A report for
Universitätsklinikum Schleswig-Holstein/Campus Kiel
on shared decision making
for obesity

Kleijnen Systematic Reviews Ltd

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LIST OF ABBREVIATIONS

% EWL	% excess weight loss
AWMF	Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften
BMI	Body mass index
BS	Bariatric surgery
CDSR	Cochrane Database of Systematic Reviews
CI	Confidence interval
CT	Conservative treatment
DARE	Database of Abstracts of Reviews of Effects
ECRI	Emergency Care Research Institute
EWL	Excess weight loss
FAQ	Frequently asked question
G-I-N	Guidelines International Network
GIQLI	Gastrointestinal Quality of Life Index
HbA_{1c}	Glycated haemoglobin A_{1c}
HDL	High density lipoprotein
HTA	Health technology assessment
ILI	Intensive lifestyle intervention
IQWiG	Institute for Quality and Efficiency in Health Care
IR	Incidence rate
ITT	Intention-to-treat
KSR	Kleijnen Systematic Reviews Ltd
LAGB	Laparoscopic adjustable gastric band
LDL-C	Low-density lipoprotein cholesterol
LMGB	Laparoscopic mini gastric bypass
LRYGB	Laparoscopic Roux-en-Y gastric bypass
LSG	Laparoscopic sleeve gastrectomy
MA	Meta-analysis
MD	Mean difference
MGB	Mini gastric bypass
MI	Myocardial infarction
Mini-GBP	Mini gastric bypass
NA	Not applicable
NAFLD	Non-alcoholic liver disease
NE	Not estimable
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NR	Not reported
NSH	Non-alcoholic steatohepatitis
NST	Non-surgical treatment
OR	Odds ratio
OSA	Obstructive sleep apnoea
OSAS	Obstructive sleep apnoea syndrome
PICOS	Participants, intervention, comparators, outcomes and study design
QoL	Quality of life
RAND	Research ANd Development
RCT	Randomised controlled trial
ROB	Risk of bias
RR	Risk ratio
RYGB	Roux-en-Y gastric bypass
SDM	Shared decision making
SF-36	Short Form (36) Health Survey
SG	Sleeve gastrectomy
SMB	Swiss Medical Board
SR	Systematic review
T2DM	Type 2 diabetes mellitus

TG	Triglyceride
VLCD	Very low-calorie diet
WMP	Weight management program

1. PROJECT OBJECTIVE

A key aim of the research project “Making SDM a reality” is to create interactive websites to inform patients as part of shared decision making (SDM).

To support this, Kleijnen Systematic Reviews Ltd (KSR) has prepared an evidence report with a synthesis of the literature underpinning the supporting evidence table of the relevant treatment options.

The topic of this evidence report is treatment of obesity.

2. METHODS

2.1 INCLUSION CRITERIA

The research question underpinning the literature searches for this topic was developed in conjunction with clinical departments at Universitätsklinikum Schleswig-Holstein/Campus Kiel. The question was framed in terms of participants, intervention, comparators, outcomes and study design (PICOS), see Table 1.

As detailed below, literature searches were carried out using a stepwise approach to identify relevant studies according to study design. In the first step, searches aimed to identify relevant systematic reviews and guidelines.

Table 1: Inclusion criteria for searches

PICOS	
Patient population	Obese patients as defined in section 2.1.1
Intervention/Comparators	• Continued conservative treatment • Very low calorie diets (in particular Optifast®) • Roux-en-Y gastric bypass • Sleeve-gastrectomy • Laparoscopic gastric band • Mini bypass
Outcomes	• Mortality • Weight loss • Quality of life • Symptoms associated with obesity • Recovery • Risks/side-effects • Other non-health related consequences
Study design	Systematic reviews (SR)/meta-analyses (MA) (or randomised controlled trials (RCTs), or studies of lower evidence levels (non-randomised/observational studies), if needed.
MA = meta-analysis; RCT = randomised controlled trial; SR = systematic review	

In consultation with the commissioner, questions frequently asked by patients in conjunction with outcomes identified in the literature were developed into an evidence table outline.

2.1.1 Population

Studies with adults with a

- Body mass index (BMI) ≥35 kg/m^2 and related co-morbidities such as type 2 diabetes mellitus (T2DM),
- BMI ≥40 kg/m^2 or
- BMI ≥50 kg/m^2

will be included.

Other relevant comorbidities that are being considered when judging the eligibility for bariatric surgery in patients with a BMI of ≥ 35 kg/m^2 include coronary artery disease, cardiac failure, hyperlipidaemia, arterial hypertension, nephropathy, obstructive sleep apnoea syndrome (OSAS), hypoventilation syndrome, Pickwick Syndrome, non-alcoholic liver disease (NAFLD), non-alcoholic

steatohepatitis (NASH), pseudotumour cerebri, gastrooesophageal reflux, asthma, chronic venous insufficiency, urinary incontinence, immobilising joint disease, decreased fertility or polycystic ovaries.[1]

Patients with a BMI <35 kg/m^2 will be excluded as these will preferentially be treated conservatively (multimodal lifestyle modification program).

2.1.2 Frequently asked questions

Table 2 shows the identified research questions (frequently asked questions; FAQs) with relevant outcomes. Two papers on the views of health professionals and preferences of patients were used to identify and prioritise outcomes.[2, 3]

Table 2: Frequently asked questions and related outcomes

FAQ 1: What does the treatment involve?
• Description of the procedure • Is the treatment reversible? • Length of hospital stay
FAQ 2: Will I live longer?
• All-cause mortality • Cause-specific mortality • Survival time
FAQ 3: Will my symptoms/my quality of life get better?

• Individual weight loss/weight stabilisation[a]
• Quality of life
• Resolution/change of symptom levels of co-morbidities, e.g.
  ○ Diabetes
  ○ Stroke
  ○ Myocardial infarction (MI)
  ○ Hypertension
  ○ Dyslipidaemia
  ○ Sleep apnoea
  ○ Cancer
• Function
• Fitness
  ○ Mobility (e.g. being able to walk, climb stairs, bend, cross legs, get up from chairs)[b]
• Mood
• Sexuality
• Being able to stop eating when feeling full[b]
• Having a healthy/balanced eating pattern
• Normality (feeling able to live a “normal life”)
• Having a positive outlook on life and expectations for the future[b]
• Feeling in control of health and well-being[b]

FAQ 4: When will I recover?
• Time to return to usual activity • Time of work/return to work[c]

FAQ 5: What are the risks/side-effects?
Surgical risks: • Bleeding wound infections or wound healing problems • Septicemia • Cardiovascular risks • Leaking anastomoses • Fistulas[c] • Gastric band eroding/growing into the stomach[c] • Band slipping out of place and needing more surgery to correct it[c] • Stroke[c] • Kidney failure[c] • Abnormal narrowing of the bowel caused by scar tissue or stapling, which might cause blockage (stenosis)[c] • Venous clot in the leg or lung (venous thromboembolism)[c] • Heart's blood supply is blocked, or interrupted, by a build-up of fatty substances in the heart's arteries (ischaemic/coronary heart disease)[c] • Bleeding from the internal bowel staples (staple line bleed)[c] • Ulcers developing at the new join between the two pieces of bowel (anastomotic ulceration), metabolic bone disease, needing medication or special diet, diabetes, hypertension[c] **What are the side-effects?** • Nausea • Reflux **Longer term:** • Depression
FAQ 6: What other – not health related – consequences are there?
• How will the treatment impact my daily life afterwards? • What are the costs for the patient?
[a] Fifth item on the preference list of patients (77.3% rating the item as "important)[2] but only rated as "extremely important" (8-9 on 9 point scale) by ≥70% of the physicians but not by the patients[3]; [b] Rated as "extremely important" (8-9 on 9 point scale) by ≥70% of the patients but not by the physicians[3]; [c] Rated as "extremely important" (8-9 on 9 point scale) by ≥70% of the physicians but not by the patients[3] FAQ = frequently asked question; MI = myocardial infarction

2.2 LITERATURE SEARCHES

Literature searches were carried out on 30 April to 1 May 2019 to identify relevant systematic reviews and evidence-based guidelines on obesity and surgical options, specifically Roux-en-Y gastric bypass, sleeve gastrectomy, laparoscopic adjustable gastric banding and mini bypasses. To inform FAQs a second targeted database search on obesity, surgical options and SDM was also undertaken.

The search strategies were developed specifically for each database and the keywords adapted according to the configuration of each database. Searches were limited by date range for systematic reviews and guidelines to 2012-2019. Searches were not limited by language or publication status. Full details of all search strategies are presented in Appendix 1.

To identify qualitative patient-related information, additional web browsing was also undertaken.

Systematic reviews and guidelines

The following systematic review specific databases were searched from 2012 to present:

- Cochrane Database of Systematic Reviews (CDSR) (Wiley): 2012-2019/05/Iss5
- Database of Abstracts of Reviews of Effects (DARE) (www.crd.york.ac.uk): 2012-2015/03/31

- Health Technology Assessment (HTA) database (www.crd.york.ac.uk): 2012-2018/03/31
- KSR Evidence (www.ksrevidence.com): up to 2019/05/02
- Epistemonikos (www.epistemonikos.org): 2012-2019/05/01

The following guidelines resources were searched from 2012 to present:

- Guidelines International Network (G-I-N) (www.g-i-n.net): up to 2019/04/29
- NHS Evidence (www.evidence.nhs.uk): 2012/01/01-2019/05/01
- ECRI Guidelines Trust (https://guidelines.ecri.org/): up to 2019/04/30
- NICE (www.nice.org.uk): up to 2019/04/30

Targeted searches

To identify questions relevant to shared decision making, targeted searches were undertaken in the following databases with no date limit:

- EMBASE (Ovid): 1974 to 2019 May 3
- MEDLINE and In-Process & Other Non-Indexed citations (Ovid): 1946 to April Week 4 2019
- MEDLINE Epub Ahead of Print and Daily Update: up to 2019 May 3

Handling of citations

Identified references from the bibliographic database searches were downloaded into EndNote bibliographic management software for further assessment and handling.

2.3 METHODS OF STUDY SELECTION AND DATA EXTRACTION

Study selection

Two reviewers independently screened the title and abstract of each record identified by the search and determined the potential relevance of each record. Due to the large number of potentially relevant records, prioritisation criteria were established and full papers were obtained for the prioritised references, independently checked, and inclusion criteria applied. Any disagreements were resolved through discussion.

Prioritisation of potentially relevant references

Step-1:

a. All guidelines
b. Any systematic reviews clearly comparing more than two interventions of interest and published in 2015 or later

Step-2:

c. Guidelines published (or updated) in 2015 or later that are not specifically looking at characteristics of interventions like “endoscopic bariatric surgery”
d. Systematic reviews without limitations of:
    i. the population based on weight (i.e. only super-obese patients) or
    ii. co-morbidities – i.e. T2DM (unless network-MAs) and
    iii. not specifically looking at characteristics of intervention like “endoscopic bariatric surgery“

An evidence hierarchy was used to select the most appropriate study(ies) to populate the evidence tables. Where more than one study could provide evidence, the most relevant studies were selected using the following criteria: recency (most recent preferred), quality (highest quality preferred), representativeness (populations representative of the general target population preferred). Where there were gaps in the evidence (no systematic review or guideline available), in a first step additional full texts of systematic reviews were prioritised by broadness of interventions covered

and date and in a second step, relevant randomised controlled trials (RCTs) would have been searched for and extracted, and where no RCTs would have been identified, observational studies would have been employed.

Data extraction

For each study, data were extracted by one reviewer and checked by another. Any disagreements were resolved by consensus.

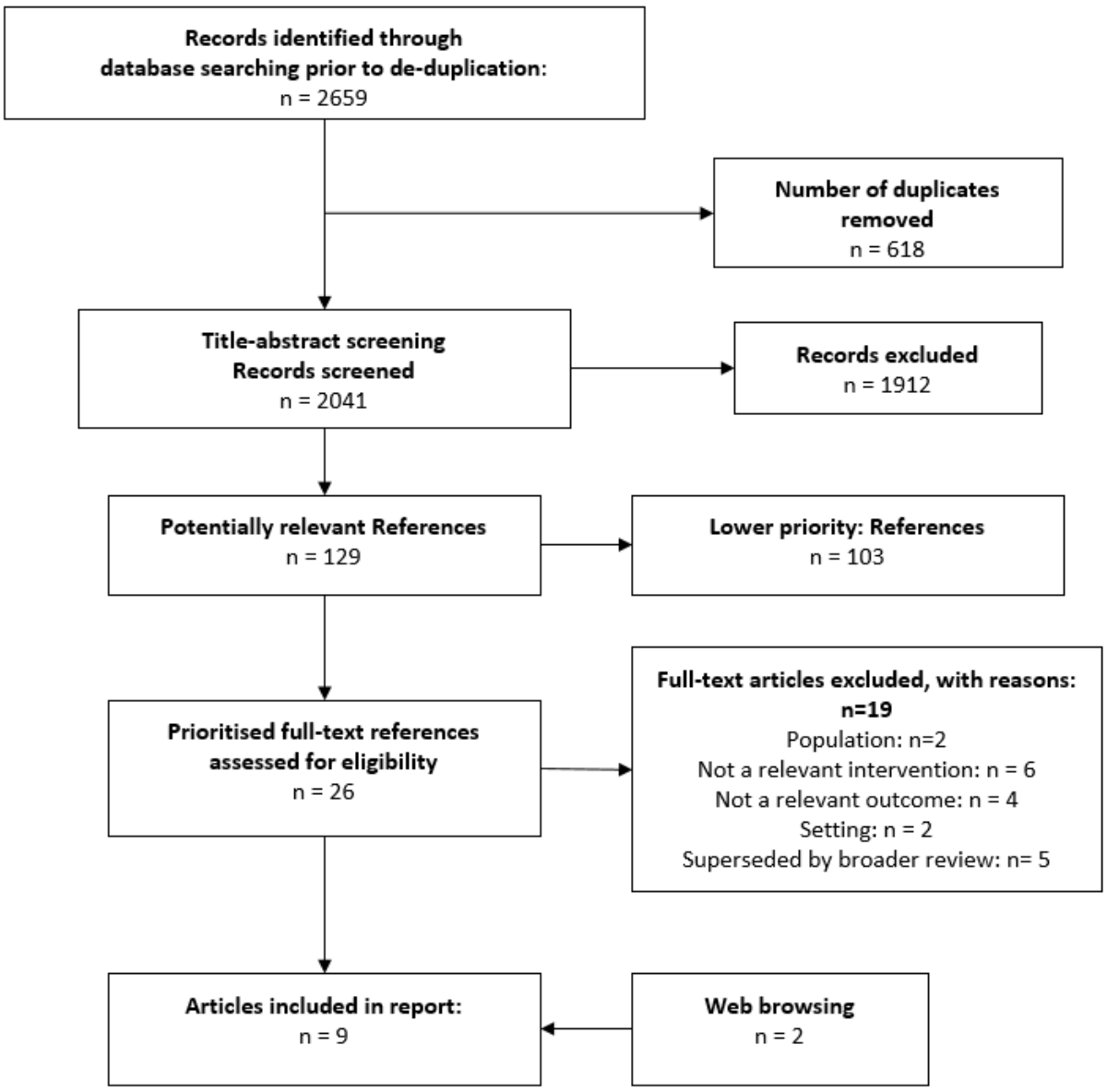
3. RESULTS

3.1 LITERATURE SEARCH RESULTS AND INCLUSION ASSESSMENT

A total of 2,659 records were retrieved from literature searches. After de-duplication, 2,041 titles and abstracts were screened by two reviewers. Of these, 129 full papers were identified as potentially relevant. After further review, 26 records were prioritised for full-text screening. In addition, internet searches were performed and retrieved two records which were used to inform FAQ 1 (What does the treatment involve?). Thus, nine records were selected for this report, please see Table 3.

A summary of the study selection process according to a modified PRISMA flow chart is reported in Figure 1.

