

Bariatric surgery in adolescents with severe obesity

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Bariatric surgery in adolescents with severe obesity [Bariatrisk kirurgi för ungdomar med svår fetma]

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HTA-centrum

Utlåtande och sammanfattande bedömning från Kvalitetssäkringsgruppen

Bariatrisk kirurgi för ungdomar med svår obesitas

Frågeställning:

1. Har bariatrisk laparoskopisk kirurgi ett bättre utfall än konservativ icke-kirurgisk behandling avseende mortalitet, hälsorelaterad livskvalitet, socialisering, sjuklighet på lång sikt, korttids-komplikationer, viktneidgång, och påverkan på diabetes typ2/ metabola syndromet hos ungdomar med svår obesitas?
2. Skiljer sig utfallet hos ungdomar jämfört med vuxna?

PICO: (Patient, Intervention, Comparison, Outcome)

P = Ungdomar 13-18 år med svår obesitas (BMI eller isoBMI >35 kg/m²)

I = Bariatrisk kirurgi

C = Konservativ icke-kirurgisk behandling (livsstilsförändringar, farmakologisk eller ingen behandling)

O = Kritiska för beslutsfattande: mortalitet, suicid, livskvalitet, långtids-komplikationer
Viktiga: korttids-komplikationer, vikt- och BMI-förändringar, diabetes typ2 /metabola syndromet

Metod och målgrupp:

Svår obesitas hos barn och ungdomar är ett allvarligt medicinskt tillstånd som påverkar hälsa och välbefinnande. Preventiva åtgärder är i vissa fall otillräckliga. Bariatrisk kirurgi har börjat tillämpas allt längre ner i åldrarna. I Sverige har ungdomar efter genomgången pubertet opererats med den laparoskopiska metoden Roux-en-Y gastric bypass. Föreliggande rapport avser alla typer av bariatrisk kirurgi.

Kunskapsläge och evidensgradering:

Litteratursökningen identifierade en randomiserad kontrollerad studie (RCT), tre kohortstudier, en systematisk översikt samt 17 fallserier, av vilka sex jämförde ungdomar med vuxna.

Mortalitet

Ett post-operativt dödsfall har rapporterats efter öppen kirurgi, samt ytterligare nio sena dödsfall (sex månader till fyra år) i nio fallserier (totalt 2375 patienter).

Hälsorelaterad livskvalitet

En RCT (n=50) mätte livskvalitet med validerat instrument (Child Health Questionnaire) vid två års uppföljning hos en grupp opererade med laparoskopisk "gastric banding" och en grupp med livsstilsintervention. Av enkätens 11 domäner, visade den opererade gruppen jämfört med den icke-kirurgiskt behandlade gruppen, en statistiskt signifikant och kliniskt relevant förbättring inom två; "physical functioning" och "change in health".

I en svensk kohortstudie (n=81) mättes livskvalitet med SF-36 vid två års uppföljning av patienter opererade med laparoskopisk "gastric bypass", men uppföljning av kontrollgruppen med konventionell behandling planeras inte förrän vid fem år. Inom den opererade gruppen, jämfört med tidpunkten före operation, noterades signifikant förbättring inom sex av åtta domäner.

Slutsats: Bariatrisk kirurgi jämfört med konventionell behandling hos ungdomar med svår obesitas förbättrar troligen hälsorelaterad livskvalitet något.

Begränsat vetenskapligt underlag (GRADE ⊕⊕○○).

Sjuklighet på lång sikt är otillräckligt studerat.

Korttids-komplikationer (inom två år) är vanliga både bland de opererade och de konventionellt behandlade. Akuta komplikationer efter kirurgi är blödningar och infektioner. Andra komplikationer är depression, gallsten/cholecystektomi, bråck, tarmvred, vitamin-, järn- och mineralbrist samt överflödigt hud som kräver bukplastik.

Slutsats: Både kirurgi och obesitas i sig är förenat med hög risk för komplikationer. Otillräckligt vetenskapligt underlag (GRADE ⊕○○○).

Vikt-och BMI-förändringar

En RCT och tre kohort studier påvisade significant viktreduktion; 28-38% vid ett och två års uppföljning efter bariatrisk kirurgi, jämfört med 3% viktreduktion till 3% viktuppgång efter icke-kirurgisk behandling.

Slutsats: Bariatrisk kirurgi jämfört med konventionell behandling hos ungdomar med svår obesitas resulterar i stor viktnedgång. Måttligt starkt vetenskapligt underlag (GRADE ⊕⊕⊕○).

Diabetes typ2 /metabola syndromet

En RCT (n=50) påvisade signifikant förbättring i insulinkänslighet hos patienter opererade med ”gastric banding” jämfört med icke-kirurgisk behandling men inga förändringar i P-insulin eller P-glukos, mätt vid två års uppföljning. Förekomsten av metaboliskt syndrom försvann helt i den opererade gruppen, men kvarstod i kontrollgruppen (p<0.03).

Slutsats: Bariatrisk kirurgi jämfört med konventionell behandling hos ungdomar med svår obesitas kan förbättra insulinkänslighet och metaboliskt syndrom. Begränsat vetenskapligt underlag (GRADE ⊕⊕○○).

Litteraturen avseende jämförelse mellan ungdomar och vuxna utgörs av sex fallserier och direkta jämförelser är endast gjorda avseende utfallet vikt- och BMI-förändringar. Viktreduktionen mätt vid ett och två år är av samma storleksordning i båda grupper (28-38%). Diabetes typ 2 var vid tidpunkten för operation vanligare bland vuxna än hos ungdomar.

Etiska aspekter:

Att överväga bariatrisk kirurgi hos en ungdom är förenat med svåra etiska överväganden. Beslut ska fattas medan individen fortfarande växer och det saknas helt data avseende långtidsuppföljning. Ofta anses en tonåring själv mogen att fatta beslut, men bariatrisk kirurgi är ett ingrepp som kommer att påverka individen för resten av livet och det kan vara svårt att överblicka för en ungdom. Ofta ses svårigheter för ungdomen att fullfölja substitutionsprogram med vitaminer och mineraler. Familjen behöver vara starkt engagerad.

Denna patientgrupp är socialt utsatt och det finns starka förhoppningar att bariatrisk kirurgi med efterföljande viktnedgång skulle kunna förbättra livskvaliteten och minska utanförskapet.

Ekonomiska aspekter:

Samhällets kostnader för fetma ökar i takt med att prevalensen av fetma och svår fetma ökar även hos ungdomar. Kostnaden för konventionell behandling skattas till 16 000 till 20 000 SEK per individ och år, men kan variera stort beroende på hur mycket sjukvården belastas. Kostnaden för kirurgi samt tre till fyra anslutande vårddagar är beräknad till 70 000 SEK per patient. De flesta patienter kommer även behöva genomgå en bukplastik, till ungefär samma kostnad.

Slutsatser:

Bariatrisk kirurgi hos ungdomar kan ses som ett behandlingsalternativ vid svår fetma, då alla preventiva åtgärder samt konventionell behandling med livsstilsförändringar och medicin har misslyckats. Metoden resulterar i en uttalad viktnedgång, men komplikationer är vanligt förekommande. Jämfört med konventionell behandling kan livskvaliteten förbättras något. Obesitas är i sig associerat med medicinska risker och data tyder på att risk för diabetes och metabola syndromet kan minska. Data från långtidsuppföljning saknas ännu helt.

HTA-kvalitetssäkringsgruppen har ett uppdrag att yttra sig över genomförda HTA i Västra Götalandsregionen. Yttrandet skall innefatta sammanfattning av frågeställning, samlat kunskapsläge och evidensgradering för patientnytta och risker samt ekonomiska och etiska aspekter för den studerande teknologin.

Projektet har pågått under perioden 2013-03-14 – 2013-10-30
Sista uppdatering av artikelsökning månad 2012

För HTA-kvalitetssäkringsgruppen 2013-10-30

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Method and patient group

Childhood obesity is a serious medical condition where excess body fat negatively affects a child's health and well-being. Although prevention is the primary step, there will be adolescents with severe obesity, who would possibly benefit from bariatric surgery. Among several laparoscopic methods, the Roux-en-Y gastric bypass technique has emerged as the preferred method, due to improved eating behavior, larger weight loss and preserved muscle mass compared to other techniques. The present report concerns all types of bariatric surgery. The patients considered for this treatment are children and adolescents 13-18 years of age with severe obesity (defined as BMI or iso-BMI >35).

Questions at issue, PICO

- Do severely obese adolescents have a better outcome of bariatric surgery compared to non-surgical treatment in terms of mortality, quality of life and socialisation, long-term morbidity, short-term complications, weight loss and impact on diabetes type-2/the metabolic syndrome?
- Does outcome differ between adolescents and adults?

Studied risks and benefits

The literature search identified one randomized controlled trial (RCT) and three cohort studies. Seventeen case series were included, of which six dealt with the comparison between adults and adolescents.

Mortality

In nine case series (in total 2 375 patients) one post-operative death within 30 days was reported after open surgery and additional nine deaths were reported six months to four years after surgery (malnutrition, heart failure, infection, necrotizing pancreatitis, drug overdose).

Quality of life

The RCT measured health-related quality of life, using a validated questionnaire at two years follow-up. Of 11 items, two (physical functioning and change in health) showed a moderate and statistically significant improvement after laparoscopic gastric banding compared with non-surgical treatment.

Bariatric surgery compared to non-surgical treatment in severely obese adolescents may improve health-related quality of life.

Low quality of evidence (GRADE ⊕⊕○○).

Long term morbidity is not adequately studied.

Short term complications were common. Acute complications were bleeding and infections. Other complications were depression, gallstone formation with cholecystectomies, internal hernia, ileus, vitamin-, iron- and mineral deficiencies and excessive skin.

Short term complications related to the surgical procedure are common, as are complications related to obesity and non-surgical treatment. In the RCT, adverse events were reported at a similar frequency after both gastric banding and non-surgical treatment (48% vs. 44%).

Very low quality of evidence (GRADE ⊕○○○).

Weight/BMI-changes

The RCT and three cohort studies observed significant weight reduction at one and two years of follow up (28-38% after bariatric surgery versus 3% weight reduction to 3% weight gain after non-surgical treatment).

Bariatric surgery compared to non-surgical treatment in severely obese adolescents results in significant weight reduction, but long term effects are unknown.

Moderate quality of evidence (GRADE⊕⊕⊕○).

Glucose metabolism/homeostasis

The RCT demonstrated a statistically significant and clinically relevant improvement in insulin sensitivity two years after laparoscopic gastric banding compared with non-surgical treatment. The presence of the metabolic syndrome disappeared in the surgical group but remained unchanged among controls.

