



HAUTE AUTORITÉ DE SANTÉ

CLINICAL PRACTICE GUIDELINES

Obesity surgery in adults

Guidelines

January 2009

The quick reference guide and full evidence report (in French) can be downloaded from
www.has-sante.fr

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Guidelines

1. Introduction

1.1 Subject and objectives of the guidelines

► Subject of the guidelines

These guidelines on strategies for managing obese adult patients undergoing obesity surgery have been drawn up in response to a request from the HAS Board (as a part of its strategy on obesity), the Ministry of Health (in the context of the French National Nutrition Health Programme) and the *Société française et francophone de chirurgie de l'obésité* (SOFFCO - French and French-speaking Society of Obesity Surgery) (which had requested guidelines on obesity surgery reoperations).

Obesity surgery has developed rapidly in France over the last ten years or so and is practised by more than 310 surgical teams. Numerous French and international assessment and guideline publications have been produced in relation to it. However, a survey conducted by the National Health Insurance (CNAMTS) between December 2002 and January 2003 showed that recommended indications and preoperative assessment of patients were not sufficiently followed and that postoperative follow-up of patients was insufficient (number of patients lost to follow-up 18% after 2 years). In addition, the health professionals and patients questioned during the preparation of these guidelines underlined the following points:

- the evolution of indications for surgery;
- the need to formalise and standardise the procedures and content of the preoperative multidisciplinary assessment;
- insufficient information provision and preparation of the patient;
- insufficient follow-up of patients;
- the lack of consensus on the choice of surgical techniques;
- the lack of consensus on the indications for obesity surgery reoperations.

► Objectives of the guidelines

The objectives of these guidelines are:

- to improve the long-term efficacy of obesity surgery and reduce the incidence of complications through:
 - better selection, information and preparation of patients,
 - choice of the technique that provides the best benefit/risk ratio in the patients selected,
 - better definition of the members and role of the multidisciplinary team;
- to reduce the severity of complications through early detection and management.

Given these objectives, the guidelines provide answers to the following questions:

- Management strategies for obese patients in the context of an **initial surgical intervention**
 - Should the current indications for obesity surgery be reviewed?
 - What procedures and content should be included in preoperative management of the patient?
 - What criteria should be taken into account concerning the choice of surgical techniques?
 - What procedures and content should be included in postoperative follow-up and management of the patient?
- Management strategies for obese patients in the context of **a reoperation**.

These guidelines cover the surgical management of adult obese patients. Obesity surgery for adolescents is not included: surgery is an exceptional procedure and the management of adolescents must be specific and differentiated from that of adults.

The following techniques have been examined:

- restrictive techniques: vertical banded gastroplasty, adjustable gastric banding, sleeve gastrectomy;
- mixed techniques: gastric bypass and biliopancreatic diversion.

The mini gastric bypass technique still under development and the jejunoileal bypass, which is no longer performed, have not been examined.

Issues related to the technical environment necessary and the organisation of obesity surgery centres are not covered.

1.2 Professionals targeted

These guidelines are intended principally for all professionals who may participate in the management of obese patients: surgeons, endocrinologists and diabetes specialists, nutritionists, dieticians, psychologists and psychiatrists, general practitioner, nurses, physiotherapists and sports medicine teachers, gastroenterologists, anaesthetists and anaesthesists, radiologists and gynaecologists and obstetricians.

1.3 Working method and grading of guidelines

These guidelines were produced using the clinical practice guidelines (RPC) method described by the HAS¹.

The proposed recommendations have been rated as grade A, B or C according to the following criteria:

- a grade A recommendation is based on scientific proof established by studies with a high level of evidence, such as powerful comparative randomised trials free of major bias, meta-analysis of randomised comparative trials, or analysis of decisions based on well-conducted studies (level of evidence 1);
- a grade B recommendation is based on scientific presumption obtained from studies with a moderate level of evidence, such as less powerful comparative randomised trials, well-conducted non-randomised comparative studies, and cohort studies (level of evidence 2);
- a grade C recommendation is based on studies with a lower level of evidence, such as case-control studies (level of evidence 3), retrospective studies, case series or comparative studies with considerable bias (level of evidence 4).

In absence of evidence, recommendations are based on professional agreement among members of the working group, after analyse of the peer reviewers' comments. The absence of any level of evidence does not mean that the recommendations are not relevant or useful. It should, however, encourage investigators to conduct additional studies

In the context of these guidelines on obesity surgery, the literature identified was plentiful but of an intermediate or predominantly low level of evidence; as a result, the guidelines are mostly grade C or based on professional agreement.

¹ Cf. Clinical Practice Guidelines - Methodology to be used in France. ANAES, 1999.

2. Management strategies for obese patients in the context of an initial surgical intervention

2.1 Should the current indications for obesity surgery be reviewed?

► What are the indications for obesity surgery?

Management of patients who are candidates for obesity surgery must be incorporated into a framework of global medical management of the obese patient (professional agreement).

Obesity surgery is indicated via a group decision, made after multidisciplinary discussion and consensus (professional agreement), in adult patients presenting all of the following conditions:

- patients with a BMI ≥ 40 kg/m² or with a BMI ≥ 35 kg/m² combined with at least one comorbidity that is likely to improve following surgery (in particular cardiovascular diseases including high blood pressure, obstructive sleep apnoea syndrome and other severe breathing disorders, severe metabolic disorders, in particular type 2 diabetes, incapacitating joint disorders, non-alcoholic steatohepatitis) (grade B);
- patients who have attempted to lose weight without success by non operative means (medical, nutritional, dietetic and psychotherapeutic treatment) properly conducted for 6-12 months (grade B);
- well-informed patients (professional agreement), having undergone multidisciplinary preoperative assessment and management (grade C);
- patients having understood and accepted the need for lifelong medical and surgical follow-up (professional agreement);
- acceptable operating risk (professional agreement).