Figure 1: Study selection process



3.2 OVERVIEW OF THE EVIDENCE

Table 3 summarises the studies used to answer the FAQs. In order to increase clarity, the table only describes the interventions and comparators of interest for this report even though some of the systematic reviews also investigated other interventions or comparisons. There was a marked overlap between the studies included in the SMB report and in the HTA by Avenell for the comparison of surgical interventions vs. conservative treatment. In both, the SMB report and the Avenell HTA, the surgical intervention was sometimes combined with a conservative treatment and sometimes not. The conservative treatment given in those instances tended to be the same as the intervention as in the comparator arm, e.g. RYGB plus lifestyle intervention would be compared to the same lifestyle intervention on its own.[4, 5]

Table 3: Evidence sources

Study	Evidence type	Intervention	Comparators	FAQ-1: What does the treatment involve?	FAQ-2: Will I live longer?	FAQ-3: Will my symptoms/ quality of life get better?	FAQ-4: When will I recover?	FAQ-5: What are the risks/side-effects?	FAQ-6: What other -not health related- consequences are there?
Avenell 2018[5]	HTA	RYGB, SG, LAGB Co-intervention: lifestyle interventions	Lifestyle interventions, dietary interventions, conservative treatment[a]			✓			
		Optifast + dietary intervention, VLCD	Dietary intervention only			✓			
AWMF 2018[1]	Guideline	Conservative treatment, RYGB, SG, LAGB, MGB	Conservative treatment, RYGB, SG, LAGB, MGB	✓	✓	✓		✓	✓
		Surgery with lifestyle intervention	Surgery without lifestyle intervention	✓					
AWMF 2014[6]	Guidelines	Conservative	Conservative treatment, Optifast	✓		✓			✓

Study	Evidence type	Intervention	Comparators	FAQ-1: What does the treatment involve?	FAQ-2: Will I live longer?	FAQ-3: Will my symptoms/ quality of life get better?	FAQ-4: When will I recover?	FAQ-5: What are the risks/side-effects?	FAQ-6: What other -not health related- consequences are there?
		treatment, Optifast							
Chiapetta 2018[7]	SR	Mini gastric bypass Co-intervention: NR	RYGB and SG	✓					
Colquitt 2014[8]	SR	LAGB, SG, and RYGB Co-intervention: Co-intervention: NR	LAGB, SG, and RYGB	✓	✓	✓	✓	✓	
Kang 2017[9]	SR	LAGB, SG, and RYGB Co-intervention: NR	LAGB, SG, and RYGB			✓		✓	
Kodama 2018	NMA	LAGB, NST, LSG, RYGB, mini gastric bypass	LAGB, NST, LSG, RYGB, mini gastric bypass			✓			
Quan 2015[10]	SR of non-randomised studies	Laparoscopic mini gastric bypass Co-intervention: NR	LAGB, LSG, and LRYGB		✓	✓	✓	✓	
Swiss Medical Board[11]	HTA	Adjustable gastric banding, sleeve gastrectomy, gastric bypass Co-intervention: with or without conservative co-interventions	• Lifestyle modifications with different types of diets and physical activity interventions and in some instances additional medical treatment, or • No intervention except information regarding healthy		✓	✓			

Study	Evidence type	Intervention	Comparators	FAQ-1: What does the treatment involve?	FAQ-2: Will I live longer?	FAQ-3: Will my symptoms/ quality of life get better?	FAQ-4: When will I recover?	FAQ-5: What are the risks/side-effects?	FAQ-6: What other -not health related- consequences are there?
			food choices and increases in physical activity						

AWMF = Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften; HTA = health technology assessment; LAGB = laparoscopic gastric banding; LRYGB = laparoscopic Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy; MGB = mini gastric bypass; NMA = network meta-analysis; NST = non-surgical treatment, RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; SR = systematic review

[a] Conservative treatment includes changes in life style such as changes in nutrition, increased physical activity, behaviour modification, and drug therapy

FAQ 1: WHAT DOES THE TREATMENT INVOLVE?

This section covers the rationale for the treatment of obesity, eligibility for treatment, and the different surgical procedures. This is set out in Table 4.

Table 4: Description of treatments for obesity

Treatment options
The treatment options covered in this report include any conservative treatment – with particular focus on the Optifast® treatment if available – and four types of surgical interventions: Roux-en-Y gastric bypass, sleeve-gastrectomy, laparoscopic gastric band, mini-bypass. The expected treatment effect and complication rates can vary markedly between interventions.[1] Two main types of surgical interventions can be differentiated: restrictive and bypass methods. The effect of the former type of intervention is based on a reduction of the size of the stomach while for the latter type of surgery the food bypasses sections of the gastrointestinal tract thereby reducing the amount that is being absorbed.[12] In some cases, a step-wise approach can be used, particularly for patients with extreme forms of obesity (BMI >50 kg/m^2) and/or significant co-morbidities.[1] The rationale for a step-wise approach is that the duration of the surgical intervention can be shortened and the overview and orientation can be improved due to a limitation of the intervention to one compartment of the abdomen.[1] This aims to reduce cardio-pulmonary and intervention-specific complications. Typically, sleeve gastrectomy is followed by bypass surgery.[1] However, evidence regarding step-wise approaches is not covered in this report though. According to the AWMF guideline, symptomatic patients should routinely have a oesophagogastrodueodenoscopy (i.e. an examination of the oesophagus, the stomach, and the upper part of the small bowel) prior to surgery as it can affect the procedure of choice and reveal findings that require treatment (expert consensus, strong consensus).[1] Asymptomatic should receive a preoperative oesophagogastrodueodenoscopy for the above mentioned reasons (expert consensus, consensus).[1] Bariatric surgery is not considered to be a single intervention but patients should also change their eating behaviour and eat smaller quantities more slowly. In addition patients are encouraged to commit to daily exercise as part of a wider change in lifestyle.[8] The greatest weight loss is usually expected over the first 12 months with an expected weight gain after two to three years.[1] Gastric bypass and sleeve gastrectomy lead to hormonal changes which reduce the appetite and affect the metabolism, which has positive effects on T2DM.[13] According to the AWMF guideline, a structured, life-long follow-up is essential for the success of the surgical interventions (expert consensus, strong consensus).[1] These recommendations include but are not limited to regular check-ups with physicians/dietary consultants, dietary advice and support to continue a healthy lifestyle, e.g. do sports or be part of self-help groups (expert consensus, strong consensus).[1] If patients had not been on a diet before surgery, this needs to be started at discharge at the latest in conjunction with life-long prophylaxis/ supplementation (vitamins and trace elements) in order to avoid nutrient deficiency.[1] Verification and – as needed – adaptation of the pharmacotherapy should be part of the post-operative check-ups (expert consensus, strong consensus).[1] In order to prevent ulcers, proton pump inhibitors (drugs which reduce the amount of acid in the stomach) may be given for four to six weeks after surgery. In the case of gastric bypass, a prolonged treatment for at least six weeks can be given as this can reduce the number of ulcers at the anastomosis (expert consensus, strong consensus).[1] According to the AWMF guideline, behavioural lifestyle interventions can be offered postoperatively in order to support weight loss and reduce weight regain but the recommendation remained open.[1] Medication may be problematic in patients with bariatric surgery and needs to be taken into

consideration for example when planning to take contraceptives.[1]

Eligibility for treatment

According to the AWMF guideline,[1] patients eligible for surgical treatment should have:

- a BMI ≥40 kg/m^2 without comorbidities, or
- for patients with a BMI ≥35 kg/m^2 with at least one co-morbidity associated with obesity, e.g. T2DM, coronary heart disease, cardiac failure, hyperlipidaemia (high lipids, e.g. cholesterol, in the blood), arterial hypertension and others, once options for conservative treatment have been exhausted.

A primary indication for bariatric surgery can be given without an initial attempt of conservative treatment if at least one of the following criteria is given for patients with a BMI ≥50 kg/m^2:[1]

- in whom a trial with conservative treatment is deemed to be unlikely to succeed or futile, or
- with particularly severe co-morbidities or diseases secondary to obesity, which do not allow for a delay of the surgical intervention.

Conservative treatment options are considered to have been exhausted when after a comprehensive lifestyle intervention of at least six months within the last two years a reduction of the original weight of >15% with a BMI of 35-39.9 kg/m^2 and of >20% with a BMI of more than 40 kg/m^2 was not achieved. In case a weight gain of >10% occurs after a successful reduction of the weight, the conservative treatment is considered to have been exhausted after one year as well.[1]

A higher age (≥65 years), Morbus Crohn, and colitis ulcerosa are no contraindications against the use of bariatric surgery.[1] Patients above the age of 65 years are eligible for LAGB, SG, pRYGB, and Omega-Loop-Bypass (expert consensus, strong consensus).[1] The choice of intervention should be made individually based on a risk-benefit-analysis and taking into consideration the wishes of the patient.[1] Considering the higher risk for nutritional deficiencies and for gastro-intestinal side-effects the decision for malabsorptive interventions should be made more cautiously in older patients.[1]

Contraindications for bariatric surgery are unstable psychopathological conditions, active substance abuse, and untreated bulimia nervosa according to the AWMF. If these conditions can be successfully treated or if the psychopathological conditions can be stabilised a re-evalution should take place. Mental health diseases, binge eating disorders or child abuse do not constitute general contra-indications for surgery (expert consensus, strong consensus).[1]

A metabolic intervention, i.e. the main aim of the surgical intervention is to improve metabolic symptoms (especially diabetes remission), is indicated in the following cases:[1]

- With a BMI ≥40 kg/m^2 and co-existing T2DM, metabolic surgery should be offered to the patient as one treatment option, irrespective of the glycaemic control or the complexity of the anti-diabetic treatment.
- People with a BMI ≥35 kg/m^2 and <40 kg/m^2 and co-existing T2DM should be offered metabolic surgery as a treatment option if it is not possible to reach the diabetes specific individual target value according to the AWMF guideline on the treatment for T2DM.
- Metabolic surgery should be considered as a possible treatment option for adults with a BMI ≥30 kg/m^2 and < 35 kg/m^2 and co-existing T2DM if it is not possible to reach the target values according to the AWMF guideline on T2DM.
- For patients with Asiatic origin, the BMI cut-offs are 2.5 points lower in each instance.
- In order to decide regarding the indication a specialist in diabetes needs to be involved regarding the decision for an indication in patients with a BMI <40 kg/m^2.

Additional groups mentioned in the guideline that are not target groups in this evidence review are:

- Metabolic surgery for adults with a BMI <30 kg/m^2 should only be performed in the context

of scientific studies (expert consensus, strong consensus).[1]

Contraindications for metabolic surgery are unstable psychopathological conditions, active substance abuse, and untreated bulimia nervosa, consuming underlying conditions, malignant tumours, untreated endocrine causes, chronic diseases, which worse through a post-operative catabolic metabolism, planned or existing pregnancy according to the AWMF.

If these conditions can be successfully treated or if the psychopathological conditions can be stabilised a re-evalution should take place. (expert consensus, strong consensus).[1]

Conservative treatment

Conservative treatment includes changes in life style such as changes in nutrition, increased physical activity, behaviour modification, and drug therapy.[1] In order to reduce body weight the reduction diet should aim at a daily energy deficit of about 500 kcal/day, in some cases also higher according to the AWMF guideline (recommendation). [6]

Depending on the situation of the patient a time limited use of formula products with an energy supply of 800 to 1200 kcal/day can be considered (open recommendation). In this case the involvement of a medical doctor should be ensured (strong recommendation). The DGEM did not agree with this statement and the following and formulated the following special statement regarding the first part of the sentence: This recommendation is being supported by high quality cohort studies, which warrants a recommendation. Herewith formula diets are the most effective dietary method for the initial weight reduction.[6]

Extremely unbalanced forms of nutrition should not be recommended due to the high medical risks and the lack of long-term success (strong recommendation).[6] In order to lose weight a stepwise approach can be helpful (open recommendation):[6]

- Solely reduction of fat and carbohydrates
- Reduction of fat and sugar (low energy density)
- Meal replacements with formula products
- Nutrition solely with formula diet (time limited, 800 to 1200 kcal/day)

For an effective weight loss one should exercise for >150 min/week with an energy consumption of 1200 to 1800 kcal/week. Weight lifting alone is not very effective for weight loss (recommendation).[6]

Drug treatment should only be used in conjunction with a basic program (nutritional, exercise and behavioural therapy) (strong recommendation). [6] If obesity is being treated with drugs only Orlistat should be used (strong recommendation). [6]

Optifast program

A specific conservative program is the commercial Optifast 52® weight loss program, a medically supervised ambulatory therapy that lasts up to 52 weeks and involves weekly group sessions, a meal replacement treatment as well as intense medical, physical, dietary and psychological counselling, activation and support. Usually, patients start the treatment with a very low calorie diet (400-500 kcal/day, Optifast). After 8-12 weeks other foods are gradually reintroduced over 4-9 weeks to reach 1000-1500 kcal/day.[4] Finally, during the maintenance phase (up to 52 weeks) patients are encouraged to participate in support sessions to help maintain their weight loss. This phase may also include partial consumption of meal replacements.[14]

The program has several phases/stages in which individuals meet with a health professional, learn about the long-term weight management plan and a healthy lifestyle. In some cases, Optifast® is

recommended before undergoing bariatric surgery for weight loss or it can be used instead of surgery (to reduce the risk of complications). [14]

According to the AWMF guideline of 2014, weight reduction programs that take into account the individual situation and the treatment goals should be offered to obese people (recommendation). They should also have proven their effectiveness.[6] In addition these programs should contain the components of the basic program, i.e. dietary, exercise and behavioural therapy (strong recommendation).[6]

Behavioural therapy

Behavioural therapy interventions and strategies for the use in the case of overweight and obesity should include various elements (strong recommendations).[6] The spectrum of appropriate interventions and strategies can include the following psychotherapeutic elements (Open recommendation):[6]

- Self-observation of behaviour and progress (weight, amount of food, exercise)
- Practicing a flexibly controlled eating and exercising behaviours (as opposed to a rigid control of behaviour)
- Cognitive restructuring (modification of the dysfunctional thought processes)
- Goal agreements
- Training in problem solving/ conflict resolution
- Training in social skills/ assertiveness
- Reinforcement strategies (e.g. rewarding of changes)
- Relapse prevention
- Strategies in dealing with renewed weight increase
- Social support

Sleeve gastrectomy (SG)

For a sleeve gastrectomy (SG) the size of the stomach is reduced by removing a large part of it so that only a tube of gastric tissue with a diameter of 2-3 cm and a volume of 100-150 ml remains.[1] Prior to surgery, measures should be taken to protect the gastric lining by stopping or reducing drugs that could affect it.[12]. As detailed before, SG can be used as definitive surgical approach or can be used as a first step in a stepwise surgical approach.[1] The AWMF recommends that in patients with a BMI >60 kg/m^2 and/or in the case of marked visceral obesity SG should be the treatment of choice (expert consensus, strong consensus).[1]

After six to 12 months, the stomach may have expanded and not restrict intake as much.[8] Depending on whether the effects following SG are completely satisfactory or not, it can be converted into a Roux-en-Y bypass, a mini-bypass, or a postpyloric bypass at that stage (with patients already experiencing some weight loss).[1, 8]

Currently no clear contraindications for SG exist but in case of existing symptomatic and/or treatment refractory gastro-oesophageal reflux, the indication for SG should be critically discussed with the patient.[12] SG is not a reversible intervention.[8, 13]

Roux-en-Y gastric bypass (RYGB)

The Roux-en-Y gastric bypass (RYGB) combines restrictive and bypass methods. For RYGB, the main part of the stomach with the attached duodenum is separated from the smaller top part of the stomach (fundus) and the small bowel. The top part of the stomach is formed into a small pouch and then connected to the small bowel.[8, 12] In contrast to SG, no part of the stomach is being removed

though the remaining lower part stomach and duodenum are attached via the duodenum to the small bowel at a site further down from the initial junction, i.e. the gastric juices of the main part of the stomach will reach the food at this new junction.[12]

Gastric bypass surgery should preferably not be performed in patients for whom an endoscopic access to remaining stomach, the duodenum, or the papilla is necessary. The RYGB technique aims to avoid linking the stomach and intestine (gastroenterostomy) via a loop as this can cause reflux of bile. The AWMF recommends that in the case of symptomatic reflux the proximal RYGB should be preferred (expert consensus, strong consensus).[1] The intervention is nearly always performed using keyhole surgery.[12] If needed, RYGB can be reversed.[8]

Laparoscopic gastric banding

Gastric banding is a reversible, restrictive, and minimally invasive surgical intervention. The band usually consists of silicon which is inserted through a surgical cut of the skin and placed around the proximal part of the stomach. This creates a small pouch at the entry to the stomach of 20-30 ml. The band is connected to a port under the skin via a tube and can be adapted in its size by filling or emptying it via the port, even after surgery. The location of the port does not affect ability to do sports.[12]

The first adjustment of the band usually takes place after four weeks (two to eight weeks). For this adjustment, normal saline solution is injected through the port and the following band adjustments after four to eight weeks are adapted individually depending on weight loss, feeling of satiety, eating behaviour, and stomach problems (e.g. vomiting).[1]

According to the AWMF guideline, long-term results for weight loss tend be less marked than with other surgical interventions and therefore this type of surgery is less relevant for extremely obese patients with a BMI >50 kg/m^2. Gastric banding should only be performed after particular consideration and at the specific request of the informed patient with a BMI <50 kg/m^2.[1]

Mini-gastric bypass

For the mini gastric bypass, the smaller top part of the stomach is disconnected from the rest of the stomach and is directly connected to the small bowel. The gastric juices from the remaining lower part of the stomach reach the small bowel via the natural route of the duodenum.[15] In some instances, a small bowel loop is attached to the stomach in order to reduce reflux.[7] This operation can be done laparoscopically.

