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Systematic guideline search and appraisal, as well as extraction of relevant information on obesity for the DMP module "Obesity"[1]

Executive Summary

[1] Translation of the executive summary of the final report "Systematische Leitlinienrecherche und –bewertung sowie Extraktion relevanter Inhalte zu Adipositas für die Erstellung eines DMP-Moduls Adipositas" (Version 1.0; Status: 06.02.2009). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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Executive summary

Background

On 19 December 2006, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to review the current state of knowledge presented in clinical practice guidelines (CPGs) on obesity for the preparation of a future disease management programme (DMP) module on obesity.

Research question

The aim of this research was to provide essential information for preparing a DMP module on obesity by means of a systematic search for current evidence-based CPGs and a synopsis of the extracted recommendations.

The procedures were organized as follows:

- Literature search for and selection of current evidence-based CPGs on obesity, which can be transferred to the German health system
- Appraisal of the methodological quality of the selected CPGs
- Extraction, synthesis and listing of recommendations from the CPGs included
- Documentation of the evidence on which, according to the CPG(s), the extracted recommendations were based
- Identification of methodologically relevant recommendations

It was not the aim of the research to issue recommendations in the sense of an IQWiG benefit assessment. The recommendations extracted from the CPGs are therefore to be understood as citations for which the underlying evidence as such was not reassessed.

Methods

A systematic search for CPGs on obesity was conducted in the CPG databases Leitlinien.de and Guidelines International Network (G-I-N), as well as in the bibliographic databases MEDLINE and EMBASE. One inclusion criterion specified by the Federal Joint Committee was "Publication period between 2002 and October 2007". In addition, the most relevant inclusion criteria were "Publications in German, English and French" and "Documentation of the evidence base of the CPG".

The evidence base of the CPG was based on the following 3 criteria:

- a systematic search of primary and secondary literature for the preparation of the CPG had been conducted;
- the majority of recommendations was supported through citations from the underlying primary and secondary literature; and
- the majority of recommendations was allocated a Level of Evidence (LoE) and/or Grade of Recommendation (GoR).

The CPGs included were evaluated using the German Instrument for Methodological Guideline Appraisal (DELBI[2]) and recommendations were extracted. All recommendations from the CPGs included relating to obese adults were extracted for the synthesis. The recommendations identified were those statements explicitly marked by the CPG authors as recommendations, or – if recommendations were not explicitly listed – statements that could be identified as recommendations on the basis of the language used. The recommendations were then summarized in continuous text, divided into recommendations based on randomized controlled trials (RCTs) and recommendations based on non-RCTs.

Results

A total of 10 evidence-based CPGs were included and appraised, and their recommendations extracted. The German CPG included was published in collaboration with the German Association for the Study of Obesity (DAG), the German Diabetes Association (DDG), the German Nutrition Society (DGE) and the German Society for Nutritional Medicine (DGEM) and comprehensively covers all care for obesity. Another 3 CPGs included originate from the rest of Europe and 6 CPGs from the USA, Australia and Canada.

The DELBI assessments showed that there is potential for improvement in the documentation of the CPG development, in particular in the areas "Stakeholder involvement" (DELBI domain 2), and "General applicability" (DELBI domain 5), and also in the area "Methodological rigour of development" (DELBI domain 3). Even though, according to the authors, the CPGs were based on a systematic literature search and criteria for the inclusion of primary literature were available, often neither the search (e.g. presentation of a search protocol) nor the inclusion criteria were adequately documented. In addition, the methodological approach in the adaptation of other CPGs was often poorly described. It is also notable that nearly all CPG developers used different systems to grade evidence and/or grades of recommendation, making a comparative appraisal of recommendations from different CPGs more difficult.

