Bariatric surgery vs. conservative treatment for obesity and overweight

Assessment / Summary

January 29, 2016

Authors (Assessment Team en ordre alphabétique):
Zanfina Ademi¹, Heiner C. Bucher², Dominik Glinz², Viktoria Gloy²,
Samia Hurst³, Heike Raatz², Urs Saxer⁴, Matthias Schwenkglenks¹,⁵,
Joris Van Stiphout¹, Yuki Tomonaga⁵

¹Universität Basel, Institut für Pharmazeutische Medizin
²Basel Institute for Clinical Epidemiology and Biostatistics (CEB), Universitätsspital Basel
³Universität Genf, Institut Ethique Histoire Humanités (IEH2)
⁴University of Zurich and Steinbrüchel Hüssy Rechtsanwälte, Zürich
⁵Universität Zürich, Institut für Epidemiologie, Biostatistik und Prävention (EBPI)
1. Summary

1.1 Background

Obesity is a serious health problem associated with an increased risk for comorbidities, such as type 2 diabetes, hypertension, obstructive sleep apnoea and musculoskeletal disorders, and increased mortality. In Switzerland, the estimated health care costs due to obesity were 5,755 Mio. CHF in 2006 and 7,990 Mio. CHF in 2011. Of the Swiss population 30.8% are overweight (defined as body mass index, BMI 25.0-29.9 kg/m²) and 10.3% are obese (BMI ≥30 kg/m²). In Switzerland an adequate conservative treatment of obesity includes any combination of nutritional counselling by a nutritionist or physician, behavioural therapy including psychotherapy, diets to reduce caloric intake, physical therapy including physiotherapy or medication.

If adequate conservative treatment fails, bariatric (weight-loss) surgery can be considered. Conservative treatment is regarded as failed if in two years of conservative treatment or thereafter a BMI of <35 kg/m² cannot be reached and maintained. Swiss statutory health insurance ("obligatorische Krankenpflegeversicherung") covers certain types of bariatric surgery in obese individuals with a BMI ≥35 kg/m² independent of existing comorbidities. In Switzerland 4,167 bariatric operations were performed in 2014 showing a marked increase from 2001 when only 703 operations were performed. About 82.5% of all bariatric operations are gastric bypass (Roux-en Y gastric bypass, RYGB), 15.7% are sleeve gastrectomy (SG), 0.8% are adjustable gastric banding (AGB) and 0.7% are biliopancreatic diversion (BPD). Vertical banded gastroplasty (VBG) is covered but de facto no longer performed in Switzerland. Most of the operations are performed laparoscopically instead of open surgery. The RYGB involves surgical rearrangements of the stomach (the stomach becomes a smaller pouch) and small intestine limiting calorie intake and absorption of calories. In the case of AGB, an adjustable ring put around the stomach allows only the ingestion of small food portions. The ring can be adjusted via an access port. In the case of SG the size of the stomach is reduced to a sleeve-like small pouch, while the pouch in the case of VBG is created using a (non-adjustable) band and staples.

While there is a relatively extensive international literature, there are only few studies for Switzerland which examine the overall cost of obesity. There is clearly no Swiss modelling of the cost-effectiveness of bariatric surgery or gastric bypass for overweight (BMI 25-29.9 kg/m²) and obese (BMI ≥30 kg/m²) adults.

1.2 Aim

The aim of this HTA report is to assess

- the effectiveness and safety
- the cost-effectiveness and budget impact analyses,
- legal and as well as ethical implications

of bariatric surgery compared to conservative treatment, both in the population currently covered by the OKP (i.e. obese individuals with a BMI ≥35 kg/m²) and in patients currently not covered by the OKP (i.e. overweight or obese individuals with a BMI of 25 - 35 kg/m²). While all the surgical interventions currently used were being considered, the main focus was gastric bypass.
1.3 Clinical effectiveness and safety

For this HTA report the clinical effectiveness and safety of bariatric surgery compared to conservative treatment was assessed. The search was conducted in July 2015 and filters for randomised controlled studies (RCT) were used. The search was not limited for the time period, but was restricted to the languages English, German, French and Italian. Study characteristics and results of the included studies were presented per study in tables and summarized descriptively. The main focus of the analysis were the combined results after 2 or 3 years follow-up, but the combined results of the 6, 9 and 12 months follow-up were analysed and presented as well. Risk of bias and quality of evidence were assessed for included studies with 2 or 3 years follow-up as the primary focus was on long-term outcome. For additional information results after a follow-up of 6 months to 1 year were pooled as well but not evaluated according to GRADE. Risk of bias was assessed according to the Cochrane Handbook and the quality of evidence was assessed according to GRADE. Where possible, outcome results were summarized quantitatively in a meta-analysis by using inverse variance models assuming random effects. Effect estimates (summary and single for each trial) with corresponding 95% confidence interval were presented as forest plots. Relative risks were calculated for binary outcomes. Continuous outcomes were presented as mean differences. In case of considerable heterogeneity methodological and clinical factors that might explain the heterogeneity were explored in subgroup and sensitivity analyses, where possible. Some of the pre-specified subgroup analyses were the surgical method (i.e. gastric bypass vs. adjustable gastric banding vs. other surgical interventions) and patients with a BMI ≥35 kg/m² vs. patients with a BMI 25-34.9 kg/m².