According to the AWMF guideline, there are concerns regarding biliary reflux being associated with a malignant transformation though currently no evidence from RCTs is available regarding this outcome. In the case of stomach ulcers or reflux resistant to conservative treatment, e.g. proton pump inhibitors, transformation surgery into RYGB can be necessary.[1]

Postoperatively, it is not possible to view the duodenum via an endoscope. For young patients, the need for a permanent adapted supplementation needs to be considered when deciding regarding the indication for this intervention.[1] Contraindications are recurrent duodenal ulcers, Morbus Crohn, and increased incidence of gastric cancer in the family.[15]

AWMF = Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften; BMI = body mass index; RYGB = Roux-en-Y gastric bypass; SG = Sleeve gastrectomy; T2DM = type 2 diabetes mellitus

FAQ 1: EVIDENCE SUMMARY

What does treatment of obesity involve?

Treatment of obesity usually consists of an intervention program that targets not just the diet and eating behaviour but also lifestyle changes and psychological support, irrespective of whether a surgical or conservative approach is chosen. A specific conservative intervention is the Optifast program, which corresponds to a medically supervised program with a very low calory diet combined with counselling, activation and support.

For the surgical interventions, two main modes of action can be differentiated: restriction and reduced absorption through bypass. Some interventions like the mini-bypass and RYGB combine both. Some surgical interventions are reversible (e.g. LAGB and gastric bypass) while SG is not. In some patients, surgery is performed in a two-step approach – e.g. SG is sometimes performed as first intervention and can then be transformed into RYGB or laparoscopic mini gastric bypass (LMBG) once the patient has lost some weight.

Currently, none of the surgical interventions is considered to be the gold standard and the choice of intervention needs be made individually.

FAQ 2: WILL I LIVE LONGER?

FAQ 2a: All-cause mortality

The German AWMF guideline reports that LAGB has the lowest perioperative mortality of all surgical options (evidence level: 2++, strong consensus).[1] (The meaning of evidence levels, degree of consensus, strength of recommendation is described in appendix 2.)

Table 5 shows the results for all-cause mortality and peri-operative mortality in obese patients with and without diabetes. The upper section of the Table shows the comparisons of the various surgical interventions against each other while the lower section compares these against conservative treatment.

Table 5: All-cause mortality general population

Outcome	Author	No of studies	Average follow up time (years)[a]	No events / N Intervention	No events / N Comparator	Pooled adjusted RR (95% CI)[b]	Pooled IR intervention (95% CI)	Pooled IR comparator (95% CI)	Quality of evidence (GRADE)
Surgical intervention compared to another surgical intervention									
All-cause mortality	Quan 2015[10]	NR	NR	LMGB 0.2%	BS 0.31% RYGB 0.5%	NR	NR	NR	NR Non-randomised studies
Perioperative mortality	Quan 2015[10]	12[a,b]	NR	LMGB Range: 0% to 0.9%	NA	NA	NA	NA	NR Non-randomised studies
All-cause mortality	Colquitt 2014[8]	2	4 to 10 years	RYGB 0/N	LAGB 1/N	NE	NE	NE	MODERATE
All-cause mortality	Colquitt 2014[8]	6	1 to 3 years	RYGB 1/N	SG 0 /N	NE	NE	NE	MODERATE
Surgical intervention compared to conservative treatment									
All-cause mortality	SMB report[11]	5	2 years	BS 0/189	CT 0/108	NE	NE	NE	VERY LOW
All-cause mortality	SMB report[11]	4	2 years	RYGB 0/85	CT 0/78	NE	NE	NE	NR
All-cause mortality	SMB report[11]	2	2 years	LAGB 0/55	CT 0/55	NE	NE	NE	NR

Outcome	Author	No of studies	Average follow up time (years)[a]	No events / N Intervention	No events / N Comparator	Pooled adjusted RR (95% CI)[b]	Pooled IR intervention (95% CI)	Pooled IR comparator (95% CI)	Quality of evidence (GRADE)
All-cause mortality	SMB report[11]	1	3 years	SG 0/49	CT 0/43	NE	NE	NE	HIGH RISK OF BIAS[c]

[a] Based on single-arm studies; [b] At least one study with <20 patients reported no events; [c] Risk of bias assessment based on Cochrane Handbook[16]

BS = bariatric surgery; CI = confidence interval; CT = conservative treatment; IR = incidence rate; LAGB = laparoscopic adjustable gastric band; LMGB = laparoscopic mini gastric bypass; LRYGB = laparoscopic Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy; NA = not applicable; NE = not estimable; NR = not reported; RR = risk ratio; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy

FAQ 2b: Cause-specific mortality

None of the prioritised evidence syntheses reported on cause-specific mortality.

FAQ 2c: Survival time

None of the prioritised evidence syntheses reported on survival time.

FAQ 2: EVIDENCE SUMMARY

Will I live longer?

Based on all included studies in two systematic reviews, only one death occurred after both RYGB and LAGB surgeries, while no deaths were reported after SG and conservative treatment (CT). Data were insufficient to provide reliable comparative effect estimates.

FAQ 3: WILL MY SYMPTOMS/QUALITY OF LIFE GET BETTER?

Table 6 and Table 7 report on the results regarding symptoms and quality of life for the treatments of interest.

FAQ 3a: Weight loss

The German website "Gesundheitsinformation.de" provides some initial estimates on the dimension of weight loss possible with the different treatment options.[17] Based on these data (which in turn are based on a range of RCT data) tthe average weight loss in the first year after gastric banding is estimated to be between 10 to 25%.[17] For sleeve gastrectomy and for gastric bypass the site reported an estimated weight loss of 15 to 25% in the first year.[17] Furthermore, a weight reduction in the range of 10 to 15kg is possible in the first year with weight loss programs that include some form of formula diet (very low calorie diet) combined with lifestyle modification. [17]

The guideline considers gastric banding less effective than other bariatric/metabolic surgeries with respect to weight reduction (evidence level: 1++ to 2++, strong consensus).[1] The weight loss following Omega-Loop-Bypass is persistent (follow-up up to 5 years) and is comparable with other bariatric and metabolic surgery such as SG and pRYGB (evidence level: 1++ to 2-, strong consensus).[1] In addition, the German guideline on bariatric surgery also states that while a sustained weight reduction, improvement of co-morbidities and quality of life can be achieved with a multimodal lifestyle modification program (including diet, pharmacotherapy, physical and behavioural components either alone or combination) is possible it is mostly not achieved (consensus). In this context the guideline stresses that bariatric/metabolic surgery is much more effective and usually reaches these treatment goals (evidence level 1+ expert consensus, strong consensus).[1] The AWMF guideline on the prevention of obesity reported the results on a large retrospective study on Optifast with 8296 patients with a baseline BMI of 40.8. On average patients achieved a weight loss of 16.4 kg in the first year but the drop-out rate was very high with 42%.[6]

Table 6 reports the results on weight loss in the included studies in this review. For a better interpretation of the results represented in Table 6, it is worth noting that BMI allows for differences in height, but it does not distinguish between mass due to body fat and due to muscular physique. Therefore, waist circumference measure might be used as a better indicator for a health risk from being overweight.[17] The %EWL measure is calculated based on the preoperative weight, the post-operative weight and the ideal body weight. The variation in the definition of preoperative weight can lead to variation in the reporting of %EWL.[18]

Kang et al. did a network-meta-analysis and found differences in BMI reduction and percentage excess weight loss for RYGB compared to LAGB and for both RYGB and SG versus LAGB but not for RYGB versus SG,[9] where effects were judged to be similar by Kang et al..[9]

Table 6: Weight loss

Author	Follow-up	No of studies	Intervention (N)	Comparator (N)	MD (95% CI)	Intervention favoured	Quality of evidence (GRADE)
Postoperative BMI							
Quan 2015[10]	3 months – 6 years	4	LMGB (705)	LAGB (213)	−6.58 (−9.37 to -3.79)	LMGB	NR Non-randomised studies
Quan 2015[10]	1 year	3	LMGB (194)	LSG (120)	1.08 (−1.32 to 3.48)	LSG	NR Non-randomised studies
Postoperative waist circumference							
Quan 2015[10]	NR	3	LMGB (334)	LAGB (64)	−14.15 (−27.23 to −1.06)	LMGB	NR Non-randomised studies
%EWL							
Quan 2015[10]	1 year	3	LMGB (241)	LSG (283)	3.33 (−6.67 to 13.33)	LMGB	NR Non-randomised studies
Quan 2015[10]	1 year	2	LMGB (366)	LRYGB (118)	10.33 (4.30 to 16.36)	LMGB	NR Non-randomised studies
BMI reduction							
Kang 2017[9]	1-5 years	6	RYGB (220)	SG (217)	0.74 (-1.6 to 3.1)	RYGB	NR
Kang 2017[9]	2-5 years	2	RYGB (135)	LAGB (113)	5.8 (2.3 to 9.1)	RYGB	NR

Author	Follow-up	No of studies	Intervention (N)	Comparator (N)	MD (95% CI)	Intervention favoured	Quality of evidence (GRADE)
Kang 2017[9]	3 years	1	SG (40)	LAGB (40)	5.1 (0.90 to 8.9)	SG	Jadad score 1[a]
%EWL							
Kang 2017[9]	1-5 years	5	RYGB (159)	SG (169)	-4.0 (-14 to 8.2)	SG	NR
Kang 2017[9]	2-5 years	2	RYGB (135)	LAGB (113)	22 (6.5 to 34)	RYGB	NR
Kang 2017[9]	3 years	1	SG (40)	LAGB (40)	26 (6.4 to 41)	SG	Jadad score 1[a]
Mean weight change (kg)							
Avenell 2018[5]	at 60 months (adjusted)[c]	2	RYGB (NR)	Lifestyle intervention (NR)	–20.23 (-23.75 to -16.71)	RYGB	NR
Avenell 2018[5]	at 60 months (adjusted)[c]	1	SG (NR)	Lifestyle intervention (NR)	–13.46 (–17.03 to -9.88)	SG	NR
Avenell 2018[5]	at 36 months (unadjusted)	1	LAGB (22)	Lifestyle intervention (NR)	-9.87 (-16.25 to -3.49)	LAGB	NR
Avenell 2018[5]	at 18 months (adjusted)[c]	2	Optifast + dietary intervention (NR)	Dietary intervention (NR)	-0.29 (-4.11 to 3.52)	Optifast + dietary intervention	NR
Avenell 2018[5]	at 24 months (adjusted)[c]	4[b]	VLCD + dietary intervention (NR)	Dietary intervention (NR)	-0.56 (-2.33 to 1.20)	Optifast + dietary intervention	NR
Avenell 2018[5]	at 12 months (adjusted)[c]	1	Optifast (rapid weight-loss) (NR)[d]	Optifast (gradual weight-loss) (NR)	-0.78 (-2.32 to 0.75)	Optifast (gradual weight-loss)	NR
Percent change of body weight							
SMB report[11]	2-3 years[f]	8	BS (362)	CT (255)	-17.94 (-21.36 to -14.51)	BS	MODERATE
SMB report[11]	2-3 years[f]	4	RYGB (151)	CT (140)	-21.22 (-26.01 to -16.42)	RYGB	NR
SMB report[11]	2 years[f]	5	LAGB (143)	CT (138)	-15.01 (-18.23to -11.80)	LAGB	NR

Author	Follow-up	No of studies	Intervention (N)	Comparator (N)	MD (95% CI)	Intervention favoured	Quality of evidence (GRADE)
SMB report[11]	3 years[f]	1	SG (49)	CT (40)	-16.90 (-20.48 to -13.32)	SG	HIGH RISK OF BIAS[e]
SMB report[11]	2 years[g]	1	LAGB (39)	Optifast (31)	-16.10 (-19.27 to -12.93)	LAGB	HIGH RISK OF BIAS[e]

[a] Jadad score ranges from 0 (very poor) to 5 (rigorous); [b] Includes studies of Nutrilett and Modifast; [c] Adjusted for dropouts; [d] Avenell reports a weight change of -9.69 kg (95% -12.55 to -6.82 kg) at 12 months for the VLCD arms alone. It is not clear though whether these are the adjusted or unadjusted data; [e] Risk of bias assessment based on Cochrane Handbook[16]; [f] dark grey background: pooled data, light grey: data by subgroups [g] Study included in MA-results presented separately in order to show effects for Optifast-arm.

% EWL = % excess weight loss; BMI =body mass index; BS = bariatric surgery; CI = confidence interval; CT = conservative treatment; EWL = excess weight loss; LAGB = laparoscopic adjustable gastric band; LMGB = laparoscopic mini gastric bypass; LRYGB = laparoscopic Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy; MD = mean difference; NR = not reported; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; SMB = Swiss Medical Board

FAQ 3b: Quality of life

Table 7 presents the available data on quality of life in the evidence syntheses. It should be noted that the study included in the HTA by Avenell reporting on Short Form (36) Health Survey (SF-36) only included patients with chronic kidney disease stage 3-4.[4] The questionnaire is used to gather information health related quality of life information from the patients while the gastrointestinal quality of life index (GIQLI) measures quality of life specifically in patients with gastrointestinal disease.[19, 20] The SF-36 survey has scales on physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health. The responses to the questions in these scales are rated on a score ranging from 0 to 100 a higher score corresponds to a more favourable health state.[21] These are then computed in a separate score for the physical health component and for the mental health component, each with a range from 0 to 100.[22] The GIQLI questionnaire contains 36 questions with 5 subscales (GI Symptoms, Emotion, Physical Function, Social Function, and Medical Treatment) which are summed up. The total score ranges from 0 to 144 with higher scores corresponding to better HRQL.[23] An MID of 12.7 has been cited in a paper investigating the instrument but it is not clear whether this refers to the intraindividual change or to group differences.[23]

Table 7: Results on quality of life

Outcome	Author	No of studies	Follow-up	Intervention	Comparator	MD (95% CI)	Quality of evidence (GRADE)
GIQLI score, baseline	Colquitt 2014[8]	1	NA	RYGB (mean 98.8, SD 17.4, N=110)	LSG (mean 99.0, SD 20.5, N=107)	NR, p ≥0.05[a]	VERY LOW
GIQLI score, mean	Colquitt 2014[8]	1	1 year	RYGB (mean 128, NR)	LSG (mean 127, NR)	NR, p ≥0.05	VERY LOW
QoL SF-36 physical component summary score	SMB report[11]	2	≥ 2 years	LAGB (N=53)	CT (N=55)	9.35 (5.72 to 12.98)	LOW
QoL SF-36 mental component summary score	SMB report[11]	2	≥ 2 years	LAGB (N=53)	CT (N=55)	-0.05 (-3.86 to 3.77)	LOW
QoL SF-36 physical function	SMB report[11]	1	6 months to 1 year	RYGB (N=19)	CT (N=19)	-3.50 (- 6.21 to - 0.79)	HIGH RISK OF BIAS[c]
QoL SF-36 mental function	SMB report[11]	1	6 months to 1 year	RYGB (N=19)	CT (N=19)	-6.00 (- 8.64 to - 3.36)	HIGH RISK OF BIAS[c]
QoF SF-36 overall	SMB report[11]	1	6 months to 1	RYGB (N=19)	CT (N=19)	-5.40 (-8.04 to -	HIGH RISK

Outcome	Author	No of studies	Follow-up	Intervention	Comparator	MD (95% CI)	Quality of evidence (GRADE)
score			year			2.76)	OF BIAS[c]
QoL SF-36, physical domain scores	Avenell 2018[5b]	1	1 year	SG +19 (SD: ±8), N=5	CT -5 (SD: ±6), N=6	+22 (8 to 36)	NR
QoL SF-36, mental domain scores	Avenell 2018[5b]	1	1 year	SG +1 (SD: ±11), N=5	CT -3 (SD: ±13), N=6	+7 (-9 to 23)	NR
QoL RAND 36-Item Health Survey, general health and bodily pain scores	Avenell 2018[5]	1	NR	RYGB (NR)	CT (NR)	p<0.05 (favours RYGB)[a]	NR

[a] No further information reported; [b] Patients with chronic kidney disease stage 3-4, extracted from MacLaughlin 2014[4]; [c] Risk of bias assessment based on Cochrane Handbook[16]

CI = confidence interval; CT = conservative treatment; GIQLI = Gastrointestinal Quality of Life Index; LAGB = laparoscopic adjustable gastric band; LSG = laparoscopic sleeve gastrectomy; MD = mean difference; NA = not applicable; NR = not reported; QoL SF-36 = quality of life measured with Short-Form-36; RAND = Research ANd Development; RYGB = Roux-en-Y gastric bypass; SD = standard deviation; SG = sleeve gastrectomy; SMB = Swiss Medical Board

FAQ 3c: Resolution/change of symptom levels of co-morbidities?