Bariatric surgery compared to non-surgery treatment in severely obese adolescents may improve insulin sensitivity and the metabolic syndrome.

Low quality of evidence (GRADE ⊕⊕○○).

Does outcome differ between adolescents and adults?

The literature search identified six case series in which adolescents were compared with adults. Mortality data could not be properly compared between these groups.

Weight reduction at one and two years was similar in the two populations (-28 to -38%), as was the frequency of short-term complications.

Ethical aspects

To decide on surgical treatment at young age, without knowing long-term effects and complications, is a major ethical problem. Often adolescent patients have difficulties with taking responsibility for the consequences of bariatric surgery; mainly the need of long-term treatment with vitamins and minerals. The majority of adolescents will probably have a need, due to age-related expectations, for plastic surgery of excessive skin. On the other hand, the future for an obese young person is not favourable. There are a lot of prejudices in the society, and difficulties with education and to establish family life, will hinder these young persons to establish a normal socio-economic life.

Economical aspects

The economic burden is large for the society as well as for the health care system, due to the increased prevalence of severe obesity in adolescence, with high consumption of hospital care and pharmacological treatment.

Costs for laparoscopic gastric bypass surgery and three to four days postoperative care is estimated at 70 000 SEK/patient. No health economy analyses have been published concerning cost-effectiveness of bariatric surgery for adolescence.

However, recent studies in adults have been unable to identify short- or long-term reduction in overall health care costs associated with bariatric surgery.

Concluding remarks

Bariatric surgery in severely obese adolescents compared with non-surgical treatment results in substantial weight loss (GRADE⊕⊕⊕○), and may improve health-related quality of life, insulin sensitivity and the metabolic syndrome (GRADE ⊕⊕○○).

Short-term complications including additional surgery are common. Long-term morbidity is insufficiently studied. Deaths directly related to the surgical treatment are rare. Ethical considerations include the conflict in treating adolescents with a procedure that will affect them for the rest of their lives without knowledge of long-term effects and complications.

Which health technology or method will be assessed?

1a Who posed the question?

Head of Dept of Pediatric surgery Kate Abrahamsson, The Queen Silvia Children Hospital SU/Östra.

1b Participants, in the project?

Gunnar Göthberg, associate Professor Dept of Pediatric Surgery and Emergency Care Queen Silvia Children's Hospital, Sahlgrenska University Hospital.

Jovanna Dahlgren, associate Professor, University lecturer, Dept of Pediatrics, Queen Silvia Children's Hospital, Sahlgrenska University Hospital.

Eva Gronowitz, pediatric nurse, PhD, coordinator, Dept of Pediatrics, Queen Silvia Children's Hospital, Sahlgrenska University Hospital.

Josefine Nordenström, Resident physician, Dept of Pediatric Surgery and Emergency Care, Queen Silvia Children's Hospital, Sahlgrenska University Hospital.

1c Participants, from the HTA centre and external reviewers

Annika Strandell, Associate Professor

Christina Bergh, Head of HTA-centrum, Professor

Eva-Lotte Daxberg, librarian

Ulla Wikberg Adania, librarian

External reviewers

Krister Järbrink, PhD, Health Economic Advisor, Health Care Committees' Secretariat, Region Västra Götaland.

Maria Skogby, RN, PhD, Frölunda Specialist Hospital, surgical department.

1d Are there any conflicts of interest for the proposer or any of the participants in the work group?

Gunnar Göthberg, Jovanna Dahlgren and Eva Gronowitz are co-authors of one of the included articles (Olbers *et al.*, 2012).

2a Obesity in adolescents

Childhood obesity is a serious medical condition where excess body fat negatively affects a child's health or well-being. Obesity is the result of a caloric imbalance, too little energy expenditure for the amount of calories consumed. This is affected by various genetic, behavioural, and environmental factors.

Due to the rising prevalence of obesity in children and it is recognized as a serious public health concern. The understanding of the causes of child obesity has increased during past years. All experts agree that prevention is the first step. However, some children will become obese regardless of preventive measures.

The first problem to occur in severely obese children is usually emotional or psychological. Severely obese children often suffer from teasing by their peers and this often leads to low self-esteem and depression (Jarvholm *et al.*, 2012). Stigmatization and discrimination may partly explain these conditions (Puhl and Latner, 2007). Severely obese children and adolescents have lower health-related quality of life (QoL) than children and adolescents with normal weight, and similar QoL as those diagnosed with cancer (Schwimmer *et al.*, 2003).

Obesity during adolescence has been found to increase mortality rates during adulthood (Park *et al.*, 2012). They are more likely to have prediabetes, a condition in which blood glucose levels indicate a high risk for development of diabetes (Carlsson *et al.*, 2012). Moreover, severe obesity leads to increased risk of various cancers (Sjöström *et al.*, 2009). Obese youths are more likely to have risk factors for cardiovascular disease.

In summary, QoL and life expectancy are reduced in obese adolescents and the results of conventional treatments are modest and insufficient for long-term reduction of the health hazards associated with obesity.

Diagnosis of obesity is often based on BMI in adults. These definitions are height dependant and cannot be used for children since BMI changes considerably with age and height. The most commonly used international definition for children is based on age and gender specific cut-off points corresponding to the adult criteria of a BMI of 25 for overweight and 30 for obesity (iso-BMI) (Cole *et al.*, 2000).

BMI standard deviation score (SDS) can also be used to compare data between children of different ages and gender. It indicates how many units of the standard deviation a child's BMI is above or below the average BMI value for their age group and sex.

2b Prevalence and incidence of obesity in adolescents

The prevalence of obesity, defined as isoBMI>30, among adolescents is four percent in Sweden (Sjöberg *et al.*, 2011). Epidemiological data from the military service registry provides indirect support for increased BMI among young people. The proportion of conscripts with obesity has increased four-fold during a 30-year period (Neovius *et al.*, 2008). It is known from data obtained in Region Västra Götaland (VGR) that there are great regional differences, with higher numbers in the east parts as well as in the suburbs of Gothenburg than in the rest of VGR (Lindblad, *et al.*, 2007, Rubinstein *et al.*, Västra Götalands handlingsprogram mot fetma, rapport från arbetsgruppen för epidemiologi 071121 vers.13). There is no exact prevalence data on severe obesity among adolescents, defined as isoBMI>35, but it is estimated to be 1%.

2c Present treatment of obesity in the outpatient setting/ in-patient setting.

Routine treatment includes several lifestyle interventions. The majority of obese and severely obese children are treated within the primary health care system (outpatient child care, school health services, outpatient child clinics). More severe cases (isoBMI >35), with or without complications, are usually cared for in specialist clinics by a team of physicians, nurses, physiotherapists and nutritionists. The results of these treatments are moderately successful if started before the age of 12 years. If the children are near puberty the effects are discouraging and often transient (Danielsson *et al.*, 2012).

2d Number of patients per year who undergo current treatment regimen for obesity?

Data from clinics in Region Västra Götaland 2011 and 2012 show that 1 583 children are treated due to obesity (personal communication, Mikael Kjerfve, Analysenheten på VGR). Of these, approximately 20% are severely obese.

Table 1: Number of patients between 13-17 years of age diagnosed with obesity in Region Västra Götaland during 2011 and 2012, subdivided by age and level of care (patients may attend both levels of care).

	2011	2012
13 years	191	243
Primary health care	56	58
Specialised care	153	208
14 years	243	207
Primary health care	78	62
Specialised care	184	172
15 years	218	220
Primary health care	68	66
Specialised care	165	176
16 years	167	197
Primary health care	49	50
Specialised care	131	165
17 years	176	164
Primary health care	67	62
Specialised care	120	117
Total of 13-17 year old	995	1 031

2e The normal pathway of a patient through the health care system

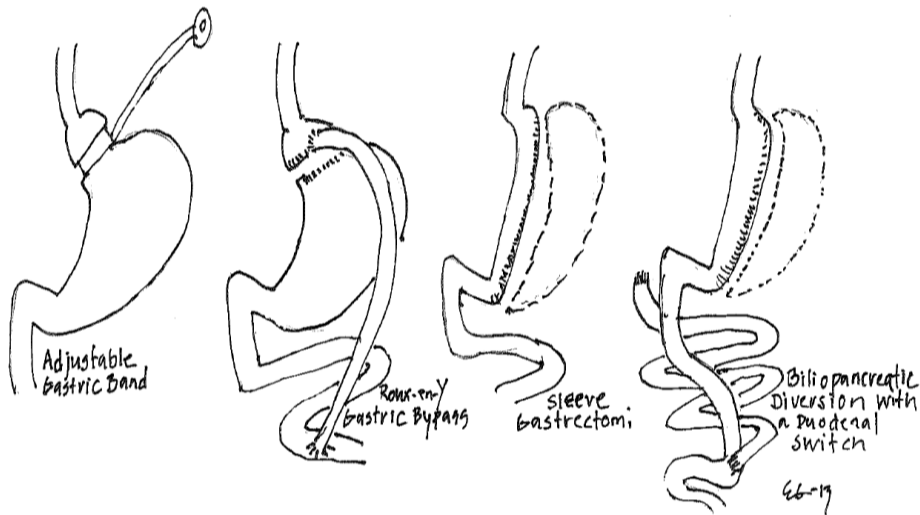
When a school nurse finds a child with obesity, she arranges a consultation with a school physician. If the doctor finds a need for further treatment, the child is referred to the primary care or directly to a pediatrician. At pediatric out-patient clinics or pediatric hospitals, teams with multidisciplinary competences will initiate life-style treatment for at least one year. If the treatment is unsuccessful, prediabetes is found or syndromic obesity is suspected, the patient is referred to a regional obesity center.

2f Actual wait time in days for medical assessment and treatment

The majority of patients wait for three months until acceptance to a child and adolescent out-patient clinic, pediatric clinic or to the regional obesity center.

3a Bariatric surgery

Currently, bariatric surgery is performed by one of four laparoscopic surgical techniques; Adjustable Gastric Banding (AGB), Roux-en Y Gastric bypass (RYGB), sleeve gastrectomy and Bilio-Pancreatic Diversion (BPD). The two methods that are most commonly used for adolescents going through bariatric surgery are gastric banding and gastric bypass. Methods as sleeve gastrectomy, and especially BPD, are rare in this population.



