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# SURGERY FOR OBESITY

## - a Health Technology Assessment

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Danish Health Technology Assessment (DACEHTA)

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# Summary


## Background

Severe obesity is an increasing problem in the West, and the issue is in focus, both in terms of prevention and treatment.

During recent years, weight loss surgery has been performed increasingly on obese individuals - so-called bariatric surgery. Combining an increased number of severely obese patients and a possibility of surgical intervention it seems that more and more severely obese individuals will be offered surgery and thereby make increasing demands on the organisational and surgical expertise. It is thus important to discuss the consequences of the initiated surgical intervention so far.

It is, however, also necessary to discuss the consequences of the intervention, including the organisational and financial consequences as well as the effect of the intervention on the patients.

## Objective

The purpose of the HTA is to update the evidence of the recommended surgical interventions for severe obesity in Denmark and the significance of the treatment for the patients operated on as well as examine the organisational and financial consequences of the interventions.

## Delimitation

As the intervention is an existing public offer the ethical aspect has not been included. The focus of the HTA is laparoscopic surgical treatment options in Danish hospitals. A socioeconomic analysis was beyond the time frame of this HTA.

## Method

Systematic literature searches have been carried out in order to examine the HTA issues regarding all HTA aspects.

The inclusion criteria were secondary and primary literature in the period 1990 - 2007, adults (20 - 60 years) in English or in Scandinavian languages.

Data were collected as a supplement to the systematic literature studies. Regarding the organisational aspect, group interviews of the staff at operating clinics were conducted, and supplementary questionnaires were handed out to departments that did not participate in the interviews. Regarding the financial aspect, the basis was DRG and DAGS rates as well as extracts from the National Hospital Discharge Register and the cost database of the National Board of Health.

## Results

### Technology

The available evidence shows that both laparoscopic banding and laparoscopic bypass result in considerable weight loss which is maintained over years but that the short-term weight loss (1 - 2 years postoperatively) is greater after laparoscopic bypass

(approx. 60 % - 70 %EWL) compared to laparoscopic banding (approx. 40 % - 50 %EWL). It is unknown whether this difference will remain over time as only few studies with follow-up >5 years and no studies comparing the two techniques over a long period of time have been performed.

Compared to a reduction in obesity-related complications, both banding and bypass show a significant effect in a large proportion of the patients (50 % - 100 %) in terms of recovery or improvement of existing type 2 diabetes, hypertension, sleep apnoea and dyslipidemia, all of which are important risk factors for cardiovascular diseases. Two well-performed case-control studies indicate that the effect may be greater after bypass with a particularly marked difference in recovery of type 2 diabetes. A comparison of bariatric surgery and conventional treatment of obesity furthermore shows an effect of surgery in terms of preventing new cases of diabetes and hypertension.

Generally, there are few deaths within 30 days of surgery (<1 %), both after laparoscopic banding and laparoscopic bypass. It is difficult to compare complications after laparoscopic banding and laparoscopic bypass due to limited documentation, characterised by substantial uncertainty due to large variation in the reporting of complications as well as substantial differences in the follow-up duration and follow-up rates. In general, both procedures are characterised by relatively few perioperative complications; however, it seems that there are further and more serious complications after laparoscopic bypass. In the longer term, the uncertainty regarding complications is even more pronounced and generally it can only be concluded that long-term complications occur more frequently than short-term complications with a significant frequency of reoperations, especially after laparoscopic banding. There is, however, a great difference between the types of long-term complications after the two procedures and thus a difference between the reasons for reoperations which complicates a direct comparison. After banding the problems particularly concern the presence of a foreign body in the abdominal cavity and beneath the skin, whereas the complications after bypass are primarily linked to the sutures in the bowel.

Overall, it is difficult to compare laparoscopic banding and laparoscopic bypass directly due to a pronounced lack of well-designed studies. There are, however, significant differences between the two procedures in relation to effect and risk with advantages and disadvantages of each procedure. Laparoscopic banding is a reversible procedure with fewer perioperative complications but also a smaller weight loss in the short term and a poorer effect on type 2 diabetes besides a tendency for more reoperations. Laparoscopic bypass is an irreversible procedure med greater elements of risk in terms of more perioperative complications but also greater advantages in terms of a greater weight loss in the short term and a tendency for a larger effect on the complications of obesity, primarily in relation to type 2 diabetes.

