# Long-term effects of bariatric surgery

This is an excerpt from the full technical report, which is written in Norwegian. The excerpt provides the report's main messages in English.

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Long term effects of bariatric surgery
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	Norwegian Knowledge Centre for the Health Services summarizes and disseminates
	evidence concerning the effect of treatments, methods, and interventions in health
	services, in addition to monitoring health service quality. Our goal is to support good
	decision making in order to provide patients in Norway with the best possible care.
	The Centre is organized under The Norwegian Directorate for Health, but is
	scientifically and professionally independent. The Centre has no authority to develop
	health policy or responsibility to implement policies.
	We would like to thank all contributers for their expertise in this project. Norwegian
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	Osio, January 2014

# Key messages (English)

Obesity increases the risk for diseases and early death. In Norway bariatric surgery is offered to persons with morbid obesity (body mass index (BMI)  $\geq$  35 kg/m<sup>2</sup> with at least one obesity related comorbidity or KMI  $\geq$  40 kg/m<sup>2</sup>) when other treatments have been ineffective. We have summarized research of long-term effects after bariatric surgery compared with non-surgical treatment in persons with BMI  $\geq$  30 kg/m<sup>2</sup>. Based on the results from eight randomized controlled studies with follow-up of up to two years and eight prospective controlled studies studies with follow-up for up to 20 years, we conclude that:

- It is unclear wether bariatric surgery reduces total mortality and cardiovascular deaths from myocardial infarction and stroke. The quality of evidence is low to very low
- Bariatric surgery may induce a significant and persistent weight loss of 15-20 % for up to 10 years, depending on surgery type. The quality of evidence is moderate.
- Bariatric surgery may reduce prevalence of type 2 diabetes mellitus and remission of hypertension. The quality of evidence is moderate for diabetes and low for hypertension.
- Bariatric surgery may increase quality of life assessed as physical component scores. The quality of evidence is low.
- It is unclear whether bariatric surgery has effect on symptoms of anxiety and depression. The quality of evidence is very low.
- Prevalence of adverse events were unsystematically and inadequately reported.

Bariatric surgery had a positive effect on several outcomes, but effect size may vary based on type of surgery and treatment in the nonsurgical groups. The largest and most important weakness is the lack of large studies of good quality with long-term follow-up.

#### Title:

Long-term effects of bariatric surgery

# Health technology assessment

Health technology assessment (HTA) is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the development of safe, effective health policies that are patient focused and that seek to achieve best value.

#### Doesn't answer everything:

- Excludes studies that fall outside of the inclusion criteria
- No recommendations

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# Updated:

Last search for studies: November 2012.

#### Peer review:

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# **Executive summary (English)**

#### Background

Overweight and obesity have increased dramatically over the last 10 years, increaseing the risk of disease and premature death. The main treatments are change in diet and increased physical activity. Bariatric surgery has only been offered to people with morbid obesity when other treatments have been without effect. Morbid obesity is defined as a body mass index (BMI) of 35 kg/m<sup>2</sup> or greater with at least one comorbidity or BMI of 40 kg/m<sup>2</sup> or greater. Weight loss after bariatric surgery has been shown to be significant compared with other treatments after one or two years, but long-term effects and complications have not been well documented. The Secretariat of the National Council for Quality and Prioritization in Health Care Services requested that the Norwegian Knowledge Centre prepare a health technology assessment (HTA) of long-term effects after bariatric surgery compared with other treatments for obesity.

#### Objective

The aim of the present HTA is the compare the long-term results of bariatric surgery with non-surgical treatment in persons with BMI  $\ge$  30 kg/m<sup>2</sup>.

#### Method

We identified a Cochrane review of high quality which could be updated, "Surgery for Obesity" by Colquitt and coworkers, 2009. A systematic search for new primary studies was conducted on November 26.2012.

The inclusion criteria were randomized controlled trials (RCTs) or controlled prospective studies. All studies should have a minimum of one year follow-up and measurements of weight before and after the intervention:

**Population**: Persons  $\geq$  16 years with a body mass index (BMI) of 30 kg/m<sup>2</sup> or more **Intervention**: Bariatric surgery interventions such as gastric bypass, gastric sleeve and gastric banding with fixed or adjustable band

**Comparator**: Non-surgical treatments such as lifestyle, pharmaceutical and standard treatments. **Outcome**: Mortality, weight loss, obesity related comorbidities such as coronary heart diseases, type 2 diabetes, and cancers, quality of life, psychological symptoms and adverse events.