Weight loss before surgery is not a contraindication to obesity surgery that has already been planned, even if the patient has obtained a BMI lower than the threshold required (professional agreement).

Preliminary data (single centre randomised controlled trials with low populations and short follow-up) have shown that obesity surgery could improve comorbidities, in particular type 2 diabetes, in subjects with a BMI between 30 and 35 kg/m². However, in the absence of data established for a larger population and over a longer time period, for the time being obesity surgery can not be recommended in diabetic subjects with a BMI between 30 and 35 kg/m² (professional agreement).

Current data, which is heterogeneous and of a low level of evidence, does not allow the benefit/risk ratio of obesity surgery to be established beyond the age of 60 years. Above the age of 60, indications for surgery must be approved on a case-by-case basis in accordance with physiological age and associated comorbidities (grade C).

► What are the contraindications to obesity surgery?

The contraindications to obesity surgery consist of the following (professional agreement):

- severe cognitive or mental disorders;
- severe and non-stabilised eating disorders;
- the likely inability of the patient to participate in lifelong medical follow-up;
- alcohol or psychoactive substances dependence;
- the absence of identified prior medical management of obesity;
- diseases that are life-threatening in the short and medium term;
- contraindications to general anaesthesia.

Some of these contraindications may be temporary. It must be possible to reassess indications for surgery following management and correction of these contraindications (professional agreement).

In cases of obesity of genetic origin or in case of craniopharyngioma, indications for surgery must be exceptional and discussed on a case-by-case basis by the multidisciplinary obesity surgery team and the health professionals usually in charge of these pathologies (for example neurosurgeon) (grade C).

2.2 What procedures and content should be included in preoperative management of the patient?

► Procedures for preoperative management of the patient

Management of patients due to undergo obesity surgery must be conducted within multidisciplinary teams, in collaboration with the general practitioner and possibly patient associations. These teams include at least one surgeon, one doctor specialising in obesity (nutritionist, endocrinologist or internist), one dietician, one psychiatrist or psychologist and one anaesthetist. These teams can seek the advice of other health professionals as required (hepatogastroenterologist, diabetes specialist, radiologist, cardiologist, pneumologist, rheumatologist, rehabilitation doctor, dental surgeon, physiotherapist, etc.) (professional agreement).

A coordinator must be appointed within the multidisciplinary team (professional agreement).

If the members of the multidisciplinary team belong to different institutions, the conditions of their cooperation must be specified in a charter (professional agreement).

Preoperative multidisciplinary management of the patient must be personal to each individual. It consists of (figure 1) (professional agreement):

- an initial consultation with a health professional (doctor or surgeon) experienced in the surgical management of obesity who is a member of the multidisciplinary team. This consultation is used to assess whether surgery could be considered for the patient;
- provision of information to the patient;
- somatic and psychological assessment and management of the patient, and a personalised therapeutic education programme;
- announcement of the result of the multidisciplinary consensus to the patient.

The objectives of preoperative multidisciplinary process are to improve the efficacy of surgery and its tolerance by the patients operated on, to help patients make their own decision regarding surgery and to ensure better compliance of patients with postoperative follow-up (professional agreement).

The following must be defined through the management process (professional agreement):

- the expectations of the patient, the risks and limitations they are capable of accepting, their motivation and ability to comply with follow-up;
- the benefit/risk ratio of obesity surgery for the patient, indications for surgery or contraindications, the type of operation;
- the conditions of patient follow-up.

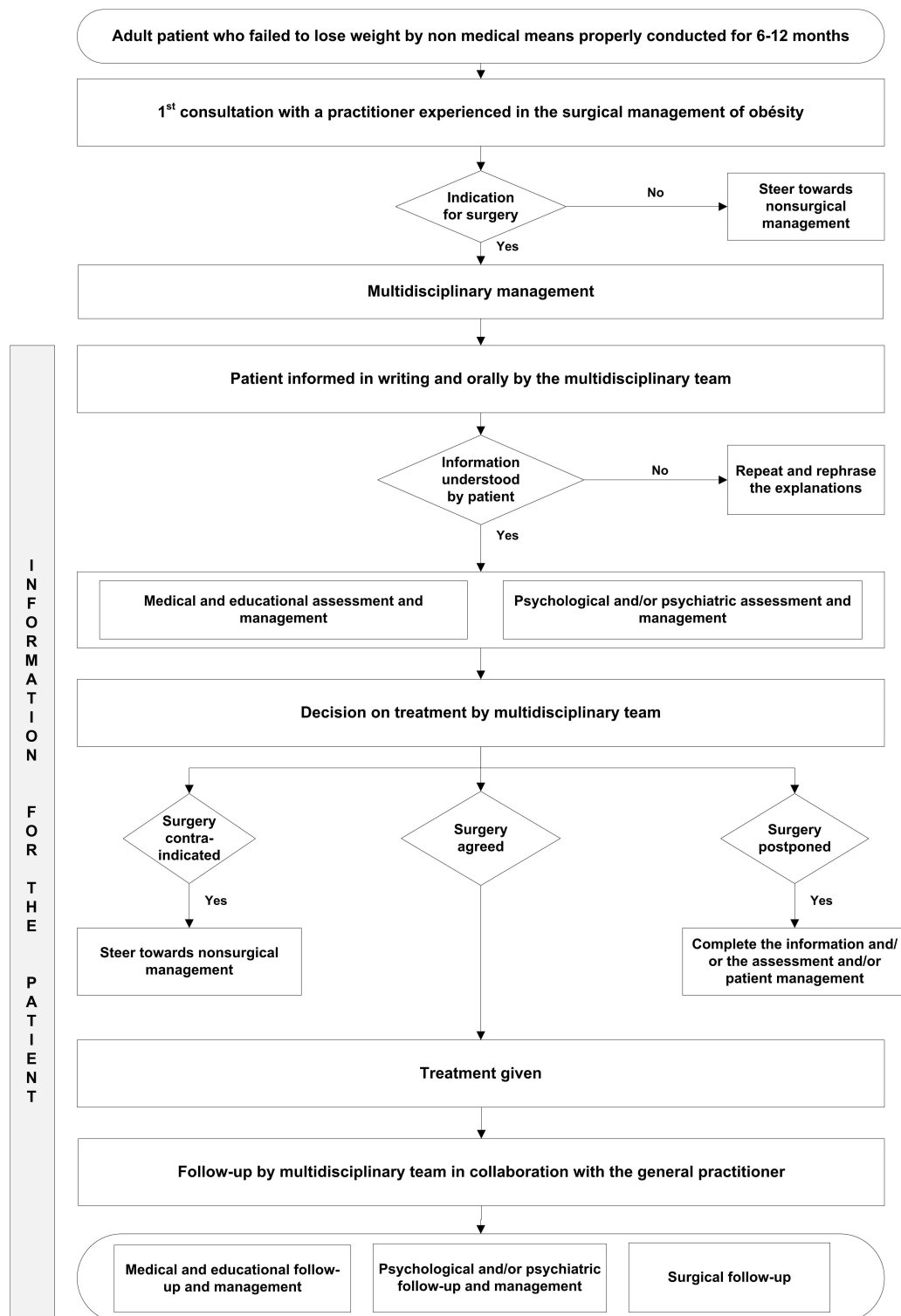
The decision to operate must be taken following discussion and consensus between the multidisciplinary team. Consensus via a physical meeting is recommended. However, if a physical meeting is not possible (for example, if team members are geographically distant, etc.), other consensus procedures are possible (telephone discussions, video conferences, Internet, etc.). The opinion of the patient's general practitioner should also be sought.