The choice of surgery type is thus not entirely simple and should be determined jointly by the patient and the surgeon. Different factors should be considered, e.g. preoperative weight, eating habits, complicationsof obesity, operation risk as well as the patient's considerations regarding the balance of risk and expected effect of the procedure. Furthermore, the most recent documentation should always be considered critically in terms of risk and effect data, and especially results from randomised, controlled studies of laparoscopic gastric banding compared with laparoscopic gastric bypass should be considered important in relation to a change in guidelines.

## Patient

The literature regarding the patients' quality of life shows that the patients experience significantly worse quality of life prior to the surgical procedure compared with the population in general. Irrespective of technique and type of intervention, literature shows concordantly that the patients' quality of life increases shortly after the surgical procedure and often reaches the level of the population in general. Studies following the patients for more than two years and with a follow-up rate of close to 100 % are, however, sparse.

The literature regarding the patients' physical, mental and psychosocial well-being indicates that depression is widespread among severely obese patients but that both types of surgical procedure result in a reduction of the patients' depressive symptoms. However, it cannot be ruled out that the depressive symptoms decrease for a number of years and then return. There is a tendency towards a decrease in the patients' level of anxiety postoperatively; this is based on studies regarding gastric bypass alone. Similarly, the patients achieve more self-respect after a surgical procedure irrespective of the type.

Between 12 % - 64 % of the patients suffer from an eating disorder in terms of overeating prior to the surgical procedure. This percentage decreases after the procedure – presumably because both gastric bypass and gastric banding makes it difficult to overeat. The mental problems behind the eating disorder will, however, still exist. The patients who do not overcome their problem of overeating furthermore regain a larger part of their postoperative weight loss. It should therefore be considered important to attempt. to treat overeating both before and after a surgical procedure instead of hoping that the procedure alone will solve the problem.

After the surgical procedure, it applies to both groups of patients that they can limit their intake of food to a higher degree, they eat less for emotional reasons and they feel less hungry. There have thus been significant changes in the patients' eating habits in terms of how much they eat, what they eat and why they eat. Furthermore, vomiting appears to be a relatively widespread problem after the surgical procedure.

The patients' physical activity has only been studied in patients who have had a gastric bypass. It shows an increase in the patients' physical activity; the patients resume activities that they were previously prevented from performing.

Only female patients' relations with possible partners has been studied. There is no unambiguous positive development in the relation with partners and the majority of the women consider the relationship unchanged. As the operated women (gastric bypass) become better at expressing their opinions and needs, the husbands seem less satisfied with their marriage. These results indicate that the changes in both the womens' appearance and behaviour may result in marital challenges. However, many patients have a better sex life after the surgical procedure.

The patients' attachment to the labour market has only been studied to a small extent. It seems that only very few of the patients who were unemployed prior to the surgical procedure found a job after the procedure. On the other hand, all patients who were employed prior to the surgical procedure remained on the labour market after the procedure.

In several respects, a chain reaction in the patients' physical, mental and social well-being after bariatric surgery seems to take place. The weight loss achieved by the patients, their quality of life, mental state, self-respect and social relations seem to interact. These complex relations are difficult to assess when focusing on the relationship between cause and effect which is the objective of many of the reviewed studies.

## Organisation

Almost every hospital (6 out of 7) performing bariatric surgery in Denmark performs both banding and bypass surgical procedures. The surgical procedures are performed as laparoscopic surgical procedures but are converted to open surgical procedures in case of complications. A larger number of bypass procedures are performed which may be explained by the relatively higher continued weight loss, a better functional result and fewer reoperations.

The framework for bariatric surgery in Denmark has been described in the report "Fedmekirurgi i Danmark" (bariatric surgery in Denmark). Operating hospitals have jointly prepared a common protocol to ensure that the care pathway in general is the same at the different hospitals and that the patients are met with similar requirements - particularly concerning weight loss. A common feature of the two surgery methods is that the pre- and post-operational course plays an important part in the overall result of the procedure. The surgical intervention must not be regarded as an isolated treatment of obesity; it is part of a continuous development focusing on the pre- and post-operational course.

Organisationally, there are only few differences between banding and bypass. On average, the bypass surgical procedure takes twice as long as the banding surgical procedure, the inpatient stay is generally longer for bypass patients, and banding patients have more control visits due to the adjustment of the band after the surgical procedure. The learning curve for bypass surgical procedures is longer, as they are technically more difficult than banding surgical procedures. The interviewed surgeons thus estimate that the individual surgeon must perform close to 100 bypass surgical procedures in order to obtain a good result; this is supported by literature.

