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HTA-Report | Summary

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Evaluation of medical and health economic effectiveness of bariatric surgery (obesity surgery) versus conservative strategies in adult patients with morbid obesity

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Health political background

Obesity with its associated medical, social, economic, and psychological complications is considered a chronic, multifactorial disorder. It is regarded an epidemic in developed as well as developing countries. The World Health Organisation (WHO) estimates the number of obese at about 300 mio. worldwide. Obese subjects suffer from a variety of adverse health effects. Given the magnitude of the challenge obesity there is a clear need for preventive as well as therapeutic measures and strategies on an individual and a public health level. In Germany, health insurance companies only accept the costs for an obesity therapy in rare and well justified cases. As obesity is related to considerable comorbidities and secondary disorders, which in turn cause treatment costs, official statistics and epidemiological survey can only partly explain the impact of obesity on health care costs. It has been shown for all developed countries that the financial burden due to nutritional diseases is constantly gaining importance for social security as well as national economics. The present Health Technology Assessment (HTA)-report therefore assesses the medical effectiveness/efficacy, safety and cost-effectiveness of surgical procedures in the therapy of morbid obesity in adults among each other and in comparison to conservative measures.

Scientific background

Overweight and obesity are defined as conditions in which excess fat has accumulated in the body tissues. The body mass index (BMI) is the most common measure to quantify overweight and obesity. The BMI is body weight in kilograms divided by the square of a person's height in metres. For adults, a BMI of 25 kg/m² to 29.9 kg/m² is defined as overweight, 30 kg/m² and above as obese. The indication for initiating a therapy of overweight or obesity depends on the degree of the disorder and on the existence of comorbidities. For subjects with morbid obesity, defined as BMI above 40 kg/m² or BMI above 35 kg/m² in the presence of severe comorbidities, that have insufficiently tried to lose weight by other means, surgical, so called bariatric procedures, may be considered. Two different types of bariatric procedures need to be differentiated: mainly restrictive, e. g. gastric banding or gastroplasty, and malabsorptive interventions, e. g. gastric bypass. These surgical therapies are subject to specific jurisdiction in Germany, regulating that the reimbursement is to be decided individually in each case by the health insurance company.

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Research questions

The goal of this HTA-report is to summarise the current literature on bariatric surgery, to evaluate their medical effectiveness/efficacy and cost-effectiveness as well as the ethical, social and legal implications of these procedures. In order to do so, the following research questions will be addressed from a medical standpoint:

- What is the medical effectiveness/efficacy of surgical procedures in the therapy of morbid obesity in adults compared to conventional strategies?
- What is the medical effectiveness/efficacy of different surgical procedures in the therapy of morbid obesity in adults compared among each other?
- What are the safety and acceptance of surgical procedures in the therapy of morbid obesity in adults compared to conventional strategies?
- What are the safety and acceptance of different surgical procedures in the therapy of morbid obesity in adults compared among each other?
- What patient or therapist related factors have an impact on the medical effectiveness/efficacy or safety of surgical procedures in the therapy of morbid obesity in adults?

Out of a health economics perspective, the following questions are of particular importance for the economic efficiency examination:

- What is the cost-effectiveness of surgical procedures in the therapy of morbid obesity in adults compared to conventional strategies?
- What is the cost-effectiveness of different surgical procedures in the therapy of morbid obesity in adults compared among each other?
- Do health economic criteria allow to favour a specific bariatric procedure?
- Does the reduction of comorbidities that follow bariatric surgery have a health economic impact?
- Which economic or health political consequences arise for the German health care system?

From an ethical, legal and social perspective the following scientific questions are central in the examination:

- Which ethical, legal and social implications have to be considered in the context of an assessment of bariatric surgery compared to conservative strategies for patients with morbid obesity. Are there any conclusions?
- Are there any ethical, legal and social criteria for the choice of a bariatic procedure?

Methods

The present report includes German and English literature published since 2001, targeting adult subjects with morbid obesity (BMI >= 40 kg/m² or BMI >= 35 kg/m² with severe comorbidities). Relevant publications are identified by means of a structured search of databases accessed through Art & Data Communications on behalf of the German Institute of Medical Documentation and Information (DIMDI) on 13.11.2006 and a further update of the literature search conducted on 12.11.2007. In addition a manual search of identified reference lists is conducted.