Sixteen RCTs fulfilled the inclusion criteria with 10 RCTs reporting 2 or 3 year data. Most of the RCTs with 2 or 3 year data included patients with specific comorbidities (type 2 diabetes: 6 RCTs, sleep apnoea: 2 RCTs, mix of possible comorbidities: 1 RCT), only one RCT did not specify a comorbidity as inclusion criterion. Of the 13 outcomes assessed those classified as critical were body weight, quality of life, HbA1c (diabetes control), stroke, myocardial infarction.

The effects observed in our meta-analyses for the 2 to 3 years results were very consistent with a statistically significant benefit in the surgical arm compared to the conservative treatment for the critical outcomes percent body weight change, physical function (quality of life summary component), HbA1c, and diabetes remission, and the important outcomes hypertension and dyslipidaemia.

No statistically significant effect was shown for mental health (quality of life summary component), stroke, all-cause mortality, serious adverse events (SAE) including reoperations, and sleep apnoea.

Data was extremely sparse (max. 1 event) or not existing for the critical outcomes stroke and the important outcomes mortality, myocardial infarction, cancer and revision rates, therefore no conclusions can be drawn for these outcomes.

In the stratified presentation of results for the different surgical techniques or on BMI (BMI 25-34.9 kg/m² vs. BMI ≥35 kg/m²), the direction of the observed effects – when they were present – consistently showed a benefit for bariatric surgery compared to conservative treatment. Results were stratified by surgical technique but effect estimates were not compared statistically by subgroup analyses because of the small number of studies within strata.

The quality of evidence was moderate for the critical outcome percentage body weight change and low for change in HbA1c. The overall quality of the evidence is judged to be very low because of the very low quality of evidence for the critical outcomes mental health and stroke and the absence of data from RCTs on myocardial infarction.
Significant uncertainties remain regarding outcomes in the long-term (>3 years) and the overweight population, where no or little data were available.

1.4 Cost-effectiveness and budget impact analyses

Relevant databases including Medline, Embase, the Cochrane Library, the Centre for Review and Dissemination (CRD) database, the UK National Health Service's Economic Evaluation Database (NHS EED) were systematically searched for relevant health economic articles. Quality of reporting was assessed against the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 24-item checklist, recommended by the ISPOR Health Economic Evaluations Publication Guidelines Task Force. For international studies, qualitative transferability to Switzerland was assessed as described in section 4.2.4. In the case of studies classified as quantitatively transferable to Switzerland, direct medical costs data were adapted to improve comparability, in three distinct steps: correction for different levels of resource utilisation, for different prices of healthcare services, and for change in level of resource utilisation and prices over time. Subsequently, adapted incremental cost-effectiveness ratios (ICERs) were calculated. Budget impact has been addressed by combining Swiss epidemiological data with Swiss and adapted international cost data. Considering the limited data available, two approaches were pursued. Firstly, the potential surgery costs for treating all eligible Swiss patients in a single year were estimated. Secondly, the potential costs of bariatric surgery over a time period of ten years, from 2011 until 2020, were assessed from a Swiss healthcare system perspective.

Twenty-one cost-effectiveness analyses and one systematic review were finally included in this report and were assessed using the CHEERS checklist. About half of the studies were performed in Europe, whereas the rest was conducted in the US or Australia, and vast majority assessed cost-effectiveness as cost per QALY gained, over time horizons ranging from 5 years to lifelong. A total of 15 articles fulfilled criteria for qualitative transferability and underwent numerical adaptation of ICER results to Switzerland. Adopted studies were from healthcare, payer and societal perspective. Their modelling of clinical effectiveness was based on short-term clinical trials and longer-term observational data (such as the SOS study).

All studies of patients with BMI values >35 kg/m² indicated bariatric surgery to be cost-saving or cost-effective, based on the criteria set by the authors. Adapted ICERs for Switzerland were below CHF 50,000 per quality-adjusted life year (QALY) gained.

When studies like Borg et al. adopted a societal perspective, adapted ICERs for females aged 45-54 with BMI 40-44 kg/m² were below CHF 3,000 when gastric bypass was compared to conventional treatment. For males aged 45-54 with BMI 40-44 kg/m², gastric bypass was cost-saving and thus dominant. Michaud et al. also reported cost-effectiveness from a societal perspective, for US patients with BMI >40 kg/m² or with BMI >35 kg/m² and a high risk of co-morbidities. The adapted ICER for gastric bypass compared to conventional treatment was CHF 8,158 per life year gained.

For patients in the BMI class <35 kg/m², the adopted ICER from societal perspective was CHF 10,458 per QALY gained for females, and the adopted ICER for males was CHF 12,365 per QALY gained in the Borg et al. study. For extended eligibility (BMI >35 or BMI >30 kg/m² with qualifying co-morbidities), the adapted ICER for gastric bypass compared to conventional treatment was CHF 10,502 per life year gained.