Gastric banding is an inflatable silicone device placed around the top portion of the stomach to slow consumption of food and thus the amount of food consumed. Gastric bypass has established as the “gold standard” in Scandinavian bariatric surgery and is the method used in more than 90% of bariatric procedures. One previous study has demonstrated that laparoscopic gastric banding is feasible and effective in adolescents recruited directly from the community when compared to the best conventional therapy (O'Brien *et al.*, 2010). In contrast, other studies have not been successful with gastric banding in adolescents (Widhalm *et al.*, 2008). A previous gastric banding study for adolescents in Sweden was stopped before planned completion due to poor results. Gastric bypass has compared favorably with gastric banding in most studies. Thus, presently gastric bypass is considered to offer the best trade-off between weight loss and initial risks with surgery (Werling *et al.*, 2013).

The laparoscopic Roux-en-Y gastric bypass is the presently used technique. It consists of a small (<20ml) gastric pouch and an ante-colic, ante-gastric Roux-en-Y construction with a 80 cm long Roux limb as described in detail elsewhere (Olbers *et al.*, 2003). The technique is original using a “double loop technique” which subsequently is reconstructed to a true Roux-en-Y construction. The gastro-entero-anastomosis and entero-entero-anastomosis are created using a combined technique of linear stapling and hand suturing.

3b The work group's understanding of the potential value of bariatric surgery in adolescents

Eighty percent of obese children become obese adults, and almost all severely obese adolescents become morbidly obese adults. These children have an increased risk to develop diabetes type 2 and cardiovascular events early in life. However, as important are the severe psychosocial consequences that these obese adolescents meet. Extreme obesity leads to a high risk of isolation, failure with education and severe difficulties to establish a normal family life.

Presently, we lack the possibility to efficiently treat children and adolescents with severe obesity in the pediatric health care system within VGR. Bariatric surgery is known to be the most efficient treatment for weight reduction in adult obesity, and to reduce co-morbidity.

If bariatric surgery would be available for adolescents, the treatment should not be offered until the adolescent has entered puberty and reached peak height velocity. Bariatric surgery in adolescents must be performed and followed up carefully. It should be centralized to a few centers with skilled surgeons; within VGR this could be performed at Queen Silvia Children's Hospital.

3c The central question for the current HTA project in one sentence

Do severely obese adolescents have a better outcome of bariatric surgery compared to non-surgical treatment in terms of mortality, quality of life and socialisation, long-term morbidity, short-term complications, weight loss and impact on glucose metabolism/homeostasis?

Does outcome differ between adolescents and adults?

3d PICO

P=Patients I=Intervention C= Comparison, O=Outcome

P= Adolescents 13 -18 years of age with obesity (BMI or isoBMI >35)

I= Bariatric surgery

C= Conservative (non-surgical treatment, diet- and life-style changes, pharmacological treatment)

O= Critical*

Mortality (30 day and long term)

Suicide

Socialisation

Quality of Life (QoL)

Long term morbidity > (5 years) (bone mineralization, drug abuse, anaemia, malnutrition)

Important*

Short term complications (<2 years)

Weight/BMI-changes

Glucose metabolism/homeostasis

Not important*

Inflammatory markers (C-reactive protein (CRP))

Cardiovascular risk factors (blood pressure, lipids, left ventricular hypertrophy)

* Implies critical, important or not important outcomes for decision-making.

4 Search strategy, study selection and references – Appendix 3

During March 2013 two librarians (ELD, UWA) performed systematic searches in PubMed, EMBASE, PsychINFO, BNI, ProQuest, the Cochrane Library, and a number of HTA-databases. Reference lists of relevant articles were scrutinised for additional references. Search strategies, eligibility criteria and a graphic presentation of the selection process are accounted for in Appendix 3. The librarians conducted the literature searches, selected studies and independently assessed the obtained abstracts and a first selection of full-text articles for inclusion and exclusion. Any disagreements were resolved in consensus. The remaining articles were sent to the participants of the project, who read the articles independently and then decided in a consensus meeting which articles should be included.

The literature search identified a total of 1 953 articles (after removal of duplicates). The librarians then excluded 1 846 articles after reading the abstracts. Another 62 articles were excluded by the librarians after reading the articles. The remaining 45 articles were sent to the project participants, and 22 of them were finally included in the report. One article is a randomized trial, and three articles are cohort studies. The articles have been critically appraised using checklists from SBU (Swedish Council on Health Technology Assessment). One systematic review is commented upon but not critically appraised. The remaining articles are case series.

5a Describe briefly the present knowledge of the health technology

The literature search identified one systematic review, one RCT and three cohort studies. Seventeen case series were included, of which six reported outcomes in both adolescents and adults. In addition to controlled studies, data from case series are presented in Appendix 1 regarding the outcomes mortality, complications, weight loss and glucose metabolism/homeostasis. Quality of evidence (GRADE) is assessed for critical and important outcomes and is solely based on controlled studies.

In a systematic review by Aikenhead *et al.* (2012) they state:

“Obese children and adolescents are more likely than others to have risk factors for cardiovascular diseases, experience other health conditions associated with increased weight, such as type 2 diabetes and sleep apnoea, perform poorly at school and suffer psychological distress. Clear evidence for successful and cost-effective non-surgical strategies for treating childhood obesity is lacking, leading the medical profession to turn increasingly to surgical treatment options.” “Surgical treatment may be advocated as a preferred and cost-effective solution for certain children and adolescents.”

In summary Aikenhead *et al.* (2012) pointed out that there are limited numbers of studies on this topic available. The report confirms that surgery leads to significant weight loss and improvements in medical conditions and quality of life.

There are no data on long-term effects (physical and mental) and safety, neither on effectiveness nor costs. Compliance can be more problematic in adolescents. Children and adolescents may have other needs for follow-up because of developmental and psychological factors.

Bariatric surgery vs. conventional treatment in severely obese adolescents

A. Critical outcomes:

Mortality, 30 days and long term (Appendix 1:1)

In nine case series (in total 2 375 patients) one perioperative death was reported day 3 after open surgery, due to sepsis or leakage. Additional nine deaths were reported six months to four years after surgery (malnutrition, heart failure, infection, necrotizing pancreatitis, drug overdose).

QoL, including socialisation (Appendix 1:2)

The RCT measured health-related quality of life, using a validated questionnaire at two years follow-up. Of 11 items, only two, physical functioning (p=0.002) and change in health (p=0.006) showed a moderate and statistically significant improvement after laparoscopic gastric banding compared with non-surgical treatment (n=50) (O'Brien *et al.*, 2010).

One cohort study reported within-group changes solely in the surgical group at two years postoperative follow-up with SF-36 (Olbers *et al.*, 2012). A significant improvement in QoL compared with baseline was demonstrated in: vitality, physical functioning, role limitation-physical health, general health (p<0.001), social functioning (p=0.04), and body pain (p=0.004). No significant improvement was seen for role limitation-emotional problems and mental health. Data for controls were not reported in this study.

Conclusion: Bariatric surgery compared to conventional treatment in severely obese adolescents may improve health-related quality of life.

Low quality of evidence (GRADE ⊕⊕○○).

Long term morbidity (Appendix 1:3)

Two case series reported long term complications. One series was based on open surgery and reported no adverse effects at five years follow-up (Anderson *et al.*, 1980). The other reported a special method of biliopancreatic diversion, resulting in malabsorption for 15% at a mean of 32 months of follow-up (Papadia *et al.*, 2007).

Conclusion: There is insufficient data to evaluate long term morbidity.

Suicide. No data reported

Socialisation. No data specifically on this outcome was reported, but the outcome is partly included in questionnaires on QoL.

B. Important outcomes

Short term complications (<2 years) (Appendix 1:4)

One RCT (laparoscopic gastric banding) and 11 case series (majority on laparoscopic gastric banding) reported short term complications. There was a large heterogeneity in methods of surgery. Short term complications occurred in 5-48 %. Acute complications were bleeding and infections including pneumonia and wound abscesses. Other complications were depression, gallstone formation with cholecystectomies, internal hernia, ileus, vitamin-, iron- and mineral deficiencies, excessive skin and unexpected pregnancies.

The only RCT (n=50) found similar rates of adverse events after gastric banding compared with non-surgical treatment (48% vs. 44%) in a sensitivity analysis accounting for loss of follow-up.

Conclusion: Short term complications related to the surgical procedure are common, as are complications related to obesity and non-surgical treatment.

Very low quality of evidence (GRADE ⊕○○○).

Weight/BMI-changes (Appendix 1:5)

One RCT and three cohort studies found significant weight reduction (ranged between 28-38%) 12 and 24 months after bariatric surgery, compared with non-surgical treatment (varied between 3% weight reduction to 3% weight gain).

Conclusion: Bariatric surgery compared with conventional treatment in severely obese adolescents results in substantial weight reduction.

Moderate quality of evidence (GRADE ⊕⊕⊕○).

Glucose metabolism/homeostasis (Appendix 1:6)

One RCT, one cohort study and seven case series reported on diabetes type 2, insulin sensitivity and/or the metabolic syndrome.

In the RCT, statistically significant and clinically relevant improvement was demonstrated in insulin sensitivity after laparoscopic gastric banding compared with non-surgical treatment. Metabolic syndrome was present in 19/25 patients undergoing surgery; all of them had a complete regression after two years. In the control group, 10/25 patients were diagnosed with the metabolic syndrome; six of these had a regression.

In the cohort study, fasting insulin, glucose and HbA1c decreased significantly after surgery but no such change was found in the control group. Comparison between groups was not reported.

All case series showed improvement of glucose homeostasis after surgery compared to baseline.

Conclusion: Bariatric surgery compared to non-surgical treatment in severely obese adolescents may improve glucose metabolism/homeostasis.

Low quality of evidence (GRADE ⊕⊕○○).

C. Outcomes not important for decision making

Cardiovascular risk factors (blood pressure and lipids) (Appendix 1:7)

The RCT showed significant decrease in blood pressure in both groups but no significant differences between groups.

The lipid profile was positively affected in both intervention and control groups in the RCT, but there were no significant differences between groups.

Inflammatory markers (CRP, SR and white blood cell count) (Appendix 1:8)

In two cohort studies, within-group changes solely for the surgery groups are presented.

Bariatric surgery in adolescents and adults

The literature search identified six case series, comparing outcomes in adults and adolescents. Mortality among adults is reported to be up to 0.2% in large registry studies (Appendix 1:9). In the case series comparing adolescents and adults, no mortality was reported in adolescents, while in other studies including adolescents with Prader-Willi's syndrome, a total of ten deaths were reported (see Appendix 1:1).

Short term complications and weight reduction were similar in both groups (Appendix 1:8, 1:9). At baseline, the adult population suffered more often from co-morbidities as diabetes type 2 (Appendix 1:11).