Tables 8 to 15 present the results from the prioritised systematic reviews for the change of symptom levels of co-morbidities.

Diabetes remission

The German AWMF guideline states that the RYGB leads to a higher remission of T2DM than SG but it also has higher complication rate (evidence level 2++, strong consensus).[1] For example for a follow-up ≥ 5 years 75% (95% CI 63-84%,) had a diabetes remission after RYGB while for SG 58.2% (95% CI 30.8 – 81.3.%) had a remission. This tendency was also visible for the other time points but particularly for SG the confidence intervals were also often very broad. The effect of the mini bypass on diabetes remission seems to be similar to that of pRYGB and SG; there are, however, no prospective randomised studies of high quality available (evidence level 1++ to 2-, strong consensus). LGB tended to have the lowest effect on diabetes remission, especially based on the data for long-term follow-up (≥ 5 years) with a remission of 24.8% (95% CI 10.9 – 47.2%).[1]

Table 8 presents the results on remission from diabetes in the evidence syntheses. In the HTA by Avenell, mean change of blood sugar levels and % HbA1c were reported and tended to be better after 12, 18, and 24 months follow-up for the group receiving VLCD and dietary intervention compared to dietary intervention only.[5] The difference was only statistically significant based on one study after 18 (HbA_{1c} mean –2.60 (95% CI –4.44 to –0.76); glucose (mmol/l) mean –4.50 (95% CI –6.88 to –2.12)) months but not for the time points of 12 (HbA_{1c} mean –0.27 (95% CI –1.19 to 0.65); glucose (mmol/l) mean –0.51 (95% CI –1.70 to 0.68)) and 24 (HbA_{1c} mean –0.17 (95% CI –1.23 to 0.89); glucose (mmol/l) mean –1.61 (95% CI –3.73 to 0.51)) months.[5] No cut-off for clinical importance of the laboratory changes was defined so that the interpretation of the relevance of these effects is difficult. The HTA did not report on remission from diabetes so that data are not comparable to those from other included reviews.[5]

The more recent network meta-analysis by Kodama et al. on remission included any study with patients who had bariatric surgery that reported on the outcome but did not define any cut-offs regarding the BMI these patients had to have prior to surgery.[24] Based on the network meta-analysis mini-GBP highest and RYGB still ranked higher than LSG and LAGB.[24] Kodama et al. stated though that the effects regarding mini-GBP needed to be interpreted with caution as they constituted the minority of bariatric surgeries.[24]

Table 8: Diabetes remission

Outcome	Author	Follow-up	No of studies	Intervention, risk (n/N)	Comparator, risk (n/N)	Effect estimate (95% CI)	Quality of evidence (GRADE)
Remission rate of T2DM	Quan 2015[10]	NR	2	LMGB, 86% (50/58)	LAGB, 56% (10/18)	RR 1.48 (0.98 to 2.25)	NR Non-randomised studies
Overall remission rate of T2DM	Quan	NR	4	LMGB, 89%	LSG, 76%	OR 2.86 (1.40	NR

Outcome	Author	Follow-up	No of studies	Intervention, risk (n/N)	Comparator, risk (n/N)	Effect estimate (95% CI)	Quality of evidence (GRADE)
	2015[10]			(122/137)	(87/114)	to 5.83)	Non-randomised studies
	Quan 2015[10]	NR	3	LMGB, 93% (310/332)	LRYGB, 78% (111/143)	OR 2.53 (1.30 to 4.93)	NR Non-randomised studies
Resolution or improvement of T2DM	Colquitt 2014[8a]	3 year	1	RYGB, 80% (4/5)	SG, 80% (4/5)	p>0.05[b]	LOW
Resolution or improvement of impaired glucose tolerance	Colquitt 2014[8a]	3 year	1	RYGB, 100% (5/5)	SG, 100% (5/5)	p>0.05[b]	
Remission of diabetes mellitus (HbA_{1c} <6.5%)	Colquitt 2014[8c]	1 year	1	RYGB, 93% (28/30[d])	SG, 47% (14/30[#])	p=0.02[b]	
Successful treatment of diabetes mellitus[e]	Colquitt 2014[8c]	1 year	1	RYGB, 57% (17/ N[d])	SG, 0% (0/30[#])	p<0.001[b]	
Withdrawal of use of diabetic medication among a subgroup of patients with diabetes at baseline	Colquitt 2014[8f]	1 year	1	RYGB, 100% (2/2)	SG, 100% (2/2)	NR	
Resolution of T2DM	Colquitt 2014[8g]	1 year	1	RYGB, 64.3% (9/14)	SG, 40% (4/10)	p≥0.05[b]	
Discontinued medication for T2DM	Colquitt 2014[8h]	1 year	1	RYGB, 67.9% (NR)	SG, 57.7% (NR)	p≥0.05[b]	
T2DM cured	Colquitt 2014[8h]	1 year	1	RYGB, 67.9% (NR)	SG, 57.7% (NR)	p≥0.05[b]	
T2DM improved	Colquitt 2014[8h]	1 year	1	RYGB, 28.6% (NR)	SG, 42.3% (NR)	p≥0.05[b]	
Patients taking no diabetes medications	Colquitt 2014[8i]	1 year	1	RYGB, 78% (38/49)	SG, 51% (25/49)	NR	
Diabetes mellitus remission	Avenell 2018[5j]	1	1	RYGB 60% (NR)	ILI 5.9% (NR)	p=0.002[b]	NR
Diabetes remission	SMB report[11,l]	2 -3 years	6	BS, 48% (143/296)	CT, 3% (6/198)	RR 10.23 (4.36 to 24.02)	LOW

Outcome	Author	Follow-up	No of studies	Intervention, risk (n/N)	Comparator, risk (n/N)	Effect estimate (95% CI)	Quality of evidence (GRADE)
Diabetes remission	SMB report[11,l]	2 years	4	RYGB, 46% (70/152)	CT, 0% (0/143)	RR 31.47 (7.86 to 125.95)	NR
Diabetes remission	SMB report[11, l]	2-3 years	3	LAGB, 53% (40/75)	CT, 8% (6/78)	RR 6.16 (2.91 to 13.02)	NR
Diabetes remission	SMB report[11,l]	3 years	1	SG, 29% (14/49)	CT, 0% (0/40)	RR 23.78 (1.46 to 386.69)	HIGH RISK OF BIAS[k]
Diabetes remission	Kodama 2018	NR	11	LSG, 47% (104/223)	RYGB, 52% (117/226)	RR 0.88 (0.74, 1.05)	NR
Diabetes remission	Kodama 2018	NR	8	RYGB, 32% (70/217)	NST, 0% (1/221)	RR 17.54 (6.91, 44.58)	NR
Diabetes remission	Kodama 2018	NR	2	LSG, 29% (17/58)	NST, 0% (0/62)	RR 23.87 (3.65, 156.10)	NR
Diabetes remission	Kodama 2018	NR	5	LAGB, 31% (29/93)	NST, 4% (5/113)	RR 5.20 (2.43, 11.14)	NR
Diabetes remission	Kodama 2018	NR	2	LSG, 26% (20/77)	Mini-GBP, 51% (40/79)	RR 0.52 (0.34, 0.78)	NR
Diabetes remission	Kodama 2018	NR	2	LAGB, 9%, (2/23)	RYGB, 21% (5/24)	0.51 (0.12, 2.12)	NR
Diabetes remission	Kodama 2018	NR	1	LSG, 91% (10/11)	LAGB, 33% (1/3)	2.73 (0.54, 13.66)	NR

[a] Extracted from Karamanakos 2008[25]; [b] No further information reported; [c] Extracted from Lee 2011[26]; [d] N calculated; [e] Defined as HbA1c <7%, LDL-C <100 mg/dl, and triglycerides <150 mg/dl; [f] Extracted from Nogués 2010[27]; [g] Extracted from Paluszkiewicz 2012[28]; [h] Extracted from Peterli 2012[29]; [I] Extracted from Schauer 2012[30]; [j] Extracted from Cummings 2016[31]; [k] Risk of bias assessment based on Cochrane Handbook[16], [l] dark grey background: pooled data, light grey: data by subgroups

BS = bariatric surgery; CI = confidence interval; CT = conservative treatment; HbA_{1c} = Glycated haemoglobin A_{1c}; ILI = intensive lifestyle intervention; LAGB = laparoscopic adjustable gastric band; LDL-C = low-density lipoprotein cholesterol; LMGB = laparoscopic mini gastric bypass; LRYGB = laparoscopic Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy; mini-GBP = mini gastric bypass; NST = non-surgical treatment; NR = not reported; OR = odds ratio; RR = risk ratio; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; SMB = Swiss Medical Board; T2DM = type 2 diabetes mellitus

Stroke

Table 9 presents the data on stroke in the evidence syntheses. None of the included evidence syntheses compared the effect of different forms of bariatric surgery on stroke.

Table 9: Stroke

Author	Follow-up	No of studies	Intervention, risk (n/N)	Comparator, risk (n/N)	RR (95% CI)	Quality of evidence (GRADE)
SMB report[11a]	3 years[d]	1	BS 1% (1/99)[b]	CT 0% (0/43)	1.32 (0.05 to 31.77)	VERY LOW
SMB report[11c]	3 years[d]	1	RYGB 0% (0/50)	CT 0% (0/43)	NE	HIGH RISK OF BIAS[e]
SMB report[11c]	3 years[d]	1	SG 2% (1/49)	CT 0% (0/43)	2.64 (0.11 to 63.16)	HIGH RISK OF BIAS[e]

[a] Pooled analysis for all interventions of interest; [b] Results of three armed studies with pooled estimates for RYGB and SG in intervention arm; [c] Subgroup analysis per type of surgery; [d] dark grey background: pooled data, light grey: data by subgroups [e] Risk of bias assessment based on Cochrane Handbook[16],
BS = bariatric surgery; CI = confidence interval; CT = conservative treatment; NE = not estimable; RR = risk ratio; SG = sleeve gastrectomy

Myocardial infarction

None of the included evidence syntheses reported on myocardial infarction.

Hypertension

Table 10 reports the available data on improvement of hypertension. In the report by the Swiss Medical Board (SMB), none of the included studies reported on this outcome for the time point two to three years follow-up therefore the data for an earlier time point (six months to one year) are being reported.[11] None of the included studies reported on this outcome for the LMGB. In the HTA by Avenell, systolic and diastolic blood pressure (mmHg) were reported and tended to be better after 12 months follow-up for the group receiving VLCD and dietary intervention compared to dietary intervention only.[5] The difference was only statistically significant for diastolic blood pressure based on one study after 12 months (mmHg mean –5.00 (95% CI –8.66 to –1.34)) but not for systolic blood pressure (mmHg mean –3.00 (95% CI –8.61 to 2.61)) at the same time point. The HTA did not report on hypertension so that data are not comparable to those from other included reviews.[5]

Table 10: Hypertension

Outcome	Author	Follow-up	No of studies	Intervention, risk (n/N)	Comparator, risk (n/N)	RR (95% CI)	Quality of evidence (GRADE)
Resolution or improvement of hypertension	Colquitt 2014[8a]	3 years	1	RYGB, 60% (3/5)	LSG, 75% (3/4)	p>0.05[b]	NR
Resolution of hypertension	Colquitt 2014[8c]	1 year	1	RYGB, 36.7% (11/30)	LSG, 32% (8/25)	p>0.05[b]	NR
Hypertension cured	Colquitt 2014[8d]	1 year	1	RYGB, 33% (NR)	LSG, 33% (NR)	p>0.05[b]	NR
Hypertension improved	Colquitt 2014[8d]	1 year	1	RYGB, 62.0% (NR)	LSG, 57.0% (NR)	p>0.05[b]	NR
Antihypertensive agents	Colquitt 2014[8e]	2 years	1	LAGB, 20.7% (6/29)	CT, 57.7% (15/26)	NR	NR
Hypertension	SMB report[11,g]	2 years	2	BS, 37% (31/83)	CT, 54% (46/85)	0.68 (0.49 to 0.95)	VERY LOW
	SMB report[11,g]	2 years	1	RYGB, 42% (25/60)	CT, 62% (37/60)	0.68 (0.47 to 0.97)	HIGH RISK OF BIAS[f]
	SMB report[11,g]	2 years	1	LAGB, 26% (6/23)	CT, 36% (9/25)	0.72 (0.31 to 1.72)	HIGH RISK OF BIAS[f]

[a] Extracted from Karamanakos 2008[25]; [b] No further information reported; [c] Extracted from Paluszkiewicz 2012[28]; [d] Extracted from Peterli 2012[29]; [e] Extracted from Dixon 2012[32]; [f] Risk of bias assessment based on Cochrane Handbook[16]; [g] dark grey background: pooled data, light grey: data by subgroups

BS = bariatric surgery; CI = confidence interval; CT = conservative treatment; LAGB = laparoscopic adjustable gastric band; LSG = laparoscopic sleeve gastrectomy; NR = not reported; RR = risk ratio; RYGB = Roux-en-Y gastric bypass; SMB = Swiss Medical Board

Dyslipidaemia

Table 11 reports the results on treatment effects on dyslipidaemia. In the HTA by Avenell, mean change of total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides were reported.[5] Studies which included Optifast provided data only after 12 and 18 months of follow-up. The group receiving dietary intervention only showed better results after 12 months for changed in total cholesterol (based on 3 studies) and after 18 months for change in triglycerides (based on one study) compared to patients who received VLCD and dietary intervention. There were no statistically significant differences reported across all mentioned risk factors (please see Table 3 in the HTA by Avenell). The HTA did not report on dyslipidaemia so that data are not comparable to those from other included reviews.[5]

Table 11: Dyslipidaemia

Outcome	Author	Follow-up	No of studies	Intervention risk (n/N)	Comparator, risk (n/N)	RR (95% CI)	Quality of evidence (GRADE)
Resolution or improvement of HDL <threshold	Colquitt 2014[8a]	3 years	1	RYGB, 100% (4/4)	LSG, 67% (2/3)	p>0.05[b]	NR
Resolution or improvement of LDL >threshold	Colquitt 2014[8a]	3 years	1	RYGB, 90% (9/10)	LSG, 75% (6/8)	p>0.05[b]	NR
Resolution or improvement of TG >threshold	Colquitt 2014[8a]	3 years	1	RYGB, 100% (5/5)	LSG, 67% (2/3)	p>0.05[b]	NR
Resolution of dyslipidaemia	Colquitt 2014[8c]	1 year	1	RYGB, 41.9% (13/31)	LSG, 16.1% (5/31)	p<0.05[b]	NR
Dyslipidaemia cured	Colquitt 2014[8d]	1 year	1	RYGB, 47% (NR)	LSG, 26% (NR)	p>0.05[b]	NR
Dyslipidaemia improved	Colquitt 2014[8d]	1 year	1	RYGB, 50% (NR)	LSG, 59% (NR)	p>0.05[b]	NR
Abnormal TGs	Colquitt 2014[8e]	1 year	1	RYGB, 0% (NR)	LSG, 0% (NR)	NR	NR
Dyslipidaemia	SMB report[11]	2 years	1	RYGB, 45% (27/60)	CT, 72% (43/60)	0.63 (0.46 to 0.87)	LOW
Dyslipidaemia	SMB report[11]	6 months to 1 year	1	LAGB, 55% (12/22)	CT, 65% (15/23)	0.84 (0.52 to 1.36)	HIGH RISK OF BIAS[f]

[a] Extracted from Karamanakos 2008[25]; [b] No further information reported; [c] Extracted from Paluszkiewicz 2012[28]; [d] Extracted from Peterli 2012[29]; [e] Extracted from Vix 2013[33]; [f] Risk of bias assessment based on Cochrane Handbook[16]

BS = bariatric surgery; CI = confidence interval; CT = conservative treatment; HDL = high density lipoprotein; LAGB = laparoscopic adjustable gastric band; LDL = low density lipoprotein; LSG = laparoscopic sleeve gastrectomy; NR = not reported; RR = risk ratio; RYGB = Roux-en-Y gastric bypass; SMB = Swiss Medical Board; TG = triglyceride

Sleep apnoea

Table 12 presents the data on the treatment effects on sleep apnoea.