The former includes the following electronic resources:
DAHTA; NHS-CRD-HTA (INAHTA); NHS Economic Evaluation Database (NHSEED); NHS-CRD-DARE (CDAR94); Cochrane Library (CDSR93); MEDLINE (ME00), EMBASE (EM00), AMED (CB85); BIOSIS Previews (BA00); MEDIKAT (MK77); Cochrane Library Central (CCTR93), German Medical Science (GA03), SOMED (SM78), CAB Abstracts (CV72), Index to Scientific and Technical Proceedings (II78), ETHMED (ED93), GLOBAL Health (AZ72), Deutsches Ärzteblatt (AR96), MEDLINE Alert (ME0A), EMBASE Alert (EA08), SciSearch (IS00), CCMed (CC00), Social SciSearch (IN73), Karger Verlagsdatenbank (KR03), Kluwer Verlagsdatenbank (KL97), Springer Verlagsdatenbank (SP97), Springer Verlagsdatenbank PrePrint (SPPP), Thieme-Verlagsdatenbank (TV01).
Titles and abstracts of the original search as well as the update are independently screened by two experts on evidence based medicine (EbM). Predetermined inclusion and exclusion criteria are applied to the selection of title and abstracts and to the assessment of full texts. The methodological quality of included studies is assessed using the criteria recommended by the Scottish Intercollegiate Guidelines Network (SIGN) Grading Review Group. Randomised as well as non-randomised studies are included, case reports and series are not considered. The documentation of methodical quality of the economic studies takes place in consideration of the checklists to evaluate the methodical quality of health economic procedures and the German Scientific Working Group Technology Assessment for Health Care.

Results

Quantitative results

Among 5,910 retrieved publications, 25 medical articles and seven health economic studies meet the inclusion criteria. Among the included medical publication are nine papers on eight randomised clinical trials (RCT), 13 papers on seven non-randomised clinical trials, and three systematic reviews with meta-analysis. The economic publications comprise of three studies and four systematic reviews. No relevant publications dealing with ethical, social, or legal aspects of the topic can be identified.

Qualitative results

Included medical publications

Three of the non-randomised studies assess bariatric vs. conventional procedures. All other studies compare different surgical procedures among each other. Follow-up time varies between one and five years in the RCT and goes up to eleven years in one clinical trial. Both medical studies assessing effectiveness of bariatric vs. conventional procedures show a significant greater weight loss after surgery and decline in comorbidities. Diabetes incidence after ten years is lower in the surgery group, but no significant differences can be seen for hypertension, dislipoproteinemia. There are two large studies available that evaluate safety of bariatric procedures compared to conventional therapies. Both demonstrate a significantly decreased mortality over eight and eleven years respectively. At the same time the frequency of hospitalisations within six years is higher in the surgery group.
The effectiveness and even more so the safety of bariatric procedures compared to each other present heterogeneously. Concerning effectiveness in the comparison of different surgical procedures among each other, all types of studies find malabsorptive procedures to lead to a more profound weight loss than purely restrictive procedures. Comparing both restrictive procedures, studies result in a weaker short term, but stronger long term effect of

a adjustable gastric banding (AGB). The weight reduction upon all procedures is accompanied by a reduced frequency of some comorbidities (mostly diabetes type 2), while evidence is inconclusive for others. It is not possible to discriminate between procedures. All eight RCT and three non-randomised studies report on adverse health effect of the surgery for the comparison of different surgical procedures only. Concerning mortality hardly any differences between the groups are observed, and few deaths occur. Early reoperations due to surgical complications are also rare. Slightly more reoperations than in the comparative groups seem to be necessary following gastric bypass (GBP). Postoperative infections are reported in eight studies, revision surgeries in all included studies. Findings are heterogeneous and do not allow to draw conclusions. It's also not possible to draw a conclusion on the frequency of vitamin deficiencies. Two systematic reviews present results on safety. Both find consistently the highest mortality after biliopancreatic diversion and the lowest after AGB.

Included health economic publications

Of the potentially relevant publications, seven economic evaluations are considered suitable with regard to methodology and content and can be included in the economic part. Among these studies are three that investigate the cost-effectiveness of certain bariatric surgeries. One study examined two bariatric operations, adjustable gastric banding and gastric bypass, for the treatment of obesity in patients with Type 2 diabetes mellitus. One of the studies included deals with a comparison of GBP vs. no treatment, whereas the other compares the two surgical procedures vertical banded gastroplasty (VBG) and AGB among each other. Furthermore, four systematic literature reviews are among the included economic publications, estimating the cost-effectiveness of bariatric treatments based on published data. The focus of the reviews lies both, on the comparison of the cost-effectiveness among the bariatric procedures, as well as on the comparison to no treatment at all.
The economic rating concentrates on the cost-effectiveness, while the medical effectiveness is based on health benefits gained from the intervention. The evaluation of the regarded studies shows that the authors come to rather incongruent conclusions, depending on the model population, method, and location chosen.