In all cases, the conclusions of this consensus must be communicated to the patient, to all members of the multidisciplinary team and to the general practitioner; they must be noted in the patient's file (professional agreement).

The conclusions of the multidisciplinary consensus must be formalised and include (professional agreement):

- the patient's contact details;
- the contact details of the coordinator and general practitioner;
- the names and specialisations of the consensus participants;
- the patient's medical and surgical history, their maximum and current BMI, prior obesity treatments implemented, anaesthetic risks;
- the initial consultation date;
- the methods used to inform the patient of the benefits expected, the risks of surgery and the mandatory nature of follow-up;
- the result of the preoperative assessment and management;
- the strategies suggested: surgical strategy (whether or not surgery is indicated, type of operation) and other forms of management (nutritional, dietetic or psychological, physical activity reconditioning, etc.);
- whether or not the strategy suggested complies with the standards used;
- the date of the decision.

Figure 1. Care pathway for patients who are candidates for obesity surgery



► Providing information to the patient

Information provided to the patient must include the following (professional agreement):

- the risks of obesity;
- the different ways of managing obesity;
- the different surgical techniques:
 - principles involved (best explained using diagrams),
 - respective benefits: estimates of short- and long-term weight loss, absence of long-term data available for certain techniques, benefits for health and comorbidities,
 - respective risks and disadvantages: perioperative mortality, adverse effects, early and late complications, nutritional consequences, reoperations, irreversibility, warning clinical signs;
- the limitations of surgery (particularly in terms of weight loss);
- the advantages and disadvantages of surgery in terms of daily life, social and family relationships;
- the advantages and disadvantages of surgery in terms of pregnancy and contraception;
- the need to change eating habits and lifestyle before and after the operation;
- the need for lifelong medical and surgical follow-up, as obesity is a chronic disease and because of the risk of late complications;
- the need to follow a therapeutic education programme;
- the possible support from patient associations;
- the possibility of reconstructive surgery.

This information must be provided by the members of the multidisciplinary team, relayed by the general practitioner, patient associations and networks when they exist. It must be transmitted through individual interviews, that may be complemented by group meetings. Arranging meetings with patients who have already been operated on is recommended (professional agreement).

Providing the patient with written information in addition to oral information is recommended. It is important to ensure that the patient has fully understood this information. The initial information must be repeated and complemented as often as necessary before and after the operation (professional agreement).

► Assessment and preparation

➤ Medical and educational assessment and management

Medical assessment and management

Before obesity surgery, the following actions are recommended:

- Take anthropometric measurements: BMI, waist circumference (grade B).
- Specify the nutritional and vitamin status of patients: determination of albumin, haemoglobin, ferritin and iron saturation, calcium, vitamin D, vitamin B1, B9 and B12. Additional tests may be given if clinically or biologically indicated (grade C). If deficits are present, these must be corrected before the operation and contributing factors identified (professional agreement).
- Together with the patient, assess their type of eating behaviour and the existence of any eating disorders (history, severity of the disorder), and any association with mental health problems (depression, psychotic disorders, addictions, etc.). These factors should be taken into account not only when deciding whether surgery is indicated but also in the patient's pre and postoperative multidisciplinary management (psychotherapy, medication, monitoring of mechanical complications in the case of gastric bands, etc.) (grade C).