Table 12: Sleep apnoea

Outcome	Author	Follow-up	No of studies	Intervention, risk (n/N)	Comparator, risk (n/N)	RR (95% CI)	Quality of evidence (GRADE)
Resolution or improvement of OSA	Colquitt 2014[8a]	3 years	1	RYGB, 67% (2/3)	LSG, 67% (4/6)	p>0.05[b]	NR
OSAS cured	Colquitt 2014[8c]	1 year	1	RYGB, 33% (NR)	LSG, 52% (NR)	p>0.05[b]	NR
OSAS improved	Colquitt 2014[8c]	1 year	1	RYGB, 67% (NR)	LSG, 45% (NR)	p>0.05[b]	NR
Achieved mild OSA	Colquitt 2014[8d]	2 years	1	LAGB, 27% (8/30)	CT, 7% (2/30)	p=0.04[b]	NR
Achieved OSA remission	Colquitt 2014[8d]	2 years	1	LAGB, 0% (0/30)	CT, 3% (1/30)	NR	NR
Sleep apnoea	SMB report[11e]	3 years	1	LAGB, 95%[f] (21/22)	CT, 96%[f] (23/24)	1.00 (0.88 to 1.13)	VERY LOW

[a] Extracted from Karamanakos 2008[25]; [b] No further information reported; [c] Extracted from Peterli 2012[29]; [d] = Extracted from Dixon 2012[32]; [e] = Extracted from Feigel-Guiller 2015[34]; [f] Calculated

CI = confidence interval; CT = conservative treatment; LAGB = laparoscopic adjustable gastric band; NR = not reported; OSA = obstructive sleep apnoea; OSAS = obstructive sleep apnoea syndrome; RR = risk ratio; RYGB = Roux-en-Y gastric bypass

Cancer

Table 13 shows the results on cancer. Only one review reported results on this outcome.

Table 13 Cancer

Author	Follow-up	No of studies	Intervention, risk (n/N)	Comparator, risk (n/N)	RR (95% CI)	Quality of evidence (GRADE)
SMB report[11 b]	2 to 3 years	2	BS, 3% (4/160)	CT, 4% (4/110)	0.69 (0.16 to 2.95)	VERY LOW
SMB report[11, b]	2 to 3 years	2	RYGB, 2% (2/110)	CT, 4% (4/110)	0.63 (0.12 to 3.18)	NR
SMB report[11, b]	3 year	1	SG, 4% (2/50)	CT, 4% (2/50)	1.00 (0.15 to 6.82)	HIGH RISK OF BIAS[a]

[a] Risk of bias assessment based on Cochrane Handbook[16], [b] dark grey background: pooled data, light grey: data by subgroups
CI = confidence interval; CT = conservative treatment; NR = not reported; RR = risk ratio; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; SMB = Swiss Medical Board

Function

Table 14 shows the results on function. Only one review reported results on this outcome.[8]

Table 14: Function

Outcome	Author	Follow-up	No of studies	Intervention, risk (n/N)	Comparator, risk (n/N)	p value[a]	Quality of evidence (GRADE)
Resolution or improvement of degenerative arthritis	Colquitt 2014[8b]	3 years	1	RYGB 83% (5/6)	LSG 80% (4/5)	p>0.05	NR
Back/joint pain cured	Colquitt 2014[8c]	1 year	1	RYGB 17%	LSG 22%	p>0.05	NR
Back/joint pain improved	Colquitt 2014[8c]	1 year	1	RYGB 71%	LSG 67%	p>0.05	NR

[a] No further information reported; [b] Extracted from Karamanakos 2008[25]; [c] Extracted from Peterli 2012[29]
LSG = laparoscopic sleeve gastrectomy; NR = not reported; RYGB = Roux-en-Y gastric bypass

Fitness

None of the included studies reported results regarding fitness.

Mood

Only one systematic review reported on the treatment effects of RYGB compared to LSG on depression, see Table 15.[8] None of the included systematic reviews reported on other outcomes regarding mood, eating habits, the feeling of normality, outlook on life, and wellbeing. According to the AWMF guideline, post-operative depression and post-operative non-normative eating behaviours are negatively associated with a post-operative change of weight (strong consensus).[1] The post-operative suicide rate is higher than in the general population according to the AWMF guidance. There are indications that the incidence of self-harming behaviour and suicide increases post-operatively. Whether there is an aetiological link with bariatric / metabolic surgery and what it consists of is unclear though (strong consensus).[1] There are indications that post-operative problematic alcohol consumption increases long-term (strong consensus).[1]

Table 15: Depression

Outcome	Author	Follow-up	No of studies	Intervention, risk (n/N)	Comparator, risk (n/N)	p value[a]	Quality of evidence (GRADE)
Depression cured	Colquitt 2014[8b]	1 year	1	RYGB, 6% (NR)	LSG, 17% (NR)	p>0.05	NR
Depression improved	Colquitt 2014[8b]	1 year	1	RYGB, 83% (NR)	LSG, 78% (NR)	p>0.05	NR

[a] No further information reported; [b] Extracted from Peterli 2012[29]
LSG = laparoscopic sleeve gastrectomy; NR = not reported; RYGB = Roux-en-Y gastric bypass

FAQ 3: EVIDENCE SUMMARY

Will my symptoms/quality of life get better?

Weight loss

Two systematic reviews (SRs) comparing BS with non-surgical interventions found that BS had a consistent effect on weight loss, regardless of the type of procedure. Two other SRs compared different types of BS and among four surgical procedures, the smallest treatment effect was observed in LAGB while conflicting results were seen between RYGB, SG and LMGB. Evidence for LMGB was based solely on non-randomised studies. One systematic review included the comparison of Optifast + dietary intervention versus dietary intervention only, however, no clear difference was observed in terms of weight loss between these treatment options. Finally, one study compared Optifast with LAGB and there was a clear difference in favour of LAGB in terms of weight loss.

Quality of life

When BS was compared with conservative treatment, improvements were reported in physical component/domain for LAGB and SG, while only small or no changes were shown in the mental component/domain. For RYGB depending on the review either no difference or better results were shown. Comparisons between different interventions were reported in one systematic reporting only limited results. This outcome was considered at very low quality of evidence. No data on LMGB were reported.

Diabetes remission

Based on two SRs and one network meta-analysis, the relative risk to achieve diabetes remission was higher in a surgical group than in a conservative treatment group. In one systematic review, LMGB showed better results in diabetes remission than other types of surgery based on non-randomised studies. Moreover, available evidence from a network-meta-analysis or RCTs suggests that mini-GBP and RYGB might be more effective in diabetes remission than SG and LAGB.

Stroke

Only one randomised controlled trial (RCT) with a follow-up of three years reported a comparison between SG, RYGB and CT. There was only one stroke after bariatric surgery and none after CT. No data on LMGB were reported.

(Continued…)

FAQ 3: EVIDENCE SUMMARY

Will my symptoms/quality of life get better?

Myocardial infarction

None of the included evidence syntheses reported on myocardial infarction.

Hypertension

Based on two SRs, the risk to have hypertension was lower in a surgical than in a conservative treatment group. No data on SG and LMGB compared to CT were reported. One SR reported a comparison between RYGB and LSG, however, no differences were found between interventions in terms of hypertension (unpooled data) but patient numbers tended to be small in the individual studies.

Dyslipidaemia

One SR reported on dyslipidaemia and results based on one RCT respectively showed that RYGB reduced the risk for dyslipidaemia compared with conservative treatment at 2 years and for LAGB compared to conservative treatment no difference was found at 6 months to 1 year. One SR reported a comparison between RYGB and LSG, however, only one study showed a meaningful difference in favour of RYGB, while others reported no relevant differences in terms of dyslipidaemia. No data on LMGB were reported.

Sleep apnoea

One RCT reported achieving mild OSA in more patients with LAGB than with CT. However, this was not confirmed by two other RCTs that also comparing LAGB vs. CT but using stricter criteria to define improvement from OSA. For the comparison of RYGB vs. LSG no relevant difference was found. No data on LMGB were reported.

Cancer

One SR reported on cancer and no differences were found between RYGB, SG and CT after three years of follow-up.

Function

One SR reported on function and no differences were found between RYGB and LSG after one and three years of follow-up.

Fitness

None of the included studies reported results regarding fitness.

Mood

One SR reported on depression and no differences were found between RYGB and LSG after one year follow-up. The German guideline mentioned though that there are indications that the incidence of self-harming behaviour, suicide, and problematic alcohol comsumption increase post-operatively.

FAQ 4: WHEN WILL I RECOVER?

FAQ 4a: Time to return to usual activity

None of the included systematic reviews reported on time to return to usual activity but two reported on length of hospital stay.[8, 10] In the systematic review by Quan et al., the results from 11 included single-arm studies were reported but not pooled.[10] Results are presented in Table 16.

Table 16: Length of hospital stay

Outcome	Author	No of studies	Intervention	Comparator	p-value[a]	Quality of evidence (GRADE)
Mean length of hospital stay	Colquitt 2014[8b]	1	RYGB 4 days	LAGB 2 days	p<0.05	NR
Mean length of hospital stay	Colquitt 2014[8c]	1	RYGB 3.1 days	LAGB 1.5 days	p<0.01	NR
Median length of hospital stay	Colquitt 2014[8d]	1	RYGB 6 days	SG 6 days	NR	NR
Hospital stay	Quan 2015[10]	11[e]	LMGB, range: 1.2 to 8.5 days	NA	NA	NR Non-randomised studies

[a] No further information reported; [b] Extracted from Nguyen 2009[35]; [c] Extracted from Angrisani 2007[36]; [d] Extracted from Paluszkiewicz 2012[28]; [e] Based on single-arm studies
LAGB = laparoscopic adjustable gastric band; LMGB = laparoscopic mini gastric bypass; NA = not applicable; NR = not reported; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy

FAQ 4b: Time off work/return to work

None of the included evidence syntheses reported on time off work or return to work**.**

FAQ 4: EVIDENCE SUMMARY

When will I recover?

Time to return to usual activity

None of the included systematic reviews reported on time to return to usual activity.

Length of hospital stay

Two RCTs reported that the mean length of hospital stay was approx. twice as long after RYGB surgery than after LAGB. Another RCT reported that the median length of hospital stay is the same for RYGB an SG. One systematic review, based on 11 studies, reported that hospital stay after LMGB ranges from 1.2 to 8.5 days.

Time off work/return to work

None of the included evidence syntheses reported on time off work or return to work**.**

FAQ 5: WHAT ARE THE RISKS/SIDE-EFFECTS?

FAQ5a: Risks and side-effects of bariatric surgery compared to conservative treatment in the general population

Three included systematic reviews reported on risk and/or side effects of the interventions. Results on depression are presented in the FAQ 3. The other results are presented in Table 17. The results for LMGB are based on single-arm studies.

The "Gesundheitsinformation" by the Institute for Quality and Efficiency in Health Care (IQWiG) also reported on some effects but as no information on the source of the data was provided they were not included in the evidence table. According to the IQWiG report, rapid weight loss can also be associated with the development of gallstones.[13]

According to the AWMF guideline, intestinal bypass surgery have a higher diabetes remission rate but also higher post-operative complication rates (strong consensus).[1] Step-wise approaches can reduce the perioperative risk and should be considered and used particularly in patients with diabetes with extreme forms of obesity (BMI > 60 kg/m^2) and/or significant comorbidity (expert consensus, consensus).[1] Patients should stop smoking at least 6 weeks prior to surgery as this is associated with lower complication rates and generally better health (expert consensus, consensus).[1] Also, the most frequent surgical complications caused by bariatric and metabolic surgery are fistulas after stapling, leaks of the anastomoses, abscesses and (re)bleeding.[1] The use of re-enforcements of the stapling or additional suturing seems to reduce the risk of rebleeding but does not influence the risk of developing fistulas in the studies (expert consensus, strong consensus).[1] this statement seems to refer to sleeve gastrectomy in particular though it is not explicitly stated in the consensus statement. Depending on their comorbidities patients with planned bariatric or metabolic surgery have an intermediate to high risk of venous thrombosis and thromboembolism respectively, according to the AWMF guideline, and all patients should receive prophylaxis in order to reduce the risk (expert consensus, strong consensus).[1]

In case of symptomatic reflux disease, the proximal RYGB should be preferred to the other options under consideration of other factors (expert consensus, strong consensus).[1] LAGB has the lowest perioperative morbidity; however, late complications causing repeat surgery are higher than with the other options. SG also has lower perioperative complications than bypass procedures.[1]

Side-effects of LAGB include heartburn and vomiting. A major complication postoperatively is that the band can slip, grow into the flesh, or tear.[13] IQWiG has estimated that about eight out of 100 people had gastric banding develop a complication and that up to 45 of 100 people will need a re-operation at some stage, either because they did not lose enough weight or because they developed problems with the band.[13] Even though the peri-operative risk and invasiveness of laparoscopic gastric banding tend to be lowest compared to the other interventions it has a high rate of long-term complications (42.7%) with the need to remove the banding (22.9%) and redo operations(36.5%) according to the AWMF-guideline.[1]

Sleeve gastrectomy can be associated with reflux and vomiting if one has eaten too much. During or after surgery, there is a risk of complications, e.g. the sutures can leak and necessitate another operation.[13] The IQWiG report estimated that about nine out of 100 people had a complication during or after surgery while three out of 100 people needed a re-operation. Less than one out of 100 people died during surgery or due to complications.[13]

Two frequent long-term side effects of gastric bypass are the early and the late dumping syndrome. In the case of the early dumping syndrome a larger amount of undigested food quickly reaches the small bowel. The body tries to “dilute” this unusual amount of food and too much water moves out of the vascular system into the small bowel. This lack of water results in a drop in blood pressure and can lead to light-headedness, vertigo, stomach ache, and sweating.[13] An early dumping syndrome usually occurs after eating refined sugar.[8] It usually occurs within 30 minutes of food intake.[13] According to the systematic review by Colquitt et al., it is thought that the dumping syndrome helps with the weight loss as the patient is conditioned against eating sweet food.[8] None of the other included systematic reviews reported on this outcome.

