Pharmacological and surgical treatment of obesity

Residential care for severely obese children in Belgium Supplement-report

KCE reports vol. 36 Supplements

Federaal Kenniscentrum voor de gezondheidszorg
Centre fédéral d'expertise des soins de santé
Belgian Health Care Knowledge Centre
2006

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Title :	Pharmacological and surgical treatment of obesity Residential care for severely obese children in Belgium Supplement-report
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GLOSSARY OF ACRONYMS

ABMI	Adjusted body Mass Index
AETMIS	Agence d'évaluation des technologies et des modes d'intervention en santé (Canada)
AHRQ	Agency for Health Research and Quality (USA)
AHT	Arterial hypertension
ANAES	Agence Nationale d'Accréditation et d'Evaluation en Santé (France)
APR-DRG	All Patient Refined Diagnosis Related Group
ATG	Adherence to guideline
ATP	Adult Treatment Panel
BAROS	Bariatric Analyses and Reporting System
BCBS	Blue Cross Blue Shield (USA)
BMI	Body Mass Index
BNI	British Nursing index
BPD	Bilio-Pancreatic Diversion
CBA	Cost-Benefit Analysis
CEA	Cost-efficacy Analysis
CHD	Coronary Heart Disease
CIES	Centre d'Etudes Interdisciplinaires en Economie de la Santé
CINHAL	Cumulative Index to Nursing & Allied Health
CT	Conventional Treatment
CUA	Cost-utility Analysis
DALY	Disability-Adjusted Life Years
DARE	Database of Abstracts of Reviews of Effects
DRG	Diagnosis Related Group
DS	Duodenal Switch
EBW	Excess Body Weight
EMEA	European agency for the evaluation of medicinal products
EU	European Union
Eur25	Euro for the 25 member states of the European Union
EWL	Excess weight loss
FTE	Full time equivalent
FU	Follow-up
GB	Gastric Bypass
GDP	Gross Domestic Product
GERD	Gastro-oesophageal reflux disease
GHD	General hospital Dendermonde (Belgium)
HBG	Horizontal Banded Gastroplasty

HDL	High-density lipoprotein
HIS	Health Interview Survey
HTA	Health Technology Assessment
ICD-9-CM	International Classification of Diseases, 9th revision, Clinical Modification
IDF	International Diabetes Foundation
INAHTA	International Network of Agencies for HTA
INAMI	Institut National d'Assurance Maladie Invalidité
INSERM	Institut National de la Santé et de la Recherche Médicale (France)
IOTF	International Obesity Task Force
LAGB	Laparocopic Adjustable Gastric Banding
LL-RYGB	Long-limb RYGB
LL-RYGB	Long Limb Roux-en-Y-Gastric Banding
LOCF	Last observation carried forward
LOS	Length of stay
LSA	Lifestyle advice
MAS	Medical Advisory Secretariat
MBDS	Medical basic data set
MDC	Major Diagnosis Category
MSAC	Medical Services Advisory committee (Australia)
NCEP	National Cholesterol Education Programme
NCHS	National Center for Health Statistics (USA)
NICE	National Institute for Clinical Excellence (United Kingdom)
NIH	National Institute of Health (USA)
NNT	Number needed to treat
PPP	Purchasing Power Parity
PSBH	Panel Studie Belgishe Huishouden
QALY	Quality-Adjusted Life Years
QoL	Quality of life
RCT	Randomised clinical trial
RD	Risk difference
RIZIV	Rijksinstituut voor Ziekte- en Invaliditeitsverzekerin (Belgium)
RYGB	Roux-en-Y-Gastric Banding
SCOUT	Sibutramine Cardiovascular Outcome Trial
SD	Standard Deviation
SIGN	Scottish Intercollegiate Guidelines Network
SOS	Swedish Obese Subjects
TG	Triglyceride
UCL	Université catholique de Louvain (Belgium)

UK	United Kingdom
US	United States of America
UZG	Universitair Ziekenhuis Gent (Belgium)
VBG	Vertical Banded Gastroplasty (sleeve gastrectomy)
VLCD	Very low calorie diet
WHO	World Health Organisation
WL	Weight loss
WLP	Weight loss programme
WM	Weight maintenance
WMD	Weighted Mean Difference
WMP	Weight management program