5b Outcome tables – Appendix 1

For details on reviewed and included articles see Appendices 1:1-1:11.

5c Excluded articles – Appendix 2

5d Ongoing research?

A search in Clinicaltrials.gov (2013-08-21) using the search terms bariatric surgery OR Bariatric surgical procedures OR Gastric bypass OR Gastric banding OR Obesity Surgery OR Stomach bypass OR Gastroplasty OR Gastroplasties OR Roux-en-y OR RYGB OR LAGB OR LRYGB OR Gastroenterostomy OR Gastroenteromies.

Limitation: Child (birth-17) identified 85 trials.

One study was relevant for our question. It is a prospective, non-randomised observational study from Ullevål, Oslo, in which adolescents aged 13-18 years undergo gastric bypass. Controls are age-matched adolescents treated conservatively for two years. The study started 2011 and recruitment is still ongoing.

An HTA report from UK is expected to be published January 2014 (Bryant *et al.*, to be published).

6 Which medical societies or health authorities recommend the new health technology?

Medical societies

Which medical society or health authority?

The Swedish Society for Pediatrics, section for endocrinology- and diabetes Barnläkarföreningens sektion för endokrinologi och diabetes (underavdelning obesitas) considers bariatric surgery in adolescents as one of several treatments in severe therapy-resistant obesity.

Ethical aspects

- 7 Ethical consequences** (Appendix 5)
- To decide on surgical treatment at young age, without knowing long-term effects and complications, is a major ethical problem. Often adolescent patients have difficulties with taking responsibility for the consequences of bariatric surgery; mainly the need of long-term treatment with vitamins and minerals. The majority of adolescents will probably have a need, due to age-related expectations, for plastic surgery of excessive skin. On the other hand, the future for an obese young person is not favourable. There are a lot of prejudices in the society and difficulties with education and to establish family life, will hinder these young persons to establish a normal socio-economic life. In surgically treated patients, support from the family and a follow up by the multidisciplinary team including psychologist, is required for a successful result. The bariatric surgery improves body size and health and relieves some of the long term risk factors. The effect on life expectancy is still unknown.

Organisation

- 8a When can bariatric surgery in adolescents be put into practice?**
The new method can be implemented rapidly, as we have the necessary surgical and logistic competence needed (see below)
- 8b Is bariatric surgery in adolescents performed in other hospitals in VGR?**
Currently in Sweden, bariatric surgery in adolescents is not performed anywhere, with exception of some cases in private clinics. The clinical knowledge and competence to manage the entire care process for obese adolescents, in which surgery is the cornerstone, is localized in Göteborg.
- 8c According to the work group, will there be any consequences of bariatric surgery in adolescents for personnel?**
There will be a need for moderate additional personnel recruitments. However, the organizational changes to admit patients are minor, as bariatric surgery has been performed in the context of a clinical study until 2009. Thus, the knowledge of procedures and routines of care are easily reintroduced.
- 8d Will there be any consequences for other clinics or supporting functions at the hospital or in Region Västra Götaland, Sweden?**
In Region Västra Götaland there is a well-developed organization around children with obesity, with a clear description of what is expected to do at every health care level. Thus, implementation in the health care process can be done rapidly. We expect to treat about 40 adolescents from our region annually and estimate an additional 40 patients to be referred from other regions in Sweden per year.

- 9a Present costs of currently used technologies**
Cost for conventional therapy is approximately 16 000-20 000 SEK per patient/year (complete team and yearly check-up).
- 9b Expected costs of bariatric surgery in adolescents?**
There are costs for preoperative evaluation and information by psychologist, nutritionist, paediatrician and surgeon. There is a cost for surgery and three to four postoperative days. The total cost is estimated to 70 000 SEK/patient. Most patients will later also need plastic surgery due to excessive skin, at approximately the same cost.
There will be specific costs for surgery equipment.
- 9c Total change of cost**
The long-term costs are difficult to predict. Morbidity to cardiovascular and metabolic risk factors will probably be lower in the surgical group. Outcomes like self-esteem, socialization and physical health has been shown to improve after bariatric surgery. This might imply that these young people more easily find partners and friends, and complete their educations which may also be cost-effective in the long run.
Two studies in JAMA have evaluated long term costs in adults undergoing bariatric surgery. A Swedish study showed that surgically treated patients used more hospital care during the first six years after bariatric surgery but not thereafter (Neovius *et al.*, 2012). Drug costs 7-20 years postoperatively, were lower for surgery patients than for control patients. A study from USA study showed that the overall costs were greater two to three years after surgery (inpatient cost was higher but prescription and office visits were lower) but similar in the later years in comparison with diagnoses closely associated with obesity (Weiner *et al.*, 2013). Thus, studies were unable to identify any short- or long-term reduction in overall health care costs associated with bariatric surgery.
- 9d Can the new technology be adopted and used within the present budget (clinic budget/hospital budget)?**
No.
- 9e Are there any available analyses of health economy? Cost advantages?**
Yes, but only for the adult population. (Neovius *et al.*, 2012 and Weiner, *et al.*, 2013).
See 9c.

Unanswered Questions

10a Important gaps in scientific knowledge?

Data on long-term outcome is needed as well as data on QoL, neuropsychiatric dysfunction and adverse events.

Data on children aged 13-15 is scarce.

10b Is there any interest in your own clinic/research group/organisation to start studies/trials within the research field at issue?

Yes, there is a great interest in starting studies in the research field at issue.

The multidisciplinary group at Queen Silvia Children's Hospital is conducting a long term (10 years) follow-up of 162 children that underwent either gastric bypass surgery or conventional treatment 2006-2009 within a national-wide study (AMOS 1).

From December 2013, a new randomized nation-wide study in 40 young adolescents (13-15 years of age) will start, comparing surgery to conventional treatment.

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:1 Intervention and comparison: Surgical vs.non-surgical treatment
 Outcome variable: Mortality (30 day and longterm)

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention Bariatric surgery					
Alqathani 2012	Saudi Arabia	Case series	222		No deaths					
Anderson 1980	USA	Case series, gastric bypass (GBP) open surgery	41		3 deaths: 1 patient without syndrome postop day 3 due to sepsis or leakage 1 patient without syndrome died suddenly at 36 months postop 1 Prader Willi syndrome (PWS) patient died 50 months postop of congestive heart failure					
Breaux 1995	USA	Case series, mixed surgery	22		1 50 month postop gastric bypass, death probably suicide/drug overdose 1 15 month postop from biliopancreatic diversion (BPD)- death midbrain tumour					
Conroy 2011	USA	Case series, gastric banding (GB)	108		No perioperative deaths					
Dillard 2007	USA	Case series	750		No deaths					
Lawson 2006	USA	Case series	36		1/36 died One mortality at 9 month postop, BMI >80 (age 18 years)					
Messiah 2012	USA	Two case series, mixed surgery (GBP or GP)	890		1 patient died 6 months postop after gastric bypass of hart failure					
Papadia 2007	Italy	Two case series, BPD, open surgery	76		No mortality at surgery 3 later mortality due to: Two patients developed protein malnutrition and one developed acute necrotizing pancreatitis	Inclusion 1976-2005, n=68 non-syndromes, 8 syndromes (7 PWS)				
Zitsman 2011	USA	Case series, gastric banding	230		No mortality					

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:2 Intervention and comparison: Surgical vs.non-surgical treatment
 Outcome variable: Health-related quality of life (QoL)

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	No. of patients n=	With draws - dropouts	Result		Comments	Directness*	Study limitations *	Precision *	
					Bariatric surgery	Non-surgical treatment					
O'Brien 2010	Australia	RCT – gastric banding	n=50 (25/25)	n=8 (1/7)	n=24	<p>Mean (SD)</p> <p>BE - General Behaviour 64.0 (21)</p> <p>FA - Family Activities 85.6 (16)</p> <p>FC - Family Cohesion 50.8 (32)</p> <p>GH - General Health 65.7 (21)</p> <p>MH - Mental Health 73.0 (3.3)</p> <p>PF - Physical Functioning 94.4 (6.6)</p> <p>SE - Self-esteem 70.3 (21)</p> <p>CH – Change in Health 4.38 (0.8)</p> <p>Sign improvements (within group) over two years for FA p= 0.006, GH p=0.003, PF p=<0.001, SE p=0.012 and CH p<0.001</p>	<p>n=18</p> <p>Mean (SD) p* Community norm</p> <p>BE 58.6 (19) 0.27 77.5</p> <p>FA 80.2 (23) 0.12 72.5</p> <p>FC 70.8 (23) 0.52 71.2</p> <p>GH 53.7 (15) 0.37 68.1</p> <p>MH 67.0 (2.5) 0.69 74.9</p> <p>PF 78.1 (24) 0.002 94.8</p> <p>SE 62.7 (22) 0.21 74.6</p> <p>CH 3.56 (1.2) 0.006 3.54</p> <p>Sign improvements over 2 years (within group) for GH p=0.04</p> <p>* p values denotes the significance level between groups at 2 years follow-up</p>	<p>Child Health Questionnaire (CHQ CF-50) has 11 validated subscores. Values range from 0 to 100 in 10 subscores, the remaining (Change in health) has 5 levels. Higher score implies higher QoL. Participants scored at baseline and 2 years after entry. Six subscores were below the community norm in both groups at entry. Three subscores did not differ within or between groups (behavioural, emotional and physical limitations), are not shown.</p>	+	?	+
Olbers 2012	Sweden	Cohort study gastric bypass (control group was not assessed for this outcome)	n=162 81/81		<p>p denotes within group changes:</p> <p>Significant improvements (p<0.001) for Vitality</p> <p>Physical functioning</p> <p>Role limitation physical health</p> <p>General health</p> <p>Social functioning p=0.04</p> <p>Body pain p=0.004</p> <p>Non-significant improvements for Role limitation emotional problems</p> <p>Mental health</p>	<p>QoL data not reported for this group.</p>	<p>SF-36 (Short Form-36 Health Survey) administered at baseline and at 2 years follow-up. Values range from 0 to 100. Higher score implies higher QoL.</p>				

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:2 Intervention and comparison: Surgical vs.non-surgical treatment
 Outcome variable: Health-related quality of life (QoL)