The late dumping syndrome is rarer and is caused by the excessive release of insulin in the body and leads to low blood sugars, which manifest as vertigo, weakness, and sweating. It can occur one to three hours after eating, in particular if the food contains many carbohydrates.[13]

Table 17: Risks and side effects of bariatric surgery and conservative treatment from RCTs (unless specified otherwise)

Outcome	Author	Follow up	Number of studies	Intervention, risk (n/N)	Comparator, risk (n/N)	Effect estimate (95% CI)	Quality of evidence (GRADE)
Revision surgery rate	Quan 2015[10a]	NR	2	LMGB, 2% (2/128)	LSG, 14% (20/142)	OR 0.11 (0.02 to 0.49)	NR
Reoperation	Quan 2015[10]	NR	9[b,c]	LMGB, range: 0% to 3%	NA	NA	NR
Overall complication rate	Quan 2015[10]	NR	12[b,c]	LMGB, range: 0% to 9%	NA	NA	NR
Wound infection	Quan 2015[10]	NR	4[b,c]	LMGB, range: 0% to 0.3%	NA	NA	NR
Leakage	Quan 2015[10]	NR	9[b,c]	LMGB, range: 0% to 2.1%	NA	NA	NR
Bleed	Quan 2015[10]	NR	7[b,c]	LMGB, range: 0% to 2.5%	NA	NA	NR
Reflux	Quan 2015[10]	NR	6[b,c]	LMGB, range: 0% to 2.0%	NA	NA	NR
Dyspepsia and/or ulcer	Quan 2015[10]	NR	7[b,c]	LMGB, range: 0% to 8.0%	NA	NA	NR
Iron deficiency anaemia	Quan 2015[10]	NR	4[b]	LMGB, range: 4.9% to 8.1%	NA	NA	NR
Reoperations	Colquitt 2014[8d]	30 days	1	RYGB 5.4% (NR)	LAGB 1.2% (NR)	p≥0.05[e]	NR
Late reoperations	Colquitt 2014[8d]		1	RYGB 7.2%	LAGB 11.6%	p≥0.05[e]	NR
Patients requiring reoperations	Colquitt 2014[8f]	4 to 10 years	2	RYGB, range: 12.6% to 28.6%	LAGB, range: 18.8% to 40.9%	NR	VERY LOW
Readmissions	Colquitt 2014[8d]	30 days	1	RYGB (6/N)[e]	LAGB 0% (0/N)[e]	p=0.04[e]	NR
Complications	Colquitt 2014[8d]		1	RYGB 45% (NR)	LAGB 17.4% (NR)	p<0.01[e]	NR

Outcome	Author	Follow up	Number of studies	Intervention, risk (n/N)	Comparator, risk (n/N)	Effect estimate (95% CI)	Quality of evidence (GRADE)
Early minor complications	Colquitt 2014[8d]		1	RYGB 15.3% (NR)	LAGB 4.7% (NR)	p=0.02[e]	NR
Late minor complications	Colquitt 2014[8d]		1	RYGB 13.5% (NR)	LAGB 0% (NR)	p<0.01[e]	NR
Late major complications	Colquitt 2014[8d]		1	RYGB 26.1% (NR)	LAGB 11.6% (NR)	p=0.01[e]	NR
Early complications requiring surgery	Colquitt 2014[8f]		1	RYGB 8.4% (2/N)[e]	LAGB 0% (0/N)[e]	NR	NR
Early complications	Kang 2017[9]	1 year	NR	RYGB 16% (n/338)[e]	SG 10.4% (n/240)[e]; LAGB 3.9% (n/153)[e]	NR	NR
Late complications	Kang 2017[9]	1 year	NR	RYGB 33.1% (n/338)[e]	SG 26.3% (n/240)[e]; LAGB 6.5% (n/153)[e]	NR	NR
Serious adverse events / reoperations	SMB report[11,i]	2-3 years	3	BS 17% (16/93)	CT 7% (5/74)	RR 2.43 (0.60 to 9.80)	VERY LOW
Serious adverse events / reoperations	SMB report[11,i]	3	1	RYGB 5% (1/20)	CT 0% (0/20)	RR 3.00 (0.13 to 69.52)	NR
Serious adverse events / reoperations	SMB report[11,i]	2-3 years	3	LAGB 21% (15/73)	CT 7% (5/74)	RR 3.20 (0.58 to 17.71)	NR
Serious adverse events / reoperations	SMB report[11,i]	6 months – 1 year	1	SG 22% (11/49)	CT 19% (8/43)	RR 1.21 (0.53 to 2.71)	HIGH RISK OF BIAS[j]
Neuropathy	SMB report[11]	NR	2	RYGB 9/N[e]	SG 5/N[e] CT 6/N[e]	NR	NR
Iron deficiency anaemia	SMB report[11]	NR	3	RYGB 23/N[e]	SG 15/N[e]; CT 6/N[e]	NR	NR
Kidney stone	SMB report[11g]	NR	3	RYGB 7/N[e]	LAGB 0/N[e]; CT 8/N[e] SG 4/N[e]	NR	NR
Kidney stone	SMB report[11h]	NR	1	RYGB 5/N[e]	SG 4/N[e]; CT 6/N[e]	NR	NR
Intravenous treatment for	SMB	NR	2	RYGB 8/N[e]	SG 4/N[e]; CT 3/N[e]	NR	NR

Outcome	Author	Follow up	Number of studies	Intervention, risk (n/N)	Comparator, risk (n/N)	Effect estimate (95% CI)	Quality of evidence (GRADE)
dehydration/ dehydration	report[11]						
Hypoglycaemic episode	SMB report[11]	NR	2	RYGB 38/N[e]	SG 40/N[e]; CT 43/N[e]	NR	NR
Dumping	SMB report[11]	NR	1	RYGB 4/N[e]	SG 1/N[e]; CT 0/N[e]	NR	NR
Anastomotic ulcer	SMB report[11]	NR	2	RYGB 7/N[e]	SG 0/N[e]; CT 2/N[e]	NR	NR

[a] Extracted from Kular 2014[37] and Lee 2014[38]; [b] Based on single-arm studies; [c] At least one study with <20 patients reported no events; [d] Extracted from Nguyen 2009[35]; [e] No further information reported, [f] Extracted from Angrisani 2007[36]; [g] Extracted from Courcoulas 2015[39]; [h] Extracted from Schauer 2014[30], [i] dark grey background: pooled data, light grey: data by subgroups; [j] Risk of bias assessment based on Cochrane Handbook[16]

CI = confidence interval; CT = conservative treatment; LAGB = laparoscopic adjustable gastric band; LMGB = laparoscopic mini gastric bypass; LSG = laparoscopic sleeve gastrectomy; NA = not applicable; NR = not reported; OR = odds ratio; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; RR = risk ratio; SMB = Swiss Medical Board

FAQ 5: EVIDENCE SUMMARY

What are the risks/side-effects?

Serious adverse events, including re-operations, were reported by three RCTs. Mean effect estimates tended to favour conservative treatment but no siginficant differences was found. The quality of the evidence was very low though. Also, different types of surgery were compared with conservative treatment in terms of specific adverse events, however, significance was not reported.

One systematic review reported that LMGB had lower revision surgery rate than LSG.

Two systematic reviews reported comparison between RYGB and LAGB. RYGB had higher rates of late major and minor complications, early minor complications and readmissions.

FAQ 6: What other – not health-related – consequences are there?

Plastic surgery

The marked weight loss often leads to lose skin. Many of those affected find those skin folds and hanging skin unattractive and bothersome. In some people large skin folds can lead to infections and rashes. Good skin care is therefore important. Plastic surgery is only covered by statutory health insurance in case of medical problems or marked psychological stress.[13]

Pregnancy

Pregnancy is possible after bariatric surgery but should be avoided in general in the first 24 months after surgery as the marked weight loss would affect the nutrition of the unborn child.[1] According to the AWMF guideline, no exact time period can be named based on the available evidence, though.[1] At a later stage, it is important to discuss possible risks with the doctor, e.g. whether additional measures need to be taken in order to avoid nutritional deficiencies.[13] Oral contraceptives are not deemed to be reliable if the absorption is not guaranteed (for example due to disconnection of the small bowel in the case of gastric bypass, or due to diarrhoea/ vomiting).[1] An individually tailored approach should be developed together with the treating gynaecologist as no general recommendation can be made.[1] Complications such as gestational diabetes, congenital malformations etc. are more frequent in obese women.[1]

Obese women have an increased rates of gestational diabetes, foetal macrosomia, pre-term deliveries, complications before and after delivery, caesarean sections, anaesthetic complications, congenital malformations, and stillbirths.[1] Sometimes obese women can only get pregnant after massive weight loss.[1]

Pregnant women should follow the recommendations of the Institute of Medicine regarding weight gain in order to protect the child against overweight and themselves against complications before, during and after delivery (recommendation). [6] According to those recommendations overweight women should gain 7 to 11.5 kg and obese women should gain 5 to 9 kg during pregnancy.[6] Patients should be informed that combined oral contraceptives and hormonal substation therapy are not linked with significant weight gain according to the AWMF guideline on prevention (recommendation).[6]

FAQ6a: How will the treatment impact my daily life afterwards?

Follow-up

In order to stabilise weight loss long-term treatment and contacts should be offered after weight loss. These should also include cognitive-behavioural therapy aspects (strong recommendation). [6]

Prior to surgery, patients should be seen by specialists in internal medicine, surgery, mental health, and a nutrition specialist. Their nutrition would be adapted already prior to surgery. During this adjustment period the adherence to that new regime will be observed as well.[1]

Patient follow-up includes many other aspects besides weight checks such as adaptation of the medication in the case of comorbidities, control of the supplementation in order to avoid deficiencies, lab checks, screening for psychiatric diseases, detection and treatment of complications, as well as encouraging and helping the patient lead a healthy life-style (sports, eating behaviour, self-help groups).[1]

Post-operative nutrition

After bypass surgery, patients will initially ingest mainly tea and liquid food so that the sutures can heal and change to puréed food after two to three weeks. The daily food should ideally be distributed into eight small meals. It Is important to drink enough fluid, i.e. two to three litres. Patients often develop food intolerances towards foods that were well tolerated before surgery.[12]

Bypass surgery affects the way food is being processed and especially bypass surgery can lead to a reduced absorption of nutrients (e.g. vitamins, micronutrients).[13] In order to avoid nutritional deficiencies regular check-ups and the supplementation of vitamins and micronutrients will be necessary.[13] Fewer supplements are necessary for LAGB than for SG and gastric bypass.[13] Prophylactic supplementation is being recommended for pRYGB and SG with protein, folic acid, vitamin B1, vitamin B12, vitamins A,D,E,K, calcium citrate, iron sulphate, magnesium, and zinc.[1] Regular checks regarding nutritional status should be performed for protein, ferritin, vitamin B12 and B1, folic acid, and calcium whether the patient had pRYGB, LAGB, and SG. For patients with SG the regular check should also include testing for vitamin D. For pRYGB checks should include additionally vitamin D, E,A, K, parathyroid hormone, and zinc.[1]

FAQ 6: EVIDENCE SUMMARY

Other questions

Plastic surgery

The marked weight loss following treatment can lead to loose skin, which is felt to be bothersome or problematic by some patients. Plastic surgery for this is only covered by statutory health insurance in case of medical problems or marked psychological problems.

Pregancy

Pregnancy is possible after bariatric surgery but should be avoided during phases of marked weight loss. Both appropriate contraception and the planning of the pregnancy should be discussed with the doctors irrespective of the type of treatment received.

Follow-up

Both conservative and surgical interventions require regular follow-up. Surgical interventions always need to be combined with conservative treatment programs in order to ensure the long-term success of the surgery.

Nutrition

Depending on the type of intervention the eating behaviour needs to be adapted and certain supplements need to be taken on a regular basis. Regular check-ups are necessary in order to avoid nutritional deficiencies.

3.3 ASSESSMENT OF THE CLINICAL REVIEW EVIDENCE

A summary of studies providing clinical evidence is set out in Table 18 below. Studies which merely provided descriptive evidence are not listed here. Only information on the evidence relevant for this report is being presented. Given the great variety of research questions addressed in the AWMF-guidelines and in many instances great overlap of the evidence in included systematic reviews, no attempt was made to try and present an overview of the characteristics of the clinical evidence in the guidelines.

Table 18: Overview of the clinical evidence

Study ID	Participants Inclusion criteria[c]	Intervention[b]	Comparators	Outcomes	Study Design	Follow-up	ROB
Avenell, 2018[5]	The majority of trials included in all SRs of RCTs in the HTA included participants with group mean ages in the 40–49 years and 50–59 years age categories. The lowest reported mean group BMI was 35 kg/m^2 and the highest was 55.7 kg/m^2. Inclusion criteria:	RYGB, SG, LAGB, **Cointervention:** each combined with a lifestyle intervention	Lifestyle interventions, dietary interventions, conservative treatment	Weight loss, diabetes remission, mean risk factor change (hypertension, dyslipidaemia)	SR of RCTs	NR	• Random sequence generation – 50% were judged to have adequately performed and described how the randomisation sequence was generated;

Study ID	Participants Inclusion criteria[c]	Intervention[b]	Comparators	Outcomes	Study Design	Follow-up	ROB
	SR 1: Adults (mean or median age ≥16 years). Mean BMI ≥ 35 kg/m^2 at start of weight loss phase	Optifast + dietary intervention, VLCD	Lifestyle interventions, dietary interventions, conservative treatment				• Allocation concealment – blinding of participants and personnel was not possible in the majority of trials, but 23.3% reported blinding outcome assessors; • Selective outcome reporting - 51.5% of the trials were judged to be at low risk of bias; • Incomplete outcome data or other bias – 40.8% were judged to be at low risk; • Other biases, such as conflict of interest - 31.3% of trials were judged to be at high risk;

Study ID	Participants Inclusion criteria[c]	Intervention[b]	Comparators	Outcomes	Study Design	Follow-up	ROB
Colquitt 2014[8]	Participants n=1798 (allocated to surgery n=1496); the majority of participants were women and, on average, in their early 30s to early 50s Inclusion criteria: Adults who are overweight or obese as defined by the study.	RYGB; LAGB; LSG **Co-interventions:** with or without conservative co-interventions	RYGB; LAGB; LSG	Measures of weight change, health-related quality of life, obesity-related comorbidities, mortality, adverse events, revision rates	SR of RCTs	1 to 10 years	• Random sequence generation – 50% low, 50% unclear; • Allocation concealment – 95% unclear, 5% low; • Blinding of participants and personnel – 77% not reported, 18% high, 5% unclear; • Blinding of outcome assessment, judgement did not differ among outcomes – 73% unclear, 27 high; • Incomplete continuous outcome data – 83% not reported, 7% unclear, 5% high, 5% low; • Incomplete binary data –

Study ID	Participants Inclusion criteria[c]	Intervention[b]	Comparators	Outcomes	Study Design	Follow-up	ROB
							41% unclear; 27% low; 23% not reported; 9% high Selective reporting – 68% unclear, 32% high
Kang 2017[9]	Pooled study sample: n=925; 26.1% male; mean age of 39.7 ± 6.4 years; mean BMI of 43.9 ± 2.9 kg/m^2 Inclusion criteria: studies included patients 17 years or older with a BMI ≥30kg/m^2	LAGB; SG; RYGB **Co-interventions:** NR	LAGB; SG; RYGB	Change in BMI; %EWL; complications	SR and NMA of RCTs	1 to 5 years	• Allocation concealment – 73% adequate, 18% not reported, 9% no; • Blinding – 82% no, 18% yes; • ITT analysis – 46% yes, 36% no, 18% unclear; • Power calculation – 64 not reported, 36% yes; • Funding – 55% not reported; 45% disclosed
Quan 2015[10]	Participants (N=2,133) Age range: 30.7-49.5 BMI range: 26.5-50.8 Inclusion criteria: None specified studies had to compare LMGB with one or more bariatric procedure	LMGB **Co-interventions:** NR	LAGB; LSG; LRYGB	Change in BMI; remission of T2DM; %EWL; Postoperative waist circumference; revision surgery	SR	3 months to 6 years	NR

Study ID	Participants Inclusion criteria[c]	Intervention[b]	Comparators	Outcomes	Study Design	Follow-up	ROB
	and had to report data on weight loss, and other diabetes or diabetes related factors.			rate; operative time			
SMB report[11]	Mean BMI > 35kg/m^2 Inclusion criteria: Overweight and obese adults (BMI ≥25kg/m^2)	RYGB; LAGB; SG **Co-interventions:** with or without conservative co-interventions	• Lifestyle modifications with different types of diets and physical activity interventions and in some instances additional medical treatment, or • No intervention except information regarding healthy food choices and increases in physical activity	Body weight, quality of life, HbA_{1c}, stroke, myocardial infarction, all-cause mortality, serious adverse events/ reoperations, diabetes remission, hypertension, dyslipidaemia, sleep apnoea, cancer, revision rates	SR of RCTs	2 to 3 years (and 6 months to 1 year)[a]	• Random sequence generation – 90% low, 10% unclear; • Allocation concealment – 50% unclear, 30% low, 20% high; • Blinding of participants and personnel – 60% high, 40% unclear; • Blinding of outcome assessment, judgement did not differ among outcomes – 60% high, 30% unclear, 10% low; • Incomplete continuous outcome data –

Study ID	Participants Inclusion criteria[c]	Intervention[b]	Comparators	Outcomes	Study Design	Follow-up	ROB
							50% high, 50% low; • Incomplete binary data – 50% low; 40% high; 10% not applicable • Selective reporting – 100% low
Kodama 2018	Participants n=1191 (1211 including studies not relevant for this report) Five studies included patients both with and without diabetes while the remaining 17 studies included only patients with diabetes. Mean age – 35 to 53 years. Median of mean BMI - 37.7 kg/m^2 Inclusion criteria: None specified but RCTs had to have at least one surgical treatment arm and report on diabetes remission rate	LAGB, mini-GBP, LSG, RYGB, NST **Co-interventions:** NR	LAGB, mini-GBP, LSG, RYGB, NST	Diabetes remission rate	NMA based on SR of RCTs	0.25 to 5 years	• Random sequence generation – 64% low; 36% high; • Allocation concealment – 77% high; 23% low • Blinding of participants and personnel – 91% high; 9% low; • Blinding of outcome assessment – 72% high; 27% low; • Incomplete outcome data – 59% low; 41%

Study ID	Participants Inclusion criteria[c]	Intervention[b]	Comparators	Outcomes	Study Design	Follow-up	ROB
							high; • Selective reporting -95% low; 5% high; • Other sources of bias – 77% low; 23% high;

[a] The SMB report separately presents data for a follow-up of 6 months to 1 year.
[b] Reported co-interventions only refer to co-interventions for weight loss.
[c] Only inclusion criteria to clarify populations of interest presented.
%EWL = % excess weight loss; BMI = body mass index; CT = conventional therapy; HbA_{1c} = glycated haemoglobin A_{1c}; ITT = intention-to-treat; LAGB = laparoscopic adjustable gastric band; LMGB = laparoscopic mini gastric bypass; LRYGB = laparoscopic Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy; NMA = network meta-analysis; NR = not reported; NST = non-surgical treatment; mini-GBP = mini gastric bypass; RCT = randomised controlled trial; ROB = risk of bias; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; SMB = Swiss Medical Board; SR = systematic review; T2DM = type 2 diabetes mellitus; VLCD = very low-calorie diet

4. DISCUSSION

4.1 STRENGTHS, LIMITATIONS AND UNCERTAINTIES

Where possible, the evidence in this report has been based on systematic reviews of RCTs. The challenges of a very broad scope and the sheer number of systematic reviews identified on the topic necessitated the implementation of a prioritisation process prior to the screening of the full-texts. Unfortunately, some of the newer systematic reviews, which covered a range of interventions of interest only reported on a couple of outcomes. Therefore, not always the newest systematic reviews were used for this report.