- Assess and manage cardiovascular or metabolic comorbidities, in particular high blood pressure, type 2 diabetes, dyslipidaemia (grade B).
- Assess thromboembolic risk (grade C).
- Test for and manage obstructive sleep apnoea syndrome (OSAS) in accordance with guidelines, nicotine addiction or other respiratory pathologies (grade C).
- Perform a hepatic assessment: as a minimum requirement, this must include determination of transaminases and gamma GT to identify non-alcoholic steatohepatitis and if necessary result in a hepatogastroenterology consultation (professional agreement).
- Perform a gastrointestinal assessment:
 - Before any obesity surgical intervention, performing an upper gastrointestinal endoscopy is recommended in order to screen for *Helicobacter pylori* (HP) infection and detect other associated digestive pathologies (e.g.: significant hiatus hernia, ulcer, gastritis, etc.) that could contraindicate certain procedures or require management before surgery (professional agreement). Before surgery excluding the stomach, taking systematic biopsies is recommended to check for preneoplastic lesions, regardless of their aetiology (HP or other infection) (professional agreement). If an HP infection is detected, it must be treated and its eradication checked before surgery (professional agreement).
 - Clinical or paraclinical suspicion of motility disorders of the oesophagus may require discussion of whether to perform an oesophageal manometry before insertion of a gastric band (grade C).
- Assess musculoskeletal and articular condition (professional agreement).
- Assess the mastication coefficient and dental condition (professional agreement).

Implementation of a therapeutic education programme

Drawing up a therapeutic education programme with the patient is recommended; it should be implemented with the multidisciplinary team before the operation and continued during the postoperative period (professional agreement).

The programme is based on the following (professional agreement):

- analysis of the patient's needs and expectations (production of an educational diagnosis);
- definition of a personalised programme including the most useful skills to acquire and learning priorities;
- planning and implementation of individual or group (or alternating) therapeutic education sessions;
- assessment of the skills acquired and implementation of the programme as a minimum requirement before the surgical intervention.

The objective of this programme is to help the patient acquire skills with regard to the following in particular (professional agreement):

- modifying their eating habits and behaviour from the preoperative period onwards with a view to stabilising their weight before the operation, and improving the efficacy and tolerance of surgery;
- planning a physical activity program.

In terms of dietetic issues, the therapeutic education programme must be adapted to the surgical technique used and to the patient. The therapeutic education sessions should be delivered by the multidisciplinary team, preferably by the dietician or nutritional doctor, with the participation of patients who have already undergone an operation (intervention in the therapeutic education sessions to complement the work of the dietician). Patient associations can also provide individual support to the patient (professional agreement).

The content of the individual or group sessions must cover in particular choice of foods, achievement of a balanced diet over the day and the week, choice and use of appropriate cooking techniques (cookery classes), hints and tips, some of which can be put into practice during shared meals (professional agreement).

In terms of physical activity, choosing an appropriate and regular activity for after the operation must be discussed individually with each patient from the preoperative period. The physical activity program suggested must be of a progressive nature and take account of the musculoskeletal and cardiorespiratory conditions of the patient, their lifestyle and preferences (professional agreement).

➤ **Psychological and psychiatric assessment and management**

Psychological and psychiatric assessment and management of the patient must be personal to each individual (professional agreement).

All patients who are candidates for obesity surgery must undergo preoperative psychological and psychiatric assessment. This must make it possible to (grade C):

- identify psychiatric contraindications to surgery (severe mental disorders, addictive behaviours, etc.);
- assess the motivation of the patient, their ability to implement the behavioural changes necessary and to participate in a long-term postoperative follow-up programme;
- assess the psychological determinants and consequences of obesity;
- assess the patient's knowledge (about obesity and obesity surgery). The patient must have sufficient intellectual resources and knowledge to give informed consent;
- assess the patient's quality of life;
- determine factors of psychosocial stress, and the presence and quality of sociofamilial support;
- offer appropriate management before surgery and provide guidance on postoperative follow-up.

This evaluation must be conducted by a psychiatrist or psychologist who is a member of the multidisciplinary team. If psychotherapeutic management before the operation is necessary, it may be conducted by a psychiatrist or psychologist who is not a member of the multidisciplinary team but in coordination with the latter (professional agreement).

➤ **Advice on pregnancy and contraception**

Obesity surgery is contraindicated in women who are pregnant (professional agreement). Before operating, systematically testing for pregnancy in women of childbearing age is recommended, by measuring plasma β -hCG in the 48 hours before the operation (professional agreement).

After obesity surgery:

- Before planning any pregnancy, a dietetic and nutritional, and clinical and biological assessment must be carried out, or failing this, at the very start of the pregnancy (grade C).
- For pregnant women, particularly after malabsorptive surgery, supplementation is recommended with iron, folates, vitamin B12, vitamin D and calcium (grade C). In compliance with international guidelines, folate supplementation must be introduced as soon as there is an intention to conceive (grade A)².

² In 2005, the HAS stated: "Pregnant women (and those planning pregnancy) must be informed that a nutritional supplement of folic acid, 28 days before conception and up to week 12 of gestation, reduces the risk of neural

- In the event of pregnancy after insertion of a gastric band, untightening the band should be discussed between the multidisciplinary team and the obstetrician (grade C).
- During pregnancy and *post-partum*, planning nutritional follow-up within the multidisciplinary team is recommended (professional agreement).

Contraception is recommended as soon as obesity surgery is planned and then usually for 12 to 18 months after the operation (grade C). A low level of evidence study (case series) suggests reduced efficacy of oral contraception following biliopancreatic diversion. In cases of malabsorptive surgery, another method of contraception (condoms, IUD, etc.) must be discussed (grade C).

2.3 What criteria should be taken into account concerning the choice of surgical techniques?

The surgical techniques recommended are the following (professional agreement):

- adjustable gastric banding (AGB);
- sleeve gastrectomy (SG);
- gastric bypass (GBP);
- biliopancreatic diversion (BPD).

Vertical banded gastroplasty (VBG) tends to no longer be practised.

It is not possible to make a classification of the different techniques based on their benefit/risk ratio. The weight loss expected but also the complexity of the technique, the risk of postoperative complications, the risk of nutritional consequences and mortality increase with the following operations: AGB, VBG, SG, GBP, BPD (grade B).