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	No. of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Bariatric surgery	Non-surgical treatment				
Silberhumer 2011	Austria	Case series gastric banding	50		<p>The improvement in quality of life analyzed by the Moorehead-Ardelt questionnaire was documented by an increase from 0.8 ± 0.3 preoperatively to 2.1 ± 0.8 points at the last follow-up. But did not show improvement, with 2.13 ± 0.8 points after at least 5 years of follow up compared to 2.1 ± 0.8 points with a mean follow up of 34.7 months</p> <p>BAROS was calculated at the time of the last follow-up.</p> <p>Quality of life showed a significant Improvement between 3 and 5 years after surgery (BAROS: 5.5 ± 1.9 increased to 6.3 ± 2.2, $p = 0.01$).</p> <p>BAROS showed that there was a significant improvement in the patients' body image combined with an increased agility in patients with a functional band .</p>		<p>Moorehead-Ardelt questionnaire Bariatric Analysis and Reporting Outcome System (BAROS)</p> <p>References to methods: *Hell E, et al. Obes Surg 2000;10: 214-9. *Moorehead MK, et al. Obes Surg 2003; 13: 684-92. *Oria HE, et al. Obes Surg 1998; 8: 487-99.</p>			
Sysko 2012	USA	Case series gastric banding	101		<p>Significant improvement in total BDI using latent growth curve modelling (βslope = -0.885, SE = 0.279, $P < 0.01$; βquadratic = 0.054, SE = 0.021, $P < 0.001$) and PedsQL (βslope = -0.885, SE = 0.279, $P < 0.001$) scores were observed following LAGB, 1,3,6,9, 12 and 15 m postop</p>		<p>Measures of depressive symptoms, and quality of life were obtained in the first year following surgery.</p> <p>Beck Depression Inventory (BDI), Pediatric Quality of Life Inventory (PedsQL)</p>			
Yitzhak 2006	Israel	Case series gastric banding	60		<p>3 yrs postop</p> <p>Improvements in physical activity 56/60 (93%) and in social life and self-esteem 43/60 (72%)</p> <p>56/60 (93 %) says yes to "will you undergo this operation again?"</p>		<p>QoL was assessed by specific questions – performing daily house-chores, sports activities, social and selfesteem changes, enrollment into the army, general health status and satisfaction from the operation. Responses were scaled before and after surgery by a scoring system adopted from the Rand SF- 36 medical outcomes study, to assess QoL.</p>			

LAGB= laparoscopic gastric banding

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:3 Intervention and comparison: Surgical vs.non-surgical treatment
 Outcome variable: Long-term morbidity

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawsals - dropouts	Result	Comments	Directness*	Study Limitations *	Precision *
					Intervention				
Anderson 1980	USA	Case series Open gastric bypass	41:30 genetically normal and 11 Prader Willi's syndrome		30 followed for 5 y No long term adverse events				
Breaux 1995	USA	Case series comparing different bariatric procedures	22		Follow up mean 32 month: Vitamin A and D deficiency 1 Folic acid deficiency 1 Protein deficiency 3 Gallstone development 1 Kidney stone 1				
Kaulfers 2011	USA	Case series	102		DEXA total body: Decreased BMC with 5.2% (12 month) and 7.4% (24 month) BMD Z-score decreased from 1.5 to 0.1 (12 month) P<0.0001 for all				
Messiah 2012	USA	Case series mixture of different bariatric procedures	259 108 GBP/ 151 LAGB		Vitamin deficiency in 24% (12 month) Gastric bypass Vitamin deficiency in 9% Gastric banding	12 month follow up			
Papadia 2007	Italy	Case series BPD	68		11/68 develops protein malabsorption 1-10 years postoperatively	Follow up varied			

GBP=gastric by pass
 LAGB= laparoscopic gastric banding
 BMC= Bone mineral content
 BMD=Bone mineral density
 BPD= Biliopancreatic diversion

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:4 Intervention and comparison: Surgical vs. non-surgical treatment
 Outcome variable: Short-term complications (<2years)

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention Bariatric surgery	Control Non-surgical treatment				
O'Brien 2010	Australia	RCT Gastric banding	50 25/25	8 1/7	N= 24 (24 months) 13 adverse events (AE) in 12 pat (48%) including dropouts in a sensitivity analysis p=0.06 Proximal gastric enlargement (n=6) Cholecystectomy (n=1) Depression (n=1) Unplanned pregnancy (n=2)	N=18 18 AE in 11 pat (44%), including dropouts. Hospital admission (n=8) including depression and intracranial hypertension Cholecystectomy (n=1) Unplanned pregnancy (n=2)	Excluding dropouts, AE-rates were 11/25 in the intervention group and 4/25 in the control group.	+	-	-
Anderson 1980	USA	Case series open gastric bypass	41: 30 genetically normal and 11 Prader Willi's syndrome		3 wound infection 2 obstruction (1 reop) 3 atelectasis 2 pneumonia 1 abscess (n=30) 1 wound infection (n=11)		All registered as "major"			
Breaux 1995	USA	Case series Different techniques	22		1 incisional hernia 1 postop laryngeal oedema 1 kidney stone 1 gallstone development					
Conroy 2011	USA	Case series Gastric banding	108		1 bleeding 1 misplaced band 1 exploration presumed obstruction 2 wound complications Late: 3 band displacement + 5 post repositions					
Kaulfers 2011	USA	Case series	102		DEXA total body: Decreased BMC with 5.2% (12 month) and 7.4% (24 m) BMD Z-score decreased from 1.5 to 0.1 (12 month) P<0.0001 for all					
Lawson 2006	USA	Case series Gastric bypass	36		14 adverse events and one death in 36 (39%) (12 m) 9 minor complications (defined as readmission <7 days postop)– food obstruction, wound infection, nausea, dumping, diarr�ea, dehydration, hypocalaemia, deep vein thrombosis 4 moderate complications (readmission 7-30 days postop)– persistent iron anemia, secondary neuropathy 2 severe complications (>30 days) –one Beri beri sequel for >2 months One death due to infection 9 months postop					

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:4 Intervention and comparison: Surgical vs. non-surgical treatment
 Outcome variable: Short-term complications (<2years)

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention Bariatric surgery	Control Non-surgical treatment				
Messiah 2012	USA	Case series Different techniques	890		Gastric bypass n= 454 / Gastric banding n= 436 Bleeding 3% / 4.5% General 16% / 9% Infection 1% / 0 Internal hernia 1.2% / 0 Band related problem 0% / 14% Pneumonia/emb. 7% / 0% Wound infection 1% / 0% Reoperation 6% / 2%					
Nguyen 2011	USA	Case series Different techniques	649		2002-2006, n=309 Gastric bypass = 62% Complication = 5.5% 2007-2009, n=340 Gastric bypass = 48% Complication = 2.9%		No mortality			
Olbers 2012	Sweden	Case series gastric bypass	81		N=81 (24 months) 15 % add surgical intervention 7% impaired psychiatry health, 5,2 % drug abuse many adolescents are not taking their supplementation medication properly Excessive skin is a major problem for many of them					
Papadia 2007	Italy	Case series BPD = Bilio pancreatic diversion	68		19 reop/14 pat/68		1976-2005			
Silberhumer 2011	Austria	Case series gastric banding	50		3/50 (6%) Cholecystectomy 6 (12%) band assoc. compl. 6 (12%) converted to gastric bypass					
Yitzhak 2006	Israel	Case series gastric banding	117	1	13% band slippage 10% reoperation					

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:5 Intervention and comparison: Surgical vs. non-surgical treatment
 Outcome variable: Weight & BMI changes

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention Bariatric surgery	Control Non-surgical treatment				
O'Brien 2010	Australia	RCT – Gastric banding	50	8	N= 24/25 (24 m) 21/25 (84%) >50% EWL Lost a mean of 34.6 kg or 12.7 BMI units (28%weight loss) p<0.001 between groups	N=18/25 (24 m) 3/25 (12%) >50% EWL Lost a mean of 3.0 kg or 1.3 BMI units (3.1 %weight loss)		+	+	+
Inge 2009	USA	Controlled study–gastric bypass	78		N=11 surgically treated (12 m) BMI change 50.4 to 33.7 34.4% weight loss p<0.001 between groups.	N=67 medically treated (12 m) BMI change 35.4 to 34.9 1.6% weight loss	Surgically and medically treated adolescents with obesity and diabetes type 2 Retrospective review of clinical data. Large baseline differences	?	-	-
Lawson 2006	USA	Controlled study-gastric bypass	44	2	N=31 BMI from 56 to 35 (12 m) Lost a mean of 20.7 BMI units p<0.001 between groups	N=13 BMI from 47.2 to 46.0 (12 m) Lost a mean of 1.2 BMI units		?	-	-
Olbers 2012	Sweden	Controlled study-gastric bypass	162	22	N=81/80 (24 m) BMI decreased from 45.5 to 30.2 32% weight loss p<0.001 between groups	N=59/81 (24 m) (conservatively treated) BMI increased from 42.2 to 42.6, 3% weight gain		+	?	+
Sinha 2013	USA	Controlled study-gastric bypass	48	2	N=23/24 (6 m) Lost a mean of 32.3 kg or 10.9 BMI units (23 %weight loss) BMI from 49.5 to 38.6 p<0.001 between groups.	N=23/24 (6 m) Gained a mean of 1.1 kg or 0.4 BMI units (2 %weight gain) BMI from 48.3 to 48.7		+	-	?