APPENDIX CHAPTER 3: CLINICAL EFFECTIVENESS OF PHARMACOLOGICAL TREATMENT OF OBESITY

A: RECENT SYSTEMATIC REVIEWS ON PHARMACOLOGICAL TREATMENT FOR OBESITY

Arterburn & al

Arterburn DE, Crane PK, Veenstra DL. The efficacy and safety of sibutramine for weight loss: a systematic review. Arch Intern Med. 2004;164(9):994-1003.
Inclusion criteria RCTs, >= 18 yrs, sibutramine 10 or 20 mg, BMI >=25, at least 8 wks duration,
Last search: april 2002
Search strategy : 10 electronic databases including Medline, Cochrane Controlled Trials Registers + handsearch of bibliography of retrieved articles and grey literature.
Search results 29 studies; only 5 with in the 44-54 weeks group
Conclusions Sibutramine is more effective than placebo in achieving moderate weight loss in obese adults that receive lifestyle modifications. Discontinuing sibutramine leads to weight regain. No evidence for dose effect (10 vs 20mg) Weight loss with Sibutramine is associated with increased diastolic and systolic blood pressure, small improvements in high-density lipoprotein cholesterol and triglyceride levels, and among diabetics patients, small improvements in glycemic levels. There is insufficient evidence to accurately determine the risk-benefit profile for Sibutramine. There is a need for high quality long-terms safety and outcomes data to inform clinical decision.

Padwal & al (Cochrane review)

Padwal R, Li SK, Lau DCW. Long-term pharmacotherapy for obesity and overweight. Cochrane Database Syst Rev. 2003(4):CD004094.
Inclusion criteria RCT, BMI >= 30kg, or >= 27 kg/m2 + co-morbidity , minimum 1 yr follow-up after randomisation
Last search : december 2002
Search strategy Medline, Embase, meta-register of CC, Cochrane Controlled Trials Registers + hand search of bibliography of retrieved articles and grey literature.
Search results Sibutramine : 3 weight loss studies and 2 weight maintenance studies
Particular comments Stratification by BMI baseline not possible.. Attrition rates 32-47%
Conclusions Sibutramine and orlistat are moderately effective in promoting weight loss, Interpretation is limited by high attrition rate. There is a need for longer and more methodologically rigorous studies of anti-obesity drugs powered to examine end-points as mortality and cardio-vascular morbidity

Avenell & al

Avenell A, Broom J, Brown TJ, Poobalan A, Aucott L, Stearns SC, et al. Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement. Health Technol Assess. 2004;8(21):iii-iv, 1-182.
Inclusion criteria RCTs, adults (> 18 yrs), mean or median duration 52 weeks or more, weight loss or prevention of weight gained to be explicitly stated as a main outcome of the study, BMI >=28
Search strategy : 13 electronic databases including Medline, Cochrane Controlled Trials Registers, HealthSTAR; hand searching of various specialised journals such as Int J of Obesity
Last search: June 2001
Search results
Orlistat : 9 studies Sibutramine: 3 weight loss, one weight maintenance study
Particular comment Limitations: inadequate sample sizes, lack of long-term follow-up, few quality of life data.
Conclusions: Orlistat and Sibutramine are associated with weight loss and generally improved risk factors, apart from diastolic blood pressure for Sibutramine.

Norris & al (Cochrane review)

Norris SL, Zhang X, Avenell A, Gregg E, Schmid CH, Kim C, et al. Efficacy of pharmacotherapy for weight loss in adults with type 2 diabetes mellitus: a meta-analysis. Arch Intern Med. 2004;164(13):1395-404. Norris SL, Zhang X, Avenell A, Gregg E, Schmid CH, Lau J. Long-term non-pharmacological weight loss interventions for adults with prediabetes. Cochrane Database Syst Rev. 2005(2):CD005270.
Inclusion criteria : Patients >= 18 y.o., with type 2 diabetes, whatever the duration of follow-up. . Only RCT's for review of efficacy, all designs for review of safety
Search strategy : Medline, Cochrane Controlled Trials Registers, DARE, CRG specialized registers, HealthSTAR; Embase, CINAHL, Web of Science, Biosis, International Pharmaceutical abstracts, hand searches of various relevant journals.
Last search: june 2004
Search results
Orlistat : 8 studies Sibutramine: 8 studies
Particular comment
Conclusions: Orlistat and Sibutramine can achieve significant statistically significant weight loss over 12 to 57 weeks. The magnitude of weight loss is modest and long-terms health benefits are iunclear. The safety of sibutramine is uncertain.