We excluded surgery types that no longer were in use due to of high risk of complication, and studies of intragastric balloon.

The effect size was estimated as relative risk or mean difference. The quality of the body of evidence for each outcome was assessed with the Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool. The quality of the documentation, that is, whether we have confidence that the effect estimate is close to a theoretically true underlying effect is assessed as high, moderate, low or very low.

#### Results

We included three RCTs and three prospective controlled studies that compared bariatric surgery with non-surgical treatments and were included in the Cochrane 2009 review. The search for new primary studies identified 5168 publications from which five RCTs and six prospective controlled trials were included. One of the studies in the Cochrane review, the SOS study, was the precursor of new publications that we identified. In total, we therefore included eight RCTs and eight prospective controlled studies.

#### Long-term follow-up

None of the included RCTs had follow-ups of more than two years. Three of the eight included prospective studies had follow-up beyond five years, one up to six years, one for up to seven years and one up to 20 years. Consistently, relatively few patients were included in each study, with the exception of two large cohort studies, the Swedish SOS study with 4047 participants and the US Utah study with 1156 participants. The SOS study and the Utah study compared three different surgery types (mainly band surgery) and gastric bypass, respectively, with standard treatment.

#### Mortality

Two studies examined overall mortality. In the SOS study, with up to 16 years follow-up (median 10.9 years), there was 29% (from 8% to 46%) reduced risk of dying in the surgery group compared with the non-surgical group. We have low confidence in the effect estimate (GRADE). In the Utah study, there was no detectable difference in overall mortality at six years (RR = 1.5, 95% CI: 0.65 to 2.81.) We have very low confidence in the effect estimate (GRADE). The results are therefore uncertain.

#### **Causes of death**

In the SOS study, there were fewer cardiovascular deaths in the surgery group than in the non-surgical group as analyzed by hazard ratio for a period of up to 20 years (median follow-up 14.7 years). We have very low confidence in the effect estimate because there were few incidents (GRADE).

## Weight

The results showed that the weight loss after surgery was significantly greater than for non-surgical treatment, and approximately 20 to 40 kg or 20 to 30% more, depending on the type of surgery, than in the non-surgical groups after two years. From six to 20 years after surgery weight loss was between 16-28% higher depending on the type of surgery. In the non-surgical groups that received standard treatment, the results showed no particular weight reduction. For non-surgical groups receiving intensive lifestyle interventions, the results showed a mean weight loss of 10 % after one year.

The mean difference between the surgery group and non-surgical groups after one and two years was: -21.2% (-19.1 to -23.2%) for the cohort studies and -21.3 (-16.3 to -26.2) for RCTs in favor of surgery. The difference in weight loss between the surgery groups and the non-surgical groups was after six years -27.8 % (-26.5 to -29.1 %) in favor of surgery group with gastric bypass. After 10 years, the difference was -18.1 % (-17.2 to -19.1 %) and after 20 years -16.33 % (-13.2 to -19.5 %) in favor of the surgery group in which the majority were gastric banding. Our confidence in the effect estimate was moderate after 10 years (due to great effect) and low after 20 years (GRADE).

#### **Coronary heart disease**

When the number of fatal and first-time non-fatal cardiovascular events such as heart attack and stroke were analyzed together, there were fewer events in the surgery group than in the non-surgical group in the SOS study over a period of 20 years (median follow-up 14.7 years). We have low confidence in the effect estimate (GRADE).

Two studies examined the incidence of hypertension and found that the incidence was lower in the surgery group than in the non-surgical group at two years followup. Long-term follow-up after six years (the Utah study) showed lower incidence in the surgery group than in the non-surgical groups, but no difference after 10 years (the SOS study). Remission of hypertension was higher in the surgery group than the non-surgical groups, both after one and two years (four studies) and after six (the Utah study) and 10 years (the SOS study). We have low confidence in the effect estimate (GRADE).