[2] Deutsches Instrument zur methodischen Leitlinien-Bewertung

Recommendations (including the level of evidence and/or the grade of recommendation and the cited literature) were extracted from all CPGs included and represented on the basis of aspects of care (diagnosis, therapy [including preventive measures], psychosocial care and advice, coordination of care, quality indicators in obesity therapy). Aspects of care are subdivided into RCT-based and non-RCT-based recommendations, whereby it should be noted that, depending on the research question, there may not be any data from RCTs for potentially important aspects of care. The evidence levels assigned by the CPG authors were used to allocate to RCT-based and non-RCT-based recommendations. A fresh appraisal of the quality of the individual studies, on which the recommendations are based, was not carried out.

Diagnosis

- **RCT-based recommendations:** The calculation of the body mass index (BMI) is documented by one CPG. In addition, 4 CPGs recommend that a detailed medical history is taken.

- **Non-RCT-based recommendations:** 6 CPGs recommend calculating the BMI and measuring the waist circumference. All 6 CPGs use the WHO weight classification table, although 3 CPGs emphasize that the BMI of older patients should be interpreted with caution, as it does not always allow firm conclusions to be made regarding the presence of obesity. Additional recommendations relate to evaluating the total patient risk of metabolic and cardiovascular complications. Moreover, the CPGs contain further detailed recommendations on medical history and diagnosis.

General therapy measures and patient information

- **RCT-based recommendations:** 3 CPGs recommend offering weight-loss therapy to obese (BMI $\geq$ 30) and overweight persons with comorbidities (BMI at least $\geq$ 25). In 4 CPGs, a lifestyle modification is recommended as the basis of therapy, consisting of the 3 components of nutrition, physical activity and behavioural therapy. No RCT-based recommendations could be identified for the care aspect of "Patient information".

- **Non-RCT-based recommendations:** 3 CPGs recommend that the components of a weight management programme are adapted to the individual circumstances of the patient, such as personal preferences, motivation and lifestyle. Some CPGs recommend in addition that the patient receives comprehensive information and education and that family members and nursing staff are involved. They also give a BMI threshold value, above which treatment steps should be introduced.

Nutrition therapy

- **RCT-based recommendations:** In 4 CPGs it is recommended that the patient is offered low-fat and/or moderate low-calorie diet plans for long-term weight loss. Low-calorie diets permit rapid weight loss, but are not suitable for long-term nutrition. 4 CPGs list meal replacements as a measure in weight loss. In 4 CPGs, very-low-calorie diet plans are recommended only as part of short-term weight loss. Various CPGs contain recommendations for taking into consideration the social environment of the patient when changing dietary habits.

- **Non-RCT-based recommendations:** 5 CPGs recommend, in addition to the RCT-based recommendations for specific diet plans, organizing the way of changing dietary habits according to the individual's personal preferences and circumstances. The CPGs also contain differentiated recommendations on various aspects of nutritional therapy.

Physical activity therapy

- **RCT-based recommendations:** 4 CPGs recommend that physical activity is increased both for weight loss and for weight maintenance. Another 2 CPGs emphasize that the increase in daily activity can also have a positive effect on comorbidities. Information on the length of time to be spent on physical activity for weight loss varies between a minimum of 10 to 30 minutes 3 days a week and 3 to 5 hours per week.

- **Non-RCT-based recommendations:** 6 CPGs are consistent in not recommending any specific form of training to increase physical activity. In addition, the CPGs contain differentiated recommendations on weight loss and weight maintenance through physical activity therapy. Individual CPGs also give information on how to deal with relative immobility and comorbidities.

Behavioural therapy

- **RCT-based recommendations:** 5 CPGs recommend behavioural therapy approaches as part of a combined therapy. Group-based behavioural modification counselling can be more effective than individual counselling.

- **Non-RCT-based recommendations:** Individual CPGs offer general recommendations on learning resources for patients and on the contact frequency of behavioural therapy counselling.

Pharmacotherapy and complementary medicine measures

- **RCT-based recommendations:** Several CPGs demonstrate that an adjuvant therapy with sibutramine or orlistat in patients with a BMI ≥ 30 kg/m² or in patients with a BMI ≥ 27 kg/m² and existing comorbidities can be considered as part of a comprehensive therapy plan.