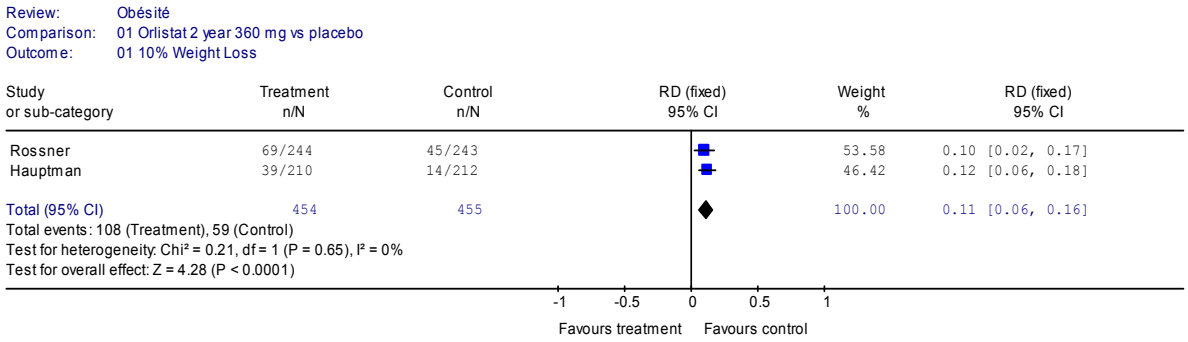
Agency for Health Care Research and Quality

Shekelle P, Morton S, MA M, Suttorp M, Tu W, Li S, et al. Pharmacological and Surgical Treatment of Obesity. Southern California-RAND Evidenced-Based Practice Center; 2004. Agency for Healthcare Research and Quality Evidence Reports (Evidence Report/Technology Assessment No. 103. AHRQ Publication No. 04-E028-2) Li Z, Maglione M, Tu W, Mojica W, Arterburn D, Shugarman LR, et al. Meta-analysis: pharmacologic treatment of obesity. Ann Intern Med. 2005;142(7):532-46.
Inclusion criteria : RCT, at least 6 month follow-up, BMI >= 27
Search strategy : numerous electronic databases including MEDLINE and EMBASE, for potentially relevant studies, + hand search of extensive reviews on sibutramine, orlistat,
Last search: July 2003
Search results Sibutramine: refers to Arterburn review. Orlistat: 29 studies
Conclusions
Qee Aterburn study
Sibutramine and Orlistat promote weight loss when given along with recommendations for diet. The amount of extra weight loss attributable to these medications is modest (less than 5 kg at one year), but this amount still may be clinically significant. No evidence indicates that any particular drug promotes more weight loss than another drug. All of these drugs have side effects.

B: ADDITIONAL DATA ON WEIGHT LOSS DRUGS

Orlistat

Table 1. Orlistat 3*120 mg + diet vs placebo + diet. Risk difference for 10% weight loss at 2 years –



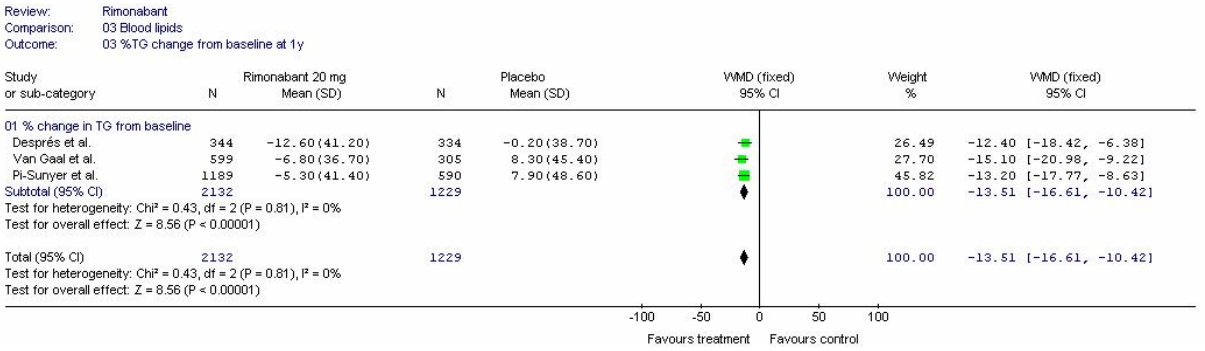
Sibutramine

Table 2. Sibutramine + diet vs placebo + diet at 18 mo. From the STORM weight maintenance study[1].