The choice of surgical technique must be made jointly by the multidisciplinary team and the patient. It must take some criteria into account, in addition to the benefit/risk ratio of each intervention, such as:

- the experience and technical environment of the surgeon and the multidisciplinary team and in particular those of the anaesthesia team (grade B);
- the severity of the obesity, the BMI and age of the patient (grade B);
- medical and surgical history (grade C);
- associated digestive pathologies (grade C);
- the presence of type 2 diabetes (professional agreement);
- ongoing treatments (AVK, etc.) (professional agreement);
- eating disorders (professional agreement).

Laparoscopy is the recommended approach (grade B).

In subjects presenting a high operating risk, in particular those whose BMI is $\geq 60\text{kg/m}^2$, a two-stage strategy (restrictive procedure followed by malabsorptive procedure) may be discussed (grade C).

It is recommended that the operating technique is carried out by a surgeon with specific training in laparoscopic surgery and obesity surgery, working within a multidisciplinary team

tube defects (anencephalia, spina bifida). The recommended dose is 400 micrograms per day (grade A). Systematic folate supplementation for the remainder of the pregnancy has not been proven to be of benefit (grade B)" (Haute Autorité de Santé. Follow-up and referral of pregnant women based on identified risk situations. Clinical Practice Guidelines. Saint-Denis La Plaine: HAS; 2007).

or a network of institutions (professional agreement). The multidisciplinary team or network of establishments must (professional agreement):

- have expertise in managing morbid obesity;
- be able to offer patients the different obesity surgery techniques.

2.4 **What procedures and content should be included in postoperative follow-up and management of the patient?**

► **Postoperative follow-up and management procedures**

Patient follow-up and management after obesity surgery must be incorporated into the personal programme set up from the preoperative phase. It is carried out by the multidisciplinary team which made the decision to operate, in collaboration with the general practitioner.

This follow-up must be carried out for life, as obesity is a chronic disease and because of the risk of late complications (surgical or nutritional complications, some of which may lead to serious neurological conditions). The patient must be informed of the potentially serious consequences of absence of follow-up (professional agreement).

Patients should be seen at least 4 times in the first year, then at least once or twice a year after that. The frequency of visits should be adapted to the procedure and the patient (professional agreement).

► **Content of postoperative follow-up and management**

➤ **Early postoperative follow-up**

Thromboembolic prevention through early ambulation, support stockings and low molecular weight heparin is recommended (grade B). Perioperative use of intermittent venous compression equipment appears to be beneficial (grade C).

In cases of cardiorespiratory comorbidities, immediate postoperative follow-up must be conducted in a continuous monitoring unit (professional agreement).

The potential seriousness of complications following obesity surgery justifies frequent surgical follow-up. Regardless of the surgical technique used, the principal complications to check for are the following (studies with level of evidence 3 and 4):

- digestive perforations and leaks;
- haemorrhagic complications;
- occlusions.

Suspected complications following the presentation of clinical signs, in particular tachycardia, dyspnoea, abdominal pain, confusion or hyperthermia, in the absence of peritoneal signs (guarding or tenderness) which are always late, must lead to early reoperation. Paraclinical examinations (UGI study, CT scan, etc.) can assist with diagnosis of complications, but must not delay any reoperation. In this case, the laparoscopic approach has the advantage of allowing immediate diagnosis and very often allows treatment of the problem (professional agreement).

The importance and modalities of postoperative feeding must be explained to the patient, as failure to comply with these modalities can lead to serious surgical complications (professional agreement).

➤ Medium- and long-term follow-up

Medical and educational follow-up and management

Following obesity surgery, the following actions are recommended:

- Assess weight loss and its kinetics (grade B).
- Monitor comorbidities, in particular, type 2 diabetes, high blood pressure, dyslipidaemia, OSAS, non-alcoholic steatohepatitis, and adapt their treatment (grade B).
- Assess the patient's quality of life (grade C).
- Conduct a food survey and reiterate the dietetic advice (professional agreement).
- Look for clinical signs of malnutrition or vitamin deficiencies, in particular signs of neurological damage (grade C).
- Conduct a nutritional and vitamin assessment, in accordance with any clinical signs (kinetics of weight loss, vomiting, etc.) and the technique used. This can include administration of albumin and prealbumin, haemoglobin, ferritin and iron saturation coefficient of transferrin, serum calcium, vitamin D, PTH, vitamin A, B1, B9, B12, zinc and selenium (grade C). Determinations are recommended 3 and 6 months after the operation, and then at least annually (professional agreement).
- Adapt the dosage of ongoing treatments: malabsorptive surgery can lead to malabsorption of various medicines and their dosage must be modified accordingly (for example, antivitamin K, thyroid hormones, antiepileptic drugs, etc.) (professional agreement).

In terms of supplementation, the following actions are recommended:

- Systematic supplementation after malabsorptive surgery, the duration of which cannot be specified (for life by default): multivitamins, calcium, vitamin D, iron and vitamin B12 (grade C). Following restrictive surgery, supplementation may be discussed if the results of the clinical and biological assessment warrant it (professional agreement).
- Increase supplementation in particular situations (B1 if vomiting or surgical complications with parenteral nutrition or rapid weight loss, B9 if pregnancy, iron if woman of menstruating age or pregnant, etc.), using parenteral forms if necessary (grade C).
- Warn patients of the risks they are exposing themselves to if deficiencies occur, of the risks run if supplements are not taken and the warning signs suggesting a serious deficiency, for example: neurological signs (occurrence of paraesthesia, etc.), very rapid weight loss, intense fatigue, sensory disorders (reduced visual acuity, etc.) (grade C).

Hydration and protein intake through food must be sufficient and regular (professional agreement).