Despite the written guidelines in the common protocol there is room for some variation in practice between the hospitals for the purpose of adjusting to the individual hospital. It has not been possible to analyse whether the differences in practice are important to the overall effect of the surgical procedure, as a national patient database is not yet available in which basic patient data, the type of surgical procedure, complications in connection with the surgical procedure, weight, quality of life, etc. are registered.

The interviewed staff expects that the demand for bariatric surgery will increase in future, in part because of an expected increase in the incidence of obesity in the population and in part because of the increased knowledge of the results of bariatric surgery. The predominant bottleneck in relation to increased capacity of bariatric surgery in Denmark is the number of qualified surgeons. At present, there are not enough skilled gastrointestinal surgeons capable of performing the advanced gastric banding and bypass surgical procedures. In the future, it will be necessary to use new methods of surgery in order to obtain satisfactory results in the increasing group of patients with an extremely high BMI, and there will be an increasing need for plastic surgery concurrent with the increasing extent of bariatric surgery.

### Economy

Overall, the quality of the literature regarding open versus laparoscopic surgery is relatively poor, and from a financial perspective it is not possible to conclude whether one method is better than the other.

The available financial literature in this area is limited to foreign studies and is in many cases methodically insufficient. Thus, no randomised studies comparing cost-effectiveness in gastric banding and gastric bypass are available. The performed cost-effectiveness studies indicate that gastric bypass is more cost-effective than gastric banding. The results should, however, be interpreted with caution as the effect estimates are based on few studies with a short time frame.

Preliminary studies of the impact of the surgical procedures on derived cost components, e.g. prescription-only medicine and admission, indicate that the surgical procedures result in a reduction of the use of such components and thereby cost savings which in some cases are of an extent that counterbalances the surgery costs.

Calculations of the overall direct variable hospital costs indicate that banding is a little cheaper than bypass, but since the calculations are vitiated by substantial uncertainty this result should be interpreted with caution. As only direct variable hospital costs are included, it is not possible to say whether the two methods differ regarding other cost components; the time consumption of the patients and increased operating room capacity are for instance not included.

## Conclusion

The two surgical methods may not be regarded as competitive methods for the same group of patients. The choice of method should be made in relation to what the patient is prepared for in terms of accepting side effects, the desired extent of weight loss and the intake of lifelong medicine.

It has been documented that surgery is an effective method of treating obesity compared to conventional therapy but documentation of the most effective method of surgery is limited. This applies to all aspects that have been examined in this HTA. The reason is primarily lack of good randomised, controlled studies and lack of long-term studies where the patients are followed for a number of years.

Bariatric surgery reduces the risk and incidence of complications. The two methods of surgery are typically chosen by different groups of patients and a direct comparison is therefore irrelevant. It is thus doubtful whether we will see randomised, controlled studies in the future for the purpose of comparing gastric bypass and gastric banding.

The patients experience increased self-respect and acceptance from their surroundings after losing weight. This may imply changed social behaviour which may result in both positive and negative consequences for their private lives.

The Danish common protocol ensures a relatively uniform care pathway whether the patient is treated in a private or public hospital. The lack of medical specialists who can perform bariatric surgery will entail that the demand for surgical procedures cannot be met.

From an overall perspective it may be concluded that the available literature does not point to a choice of either bypass instead of banding or vice versa, as there does not seem to be significant differences between the two methods, neither technologically, patient-wise or financially. The choice should therefore be made on the basis of the patient-doctor dialogue.

## Perspectives

In order to ensure that bariatric surgery is performed in the most appropriate way analyses of the organisation, the care pathway and the clinical results of bariatric surgery in Denmark are important. A national database – possibly in terms of Nordic cooperation – will enable a review of the effect of different clinical and organisational factors. Future analyses of data from a national database may thus form the basis for recommending measures that ensure the best effect and cost-effectiveness in terms of bariatric surgery.

In general, it is necessary to gather more information of the challenges faced by the patients in relation to adapting to the changes caused by the surgical procedure, including new eating habits, altered social relations and a changed body.

As the number of patients demanding surgical treatment of obesity is expected to increase, there will be an increased need for finding resources in terms of more staff and increased surgery capacity. Because of the increased number of patients with a considerable weight loss, there will also be an increased need for plastic surgical removal of surplus skin which is often a consequence of the large weight loss.

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