Outcome Change in	Weighted mean difference 95% CI	Test for overall effect (p)
Weight (kg)	- 3.40 (--4.45 to -2.35)	< 0.00001
Tot cholesterol (mmol/l)	-0.19 (- 0.49 to 0.11)	0.70
LDL cholesterol (mmol/l)	-0.16 (- 0.37 to 0.05)	0.07
HDL cholesterol (mmol/l)	0.13 (0.05 to 0.21)	< 0.00001
Triglycerides (mmol/l)	- 0.33 (- 0.60 to – 0.06)	0.0005
HbA_{1c}%	-0.16 (-0.36 to 0.04)	0.76
Fasting plasma glucose (mmol/l)	-0.12 (-0.50 to 0.26)	0.67
Change in SBP (mm Hg)	1.16 (-0.60 to 2.93)	0.20
Change in SDP (mm Hg)	2.04 (0.89 to 3.20)	0.0005

Rimonabant

Table 3. Rimonabant 20 mg + diet, against placebo + diet.
One year outcomes.
Triglicerides: change from baseline (%).



Meta-analysis of selected outcomes for adverse events are shown in the following tables.

Table 4. Rimonabant 20 mg + diet vs placebo + diet.
One year outcomes.
Any serious adverse event (risk difference).

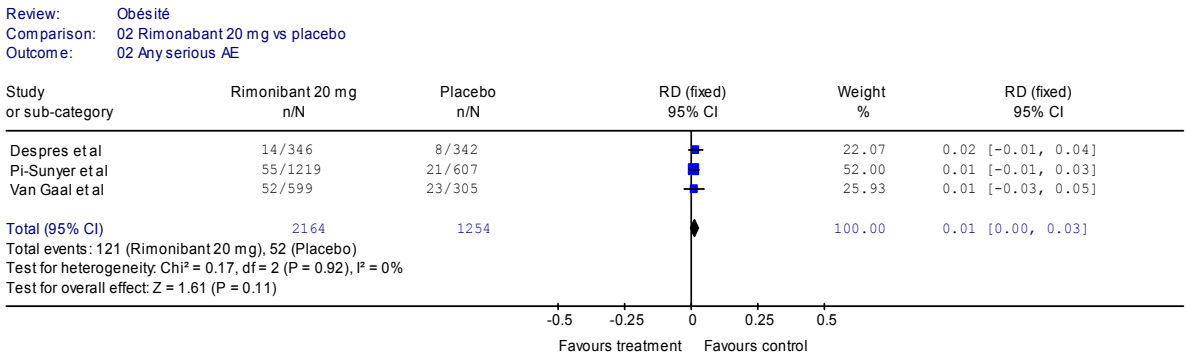


Table 5. Rimonabant 20 mg + diet vs placebo + diet.
One year outcomes
Any adverse leading to discontinuation (risk difference)

Review: Obésité
Comparison: 02 Rimonabant 20 mg vs placebo
Outcome: 03 Any AE leading to discontinuation