The educational follow-up established in the preoperative phase must be continued in order to ensure that skills acquired by the patient in terms of diet and physical activity is implemented and maintained, and to assess how they are adapting to their situation (professional agreement).

Following malabsorptive surgery, in order to prevent gallstones and in the absence of cholecystectomy, the prescription of ursodeoxycholic acid at a dose of 600 mg/day for 6 months may be offered (without marketing authorisation) (grade B).

Giving the patient a card or booklet with information on the operation performed and the supplementation prescribed is recommended (professional agreement).

Psychological and psychiatric follow-up and management

Psychological and psychiatric follow-up of the patient after obesity surgery is recommended for patients who presented eating disorders or psychiatric pathologies in the preoperative

phase. For other patients, this follow-up can be proposed on a case-by-case basis (grade C).

Postoperative psychological and psychiatric follow-up has the following objectives (professional agreement):

- to assess the psychological, social and familial repercussions of the operation and weight loss;
- to identify any difficulties in implementing the behavioural changes necessary and to help the patient overcome these difficulties;
- to support the patient in making psychological adjustments related to the surgery and the loss of weight (modification of body image, etc.) and if necessary, offer appropriate management.

This must be conducted by a psychiatrist or psychologist who may or may not be a member of the multidisciplinary team. If they are not a member, they must work in coordination with the psychiatrist or psychologist in the multidisciplinary team (professional agreement).

Surgical follow-up and management

Surgical follow-up is recommended after all types of obesity surgery to detect complications which may occur later. Pain, vomiting and dysphagia are warning signs that must result in the patient consulting the surgeon of the multidisciplinary team (grade C).

Following insertion of an adjustable gastric band, it is recommended that its calibration is (professional agreement):

- adapted to the weight loss, to the tolerance and eating behaviour of the patient;
- performed by a health professional experienced in obesity surgery;
- controlled radiologically to check its adjustment and detect complications (pouch dilation, oesophagectasia, incorrect positioning of the band, etc.).

Possibility of reconstructive surgery

It is recommended that patients are informed of possible reconstructive surgery. This can be performed no earlier than 12 to 18 months after the obesity surgery, provided there is no malnutrition (professional agreement).

It is recommended that the reconstructive surgery team has experience of managing obese patients. Indications for reconstructive surgery must be discussed with the patient, the reconstructive surgery team and the multidisciplinary obesity surgery team (professional agreement).

3. Management strategies for obese patients in the context of a obesity surgery reoperation

All of these recommendations are based on professional agreement.

Performance of a second restrictive or malabsorptive obesity surgery procedure is indicated if the obesity surgery fails or the surgical procedure malfunctions. In these cases, the BMI to be taken into account is the maximum BMI recorded. A BMI lower than 35 kg/m² does not contraindicate a second intervention. The failure can be defined in terms of weight loss that is judged insufficient by the patient and the care team in the long term in accordance with the somatic and psychological context.

Patients undergoing a second obesity surgery procedure must be managed within multidisciplinary teams as recommended for the initial operation.

The indications for a second obesity surgery procedure must be approved following preoperative assessment and management comparable to those conducted before the initial operation. In particular, it is necessary to identify the cause of the failure and to offer appropriate management. The knowledge of patients must be reassessed and additional information on the risks of reoperations must be provided to the patient.

In cases of failure or malfunctioning of the surgical procedure, the decision to operate again must be taken following discussion and consensus between the multidisciplinary team. The conclusions of this consensus must:

- be communicated to the patient, to all members of the multidisciplinary team and to the general practitioner;
- be recorded in the patient's file;
- in particular, specify the type of initial operation, the reason for a second intervention, compliance with postoperative follow-up, the type of procedure, etc.

The choice of surgical technique must be made jointly by the multidisciplinary team and the patient. It must take account of the following factors:

- follow-up of the patient;
- the weight curve;
- the type of initial intervention;
- the reason for the reoperation;
- the benefit/risk ratio of each possible type of reoperation;
- medical and surgical history;
- comorbidities;
- nutritional status;
- eating disorders;
- perioperative observations.

It is recommended that a second restrictive or malabsorptive obesity surgery procedure is performed by a surgical team experienced in carrying out both types of procedure, as the risk in reoperations is higher than in initial interventions.

4. Recording obesity surgery operations in a national register

It is recommended that all obesity surgery operations conducted in France are recorded in a national register, the objectives of which are to:

- assess the impact of the recommendations on practices and their appropriation by professionals;
- identify short- and long-term efficacy and safety data of French medical and surgical teams, outside major therapeutic trials;
- monitor the development of techniques.

In this context, in 2007 SOFFCO set up a national register for obesity surgery operations, the content of which has been validated by the HAS.

This register covers all types of operation and includes data on the different stages of patient management for surgery:

- preoperative: assessment of patient obesity, comorbidities and history;
- operative: type of operation, duration, repercussions;

- postoperative: efficacy (percentage of excess weight loss, improvement of comorbidities, quality of life (BAROS score)) and safety (analysis of specific and general complications, in the short and long term).

Guideline limits and prospects

Guideline limits

These guidelines have attempted to define the management of adult patients who are candidates for obesity surgery. The role of obesity surgery and the conditions for its performance will need to be reassessed for adolescents. In 2003, there was little data in the literature and the ANAES had not recommended obesity surgery in the management of childhood obesity. Since 2003, several teams have published results on obesity surgery in adolescents.

This report on managing obesity surgery in adults has not given guidelines on:

- perioperative management of patients (in particular anaesthesia, ventilation, prophylactic antibiotic therapy, management of postoperative pain). Guidelines on perioperative management of obese patients undergoing abdominal surgery (including obesity surgery) would be a useful addition;
- dietetic management in the context of obesity surgery, in particular postoperative postoperative feeding;
- the technical environment necessary and the organisation of obesity surgery centres. These issues are covered in the French National Nutrition Health Programme.

