery (BS) in its current indications (class 2 and 3 obesity), in terms of perioperative and postoperative safety, in terms of either nature, severity or frequency. However, the published safety data is still very limited.

The experts consulted consider that these efficacy and safety results are clearly in favour of MS for T2DM patients with class 1 obesity.

In the absence of direct comparative data, it is not possible to propose a preferred surgical technique among the three indicated with a sufficient level of certainty.

There is too little data concerning patients in the overweight category ($25 < \text{BMI} < 30\text{kg/m}^2$) to be able to offer them MS as part of routine care.

On the basis of currently available data, the OAGB, BPD-DS, SADI-Sleeve, SG-TB and Endosleeve techniques in the metabolic surgery indication for type 2 diabetes patients with class 1 obesity or overweight may only be performed in the context of clinical trials, after informing the patient. These techniques will be assessed by the HAS once additional results have been obtained, as in the bariatric surgery indication.

Alongside the development of MS, new antidiabetic drugs have also arrived on the market for routine care. The respective roles of these treatment options in the management of T2DM patients with class 1 obesity will be determined in the type 2 diabetes management guidelines that the HAS is in the process of drawing up.

The information to be provided to patients must include the following points, in particular:

- T2DM remissions are observed at three years in 30 to 40% of cases;
- the T2DM remission may not be definitive, and patients may require antidiabetic drugs again after several months or years;
- monitoring to identify micro- and macro-angiopathic complications must be continued;
- there are benefits other than T2DM remission, such as therapeutic de-escalation, weight loss, resolution of other comorbidities, etc.;
- they will have to undergo and adhere to lifelong follow-up after metabolic surgery.

In addition to the specific points listed above, patients should receive the same information as that provided for BS.

This work is part of a long-term strategy implemented by the HAS to improve the care of people with obesity. As part of this strategy, it has regularly published and updated guidelines on the management of obesity and T2DM, in addition to care pathways. The HAS is also one of the players involved in the ministerial obesity roadmap overseen by the French Directorate General for Healthcare Provision (DGOS), the Directorate General for Health (DGS) and the CNAM (2019-2022).F

Recommendations

Inform patients

The information to be provided to patients must include the following points, in particular:

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Methods

As decided in the scoping document, this work was conducted in accordance with the standard method for assessment of a professional procedure consisting of:

- a. a critical analysis of the literature identified following a systematic literature search and then selected on the basis of explicit criteria, defined in the PICOTS grids presented above, with a view to performing a systematic review per assessment question, with meta-analysis (MA) depending on the data available;
- b. professionals and patients will also be consulted using two different methods:
 - i. face-to-face consultation of external experts (healthcare professionals and patients/users), assembled in an expert group, in order to collect their individual positions, backed up and supported by their knowledge, experience and practices, with regard to the data in the literature,
 - ii. consultation of the professional bodies and patient and user associations concerned by the subject, contacted as stakeholders, in order to gather their collective views on a provisional version of the report containing the elements collected previously (data analysis and expert positions) and any conclusions that may be drawn from them;
- c. compilation of these different elements in a technological assessment report version that will be submitted to the Guidelines, relevance, pathways and indicators committee (CRPPI) for examination then to the HAS Board for validation.

Further research/reviews required

Metabolic surgery for Type 2 diabetes patients with Class I obesity will be included in the “Adult overweight and obesity” care pathway, currently being drafted at HAS.

Together with making metabolic surgery available for these patients, HAS encourages exhaustive prospective real-life data collection on the benefit (mortality, cardiovascular events, remission from T2DM at over 60 months, impact on healthcare consumption and quality of life, etc.), and risks (failures, adverse events, re-operation, re-intervention, etc.). Based on these new data, HAS will then seek to reassess this procedure.

Alongside the development of metabolic surgery, new antidiabetic medications (particularly SGLT2 inhibitors) have arrived on the market in routine care. The respective rank of these two therapeutic operations will need to be specified in the guidelines for the care of T2DM patients.

Therefore, following this report, the use of new procedures, including OAGB, BPD-DS, SADI-Sleeve, SG-TB, and

Endosleeve, in the metabolic surgery indication, remains within the realm of clinical research. These procedures will be assessed once additional findings have been obtained, as for the bariatric surgery indication.

Improving obesity practices and care

This review is part of a long-term approach led by HAS, to improve the care of people with obesity. As such, guidelines on adult and paediatric obesity care, and on obesity surgery have been published by HAS, and are updated regularly. Furthermore, HAS is one of the actors of the ministerial obesity roadmap led by the French Ministry of Health and French national health insurance (2019-2022).

Written by

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