Included ethical, social and legal publications

Due to the lack of expert publications on ethical, social and legal implications of obesity surgery, an evaluation of the literature is not possible.

Discussion

Discussion of medical aspects

Primary objective of the present HTA-report is a comparison of surgical and conventional therapies in morbid obesity. Only three medical non-randomised clinical studies target this comparison. All other studies, including all RCT as well as all reviews, only present findings on the comparison of different surgical procedures among each other. Overall there is a lack of valid studies, thus only few conclusions can be drawn. Not one of the included studies fulfils all a priori layed down quality criteria and only about half can be rated as good quality. Studies show considerable heterogeneity

regarding the surgical techniques, the definition of the study population, the length of follow-up, and the presentation of outcomes. Thus comparability of studies among each other is limited. Furthermore none of the included studies are blinded. However blinding of the investigator and the statistician with respect to the outcome would have been possible and desirable. Especially studies comparing different surgical procedures often have a short follow-up and are of limited methodological quality. In conclusion however, the present HTA-report could show a greater weight loss after bariatric surgery. Comparing bariatric procedures among each other, malabsorptive procedures lead to a more profound weight loss than purely restrictive procedures. The weight reduction following either procedure is accompanied by a lower frequency of comorbidities (mostly diabetes type 2) and a decrease overall mortality. The evidence is not sufficient to quantify these effects for individual procedures. Only few studies assess long-term outcomes and safety. However, latest study results show lasting effects accompanied by a survival benefit for surgically treated patients for up to ten years.
Future studies should not exclusively focus on weight loss, but also comorbidities of obesity and surgical interventions, and assess nutritional difficulties, micronutrient deficiencies and patient relevant outcomes such as quality of life or satisfaction. The investigator and statistician at least should be blinded. As the superiority of individual bariatric procedures can not be concluded based on the present studies, further data on the surgeries and possible complications is needed. In this context the effect of patient or therapist related factors on the medical effectiveness/efficacy or safety of individual surgical procedure needs to be thoroughly assessed.

Discussion of economic aspects

One study that deals specifically with the question whether a bariatric surgery procedure is cost-effective over a conservative treatment can be identified within this HTA-report. Adjustable gastric banding and gastric bypass were cost-effective in the three European countries. Specifically, both bariatric surgical approaches were more effective and less expensive than conventional treatment in France and Germany, while they were highly cost-effective in the UK. One study compares GBP to no treatment. The other study assesses the two surgical procedures VBG and AGB. All included systematic reviews compare different surgical procedures with each other. They conclude that treatments with a GBP are cost-effective over VBG. The comparison of GBP and laparoscopic adjustable gastric banding LAGB indicates none to be cost-effective over the other. The application of an AGB is cost-effective, compared to treatment with a VBG.
In summary, all bariatric procedures seem to be cost-effective over conservative treatments and over no treatment, but with number, quality, and transferability of the cost-effectiveness analyses being quite low, do not permit a final conclusion. Furthermore, no final conclusion can be drawn on the comparability of the cost-effectiveness of bariatric surgery procedures with each other. The most efficient surgical procedure cannot be identified because the number of cost-effectiveness studies is limited, not every surgical possibility is included in the comparison, and post-surgical monitoring time span is too short to derive reliable results. Additionally, the various studies reach different conclusions, thus disabling a common basis for a decision process in health politics.

Discussion of ethical, social and legal aspects

No relevant publications dealing with ethical, social, or legal aspect of the topic can be identified in the course of this HTA-report. However, psychological aspects play an important role in the course of and the coping with the disease, since obesity in most cases seriously diminishes life quality.

Conclusion/recommendations

The short and medium term effectiveness of bariatric procedures on weight loss can be assumed and is cost-effective. The weight loss is generally accompanied by a reduction of comorbidities, in particular diabetes, and a decreased overall mortality. There is a lack of studies that focus long term effects and costs. Therefore, based on the available literature no recommendation can be given with respect to the choice of a certain bariatric procedure in usual care or to the selection of particular groups of patients. However, the present results can be seen as a basis for discussion about the very restrictive practice regarding decisions on reinbursability of bariatric procedures. Furthermore, comprehensive quality assurance is needed, including the implementation of competence centres with standardised follow-up programms and the fixing of minimum amounts for procedures. In this context the long term assessment and evaluation of all patients and their course of disease is necessary, aiming at the highest possible effectiveness of medical treatment and still allowing for economic limits.