Other developments

Reimbursement by National Health Insurance of certain medical procedures and products

Several medical procedures and products included in the recommended surgical management of obesity are not reimbursed by National Health Insurance. For example, this is the case for:

- certain vitamin supplements required after the operation, the cost of which is estimated at between 9 and 25 euros a month;
- protein supplements;
- psychological and dietetic consultations;
- certain blood tests (for example determination of vitamin B1);
- certain reconstructive surgery procedures (for example mammoplasty).

There is no valuation of therapeutic education sessions.

In addition, apart from procedures to change, reposition or ablate gastric bands, no specific reoperation procedures are described in the joint classification of medical procedures (CCAM), while reoperations are judged to be technically more difficult to perform than initial operations, and as a result require greater experience. The principal reoperations descriptions are as follows:

- conversion of a gastric banding into a sleeve gastrectomy;
- conversion of a gastric banding into a gastric bypass;
- conversion of a gastric banding into a biliopancreatic diversion;
- reoperation to correct malabsorptive surgery (shortening or lengthening the common channel);
- reestablishing normal digestive continuity after failure of malabsorptive surgery.

Similarly, certain revision procedures are not included in the CCAM (revision of sleeve gastrectomy, gastric bypass or biliopancreatic diversion).

Finally, the sleeve gastrectomy is in the process of being included in the joint classification of medical procedures. As a reminder, in February 2008 the HAS recommended its inclusion on the list of procedures that are reimbursed by National Health Insurance.

Improving the training of medical and paramedical personnel to manage obesity

When these guidelines were being drawn up, the members of the working group emphasised the lack of health, medical and paramedical professionals (psychologists, dieticians, physiotherapists, other physical activity professions), with the specific skills required to manage obese patients.

Updating the guidelines and additional work

These guidelines should be updated in 5 years to reflect new developments in surgical techniques and new data available.

Analysis of the literature highlighted the poor quality of data (low level of evidence, small sample size, insufficient follow-up) on:

- the benefit/risk ratio of obesity surgery for cases of BMI between 30 and 35 kg/m². These guidelines have restricted obesity surgery to adult patients with a BMI ≥ 40 kg/m² or ≥ 35 kg/m² with comorbidities. However, the assessment made in this report has shown that increasing numbers of teams were offering obesity surgery to patients with a BMI between 30 and 35 kg/m² presenting severe comorbidities, in particular type 2 diabetes. The data are promising but not yet sufficient to recommend surgery for this indication;
- the longer-term efficacy and safety of the sleeve gastrectomy (few or no results with 2 years of follow-up);
- reoperations: the lack of data available and insufficient follow-up does not allow definition of a reoperation strategy;
- the intake of nutrients and vitamins necessary to prevent and treat deficiencies;
- the impact of preexisting eating disorders on the results of surgery and the evolution of eating disorders following surgery.

Based on these guidelines, the HAS is currently producing several documents on obesity surgery:

- information document for the patient;
- information document for general practitioners;
- quality criteria with a view to assessing and improving professional practices.

The Clinical Practice Guideline Method

Clinical practice guidelines (CPG) have been defined as proposals developed by an explicit method to help the practitioner and the patient to find the most appropriate care in a given clinical situation.

The clinical practice guidelines method is one of the methods used by the Haute Autorité de Santé (HAS -French National Authority for Health) to produce clinical guidelines. It is based on critical analysis and review of the available medical literature as well as on the opinion of a multidisciplinary group of professionals involved in the subject area of the guidelines.

• Choice of topic area

The HAS Board chooses the topics for clinical guidelines. For this purpose the Board takes into account public health priorities and any requests from Ministry for health and national health insurance. The HAS Board may also consider topics proposed by learned societies, the French national cancer institute, the French Association of National Health insurance, the French national union of health professionals, organisations representing health care professionals or establishments, or registered user groups.

For each chosen topic, the working method follows the next steps. A HAS project manager coordinates the work as a whole and ensures that it conforms to HAS' methodological principles.

• Steering committee

HAS sets up a steering committee composed of representatives of the learned societies, professional or user organisations and, if need be, of the relevant health agencies and institutions. The steering committee specifies the exact subject area of the guidelines, the issues to be dealt with, the patient populations and the professionals for whom the guidelines are intended. It draws attention to relevant publications, notably guidelines. It proposes suitable professionals to take part in working and peer review groups. Finally it takes part in the peer review.

• Working group

HAS sets up a multidisciplinary and multiprofessional working group composed of healthcare professionals in public or private practice, from various geographical areas or schools of thought, and, if appropriate, of other professionals involved in the area and representatives from patient and user groups. HAS appoints a working group chair to coordinate the group's work in collaboration with the HAS project manager. A report author is also designated by HAS to select, analyse and summarise the relevant medical and scientific literature. The report author drafts the evidence report and specifies the level of evidence of the studies considered, under the supervision of the HAS project manager and the working group chair. The evidence is regularly updated until the end of the project.

Sources for drafting the evidence report

- Medical and scientific databases searched systematically over an appropriate time period for the subject (languages: French, English). In particular, search for clinical practice guidelines, consensus conferences, medical decision-aid articles, systematic reviews, meta-analyses and other assessments.
- If appropriate, more specific databases (e.g. health economics)
- All useful internet sites (government agencies, learned societies, etc.)
- Grey literature (documents which cannot be accessed through conventional channels)
- Legislative and regulatory texts which could be related to the subject
- Cited references in the articles retrieved (manual search)
- Articles provided by the members of the working group and by peer reviewers.

- **First version of the guideline**

A first version of the guideline is drafted by the working group based on the evidence report and the opinions expressed during the working group meetings (usually two meetings). Recommendations are graded based on the scientific evidence level (table 1)

This first draft guideline is then submitted to the peer reviewers.

