

## Statement from the Regional HTA Centre of Region Västra Götaland, Sweden

### Bariatric surgery

#### Question at issue:

Does bariatric surgery have a positive effect on mortality and sequelae of obesity, compared with other treatments, or no treatment?

#### PICO (Patient, Intervention, Comparison, Outcome)

- P= BMI > 30 kg/m<sup>2</sup>, age 18-65 years.  
 I= Bariatric surgery, all types.  
 C= All other treatments  
 O= Mortality, co-morbidity, complications, adverse events.

#### **Summary of the mini-HTA:**

##### Method and patient category:

Weight-loss surgery has existed as a treatment for obesity for a long time and has, unlike non-surgical methods, a documented positive effect in terms of sustained weight loss. A variety of different weight-loss surgical techniques exist, but laparoscopic gastric bypass (GBP) has become the standard method in Sweden.

Obesity is defined as BMI  $\geq 30$  kg/m<sup>2</sup> and constitutes a global health problem that has continuously increased over the last 20 years. In Region Västra Götaland approximately 134,000 individuals have a BMI  $\geq 30$  kg/m<sup>2</sup> and about 30,000 individuals have a BMI  $\geq 35$  kg/m<sup>2</sup>. A significant proportion of these individuals are affected by or are at increased risk for complications.

##### Conclusions and level of evidence for studied patient benefit:

- Mortality. There were seven controlled trials, (four of moderate and three of low quality). Bariatric surgery in patients with BMI > 35-40 kg/m<sup>2</sup> reduces mortality (low level of evidence).
- Incidence of diabetes. There were four controlled studies (two of moderate and two of low quality). Bariatric surgery in patients with BMI > 35 kg/m<sup>2</sup> reduces the incidence of diabetes (low level of evidence).
- Remission (reversion) of diabetes. There were six controlled studies (one of high, two of moderate and three of low quality). Bariatric surgery in patients with BMI > 35 kg/m<sup>2</sup> promotes remission of diabetes, during an observation period of 2-10 years (low level of evidence).
- Hypertension. There were three controlled trials (two of moderate and one of low quality). Bariatric surgery may have a positive effect on hypertension (very low level of evidence), but the scientific documentation is insufficient.
- Other obesity-related morbidities (i.e. heart failure, myocardial infarction hypertension, dyslipidemia, musculoskeletal pain, sleep apnea) and health-related quality of life. There are a few isolated studies suggesting a positive effect (low to moderate quality). Overall, there is insufficient scientific documentation to conclude on how bariatric surgery affects these complications, or health-related quality of life (very low level of evidence).

Risks:

Risks associated with the therapy can be divided into three categories:

1. Risks related to the operation itself.
  2. Long-term surgical complications.
  3. Long-term nutritional complications.
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1. In large series, the peri- and postoperative mortality varies between 0.1 and 4%, largely depending on the surgical technique used, the level of co-morbidity and age group treated. Swedish data based on more than 20 years of bariatric surgery show mortality rates around 0.15 to 0.25%. Risks of serious complications associated with surgery are currently 1-2% at the Sahlgrenska University Hospital (bleeding, leakage, pulmonary embolism).
  2. The long-term surgical risk is dominated by bowel obstruction, which occurs in approximately 2% of the patients.
  3. Lack of mainly vitamin B12, calcium and iron can occur. Individualized substitution and annual blood sampling are recommended.

Ethical aspects:

1. Is it justified to increase the volume of bariatric surgery when the overall level of evidence for therapeutic benefits is low?
2. Are the risks of complications reasonable compared to the benefits of the intervention?
3. Will an expanded bariatric surgery displace other health care interventions?
4. Is it ethical not to increase the volume of bariatric surgery in Region Västra Götaland when the patient benefit regarding weight loss is so significant?

Economic aspects

The total cost per patient, undergoing surgery, is 2008 estimated to 100,000 SEK.

Concluding remarks

1. It is previously well documented that bariatric surgery is effective in terms of sustained weight reduction.
2. There is, albeit with low level of evidence, support for a positive effect in terms of mortality rate and diabetes.
3. The prerequisites to be able to conduct rigorous randomized trials are considered small.
4. Complication risks are judged to be reasonable in comparison with benefits of the intervention.
5. There is a displacement problem regarding other surgical care.

On behalf of the Regional HTA Centre of Region Västra Götaland, Sweden.

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