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:5 Intervention and comparison: Surgical vs. non-surgical treatment
 Outcome variable: Weight & BMI changes

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention Bariatric surgery	Control Non-surgical treatment				
Anderson 1980	USA	Case series gastric bypass	41		30 genetically normal 238-187% IBW (5 years) 11 Prader Willi 231-176% IBW (5 years)		Both groups had gastric bypass surgery. In growing patients: to compare change in percent of IBW as determined by the 50 th percentile for age and height (actual body weight *100/ideal body weight)			
Breaux 1995	USA	Case series- "Bariatric surgery" different techniques	22		N=11 without sleep apnea Lost a mean of 52 kg or 20.9 BMI units (35%weight loss) BMI from 56 to 36 N=11 with sleep apnea Lost a mean of 74 kg or 23.8 BMI units (38 %weight loss) BMI from 68 to 47		Average follow up 50 months Both groups had bariatric surgery			
Conroy 2011	USA	Case series-gastric banding	108	63	N=45 (12m) BMI decreased from 48.8 to 42.9 and an average 15 kg weight loss p<0.001					
Kaulfers 2011	USA	Case series gastric bypass	61		N=61 (12 m) Weight from 155 to 97 kg p<0.001					
Messiah 2012	USA	Case series Gastric bypass (GBP) /gastric banding (GB)	890	631	GBP N=108/454 (12 m), BMI from 51 to 34, 33.7% weight loss GB N= 151/436 (12 m), BMI from 46 to 39, 15% weight loss p<0.001 between groups					
Silberhumer 2011	Austria	Case series gastric banding	50	5	N=45 (5 years), BMI from 45.2 to 27.3, p<0.001					
Yitzhak 2006	Israel	Case series gastric banding	117	57	N=60 (<3years), BMI from 42.7 to 30, p<0.001					

BMI= body mass index ($mass(kg)/(height(m))^2$) EWL =excess weight loss, IBW= ideal body weight

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:6 Intervention and comparison: Surgical vs. non-surgical treatment
 Outcome variable: Glucose metabolism/homeostasis

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With draws - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention Bariatric surgery	Control Non-surgical treatment				
O'Brien 2010	Australia	RCT gastric banding (ITT-analysis)	50	8	N=24 (gastric banding) Plasma glucose (mg/dl) -6.0 NS between groups Plasma insulin (uIU/ml) -15.2 NS between groups Homa insulin sensitivity (%) 89 p=0.01 between groups 9/25 had the metabolic syndrome at start, 0/24 at 2 years post op p=0.03 between groups	N=18 (conservatively treated) Plasma glucose (mg/dl) 2.8 Plasma insulin (uIU/ml) -11.2 Homa insulin sensitivity (%) 14.6 10/25 had the metabolic syndrome at start, 4/18 at 2 years post op	Changes at 2 years Metabolic syndrome criteria according to <i>Joliffe CJ et al. 2007</i>	+	+	+
Sinha 2013	USA	Controlled study-gastric bypass	48	2	N=23/24 Change at 12 months within groups P-glucose (mg/dl) -9 p=0.0007 P-insulin (mU/ml)-22 p<0.003(n=9) HbA1C (%) -0.4 p<0.001 Two had diabetes type 2 at baseline and 0 at 12 m follow-up	N=23/24 Change at 12 months within groups P-glucose (mg/dl) 1 p=0.55) HbA1C (%) 0.0 ns P-insulin and data on the prevalence of diabetes are not reported in this group		+	-	?

HOMA insulin sensitivity= Insulin x glucose/22.5, NS= not significant, IR = insulin resistance

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:6 Intervention and comparison: Surgical vs. non-surgical treatment
 Outcome variable: Glucose metabolism/homeostasis

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With draws - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention Bariatric surgery	Control Non-surgical treatment				

Conroy 2011	USA	Case series gastric banding	108		37 subject had Metabolic syndrome (Mes) at baseline and at 6 m 21/37 (56.8%) were resolved, p=0.0004	Mes criteria according to <i>Cook et al. 2003</i>			
Inge 2009	USA	Case series gastric bypass	11		N=11 diab type 2, at 12 m only 1 remained diabetic				
Lawson 2006	USA	Case series gastric by pass	24	10	14/24 Changes at 12 months Plasma glucose (g/dl) -12, P=0.02 Plasma insulin (µU/ml) -21, p=0.0002 HOMA-IR -4.6, P=0.004				
Olbers 2012	Sweden	Case series gastric by pass	81	1	N=80/81 Changes at 24months p-glucose -0.1 8 (ns) p-insulin (mU/l)-23.5 p<0.0001 HbA1C (%) -0.2 p<0.0001 1 diab type 2 at baseline, 0 at follow up				
Papadia 2007	Italy	Case series BPD	68		Two had diab type 2 at baseline and 0 had it at 5 years follow-up	1976-2005			
Silberhumer 2011	Austria	Case series gastric banding	50		N=50 Five had diab type 2 at baseline and 0 had it at 5 years follow-up				
Yitzhak 2006	Israel	Case series gastric banding	60		N=60 Two diab type 2 at baseline and 0 at 3 years follow-up				

HOMA insulin sensitivity= Insulin x glucose/22.5, NS= not significant, IR = insulin resistance

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:7 Intervention and comparison: Surgical vs. non-surgical treatment
 Outcome variable: Cardiovascular risk factors; serum- lipids, hypertension

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawsals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention Bariatric surgery	Control Non-surgical treatment				
O' Brien 2010	Australia	RCT gastric banding	50	8	BP 122/72 baseline (difference in systolic BP at baseline p=0.01) Changes over 2 years in systolic BP -12.5 (p<0.002) Between-group difference syst BP (p=0.21) Changes over 2 years in diastolic BP -6.0 (p<0.01) Between-group difference diast BP (p=0.79) At baseline: Total cholesterol 173 p=0.53 HDL cholesterol 46 p=0.50 Triglycerides 124 p=0.82 Changes over 2 yr Total cholesterol not shown HDL cholesterol +9.3 p<0.005 Triglycerides -52 p<0.001 Between-group difference: triglycerides (p=0.29) HDL cholesterol (p=0.22)	BP 133/76 baseline Changes over 2 years in systolic BP -20.3 (p<0.001) Changes over 2 years in systolic BP -6.9 (p<0.03) At baseline: Total cholesterol 178 HDL cholesterol 46 Triglycerides 141 Changes over 2 yr Total cholesterol not shown HDL cholesterol+3.9 p=0.50 Triglycerides -32 p=0.12	24 m follow up	?	+	+
Olbers 2012	Sweden	Cohort study gastric bypass	81		BP 125/77 baseline at 2 years 117/70 (p<0.0001) Within group differences: TG 1.3 - 0.8 (p<0.0001) HDL 1.1 - 1.5 (p<0.0001) LDL 2.6 - 1.9 (p<0.0001) Apo-A1 1.16-1.43 (p<0.0001) Apo-B 0.87-0.66 (p<0.0001)	BP and lipids are not analysed in the control group	24 m follow up			
Sinha, 2013	USA	Cohort study	48 24/24		Within group changes at 1 year Total cholesterol -38 p=0.002 HDL cholesterol 0 p=0.55 LDL cholesterol -34 p=0.0005 Triglycerides -33 p=0.03	Within group changes at 1 year Total cholesterol -14 p=0.21 HDL cholesterol +2p=0.30 LDL cholesterol -9p=0.10 Triglycerides -4 p=0.55	12 m follow up			

BP=blood pressure; TG= triglycerides, HDL= high density lipoprotein; LDL= low density lipoprotein; Apo-A1=apolipoprotein A1; Apo-B=apolipoprotein B

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:8 Intervention and comparison: Surgical vs. non-surgical treatment
 Outcome variable: Inflammatory markers (only reported in intervention groups)

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations*	Precision*
					Intervention Bariatric surgery	Control Non-surgical treatment				
Olbers 2012	Sweden	Cohort study gastric bypass	81		Within group changes: Hs-CRP 7.2 -2.8 (p<0.0001) WBC 8.2 - 6.5 (p<0.0001)		24 m follow up			
Sinha, 2013	USA	Cohort study retrospective	48		Decline in inflammatory markers Within group changes: Hs-CRP -6 p=0.0007 SR -9 mm/h p=0.0001 WBC -2.2 p=0.001	Not sufficient control data for analysis	Median follow up time of 6 months (median 196 days , range 155-312days)			

Hs-CRP=High sensitivity C-reactive protein SR= Sedimentation rate WBC= White blood cell count

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:9 Intervention and comparison: Bariatric surgery in adolescents vs. adults.
 Outcome variable: Mortality

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention surgery 13-18years	Control surgery > 18 years				
Pallati 2012	USA	Case series, mixed surgery			N=329 adolescents Mortality 0	N=49.000 adults Mortality 0.07%	Large cohort, mortality only in adults No sign. different between groups			
Valera 2007	USA	Case series, mixed surgery			N=309 adolescents	N=55.000 adults Mortality only in adults with open surgery (0.2%)				
Tsai 2007	USA	Case series, mixed surgery			N=0/771	N=212/104702	Mortality only in adults with all kinds of bariatric surgery (0.2%) (In hospital death)			
Zitsman 2011	USA	Case series, gastric banding			N=0/115	N=0/115				

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:10 Intervention and comparison: Bariatric surgery in adolescents vs. adults
 Outcome variable: Short-term complications

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With draws - dropouts	Result		Comments	Directne	Study limitation	Precisio n *
					Intervention Surgery 13-18yrs	Control Surgery > 18yrs				
Alqahtani 2012	Saudi Arabia	Two Case series sleeve gastrectomy	222		N=108 72% follow-up (24m) 6% complications No major 5 minor	N=114 61% follow-up (24 months) 7% complications 3 major (2 reop) 5 minor				
Dillard 2007	USA	Case series Gastric banding	24/716		N=24 Trocar site hernia * 0 Port leakage * 1,4% Band slippage * 0 Pouch enlargement*6,25% Reop. for enlargement 2,8.4%	N=716 2, 0.1% 18, 2.5% 17, 2% 128, 18% 11, 1.5%	* ns between groups p=0.059 between groups			
Pallati 2012	USA	Case series Different techniques	329/49519		N=329 30 day readmission rate 0.30%) Overall morbidity 0% (during the perioperative period within 30 days)	N=49519 2.02% 2.2%	p=0.04 between groups p=0.01 between groups			
Tsai 2007	USA	Case series, gastric bypass	771/104702		N=771 4,2% any complication	N=104702 6,6% any complication	No sign different between groups			
Varela 2007	USA	Case series Different techniques	309/55197		N=309 30 day complication 5,5%	N=55197 30 day complication 9,8% Mortality = 0.2%	Data base had no info of complication after the patient left hospital, gastric bypass = 62% of procedures			
Zitzman 2011	USA	Case series Gastric banding	230		9/115 reop adolescents	10/115 reop adults	Major complications Band slippage Mechanical complications			

Project: Bariatric surgery in adolescent with severe obesity

Appendix 2: Excluded articles

Study (author, publication year)	Reason for exclusion
Alqahtani <i>et al</i> , 2007	Duplicate publication with Alqathani, Alamri et al ,2012 (included)
Alqahtani <i>et al</i> , 2011	Duplicate publication with Alqathani, Alamri et al 2012 (included)
Alqahtani <i>et al</i> , 2012	Duplicate publication with Alqathani, Alamri, et al Surg Endosc 2012, (included)
Angrisani <i>et al</i> , 2005	Too few patients
Boza <i>et al</i> , 2012	Too few patients
Canoy <i>et al</i> , 2011	No RCT:s studies included under option “Bariatric surgery”
de la Cruz-Munoz <i>et al</i> , 2010	To few patients
de La Cruz-Munoz <i>et al</i> , 2013	To few patients
Dolan & Fielding, 2004	To few patients
Friebe <i>et al</i> , 2011	Outcomes for children/Adolescents not stated
Inge <i>et al</i> , 2010	Too few patients
Kalra <i>et al</i> , 2007	Too few patients
Lee <i>et al</i> , 2012	Too few patients
Modi <i>et al</i> , 2008a	Data not extractable
Modi <i>et al</i> , 2008b	No intervention