Table1. Grading of guidelines

Grade	Scientific evidence level
A	trials of a high level of evidence (level of evidence 1), e.g. high-power randomised controlled trials (RCTs) free of major bias and/or meta-analyses of RCTs or decision analyses based on level 1 trials.
B	studies of an intermediate level of evidence (level of evidence 2), e.g. RCTs with some bias, meta-analyses based on questionable methodology, well-conducted non-randomised controlled trials or cohort studies;
C	studies of a lower level of evidence, e.g. case control studies (level of evidence 3) or case series (level of evidence 4).

In the absence of reliable publications, the guidelines are based on professional agreement among members of the working group and peer reviewers.

- **Peer review group**

HAS appoints the peer reviewers using the same criteria as for working group members. The peer reviewers are consulted by e-mail and give an opinion on the content and structure of the evidence report and guideline, in particular on guideline's legibility and applicability.

- **Final version of the guideline**

The working group analyses the peer reviewers' comments, amends the evidence report if necessary, and drafts the final version of the guideline and a quick reference guide (QRG), during a working session.

The final version of the evidence report and guideline and the development process are discussed by the *Committee of guidelines approval*. At its request, the evidence report and the guideline may be amended by the working group. The committee submits its opinion to the HAS Board.

- **Validation by the HAS Board**

Acting on the proposal from the *Committee of guidelines approval*, the HAS Board validates the final documents and authorises their publication.

- **Publication**

HAS makes available on its website (www.has-sante.fr), free of charge, the evidence report, the guideline and the Quick Reference Guide (QRG). HAS may decide to print both the QRG and the guideline.

- **Grading of the recommendations**

Each article selected is analysed according to the principles of a critical literature review with the aid of reviewing checklists; in this way, a level of scientific evidence can be attributed to each one. Depending on the level of evidence of the studies on which they are based, the recommendations are graded from A to C on the scale proposed by HAS (see section 1.4).

In absence of evidence, recommendations are based on professional agreement among members of the working group, after analysing the peer reviewers' comments. In this text, ungraded guidelines are those based on expert consensus. The absence of any level of evidence does not mean that the recommendations are not relevant or useful. It should, however, encourage investigators to conduct additional studies.

For further details on the method used to develop clinical practice guidelines, see the guide published by ANAES in 1999: *Recommandations pour la pratique clinique – Base méthodologique pour leur réalisation en France* [Clinical Practice Guidelines – Methodological basis for their production in France]. This guide may be downloaded from the HAS website: www.has-sante.fr

Participants

Declarations of conflict of interest

The participants of the organising committee and working group have communicated their declaration of interests to HAS. They may be consulted at HAS web site www.has-sante.fr (in French).

Learned societies and professional associations

The following learned societies and professional associations were asked to participate in compiling these guidelines:

- *Association de langue française pour l'étude du diabète et des maladies métaboliques*
- *Association de recherche en soins infirmiers*
- *Association des diététiciens de langue française*
- *Association française d'études et de recherches sur l'obésité*
- *Collège national des généralistes enseignants*
- *Fédération de chirurgie viscérale et digestive*
- *Fédération d'hépto-gastro-entérologie et de nutrition clinique*
- *Fédération des spécialistes des maladies de l'appareil digestif*
- *Fédération française de psychiatrie*
- *Fédération française des psychologues et de psychologie*
- *Fédération nationale des associations médicales de nutrition*
- *Société de formation thérapeutique du généraliste*
- *Société française d'anesthésie-réanimation*
- *Société française de documentation et de recherche en médecine générale*
- *Société française de kinésithérapie*
- *Société française de médecine générale*
- *Société française de psychologie*
- *Société française et francophone de chirurgie de l'obésité*
- *Société française de nutrition*

User associations

The following user associations were asked to participate in compiling these guidelines:

- *Allegro fortissimo*
- *Collectif national des associations d'obèses*
- *Pulpe club*

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Descriptive leaflet

TITLE	Obesity: managing surgery in adults
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Date of online publication	April 2009
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Objective(s)	<p>To improve the long-term efficacy of surgery and reduce the incidence of complications through:</p> <ul style="list-style-type: none"> - better selection, information provision and preparation of patients; - choice of the technique that provides the best benefit/risk ratio in the patients selected; - better formalisation of the members and role of the multidisciplinary team <p>To reduce the seriousness of complications through early detection and management.</p>
Professional(s) concerned	Surgeons, endocrinologists and diabetes specialists, nutritionists, dieticians, psychologists and psychiatrists, generalist physicians, nurses, physiotherapists and sports medicine teachers, gastroenterologists, anaesthetists and resuscitation specialists, radiologists and gynaecologists and obstetricians.
Requested by	Ministry of Health, Société française et francophone de chirurgie de l'obésité
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Project management	<p>Coordination: Dr Valérie Lindecker-Cournil, Project Manager, HAS Guidelines Department (Head of Department: Dr Patrice Dosquet)</p> <p>Secretarial services: Laetitia Cavalière</p> <p>Documentation research: Emmanuelle Blondet, with the assistance of Sylvie Lascols (Head of Documentation Department: Frédérique Pagès)</p>
Participants	<p>Learned societies, steering committee, working group, peer reviewers: see list of participants.</p> <p>Steering committee and working group members completed declarations of interest.</p>
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Literature search	January 2002 to December 2008 (cf. documentation research strategy in the evidence review)
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Validation	<p>Opinion of the guideline validation committee in December 2008</p> <p>Validation by the HAS Board in January 2009</p>
Other formats	Summary of the guidelines and scientific evidence review can be downloaded from www.has-sante.fr
Related documents	Technological assessment report "Sleeve gastrectomy for obesity", HAS, February 2008