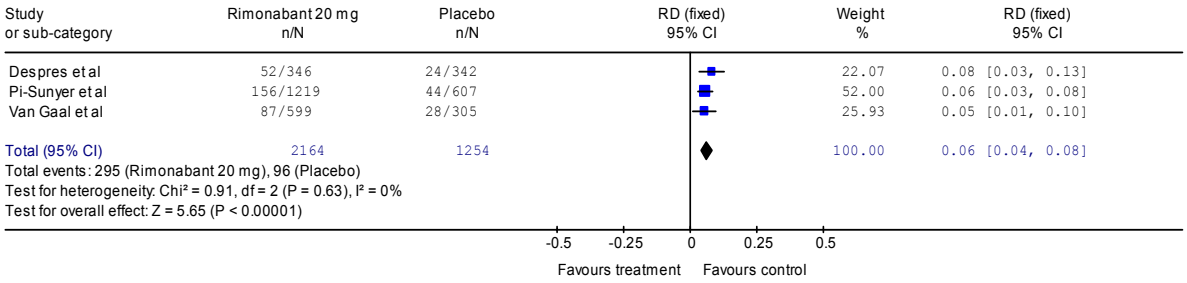
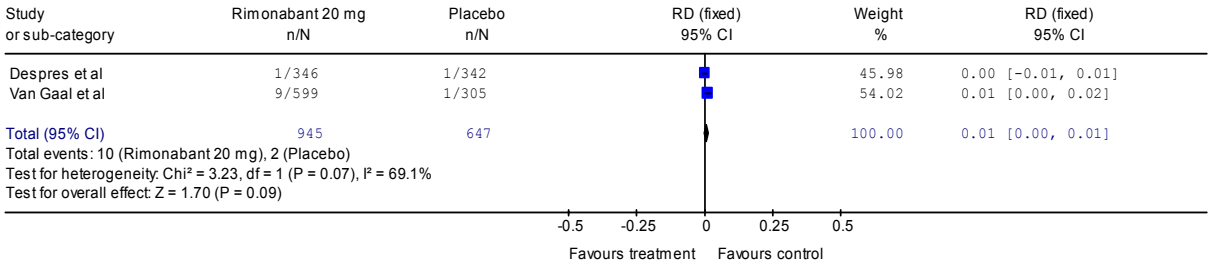


Table 6. Rimonabant 20 mg + diet vs placebo + diet.
One year outcomes
Any serious psychiatric disorders (risk difference).

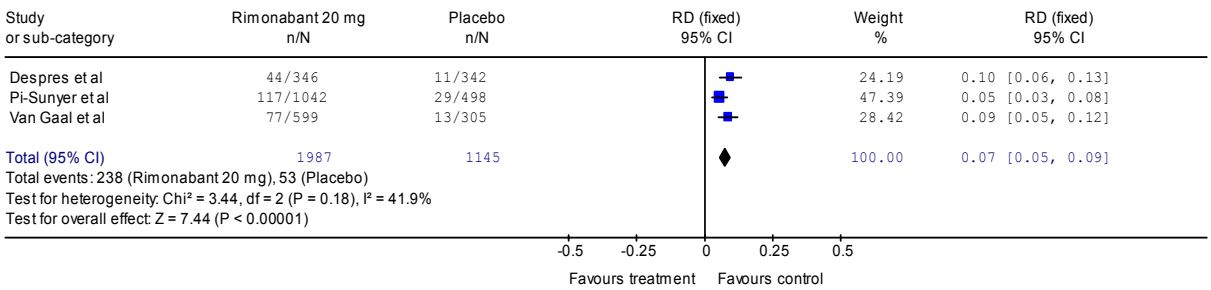
Review: Obésité
Comparison: 02 Rimonabant 20 mg vs placebo
Outcome: 04 Any Serious Psychiatric Disorder



Data not available in Pi-Sunyer study.

Table 7. Rimonabant 20 mg + diet vs placebo + diet.
One year outcomes.
Nausea (risk difference)

Review: Obésité
Comparison: 02 Rimonabant 20 mg vs placebo
Outcome: 05 AE: Nausea (all)



REFERENCE

1. James WP, Astrup A, Finer N, Hilsted J, Kopelman P, Rossner S, et al. Effect of sibutramine on weight maintenance after weight loss: a randomised trial. STORM Study Group. Sibutramine Trial of Obesity Reduction and Maintenance. Lancet. 2000;356(9248):2119-25.

APPENDIX CHAPTER 4: COST-EFFECTIVENESS OF PHARMACOLOGICAL TREATMENT

LITTERATURE REVIEW ON COST-EFFECTIVENESS

Research strategy

Via Ovid :

Keywords :

Cost or economic or cost-efficacy or cost-effectiveness or cost-utility or cost-benefit

And obes$

And surg$ or therapy or treatment or pharmaco$ or medical or sibutramine or orlistat or rimonabant

And between 1995-2006

Results :

Medline search :	663
Cochrane Library :	188
CINAHL :	105
ACP Journal Club :	16
DARE	75
BNI :	1
Total :	1048

Via NHS CRD :