Procedure-specific differences in terms of benefit and efficiency appear to exist. When gastric bypass and gastric banding were compared to conventional treatment, gastric bypass appeared
to be better than gastric banding in terms of benefits (QALYs gained and life years saved), but also more expensive.

According to first approach, in 2012 there were almost 25,000 persons in Switzerland with a BMI >40 kg/m². The costs for surgical treatment of all these individuals in a single year would reach CHF 353 Mio. In addition, if 10-30% of people in Switzerland with BMI 35-40 kg/m² were surgically treated due to the presence of relevant co-morbidities, the total costs of surgery would reach CHF 496-781 Mio. In 2014, the estimated total surgery costs for the 4,153 surgeries actually performed in Switzerland were CHF 61.1 Mio.

In the second approach, the budget impact estimation was based on a single, European cost-effectiveness study by Ackroyd et al. The results of the budget impact estimation over ten years strongly depended on the assumptions made. For example, if the diabetes prevalence in obese patients was 10%, the incremental costs of bariatric surgery in 2016 might reach CHF 55.1 Mio. In contrast, a diabetes prevalence in obese patients of 40% might make bariatric surgery cost-saving (CHF -1.2 Mio.).

Virtually all studies found bariatric surgery to be cost-saving or cost-effective, compared to conventional treatment. Adapted ICER results for patients with a BMI >35 kg/m² indicated a cost-saving (dominant) situation or showed ICERs of CHF 8,000 to CHF 44,000 per QALY gained. Adapted ICER results for patients with a BMI <35 kg/m² suggested a cost-effective situation with cost of CHF 3,000 to CHF 50,000 per QALY gained. Differences were due to approaches to the modelling of effectiveness (in terms of duration of BMI changes and dependent effects on morbidity, mortality and costs), time horizon, population studied, exact type of intervention studied, and possibly other reasons.

The first part of the budget impact analysis can only be used to describe the potential magnitude of immediate surgical intervention costs at the national level. The second part of analysis over ten years was based on single study for Germany, selected for availability of sufficient numerical detail. It was performed under numerous assumptions and is subject to substantial limitations. The results can't be considered accurate and definitive, but may be give a rough idea of the potential magnitude of bariatric surgery-related budget impact.

1.5 Assessment of the legal domain

Starting point of the legal analysis are the pertinent provisions of the Federal Swiss Health Insurance Act (HIA). The HIA establishes a system of compulsory social health insurance for all Swiss residents.

Obesity and overweight are not generally considered as illness according to the legal definition in Art. 1a (2) (a) HIA. Only extremer forms qualify as an illness. The details are regulated by an ordinance of the Swiss Government and by the Medical Guidelines of the SMOB. Overweight has to pass a certain threshold to qualify as an illness. To cure that illness, the applicable legal rules provide for both conservative treatments as well as bariatric surgery. The methods and treatments not covered by the mandatory health insurance may be applied nonetheless if they are medically sound and based on an agreement between doctor and patient. Coverage of the costs, however, depends on whether the status of a person may be qualified as an illness.

According to the findings of the report as well as of the SMOB in the Medical Guidelines there is some evidence for a certain superiority of bariatric surgery over conservative treatments. The
applicable legal norms, however, require as a general rule first a two year conservative treatment. The costs of earlier bariatric surgery are therefore usually not covered by the public health insurance. Health law thus displays a bias for conservative treatment and against bariatric surgery. This may not be justified as shown by the present report, because for some outcomes bariatric surgery was shown to be more effective e.g. on body weight loss at lower costs than conservative treatment. Therefore, the ordinance regulating the benefits of the public health insurance should be accordingly amended so that doctors from the very beginning may make an independent assessment in a specific situation which method has the most positive impact on a patient’s health status.

1.6 Assessment of ethical issues

The evidence for the ethical assessment was reviewed based on:

1. issues which became apparent during scoping, and in subsequent discussions during assessment;
2. a systematic analysis of possible ethical issues based on three grids;
3. a literature search in Pubmed and EBSCO for ethical issues associated with bariatric surgery using keywords associated with both of these terms, followed by screening of resulting titles, abstracts and papers. As recommended by EUnetHTA, this literature search was complemented by a reflective process of literature consultations on ethical issues associated with other, more studied, situations or technologies that pose similar issues.

The purpose of the ethics component of the assessment phase is to yield a series of questions, issues and comments to be integrated during ethical evaluation in the appraisal phase. The interventions involved in weight loss surgery are, for the most part, not new and have been used in other indications. The main ethical issues are thus not associated with the use of new interventions per se but with their increasing use in the treatment of obesity. The main questions raised here are associated with the status of obesity as a disease, the risk of stigmatizing patients or of medicalising social problems through the surgical approach of obesity. Although questions related to personal responsibility for health have been raised in the literature, counter-arguments to integrating this aspect into decisions regarding treatment and coverage have also been brought forward. Other issues are raised by the increased use of bariatric surgery itself, such as how to respect patient autonomy, what requirements can be justified before undergoing surgery, operating on children and adolescents, unequal access, and risks associated with a commercialized innovation.