Primary RCT-based evidence was often scarce, particularly evidence on LMGB and on Optifast. Inclusion of the most recent systematic reviews with the most up to date evidence on the interventions of interest meant that the inclusion criteria of the systematic reviews used did not always completely match the population of interest for this report. For example, the SMB and the Colquitt report also included studies on overweight patients, while the review by Kodama et al. did not pre-specify any inclusion criteria regarding weight at all but included any RCT with bariatric or metabolic surgery.[11, 24]. The SMB report for example had performed subgroup analyses comparing studies where the BMI was 25-34.9 kg/m2 versus studies with a BMI of ≥35 kg/M^2. Though some point estimates seemed quite different, e.g. for remission from diabetes, the number of studies and patients was small and confidence intervals were broad so that differences in magnitude could not be quantified.[11] The relevance and impact of any differences in baseline weight therefore remain unclear.

The amount of evidence available from RCTs varied depending on the comparisons of interest. While most reviews compared one or more surgical interventions with conservative treatment, the evidence tended to be scarcer on the comparison of different surgical techniques and in particular for LMGB where the evidence was only based on a systematic review of non-randomised studies and one RCT. None of the included systematic reviews that reported on mortality had sufficient data in order to provide effect estimates.

While many reviews reported on weight loss the measures reported varied widely. The German website gave data on percentage weight loss for the surgical interventions while for the formula based lifestyle interventions it just reported an average weigt loss to be expected. Given that for the surgical interventions the weight loss of 10 to 25% was estimated to correspond to a weight loss of about 10 to 30 kg on the website the weight loss with the conservative treatment formula based diet would roughly correspond to 5 to 12,5% weight loss but the exact percentage depends on the baseline weight. The German AWMF-guideline on prevention also pointed out that in their overview of the effects of different conservative treatment programs the absolute and relative weight loss differ significantly from each other depending on the various target groups (average BMI of the participants).[1]

In the studies comparing surgical interventions versus conservative treatment, the amount of weight lost (whether measured as mean weight change or as percent change of body weight) was greater for bariatric surgery compared to CT. This also applied for the one RCT that compared LAGB versus Optifast. One needs to be aware though that the primary studies included in Avenell 2018 and the report by the Swiss Medical Board were nearly identical.[5] The amount of weight lost tended to be

greatest in studies where RYGB was used as an intervention. Kang et al. did a network-meta-analysis and found differences in BMI reduction and percentage excess weight loss for RYGB compared to LAGB and for both RYGB and SG versus LAGB but not for RYGB versus SG.[9] With effects judged to be similar for RYGB and SG by Kang et al.[9] Quan et al. found a greater reduction of the postoperative BMI for LMGB compared to LAGB and compared to LRYGB but not compared to LSG. These data were based solely on non-randomized studies. In view of the fact that the German guideline group describes some expected weight gain 2-3 years after surgery it is important to compare studies with a similar duration of follow-up when no data from direct comparisons are available.

When comparing Optifast + dietary intervention versus dietary intervention only, no clear difference was observed in terms of weight loss (measured as mean weight changed). Judging the comparability of the patients in the studies comparing Optifast + dietary intervention versus dietary intervention to the studies comparing the surgical interventions versus dietary interventions was hampered by the fact that the HTA report by Avenell did not report effect estimates per treatment arm. This might have given a rough impression regarding the comparability of treatment effects in the respective comparator arms. In view of the fact that no clear difference between VLCD and dietary intervention vs. dietary intervention alone was found it seems unlikely that effects of surgery compared to VLCD and dietary intervention will differ markedly from the effects found compared to dietary interventions alone. The absolute weight loss reported for Optifast in the older AWMF guideline on the treatment and prevention of obesity is likely to be not representative of the true treatment effect in view of the large proportion of dropouts (42%) and the non-conservative assumption that the weight remained stable after drop-out (last observation carried forward). In view of the high drop-out rate this estimate may not apply to those patients who persevered with the treatment nor those who dropped out. Avenell et al. discuss in their report that weight management programs have focussed on achieving a weight loss of 5 to 10% in order to achieve cardiovascular benefits but that for people with severe obesity who are at risk of a number of other co-morbidities which are just as important this degree of weight loss may not be sufficient.[5] The AWMF guideline specified that a weight loss of less than 15% with an adequate (in type and duration) conservative intervention is used as a cut-off to define the indication for a surgical intervention in patients with a BMI of 35-39.9 kg/m^2 because conservative treatment has been exhausted. The current data seem to be consistent with the statement by the AWMF that a persistent weight loss, improvement of co-morbidities and quality of life with higher degree obesity are possible with nutritional, exercise, behavioural, and pharmacological therapy but can usually not be achieved.[1]

Data on quality of life showed differences for the physical scores of SG compared to CT and for LAGB compared to CT but were sparse and based on single, small studies for each of the comparisons covered by the systematic reviews. The reliability of these estimates therefore seems questionable. Patients who had bariatric surgery had better results regarding the remission from diabetes than patients who received conservative treatment.[11] The definitions of what constituted remission from diabetes varied considerably though, limiting the comparability of the observed effects. Bariatric surgery was more frequently associated with diabetes remission than conservative treatment.[11] Based on the data from the reviews by Quan et al. and Kodama et al., LMGB is superior to any of the other surgical interventions.[10, 24] The data from the SR by Quan were based on non-randomised studies though and Kodama et al. caution that their network only included two, small RCTs on mini-

GBP and that effect estimates might therefore not be reliable.[24] RYGB in turn was ranked higher than LSG and LAGB in this network meta-analysis.[24]

For patients with existing T2DM, SG, pRYGB, and LMGB are the interventions covered in this review, which should be used as primary interventions according to the AWMF guideline.[1] The choice of treatment should consider glycaemic control, duration and medication of the existing T2DM, BMI, comorbidities, age, gender, adherence and profession.[1] In the case of insulin dependent diabetics surgical interventions with an intestinal bypass should be used as they have higher remission rates than SG. LAGB is not recommended as primarily metabolic intervention due to its comparatively poor results.[1]

For stroke, the SMB report included one three-armed study where relative effects were either not estimable between treatment arms or had broad confidence intervals.[11] Better results were found for hypertension and dyslipidaemia for bariatric surgery compared to CT but effects were not statistically significant for the comparison of LAGB vs. CT.[11] There was no clear evidence that RYGB is better than LSG though results tended to be better in the various RCTs and had not been pooled.[8] For sleep apnoea, no clear differences were seen for improvement or cure though the evidence was sparse.

For the outcomes cancer, function and mood, evidence was very sparse. The evidence for these outcomes was based on one RCT. No relevant differences were found regarding cancer for RYGB versus CT and SG versus CT. For all outcomes on function and mood, the RCTs found better results for RYGB compared to LSG. The German guideline reports though that there are indications for poorer post-operative outcomes regarding self-harm, suicide and problematic alcohol consumption. None of the included evidence syntheses reported on myocardial infarction or fitness.

For FAQ 4, only information on the duration of the hospital stay was identified, which was longer for RYGB compared LAGB in two RCTs. As this outcome may vary depending on local practice, hospital-based data may be more informative.

Information on adverse effects was sparse in the RCTs and therefore information from the Gesundheitsinformation was added as well, the sources of the evidence were listed though not directly cited and the type and quality of the evidence for the reported outcomes were not reported. One RCT included in the systematic review reported a higher risk of adverse events (such as readmissions and complications) for RYGB compared to LAGB.[8] The duration of follow-up was not entirely clear for this study though for readmissions it was 30 days. Even though the peri-operative risk and invasiveness of laparoscopic gastric banding tend to be lowest compared to the other interventions it has a high rate of long-term complications (42.7%) with the need to remove the banding (22.9%) and redo operations(36.5%).[1]

For RYGB surgery the dumping syndrome has been described. This is an adverse event, which is caused by eating refined sugar and presents with rapid heart rate, nausea, tremor, feeling faint and diarrhoea.[8] According to the systematic review by Colquitt et al., it is thought that the dumping syndrome helps with the weight loss as the patient is conditioned against eating sweet food.[8] None of the included systematic reviews reported on this outcome though.

The AWMF guideline states that the current evidence does not allow the definition of a surgical “gold standard” for primary bariatric surgery and that it is not possible to choose the approach based on objective parameters. They suggest that the treatment choice should be made individually

based on patient criteria that include the psychosocial circumstances and the experience of the bariatric surgeon.[1]

Table 19 summarises the evidence for bariatric surgery versus conservative treatment.

Table 19: Summary of evidence for bariatric surgery versus conservative treatment

Evidence	Favours bariatric surgery/intervention[a]	Favours conservative treatment	Notes
FAQ2: What is the effect of the different treatment options on all-cause mortality?			
All-cause mortality	NE	NE	Effect estimates identified in the literature for overall mortality based on RCTs comparing the surgical interventions against each other or against conservative treatment could not be estimated
FAQ3: Will my symptoms/quality of life get better?			
Weight loss	✓		Compared with non-surgical interventions, bariatric surgery had a consistent and significant effect on weight loss, regardless of the type of procedure.
LMGB	-/✓		No data comparing LMGB versus conservative treatment were available. At one year LMGB led to greater weight loss than RYGB. In direct comparison short-term weight loss seemed to be greater than with LAGB and no difference was found compared to LSG.
RYGB	✓		Data from 2-3 years follow-up show a consistent and significantly larger effect in patients treated with RYGB compared to conservative treatment. Based on a network meta-analysis with a follow-up of 1-5 years RYGB and SG were judged to yield similar results (effects were conflicting) and to be better than LAGB.
SG	✓		Data from 3 and 5 years follow-up show a consistent and significantly larger effect in patients treated with SG. Based on a network meta-analysis with a follow-up of 1-5 years RYGB and SG were judged to yield similar results (effects were conflicting) and to be better than LAGB.
LAGB	✓		Data from 2 and 3 years follow-up show a consistent and significantly larger effect in patients treated with

Evidence	Favours bariatric surgery/intervention[a]	Favours conservative treatment	Notes
			LABG. Based on a network meta-analysis with a follow-up of 1-5 years LAGB ranked last compared to RYGB and SG.
OPTIFAST	-	-	Data from 18 months follow-up suggest that there is no clear difference in terms of weight loss between Optifast+dietary intervention and dietary intervention only.
Quality of life	✓		Bariatric surgery showed significant improvements in physical component/domain compared with conservative treatment, while no significant changes were reported in mental component/domain. For RYGB depending on the review better results or no difference was shown. Effect estimates were based on very small, single studies.
Diabetes remission	✓		The relative risk to achieve diabetes remission was significantly higher with surgery than with conservative treatment.
Mini-GBP	(✓)		No data on effects compared to conservative treatment available. Based on a network meta-analysis Mini-GBP performed better than the other surgical interventions regarding remission from diabetes. Evidence is based on only 2 small RCTs though.
RYGB	✓		Based on two systematic reviews, RYGB has clearly better effect for diabetes remission than conservative treatment. Based on a network meta-analysis RYGB performed better regarding remission from diabetes than SG and LAGB.
SG	✓		Available evidences suggest that SG is clearly more effective for diabetes remission than conservative treatment. Based on a network meta-analysis SG performed better regarding remission from diabetes

Evidence	Favours bariatric surgery/intervention[a]	Favours conservative treatment	Notes
			than LAGB
LAGB	✓		Available evidences suggest that LABG is clearly more effective for diabetes remission than conservative treatment. Based on a network meta-analysis LAGB ranked last compared to the other three surgical interventions.
OPTIFAST	NR	NR	Although diabetes remission was not reported in any of the Optifast studies, one study reported that mean change of blood sugar levels and % HbA1c tended to be better for the group receiving VLCD and dietary intervention compared to dietary intervention only.
Stroke	-	-	One stroke after bariatric surgery and none after conservative treatment were reported after 3 years follow-up.
Myocardial infarction	-	-	None of the included evidence syntheses reported on myocardial infarction
Hypertension	✓		Risk to have hypertension was significantly lower in a surgical than in a conservative treatment group. No data on SG and LMGB compared to CT were reported
Dyslipidaemia	✓		One RCT showed that bariatric surgery significantly reduced the risk for dyslipidaemia compared with conservative treatment, however, the effect depends on type of the surgery.
Sleep apnoea	✓		One RCT reported achieving mild OSA in more patients with LAGB than with CT, however, other RCTs found no significant difference or did not report on the significance
Cancer	-	-	One RCT reported a comparison between RYGB, SG and CT and no differences were found.
Mood	-		No data comparing bariatric surgery versus conservative treatment were available. The German

Evidence	Favours bariatric surgery/intervention[a]	Favours conservative treatment	Notes
			guideline mentioned though that there are indications that self-harm, suicide, and problematic alcohol consumption may increase post-operatively. One SR reported on depression and no differences between RYGB and LSG were found after.
FAQ4: When will I recover?			
Time to return to usual activity	NR	NR	Not reported
Length of hospital stay	-	-	Not applicable
Time of work/return to work	NR	NR	Not reported
FAQ5: What are the risks/side-effects?			
Serious adverse events / reoperations	-	-	One systematic review reported a comparison between bariatric surgery and CT. There was no significant difference between the surgical and CT group.
KEY			
-	No noticeable difference		
✓	Statistically significantly better for some types of surgery or conservative treatment but not all		
✓	Statistically significantly better or guideline recommendation with any type of bariatric surgery or conservative treatment.		
Results ranked according to ranking in network-MA			
✓	Intervention was better than conservative treatment in MA and in an NMA ranked highest[b] compared to other surgical interventions.		
✓	Intervention was better than conservative treatment in MA and in an NMA ranked second[b] compared to other surgical interventions.		
✓	Intervention was better than conservative treatment in MA and in an NMA ranked third[b] compared to other surgical interventions.		
✓	Intervention was better than conservative treatment in MA and in an NMA ranked last[b] compared to other surgical interventions.		

[a] Intervention corresponds to bariatric surgery unless specified otherwise.

[b] Place of the rank my differ from the original publication if network meta-analysis evaluated more interventions than reported here.