Keywords : Cost and obes$

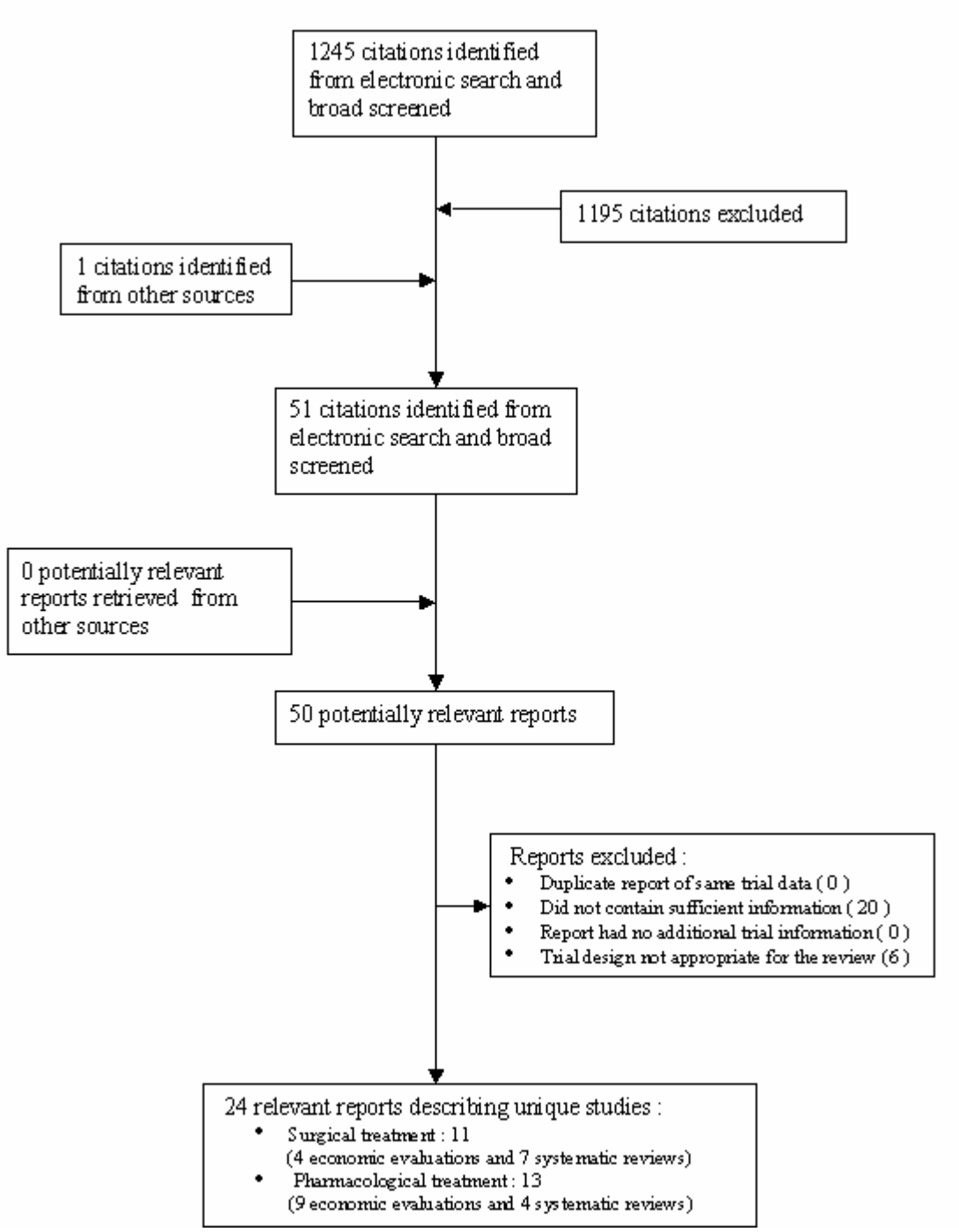
Results :

NHS EED :	170
HTA :	27
Total :	197

Total

Total number of citations :	1245
Citations indentified from other sources :	1
Selection on abstract :	50
Number of relevant report :	24
Surgical treatment :	11
Orlistat / Sibutramine :	13