## **Type 2 Diabetes Mellitus**

Three cohort studies found that the incidence of diabetes was lower in the surgery group than in the non-surgical groups, both after two years and after six and 15 years. Our confidence in the overall quality of the documentation is moderate. In one RCT, there was no difference between the groups. We assessed the quality of the RCT to be very low (GRADE). Remission of diabetes was higher in the surgery group than in the non-surgical groups, both after one and two years (three RCTS and five cohort studies) and after six and 10 years (the Utah and the SOS study). We have

moderate confidence in the overall quality of the evidence, because the effect was large (GRADE).

#### Cancer

One study, the SOS study, found that the incidence of cancer was lower in the surgery group than in the non-surgical group after a median follow-up of 10 years. We have low confidence in the effect estimate (GRADE). When men and women were analyzed separately, the number of new cases of cancer was lower in women in the surgery group than in the non-surgical group. In men, there was no detectable difference. We have low confidence in the effect estimate for women and very low for men because of few events (GRADE).

## **Quality of life**

Quality of life, assessed as component scores for physical health and for mental health and social functioning in different questionnaires in five studies showed better physical health in the surgery group than in the non-surgical groups after one and two years. After six and 10 years, the results showed a change for the better in physical health in two studies, but no difference in absolute value (scores) in one of the studies (the SOS study).

The results for component scores of mental health and social functioning were inconsistent. Two studies showed no difference between the surgery groups and the non-surgical groups, and three studies showed better mental health and social functioning in the surgery groups after two years. After six years there was no difference between the groups in the Utah study, while the SOS study, with 10 - year follow-up, showed change for the better in the surgery group, but no difference between the groups in absolute value.

It was not possible to calculate effect estimates, but we concidered the quality of the documentation for component scores of physical health to be low. For component scores for mental health and social functioning, we considered the quality of the documentation to be very low and downgrade because of inconsistent results (GRADE).

## **Psychological symptoms**

Four studies examined the effect of bariatric surgery on psychological symptoms. The results showed no difference between the surgery groups and the non-surgical groups in symptoms of anxiety and depression reported in various questionnaires. One exception was the SOS study, which found fewer symptoms of anxiety and depression after two years, but more symptoms of anxiety in the surgery group and no differences in symptoms of depression after 10 years. There was no basis for calculating the effect estimate. We considered the quality of the documentation to be very low and downgrade because of inconsistent results (GRADE).

#### **Adverse events**

Adverse events were not systematically reported, making it difficult to draw any conclusions. At one and two years after surgery most studies only listed occurrence of adverse events, such as vitamin and mineral deficiencies and gastro-intestinal symptoms, in the surgical and non-surgical group. Reoperations, including conversion from gastric banding to another bariatric operation were reported in the SOS-study, and occurred in between 17 % (gastric bypass) and 30% (banding) of the surgery patients during 10 years.

#### Discussion

Our results correspond with the findings of other systematic reviews in terms of weight loss and incidence and remission of type 2 diabetes mellitus. Other reviews report better results for cardiovascular diseases, such as hypertension, than we found in our study, which may be due to differences in study design. We compared all kinds of surgery with all types of non-surgical treatment. This will affect the size of the effect estimates, because the surgery types, and also various non-surgical interventions, provide different effects on weight loss and certain obesity-related comorbidities. For health-related quality of life, the use of different questionnaires made it impossible to compile results.

#### Conclusion

It is uncertain whether obesity surgery reduces total mortality and the number of cardiovascular deaths. Bariatric surgery is more effective than other treatments for weight loss and incidence and remission of type 2 diabetes mellitus over a period of 10 years, but the effect estimate varies based on the type of surgery. It is possible that obesity surgery also has a positive long term effect on hypertension, but the size of the effect estimate is uncertain. One study reported that cancer incidence was lower in women, but not in men. It appears that physical health improves after bariatric surgery, but the results for mental health and social functioning reported in various quality of life questionnaires are uncertain. For symptoms of anxiety and depression the effect of bariatric surgery is uncertain. We found only incomplete and highly uncertain results concerning the incidence and number of side effects and the recurrence of comorbidities after remission. There are also many ethical issues related to the treatment. The largest and most important weakness is the lack of large studies of good quality with long-term follow-up.