Project: Bariatric surgery in adolescent with severe obesity

Appendix 2: Excluded articles

Study (author, publication year)	Reason for exclusion
<i>Nadler et al, 2007</i>	Too few patients
<i>Nadler et al, 2008</i>	Too few patients
<i>Peltier et al, 1979</i>	Outcomes for children/Adolescents not stated
<i>Picot et al, 2009</i>	Later SR is available
<i>Silberhumer et al, 2006</i>	Too few patients
<i>Weismann et al, 2013</i>	Too few patients
<i>Woodard et al, 2011</i>	Too few patients
<i>Zitsman et al, 2011</i>	Too few patients

Project: Bariatric surgery in adolescents with severe obesity
 Appendix 1:11 Intervention and comparison: Bariatric surgery in adolescents vs. adults
 Outcome variable: Weight & BMI changes

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention Surgery 13-18 years	Control Surgery >18 years				
Alqahtani 2012	Saudi Arabia	Case series, sleeve gastrectomy	222	137	N=41/108 (12 m) BMI from 49.6 to 32.4 32.5% weight loss	N=44/114 (12 m) BMI from 48.3 to 31.8 34.7% weight loss	1 year follow up No significant difference between groups			
Dillard 2007	USA	Case series, gastric banding	740	510	N=14/24 (12 months) EWL 41%	N=216/716 (12 months) EWL 41%	1 year follow up No significant difference between groups			
Olbers 2012	Sweden	Case series gastric bypass	162		N=81 (24 m) BMI from 45.5 to 30.2 32% weight loss	N=81 (24 m) BMI from 43.5 to 29.7 31% weight loss	2 year follow up No significant difference between groups			
Zitsman 2011	USA	Case series, gastric banding	230	111	N=61/115 (12 m) weight loss 13.7% EWL 32.9%	N=58/115 (12 m) Weight loss 17.5% EWL 32.5%	No significant difference between groups neither at 12 months nor at 24 months			

BMI= body mass index ($mass(kg)/(height(m))^2$), EWL excess weight loss

3, Search strategy, study selection and references

Question(s) at issue:

Do severely obese adolescents have a better outcome of bariatric surgery compared to non-surgical treatment in terms of mortality, quality of life and socialisation, long-term morbidity, short-term complications, weight loss and impact on glucose metabolism/homeostasis?

Does outcome differ between adolescents and adults?

PICO (*P=Patient I=Intervention C=Comparison O=Outcome*)

P = Adolescents 13- 18 years of age with obesity (BMI or isoBMI >35)

I = Bariatric surgery

C = Conservative (non surgical treatment, diet- and life-style changes, pharmacological treatment)

O = Critical*

Mortality (30 day and long-term)

Suicide

Socialisation

Quality of Life (QoL)

Long term morbidity (>5 years bone mineralisation, drug abuse, anaemia, malnutrition)

Important*

Short-time complications (<2 years)

Weight /BMI-changes

Glucose metabolism/homeostasis

Not important*

Inflammatory markers (C-reactive protein (CRP))

Cardiovascular risk factors (blood pressure, lipids, left ventricular hypertrophy)

*Implies critical, important or not important outcomes for decision-making.

Eligibility criteria

Study design:

RCT

Systematic reviews

Non-randomized controlled studies

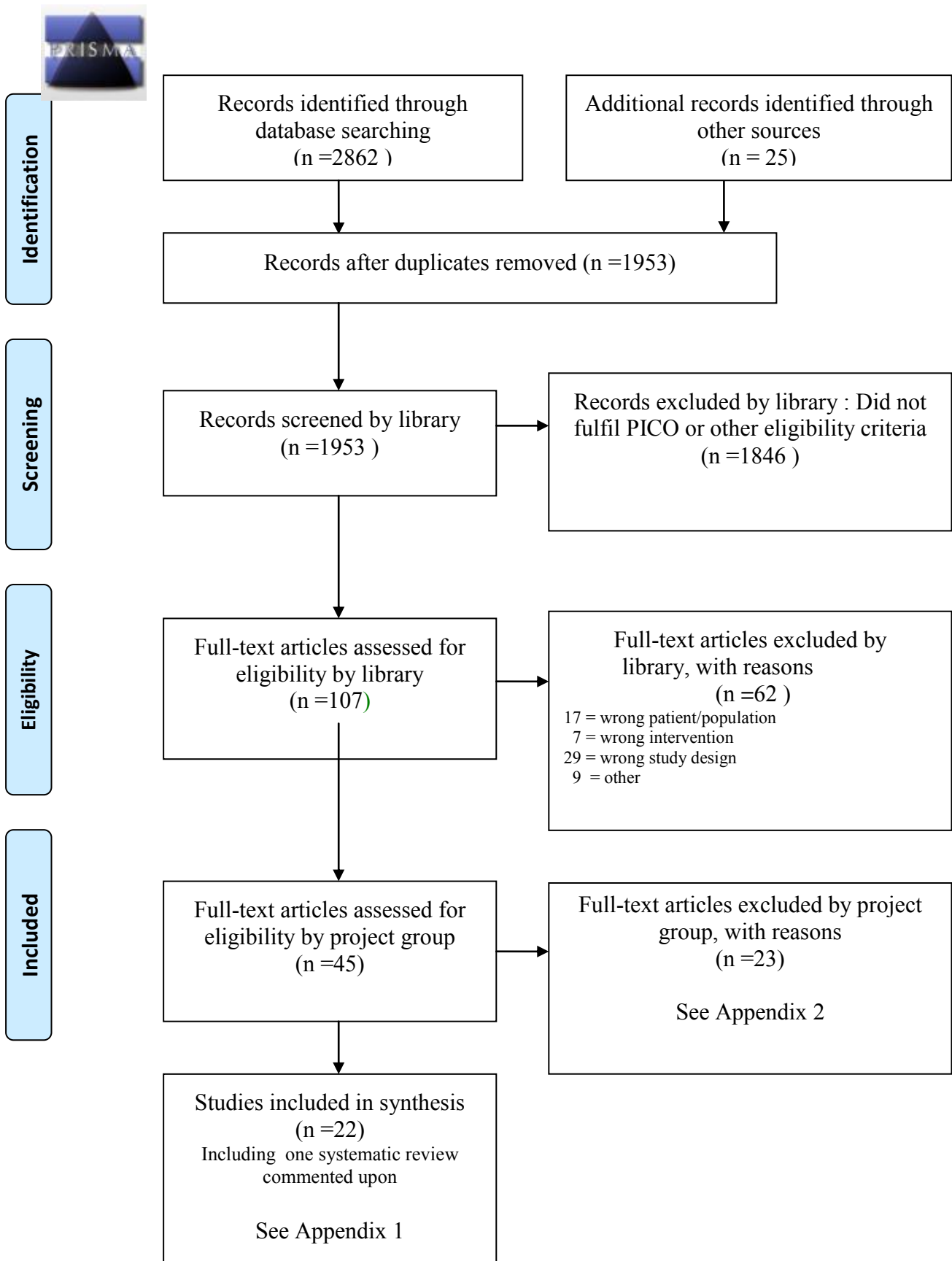
Case series >100 patients (no limit for mortality)

Language:

English, Swedish, Norwegian and Danish

Publication date: No limits

Selection process – flow diagram



Search strategies

Database: PubMed

Date: 2013-03-26

No of results: 1304

Search	Add to builder	Query	Items found
#15	Add	Search (#10) NOT #9 Filters: English; Danish; Norwegian; Swedish	1304
#11	Add	Search (#10) NOT #9	1468
#10	Add	Search (#6) NOT #8	1470
#9	Add	Search ((animals[mh]) NOT (animals[mh] AND humans[mh]))	3764985
#8	Add	Search Editorial[ptyp] OR Letter[ptyp] OR Comment[ptyp]	1226624
#6	Add	Search ((#1) AND #4) AND #5	1514
#5	Add	Search Bariatric Surgery[Mesh:NoExp] OR Bariatric surgery[tiab] OR Bariatric surgical procedure*[tiab] OR Bariatric operation*[tiab] OR Gastric bypass[mh] OR Gastric bypass[tiab] OR Stomach bypass[tiab] OR Obesity/surgery[mh] OR Obesity surgery[tiab] OR Gastroplasty[mh] OR Gastroplasty[tiab] OR Gastroplasties[tiab] OR Gastric banding[tiab] OR RYGB[tiab] OR Roux-en-Y[tiab] OR LAGB[tiab] OR LRYGB[tiab] OR Gastroenterostomy[mh] OR Gastroenterostomy[tiab] OR Gastroenterostomies[tiab]	20558
#4	Add	Search (#2) OR #3	1550687
#3	Add	Search Filters: Adolescent: 13-18 years	1507022
#2	Add	Search Adolescence[tiab] OR Adolescent[mh] OR Adolescent[tiab] OR Adolescents[tiab] OR teen[tiab] OR teens[tiab] OR teenager[tiab] OR teenagers[tiab] OR Youth[tiab] OR Youths[tiab]	1550687
#1	Add	Search Overweight[mh] OR Overweight[tiab] OR Obesity[mh] OR Obesity[tiab] OR Obesity, morbid[mh] OR Obese[tiab] OR Body Mass Index[mh] OR BMI[tiab] OR Body Mass Index[tiab]	277851

Database: EMBASE (OVID SP)

Date: 2013-03-26

No of results: 994 träffar

#	Searches	Results
1	exp adolescent/	1232593
2	exp adolescence/	58712
3	(adolescent or adolescents or adolescence or teen or teens or teenager or teenagers or youth or youths).ti,ab,tw.	227996
4	exp obesity/	249583
5	exp morbid obesity/	10739
6	exp body mass/	154344
7	(obesity or Obese or Overweight or BMI or "Body mass index").ti,ab,tw.	318323
8	exp stomach bypass/	8061
9	exp bariatric surgery/	13277
10	exp gastroplasty/	2977
11	exp gastric banding/	3710
12	(gastric bypass or stomach bypass or bariatric surgery or bariatric operation or bariatric operations or bariatric surgical procedere or bariatric surgical procedures or gastroplasty or gastroplasties or gastric banding or RYGB or Roux-en-Y or LAGB or LRYGB or Gastroenterostomy or Gastroenterostomies).ti,ab,tw.	19213
13	1 or 2 or 3	1308820
14	4 or 5 or 6 or 7	421295
15	*gastroenterostomy/	1226
16	8 or 9 or 10 or 11 or 12 or 15	25478
17	13 and 14 and 16	1126
18	limit 17 to (danish or english or norwegian or swedish)	994

