

Second scoping draft on Bariatric surgery (Gastric Bypass)

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1. Rationale for the Scope

Three considerations played a major role in the scoping of the question on bariatric surgery: 1. The question should be of clinical interest. 2. It should be of interest to investigate the possible economic, legal and ethical implications of the results on the clinical effectiveness and safety, 3. The subject should be feasible with the available resources.

Currently the Swiss obligatory health insurance (“obligatorische Krankenpflegeversicherung, OKP”) only covers bariatric surgery in obese individuals with a BMI ≥ 35 kg/m². It seems to be relatively clear that patients with a BMI ≥ 35 kg/m² benefit from bariatric surgery in clinical terms, while economic, legal and ethical implications are unknown. At the same time, it seems to be unclear whether overweight or obese patients (BMI 25.0-34.9) and co-morbidities would also profit from bariatric surgery and whether it should be offered to this population as well or not. Gastric bypass is the most frequently used surgical technique in Switzerland (approx. 80% of bariatric surgery) and internationally but the evidence base – especially for the overweight and obese population with a BMI < 35 kg/m² is relatively slim. Therefore we suggest investigating the possible consequences of extending bariatric surgery in general to patients with a BMI < 35 kg/m² but with a special focus on patients treated with gastric bypass.

In order to do this we would assess the effectiveness and safety as well as the economic, legal and ethical implications of bariatric surgery compared to conservative treatment both in the population currently covered by the OKP (i.e. with a BMI ≥ 35 kg/m²) and in patients currently not covered by the OKP (i.e. with a BMI < 35 kg/m²). The impact of extending the treatment to this population would be explored.

During scoping two other potential topics emerged in the discussion with clinicians. The first topic is less broad than the one we are suggesting while the second topic has a different focus from the initial topic submitted to the SMB. If the SMB is interested in this second topic as well it could be included in the report but it would require additional funds.

- Alternative topic 1: Comparison of gastric bypass with conservative treatment in patients with a BMI ≥ 35 kg/m²: for the medical community it seems to be quite clear that gastric bypass is superior to conservative treatment. A HTA report limited to this population would mainly add information on the economic, ethical and legal implications of the coverage of this treatment in Switzerland.
- Alternative topic 2: Comparison of gastric bypass vs. sleeve gastrectomy in patients with a BMI ≥ 35 kg/m²: from a clinical point of view there seems to be some debate which surgical technique is better, even though there are some instances where one technique would be used and the other is contra-indicated. Identifying the costs associated with sleeve gastrectomy may prove a bit difficult though and it seems unlikely they will differ hugely from the costs for a gastric bypass. It also seems probable that the effectiveness and safety of the 2 techniques will not differ hugely. So while it would be interesting from a clinical point of view

to investigate which technique is better, it seems doubtful that a change of the surgical technique in Switzerland would have important economic, legal and ethical implications for the country – diminishing the interest this topic might have for a HTA.

2. PICO-Question

- **Population:** Overweight (BMI 25-29 kg/m²) and obese (BMI ≥30 kg/m²) adults
- **Intervention:** Bariatric surgery (see also section 2.1)
- **Comparator:** Conservative treatment (see also section 2.2)
- **Outcomes for the effectiveness and safety assessment (see also section 2.3):**
 - **Critical:**
 1. Percent body weight loss
 2. Quality of life
 3. Obesity related co-morbidities:
 - i. HBA1_c (diabetes control)
 - ii. Stroke
 - iii. Myocardial infarction
 - **Important:**
 4. Mortality
 5. Serious adverse events/ reoperations (both perioperative (≤ 30 days after surgery) and longer term (> 30 days after surgery))
 6. Diabetes remission
 7. Control of hypertension
 8. Dyslipidemia
 9. Sleep apnoea
 10. Cancer
 11. Revision rates (planned or unplanned)
 - **Not so important (were discussed during scoping, but won't be assessed as part of the report/ meta-analysis):**
 1. Excess weight loss
 2. Metabolic syndrome
 3. Non-alcoholic steatohepatitis (NASH)
 4. Absolute change in weight
 5. Absolute change in BMI
 6. Change in depression
 7. Change in number of medications taken (excluding vitamins and supplements)
 8. Adverse events (e.g. malnutrition/ nutritional deficits, dumping syndrome)
- **Economic Outcomes:**
 1. Quality adjusted life years (QALYs), life years gained (LYG)
 2. Direct costs (including inpatient, outpatient, and treatment costs)
 3. Indirect costs (in particular costs related to productivity loss)
 4. Incremental cost-effectiveness ratio (cost per quality-adjusted life year gained, cost per life year gained)

2.1. Intervention

Any form of bariatric surgery will be included in the HTA report.