- **Non-RCT-based recommendations:** Various CPGs indicate potential side effects from the drug therapy. Additional recommendations refer to the duration and response rate of the drug therapy. Other CPGs refer to the insufficient level of evidence for complementary medicine measures.

Surgical therapy

- **RCT-based recommendations:** 4 CPGs describe surgical procedures as a therapy option for patients with a BMI ≥ 40 and for patients with a BMI ≥ 35 plus obesity-related comorbidities. Moreover, 4 CPGs indicate that weight loss varies depending on the surgical procedure. Regarding the choice of surgical technique, 2 CPGs mention that the laparascopic approach is associated with lower complication rates, but the decision should also take into account the individual patient status.

- **Non-RCT-based recommendations:** 5 CPGs recommend that all conservative measures should be tried before surgical therapy. 6 CPGs emphasize the necessity for informed consent from the patient. Other recommendations refer to additional indication criteria, pre-surgical examinations, the surgical technique, post-surgical complications, treatment by a multi-discipline team, patient aftercare, requirements relating to the structural quality of surgical facilities and to plastic surgery procedures.

Monitoring/measures for weight maintenance including preventive measures

- **RCT-based recommendations:** A low-fat diet is recommended for weight maintenance. In addition, one CPG recommends offering a complementary programme for weight maintenance to persons who have decided to give up smoking.

- **Non-RCT-based recommendations:** Several CPGs emphasize the necessity for the therapy programme to be a long-term arrangement.

Psychosocial care and advice

- **RCT-based recommendations:** One CPG recommends that the patient's willingness to change and possible barriers to the success of the therapy should be assessed after the necessity for treatment has been established. Another CPG recommends that close family or friends should be involved in the therapy process.

- **Non-RCT-based recommendations:** 4 CPGs recommend that the patient's willingness to change and possible barriers should be assessed after the necessity for treatment has been established. Further CPGs give recommendations as to how a lack of motivation on the part of the patient at the initial examination can be dealt with and how the personal circumstances and the social environment of the patient can be taken into account.

Coordination of care

- **RCT-based recommendations:** No RCT-based recommendations could be identified.
- **Non-RCT-based recommendations:** 2 CPGs emphasize the central role of the GP in coordinating care. Further recommendations refer to the cooperation between GPs, consultants and inpatient facilities.

Quality indicators in obesity therapy

- **RCT-based recommendations:** No RCT-based recommendations could be identified.
- **Non-RCT-based recommendations:** One CPG proposes 4 goals and several possible indicators for each goal for the development of quality indicators.

Conclusions

This extraction of recommendations from evidence-based and topic-relevant CPGs provides an overview of the current standard of care of obese adult patients for the development of a DMP module on obesity.

RCT-based recommendations exist particularly in the care areas of nutrition therapy, physical activity therapy, behavioural therapy, pharmacotherapy and surgical therapy. In contrast, hardly any RCT-based recommendations could be identified for the care aspects of diagnosis, monitoring and long-term weight maintenance, or for care coordination and quality indicators.

When diagnosing obesity, the CPGs recommend measuring BMI and waist circumference and also taking a careful medical history. According to the CPGs included, effective therapeutic options are nutrition therapy, physical activity therapy, behavioural therapy and pharmacotherapy, as well as surgical therapy. Nutrition, physical activity and behavioural therapy are the first-line treatment approaches and should be combined, if possible. An adjuvant pharmacotherapy according to the CPG recommendations represents a therapy option for patients with a BMI above 30 kg/m^2 and for patients with comorbidities and a BMI above 27 kg/m^2. According to the CPGs, surgical therapy for obesity can be recommended above a BMI of 40 kg/m^2 and for patients with obesity-related comorbidities above a BMI of 35 kg/m^2.

Keywords: disease management programme (DMP), obesity, methodological appraisal of clinical practice guidelines, evidence-based clinical practice guidelines

The full report (in German) is available on www.iqwig.de/index.616.html