Database: The Cochrane Library (Wiley)

Date: 2013-03-26

No of results: 101

Cochrane Reviews 5

Other Reviews 8

Trials 75

Technology Assessments 2

Economic Evaluations 11

ID	Search	Hits
#1	overweight or Obesity or Obese or "Body Mass Index" or BMI:ti,ab,kw (Word variations have been searched)	17902
#2	Adolescence or adolescent or Adolescents or teen or teens or teenager or teenagers or Youth or Youths:ti,ab,kw (Word variations have been searched)	81226
#3	Bariatric Surgery or Bariatric surgical procedure* or Bariatric operation* or Gastric bypass or Stomach bypass or Obesity surgery or Gastroplasty or Gastroplasties or Gastric banding or RYGB or Roux-en-Y or LAGB or LRYGB or Gastroenterostomy or Gastroenterostomies	1957
#4	#1 and #2 and #3:	101

Database: PsychINFO, BNI och ProQuest NAHS = 230 träffar

Date: 2013-03-26

No of results: 230

Set		Results
S3	all(obesity) OR all(obese) OR all(overweight) OR all(BMI) OR all(Body Mass Index)	719105
S4	all(adolescence) OR all(Adolescent) OR all(Adolescents) OR all(teen) OR all(teens) OR all(teenager) OR all(teenagers) OR all(youth) OR all(youths)	622934
S9	all("bariatric surgery") OR all(("bariatric surgical procedure" OR "bariatric surgical procedures")) OR all(("bariatric operation" OR "bariatric operations")) OR all(("gastric bypass" OR gastroplasties)) OR all(("stomach bypass" OR LRYGB)) OR all(("obesity surgery" OR Roux-en-Y)) OR all((gastroplasty OR Gastroenterostomy)) OR all((RYGB OR Gastroenterostomies)) OR all(LAGB) OR all("gastric banding")	6475
S10	S3 AND S4 AND S9	319
S11	(S3 AND S4 AND S9) AND SCHOL(yes)	230

Database: CRD

Date: 2013-03-26

No of results: 232

DARE: 173

NHS EED : 40

HTA: 19

The web-sites of **SBU, Kunnskapssenteret, Sundhedsstyrelsen** and **NHS Evidence** were visited. 2013-03-26. One reference/report which was commented on in the report was identified.

Reference lists

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Appendix 4

Summary of Findings: Bariatric surgery in adolescents with severe obesity

Outcome variable	Design Number of studies	Study limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	Results	Quality of evidence GRADE
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Quality of Life	1 RCT (n=50)	No limitations	Not applicable	No uncertainty	Very serious imprecision (-2)	Unlikely	n.a.	2/11 sub-scores in questionnaire showed statistical and clinical difference in favor of surgery	⊕⊕○○ Low
Short term complications	1 RCT (n=50)	Very serious limitations (-2)	Not applicable	No uncertainty	Serious imprecision (-1)	Unlikely	n.a.	Adverse events 48% vs 44%	⊕○○○ Very low
Weight/BMI changes	1 RCT 3 cohort studies	No limitations Serious limitations (-1)	Not applicable No serious inconsistency	Some uncertainty (-1)	No imprecision	Unlikely	n.a. Very large effect (+2)	Ranges: -28% to -38% vs. -3% to +3%	⊕⊕⊕○ Moderate
Diabetes metabolism/ homeostasis	1 RCT 1 cohort study	No serious limitations	No serious inconsistency	Some uncertainty (-1)	Serious imprecision (-1)	Unlikely	n.a.	More favourable outcomes (insulin sensitivity and metabolic syndrome) after surgery	⊕⊕○○ Low

n.a = not applicable

High quality of evidence = ⊕⊕⊕⊕
 Moderate quality of evidence = ⊕⊕⊕○

Low quality of evidence = ⊕⊕○○
 Very low quality of evidence = ⊕○○○

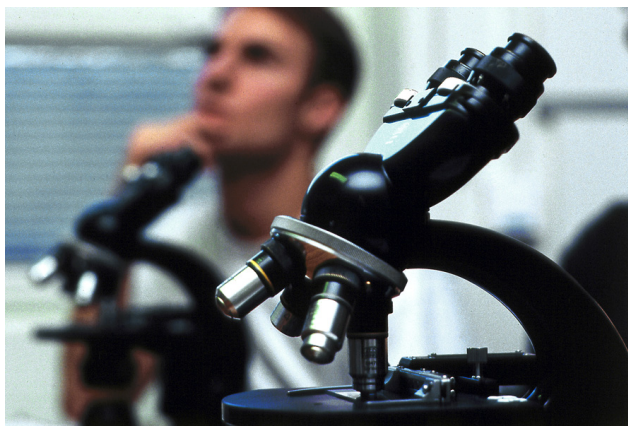
ETHICAL ANALYSIS OF BARIATRIC SURGERY FOR SEVERELY OBESE ADOLESCENTS

Question	Answer/ comment
1. From the patient's perspective, how does bariatric surgery affect the patient's quality of life and life expectancy?	Obese children experience very low quality of life with teasing and social isolation. In adolescents that have gone through bariatric surgery, quality of life is reported to be improved in the short term. Preliminary data show that this is also maintained for the long-term. In clinical experience, self-esteem, socialization and physical health are significantly improved five years after surgery. In a clinical setting, these patients may report that they find partners and friends easier and finalize education. However, we do not know about life expectancy, as the long-term data is lacking.
2. How severe is the patient's need that the bariatric surgery must meet?	The needs are severe, with severe metabolic consequences if not treated at a young age.
3. Does bariatric surgery have any influence on how others view the patient (concerning humanity and human dignity), or on how the patient views himself or herself (concerning humanity and human dignity)?	There are a lot of prejudices in the society, including the medical profession. Despite the large costs for long-term consequences, health care providers often do not prioritise the treatment of child and adolescent obesity. Unfortunately, there are large differences in health care for obese children in Sweden due to regional recommendations and resources.
4. Can bariatric surgery affect the patient's ability and possibility to be independent?	The future for an obese young person is not favourable. There are a lot of prejudices in the society. Young obese persons have difficulties with education, find employment and to establish family life, which will hinder them from establishing a normal socio-economical life. Surgery may improve these outcomes.
5. If implemented, does bariatric surgery require any special steps to not compromise the patient's autonomy?	Young age may be a serious concern in itself. Often the adolescent patient has difficulty in taking responsibility for the consequences of bariatric surgery, such as the need for long-term treatment with vitamins and minerals.
6. How does bariatric surgery affect the patient's physical, moral and personal integrity?	The influence on the individual integrity is also of concern. The intervention is regarded as permanent, but may in very rare cases be surgically reversed. The rapid change in body shape could lead to difficulties to cope with the new body image at start, but this change in body size is the essence of the wish of the young individual.
7. Is bariatric surgery cost-effective?	No health –economic analysis on adolescence undergoing bariatric surgery is available. Neovius <i>et al.</i> (2012) showed that, adult surgically treated patients compared with controls consumed more inpatient and non-primary outpatient care during the first 6-year period after surgery but not thereafter. In long term follow up (7-20 years) drug costs were lower for surgery patients than for control patients.
8. How bariatric surgery affect resources?	The numbers of bariatric surgery in adolescents may in the future be of such a magnitude, that this

	requires extra surgical resources. In the Region Västra Götaland about 40 bariatric surgical procedures per year are calculated. An additional 40 procedures may be referred from other parts of Sweden.
9. Is bariatric surgery in conflict with professional values?	No. Today the medical profession working with severe obesity lacks bariatric surgery as the ultimate treatment when all other treatment has failed.
10. Does bariatric surgery change the role of the professional in relation to the patient?	No.
11. Does bariatric surgery affect, or does it put any new demands on, a third party?	It has to be pointed out for the family and the adolescent that the method is not a “quick-fix”. Indication for surgery is based on metabolic co-morbidities and weight excess. Successful results can only be achieved by combining life-style changes, support from the family and a follow up by the multidisciplinary team including psychologist. On the other hand, only life-style changes without surgery are often felt as a large burden for the families.
12. Is there any legislation of relevance with regard to bariatric surgery?	Legislative aspects of bariatric surgery in adolescents should not be of concern as the society of today regards children from an age of 15 years to be mature enough to make decisions of their own.
13. Is there any risk of conflict between the procedure of bariatric surgery and values of the society, or values of different groups?	No. Today the surgery is accepted in adults when all other treatment has failed and this would also be accepted for adolescents. However, we believe that the society expects us to have a more strict follow-up including psychological support of these young persons during the coming years after surgery.
14. Is there a risk that an introduction of bariatric surgery will cause a conflict with particular interests?	Hypothetically the introduction of bariatric surgery in adolescents may lead to displacement effects but the number of surgical procedures per year is modest. The new regional obesity centre will change in character with a true multidisciplinary team including both physicians and surgeons
15. Can an introduction bariatric surgery influence the trust of the health care system?	No. In the Region Västra Götaland, there is already a large demand for surgery in adolescents with referral from the major hospitals of the region as well as from northern Sweden. Today these adolescents are hindered from this treatment, due to an arbitrary age cut-off.
CONCLUSIONS	The bariatric surgery improves body size and health and may improve quality of life. Knowledge of long-term effects is lacking.

Region Västra Götaland, HTA-centrum

Health Technology Assessment
Regional activity-based HTA



HTA

Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technologies, i.e. interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care.

To evaluate the quality of evidence the Centre of Health Technology Assessment in Region Västra Götaland is currently using the GRADE system, which has been developed by a widely representative group of international guideline developers. According to GRADE the level of evidence is graded in four categories:

High quality of evidence	= (GRADE ⊕⊕⊕⊕)
Moderate quality of evidence	= (GRADE ⊕⊕⊕○)
Low quality of evidence	= (GRADE ⊕⊕○○)
Very low quality of evidence	= (GRADE ⊕○○○)

In GRADE there is also a system to rate the strength of recommendation of a technology as either “strong” or “weak”. This is presently not used by the Centre of Health Technology Assessment in Region Västra Götaland. However, the assessments still offer some guidance to decision makers in the health care system. If the level of evidence of a positive effect of a technology is of high or moderate quality it most probably qualifies to be used in routine medical care. If the level of evidence is of low quality the use of the technology may be motivated provided there is an acceptable balance between benefits and risks, cost-effectiveness and ethical considerations. Promising technologies, but a very low quality of evidence, motivate further research but should not be used in everyday routine clinical work.

Christina Bergh, Professor, MD.
Head of HTA-centrum