A particular focus will lie on the assessment of the effects of gastric bypass. Studies investigating the following forms of gastric bypass will be considered to be relevant for the gastric bypass group:

- Laparoscopic gastric bypass
- Banded gastric bypass
- Gastric bypass with robotic assistance

Studies investigating the following forms of gastric bypass will be **excluded from the gastric bypass group** but would be considered in the group “other surgical interventions”:

- Open gastric bypass
- Distal gastric bypass
- Mini bypass
- Omega loop bypass
- Very long limb bypass

Surgical techniques, which will **not** be considered in the systematic review are:

- Jejunioileal bypass/plication
- Gastric imbrication/plication

2.2. Comparator

Conservative treatment includes different kinds of non-surgical treatment as specified in the publications like usual care, pharmacotherapy, diets, life-style modification etc. either on their own or in combination.

2.3. Outcomes

Re-operation will be defined as operations performed due to problems/complications of the initial intervention like treatment of hernias, developed post-operatively, insufficiency of the anastomosis etc. Revisions are performed when the initial intervention is for example ineffective: i.e. and there for the procedure is being changed into another one (Umwandlungsoperation).

3. Systematic Review

The clinical effectiveness and harm of bariatric surgery compared to conservative treatment will be assessed in randomized controlled trials (RCTs) published in German, French, English or Italian. In subgroup analyses we will look at the effects of gastric bypass surgery and surgery in overweight and obese patients with a BMI below $<35 \text{ kg/m}^2$ though we expect the evidence base for the latter outcome to be very small.

Subgroup analyses in the systematic review

- **Intervention**
Gastric bypass vs. adjustable gastric bypass vs. other surgical interventions (see also section 2.1)
- **Population:**
Patients with a BMI $\geq 35 \text{ kg/m}^2$ with comorbidities vs. patients with a BMI $25\text{-}34 \text{ kg/m}^2$ with comorbidities

If possible we will investigate the influence of the risk of bias on the observed effects by investigating subgroups, i.e.:

- Adequate vs. inadequate allocation concealment and randomisation
- Adequate vs. inadequate blinding of patients, carers, and outcome assessors
- Complete vs. incomplete outcome data.

Sensitivity analyses

We will include any kind of gastric bypass technique in the gastric bypass group (including the excluded techniques as specified in the paragraph on intervention.)

4. Health economic assessment

4.1. Description and rationale

As part of the scoping process we have performed a literature search to identify available Health Technology Assessments and economic studies with regards to the above-defined PICO question. While there is a relatively broad international literature, there are only few studies for Switzerland, which examine the cost (economic burden) of obesity. There is clearly no modelling of the cost-effectiveness of bariatric surgery/ gastric bypass for patients with comorbidities and a BMI ≥ 35 kg/m² or BMI < 35 kg/m² in Switzerland. International cost-effectiveness results vary between studies due to inclusion criteria with regards to BMI, disease comorbidities, and the health system perspective. Mainly the respective studies showed that QALY gains were higher in the surgery group compared to usual care group (i.e. without surgery) with regards to patients with comorbidities and a BMI ≥ 35 kg/m². Results were highly dependent on the type of economic evaluation performed (e.g. inclusion of direct/indirect costs), definition and severity of obesity, and comparator used. Due to lack of available data in Switzerland in terms of healthcare resource use we propose to undertake systematic review of the economic literature to understand the impact of bariatric surgery in terms of cost effectiveness and budget impact.

4.2. Systematic review of the health economic evaluations

4.2.1. Search strategy

The aim of the literature search will be to identify literature on the cost and cost-effectiveness of gastric bypass surgery for overweight and obese, adult patients.

4.2.2. Quality assessment of the selected health economic evaluations

The quality of the identified economic studies will be critically assessed. As one tool, the “Consolidated health economic evaluation reporting standards” (CHEERS) checklist will be used. The CHEERS checklist has been issued by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) as an instrument to assess the quality of reporting of health economic evaluations. The primary focus of CHEERS is to examine the quality of reporting of health economic evaluations and recommendations are subdivided into six main categories: 1) title and abstract, 2) introduction, 3) methods, 4) results, 5) discussion, and 6) other.

4.2.3. Transferability and validation

Transferability of international results to Switzerland and validation of the results will be critically assessed.

4.2.4. Data extraction

Data of relevance for Switzerland will be extracted from the national and international literature. In a first section, the identified literature will be reviewed to assess the impact of the intervention on health-related quality of life, QALYs gained and/or LYG. In a second section the costs of the intervention and comparator as well as the cost per QALY or LYG will be reviewed and extracted.

4.2.5. Data adaptation

Given that there is little evidence on the economics of bariatric surgery in Switzerland, the review of the economic literature will mainly be based on international publications. In this view, an adaptation of the results to the Swiss context is necessary. Based on what will be extracted from the literature in terms of costs and cost per QALY, an adaptation to the Swiss health system setting will take place. In order to perform the adaptation we will take into account aspects such as purchasing power parity, health care expenses per capita, etc.

4.2.6. Budget impact analysis

The expenditure of bariatric surgery (in particular of bariatric bypass) and its impact on the Swiss healthcare system will be investigated. Swiss epidemiological data concerning disease prevalence will be combined with the estimated costs of surgery in Swiss hospitals and/or the cost difference between the intervention and comparator strategies to derive the yearly budget impact.