CT = conservative treatment; FAQ = frequently asked question; LAGB = laparoscopic adjustable gastric band; NA = not applicable; NE = not estimable; NR = not reported; RCT = randomised controlled trial; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy

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APPENDIX 1 – SEARCH STRATEGIES

Database	Dates	Results
CDSR	2012 – 2019/05/Iss5	24
DARE	2012 – 2015/03/31	117
HTA	2012 – 2018/03/31	
KSR Evidence	2012 – 2019/05/02	775
Epistemonikos	2012-2019/05/01	554
NHS Evidence	2012/01/01-2019/05/01	716
NICE	up to 2019/04/30	32
GIN	2012-2019/04/29	55
ECRI	up to 2019/04/30	106
Total		**2379**
Total after de-duplication		**1806**

SDM database searches

Database	Dates	Results
Embase	1974-2019 May 3	91
MEDLINE & In-Process	1946-2019/Apr week 4	188
MEDLINE DU & Epub	Up to 2019 May 3	1
Total		**280**
Total after de-duplication		**235**

CDSR (Wiley): up to Issue 5, May 2019
Search strategy: SDK_SDM Obesity_CDSR

#1 MeSH descriptor: [Obesity] explode all trees 12101
#2 MeSH descriptor: [Body Weight] this term only 7806
#3 MeSH descriptor: [Weight Loss] this term only 5363
#4 MeSH descriptor: [Weight Gain] this term only 2305
#5 MeSH descriptor: [Body Weight Changes] this term only 60
#6 MeSH descriptor: [Body Mass Index] this term only 9542
#7 ((BMI or "body mass ind*") NEAR/2 (great* or over or gain* or los* or chang*)):ti,ab,kw 1783
#8 (obesity or obese or antiobes* or overweight or "over weight" or "over eat*" or overeat* or "weight reduc*" or "weight chang*" or "weight control*" or fatness):ti,ab,kw 39319
#9 ((weight NEAR/2 gain*) or (weight NEAR/2 los*) or (body NEAR/2 (composition or fat* or weight or adipos*))):ti,ab,kw 65229
#10 #1 or #2 #3 or #4 or '6 #6 #7 or #8 or #9 84954
#11 MeSH descriptor: [Bariatric Surgery] this term only 228
#12 (bariatric NEAR/5 (surg* or operation* or procedure* or treatment$)):ti,ab,kw 1974
#13 (obesity NEAR/5 (surg* or operation* or procedure*)):ti,ab,kw 2076
#14 MeSH descriptor: [Gastric Bypass] this term only 416
#15 MeSH descriptor: [Anastomosis, Roux-en-Y] this term only 123

#16 ((Gastric NEAR/4 (band* or sleev* or stapl* or resection* or reduction* or stimulation or bypass)) or RYGB or "roux-en-y"):ti,ab,kw 2917
#17 MeSH descriptor: [Gastrectomy] this term only 917
#18 (Gastrectom* or LAG or SG):ti,ab,kw 6170
#19 (mini NEAR/2 bypass) or MGB:ti,ab,kw 96
#20 #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 9919
#21 #10 and #20 with Cochrane Library publication date Between Jan 2012 and May 2019 3226

CDSR = 24
Cochrane Protocols = 3
CENTRAL = 3199

DARE (www.crd.york.ac.uk): 2012 – March 2015
HTA (www.crd.york.ac.uk): 2012 – May 2019
Searched: 1.5.19

1 MeSH DESCRIPTOR Obesity EXPLODE ALL TREES
2 MeSH DESCRIPTOR Body Weight EXPLODE ALL TREES
3 MeSH DESCRIPTOR Weight Loss EXPLODE ALL TREES
4 MeSH DESCRIPTOR Weight Gain EXPLODE ALL TREES
5 MeSH DESCRIPTOR Body Weight Changes EXPLODE ALL TREES
6 MeSH DESCRIPTOR Body Mass Index EXPLODE ALL TREES
7 (body mass inde*):TI OR (BMI):TI
8 (obesity or obese or antiobes* or overweight or "over weight" or "over eat*" or overeat* or "weight reduc*" or "weight chang*" or "weight control*" or fatness):TI
9 (weight):TI AND (gain* or los*):TI
10 (body):TI OR (composition or fat* or weight or adipos*):TI
11 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10
12 MeSH DESCRIPTOR Bariatric Surgery EXPLODE ALL TREES
13 (bariatric):TI AND (surg* or operation* or procedure* or treatment*):TI
14 (obesity):TI AND (surg* or operation* or procedure*):TI
15 MeSH DESCRIPTOR Gastric Bypass EXPLODE ALL TREES
16 MeSH DESCRIPTOR Anastomosis, Roux-en-Y EXPLODE ALL TREES
17 (gastric):TI AND (band* or sleev* or stapl* or resection* or reduction* or stimulation or bypass):TI
18 (RYGB or "roux-en-y"):TI
19 MeSH DESCRIPTOR Gastrectomy EXPLODE ALL TREES
20 (gastrectom* or LAG or SG):TI
21 (mini):TI AND (bypass):TI
22 #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21
23 #11 AND #22
24 (#23) FROM 2012 TO 2019
25 (#24) IN DARE, HTA

117 results

KSR Evidence (www.ksrevidence.com): 2012 – 2 May 2019

Searched: 2 May 2019

#	Query	Results
1	((BMI or "body mass ind*") and (great* or over or gain* or los* or chang*)) in All text Date published: 2012–2019;	639
2	(obesity or obese or antiobes* or overweight or "over weight" or "over eat*" or overeat* or "weight reduc*" or "weight chang*" or "weight control*" or fatness in All text Date published: 2012–2019;	3434
3	((weight gain*) or (weight los*) or (body and (composition or fat* or weight or adipos*))) in All text Date published: 2012–2019;	3815
4	#1 or #2 or #3	5835
5	(bariatric and (surg* or operation* or procedure* or treatment*)) in All text Date published: 2012–2019;	416
6	(obesity and (surg* or operation* or procedure*)) in All text Date published: 2012–2019;	718
7	((Gastric and (band* or sleev* or stapl* or resection* or reduction* or stimulation or bypass)) or RYGB or "roux-en-y" in All text Date published: 2012–2019;	480
8	Gastrectom* or LAG or SG in All text Date published: 2012–2019;	399
9	mini bypass in All text Date published: 2012–2019;	13
10	#5 or #6 or #7 or #8 or #9	1267
11	#4 and #10	775

Epistemonikos (www.epistemonikos.org): 2012 - 2019

Searched: 1.5.19

(title:((title:(((BMI OR "body mass ind*") AND (great* OR over OR gain* OR los* OR chang*))) OR abstract:(((BMI OR "body mass ind*") AND (great* OR over OR gain* OR los* OR chang*)))) OR (title:((obesity OR obese OR antiobes* OR overweight OR "over weight" OR "over eat*" OR overeat* OR "weight reduc*" OR "weight chang*" OR "weight control*" OR fatness)) OR abstract:((obesity OR obese OR antiobes* OR overweight OR "over weight" OR "over eat*" OR overeat* OR "weight reduc*" OR "weight chang*" OR "weight control*" OR fatness))) OR (title:((weight AND gain*) OR (weight AND los*) OR (body AND (composition OR fat* OR weight OR adipos*))) OR abstract:((weight AND gain*) OR (weight AND los*) OR (body AND (composition OR fat* OR weight OR adipos*)))) AND (title:((bariatric AND (surg* OR operation* OR procedure* OR treatment*)) OR (obesity AND (surg* OR operation* OR procedure*)) OR ((Gastric AND (band* OR sleev* OR stapl* OR resection* OR reduction* OR stimulation OR bypass)) OR RYGB OR "roux-en-y") OR (Gastrectom* OR LAG OR SG) OR (mini AND bypass) OR MGB) OR abstract:((bariatric AND (surg* OR operation* OR procedure* OR treatment*)) OR (obesity AND (surg* OR operation* OR procedure*)) OR ((Gastric AND (band* OR sleev* OR stapl* OR resection* OR reduction* OR stimulation OR bypass)) OR RYGB OR "roux-en-y") OR (Gastrectom* OR LAG OR SG) OR (mini AND

bypass) OR MGB))) OR abstract:((title:(((BMI OR "body mass ind*") AND (great* OR over OR gain* OR los* OR chang*))) OR abstract:(((BMI OR "body mass ind*") AND (great* OR over OR gain* OR los* OR chang*)))) OR (title:((obesity OR obese OR antiobes* OR overweight OR "over weight" OR "over eat*" OR overeat* OR "weight reduc*" OR "weight chang*" OR "weight control*" OR fatness)) OR abstract:((obesity OR obese OR antiobes* OR overweight OR "over weight" OR "over eat*" OR overeat* OR "weight reduc*" OR "weight chang*" OR "weight control*" OR fatness))) OR (title:((weight AND gain*) OR (weight AND los*) OR (body AND (composition OR fat* OR weight OR adipos*))) OR abstract:((weight AND gain*) OR (weight AND los*) OR (body AND (composition OR fat* OR weight OR adipos*)))) AND (title:((bariatric AND (surg* OR operation* OR procedure* OR treatment*)) OR (obesity AND (surg* OR operation* OR procedure*)) OR ((Gastric AND (band* OR sleev* OR stapl* OR resection* OR reduction* OR stimulation OR bypass)) OR RYGB OR "roux-en-y") OR (Gastrectom* OR LAG OR SG) OR (mini AND bypass) OR MGB) OR abstract:((bariatric AND (surg* OR operation* OR procedure* OR treatment*)) OR (obesity AND (surg* OR operation* OR procedure*)) OR ((Gastric AND (band* OR sleev* OR stapl* OR resection* OR reduction* OR stimulation OR bypass)) OR RYGB OR "roux-en-y") OR (Gastrectom* OR LAG OR SG) OR (mini AND bypass) OR MGB))))

Filtered: 2012-2019, Systematic Review

554 results

NHS Evidence (www.evidence.nhs.uk) 2012 – May 1 2019
Searched: 1.5.19

Search terms	Filtered to Systematic Reviews or Guidance, 2012-2019
Bariatric surgery obesity	311
"Gastric bypass"	187
"weight reduction" surgery	104
Roux-en-Y obesity	121
"gastric band"	32
"gastric sleeve"	9
"gastric staple"	1
RYGB	42
Gastrectomy	315
"mini bypass"	0
"obesity surgery"	80
Total	1202
Total after de-duplication	**716**

SDM Obesity
NICE Guidance (www.nice.org.uk)
Searched: 30.4.19

Title search	Hits
Weight	7

Overweight	4
BMI	1
Body mass	0
Body fat	2
Bariatric	0
roux-en-y	0
gastric bypass	0
gastric band	0
gastric sleeve	0
gastric staple/stapling	0
gastric reduction	0
Gastrectomy	1
Mini bypass	0
Total from title search	15
NICE Guidance / Conditions and diseases / Diabetes and other endocrinal, nutritional and metaolic conditions / Obesity	37
Total, duplicates removed and limited by date 2012 -2019	**32**

International Guideline Library (www.g-i-n.net)
Searched: 29.4.19

Search terms	**2012-2019**
Obesity	36
Weight	18/34 (duplicates removed
Overweight	0/13 (duplicates removed)
Body fat*	1/3 (duplicates removed)
Adipos*	0/6 (duplicates removed)
Body mass	0/2 (duplicates removed)
BMI	0/1 (duplicates removed)
Waist	0/1 (duplicates removed
Obese	0/4 (duplicates removed)
Bariatric	0/2 (duplicates removed)
roux-en-y	0
Gastric bypass	0
Gastric band*	0
Gastric sleeve*	0
Gastric stapl*	0
Gastric resection*	0
Gastric reduction	0
Gastrectom*	0
Mini bypass	0
Total	**55**

ECRI Institute (www.guidelines.ecri.org)
Searched: 30.4.19

Search terms filtered to All adult / Counseling / Management / Risk Assessment / Treatment	Hits
Obesity	77
Overweight	35
BMI	36
Body mass index	51
Bariatric surgery	12
Roux-en-Y	3
Gastric bypass	4
Gastric band	3
Gastric sleeve	0
Gastric staple	0
Gastric stapling	0
Gastric resection	0
Gastric reduction	9
Gastrectomy	1
Mini bypass	0
LAGB	1
Total	232
Total after de-duplication	**106**

Embase (Ovid): 1974 to 2019 May 3
Searched: 9.5.19

1 exp obesity/ (470290)
2 body weight/ (262578)
3 body weight loss/ (18736)
4 body weight gain/ (8456)
5 ((BMI or body mass ind$) adj2 (great$ or over or gain$ or los$ or chang$)).ti,ab,ot. (16819)
6 (obesity or obese or antiobes$ or overweight or over weight or over eat$ or overeat$ or weight reduc$ or weight chang$ or weight control$ or fatness).ti,ab,ot. (442756)
7 ((weight adj2 gain$) or (weight adj2 los$) or (body adj2 (composition or fat$ or weight or adipos$))).ti,ab,ot. (486289)
8 or/1-7 (1031209)
9 bariatric surgery/ (28013)
10 (bariatric adj5 (surg$ or operation$ or procedure$ or treatment$)).ti,ab,ot. (29080)
11 (obesity adj5 (surg$ or operation$ or procedure$)).ti,ab,ot. (10623)
12 gastric bypass surgery/ (2601)
13 Roux Y anastomosis/ (8509)
14 ((Gastric adj4 (band$ or sleev$ or stapl$ or resection$ or reduction$ or stimulation or bypass)) or RYGB or roux-en-y or roux y anastomosis).ti,ab,ot. (41769)
15 gastrectomy/ (31164)
16 sleeve gastrectomy/ (9254)
17 laparoscopic sleeve gastrectomy/ (2449)

18 (gastrectom$ or LAG or SG).ti,ab,ot. (90625)
19 ((mini adj2 bypass) or MGB).ti,ab,ot. (2041)
20 or/9-19 (158886)
21 shared decision making/ (4363)
22 ((share$ or sharing$ or inform$) adj3 (decision$ or deciding$ or choice$)).ti,ab. (42643)
23 sdm.ti,ab. (2734)
24 or/21-23 (45522)
25 8 and 20 and 24 (91)

MEDLINE and In-Process & Other Non-Indexed citations (Ovid): 1946 to April Week 4 2019
Searched: 9.5.19

1 exp obesity/ (196425)
2 body weight/ (183753)
3 Weight Loss/ (33545)
4 weight gain/ (29754)
5 body weight changes/ (5)
6 body mass index/ (116917)
7 ((BMI or body mass ind$) adj2 (great$ or over or gain$ or los$ or chang$)).ti,ab,ot. (10024)
8 (obesity or obese or antiobes$ or overweight or over weight or over eat$ or overeat$ or weight reduc$ or weight chang$ or weight control$ or fatness).ti,ab,ot. (296933)
9 ((weight adj2 gain$) or (weight adj2 los$) or (body adj2 (composition or fat$ or weight or adipos$))).ti,ab,ot. (344145)
10 or/1-9 (753294)
11 bariatric surgery/ (8488)
12 (bariatric adj5 (surg$ or operation$ or procedure$ or treatment$)).ti,ab,ot. (14773)
13 (obesity adj5 (surg$ or operation$ or procedure$)).ti,ab,ot. (6419)
14 gastric bypass/ (8400)
15 anastomosis, Roux-en-Y/ (3379)
16 gastrectomy/ (33453)
17 ((Gastric adj4 (band$ or sleev$ or stapl$ or resection$ or reduction$ or stimulation or bypass)) or RYGB or roux-en-y or roux y anastomosis).ti,ab,ot. (25826)
18 (gastrectom$ or LAG or SG).ti,ab,ot. (70528)
19 ((mini adj2 bypass) or MGB).ti,ab,ot. (1243)
20 or/11-19 (119951)
21 exp Decision Making/ (186997)
22 ((share$ or sharing$ or inform$) adj3 (decision$ or deciding$ or choice$)).ti,ab. (29995)
23 sdm.ti,ab. (2055)
24 or/21-23 (210448)
25 10 and 20 and 24 (188)

MEDLINE Epub Ahead of Print, Daily Update: up to May 3 2019
Searched: 9.5.19

1 exp obesity/ (160)
2 body weight/ (48)
3 Weight Loss/ (26)
4 weight gain/ (19)
5 body weight changes/ (0)
6 body mass index/ (79)
7 ((BMI or body mass ind$) adj2 (great$ or over or gain$ or los$ or chang$)).ti,ab,ot. (236)
8 (obesity or obese or antiobes$ or overweight or over weight or over eat$ or overeat$ or weight reduc$ or weight chang$ or weight control$ or fatness).ti,ab,ot. (6426)

9 ((weight adj2 gain$) or (weight adj2 los$) or (body adj2 (composition or fat$ or weight or adipos$))).ti,ab,ot. (6187)
10 or/1-9 (10935)
11 bariatric surgery/ (19)
12 (bariatric adj5 (surg$ or operation$ or procedure$ or treatment$)).ti,ab,ot. (546)
13 (obesity adj5 (surg$ or operation$ or procedure$)).ti,ab,ot. (239)
14 gastric bypass/ (6)
15 anastomosis, Roux-en-Y/ (1)
16 gastrectomy/ (16)
17 ((Gastric adj4 (band$ or sleev$ or stapl$ or resection$ or reduction$ or stimulation or bypass)) or RYGB or roux-en-y or roux y anastomosis).ti,ab,ot. (564)
18 (gastrectom$ or LAG or SG).ti,ab,ot. (1382)
19 ((mini adj2 bypass) or MGB).ti,ab,ot. (25)
20 or/11-19 (2215)
21 exp Decision Making/ (195)
22 ((share$ or sharing$ or inform$) adj3 (decision$ or deciding$ or choice$)).ti,ab. (1314)
23 sdm.ti,ab. (72)
24 or/21-23 (1519)
25 10 and 20 and 24 (1)

APPENDIX 2 – CLASSIFICATIONS USED IN THE AWMF GUIDELINES

Table 20: SIGN-classifcation of evidence levels

Levels of evidence	
1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort or studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

Table 21: Degree of recommendation

Degree of recommendation	**Description**
A	Strong recommendation
B	Recommendation
0	Open recommendation

Strong consensus	**Consensus**	**Agreement by majority**	**No consensus**
>90% agreement	>75-90% agreement	>50-75% agreement	<50% agreement