Flow diagram



DATA EXTRACTION FORM

Author	Lamotte M, Annemans L, Lefever A, Nechelput M, Masure J
Funding	Roche Pharmaceuticals
Year	2002
Country	Belgium
Design	CEA - markov model (with 6-month cycles)
Perspective	Health-care consumer
Time window	10 year
Interventions	Orlistat versus no Orlistat (2-year treatment)
Population	Obese type 2 diabetic patients without micro- or macrovascular complications. Four sub-groups : patients with hypertension (AHT), with hypercholesterolemia, with both or with no other conditions
Assumptions	1) Patients could not have both micro- and macrovascular complications states within the same 6 months
	2) Improvements of risk factors lead to a reduction of the number of complications
	3) The effects of orlistat on LDL cholesterol were independent of effects on HbA_{1c}
	4) 4,2% of patients treated with orlistat could stop oral antidiabetes treatments and that 10,1% reduced medication by 24,8%
	5) Risk for complications and mortality returns to placebo values 5 years after discontinuation of orlistat, thus after 7 years.
	6) HbA_{1c} values increased over time
	7) Micro and macrovascular complications were not present at entry and increased linearly over time
Data source for costs	Van Gaal et al.[1]
Cost items included	Not specified
Data source for outcomes	Weight-loss : 1-year, randomised, placebo-controlled, double-blind comparative trial in obese patients with type 2 diabetes : Hollander[2] / Diabetic complications : Clark[3], Koskinen[4], UKPDS 33[5], UKPDS 34[6], UKPDS 38[7]
Discounting	Costs : 3% / effects : 0%
Costs results	Total incremental costs per patient
	For patients free of events : 1,608 €
	For patients with Hypercholesterolemia : 1,514 €
	For patients with AHT : 1,678 €
	For patients with Hypercholesterolemia and AHT : 1,641 €
Outcomes results	Life-years gained by patient
	For patients free of events : 0,08
	For patients with Hypercholesterolemia : 0,204
	For patients with AHT : 0,227
	For patients with Hypercholesterolemia and AHT : 0,474

Cost-effectiveness	Incremental cost-effectiveness ratio (ICER) by patient : (euros per life-year gained)
	For patients free of events : 19,986 €
	For patients with Hypercholesterolemia : 7,407 €
	For patients with AHT : 7,388 €
	For patients with Hypercholesterolemia and AHT : 3,462 €
Sensitivity analysis	Discounting effects by 3% increased the ICER to 23,522 € for patients free of events and to 4,062€ for patients with both AHT and hypercholesterolemia
	With a variation in the effect of orlistat on HbA1c using the standard deviation as interval, the ICER ranged between 28,164 € and 14,751 € for patients free of events and between 3,930 € and 3,055 € for patients with both AHT and hypercholesterolemia
	With a reduction of 50% in effect of orlistat on LDL cholestreol, the ICER amounted to 4,339 € for patients with hypercholesterolemia and 9,596 € for patients with both AHT and hypercholesterolemia
	With a reduction of the catch-up period to regain weight to 2,5 years, the ICER increased to 26,527 € for patients free of events and to 4,565 € for patients with both AHT and hypercholesterolemia
Conclusion	Orlistat is cost-effective in the management of obese diabetic patients, especially with the presence of hypercholesterolemia and/or hypertension.
Remarks	1) They did not directly assess the effect of weight loss on complications and death. They used estimated risk factors associated with orlistat and the related weight loss.
	2) Other complications like end-stage renal disease, blindness or second amputations were not modelled
	3) Results are sensitive to the period of treatment effects persistence and the long-term clinical impact of orlistat for this population is unknown
	4) The health-related quality of life was not calculated.

Author	Foxcroft R
Funding	Commissioned by Roche Products Ltd
Year	2005
Country	UK
Design	CUA - model
Perspective	Health care payer perspective (not clearly specified)
Time window	1 year
Interventions	Orlistat 120 mg 3x/day + mildly hypocaloric diet versus placebo + mildly hypocaloric diet during 1 year. Two models are compared : Guidance from the NICE (National Institute for Clinical Excellence) and guidance from the EMEA (European agency for the evaluation of medicinal products). NICE criteria responders (> 2,5 kg weight loss pre-treatment, > 5% weight loss at 3 months, > 10 % weight loss at 6 months), EMEA criteria responders (> 2,5 kg weight loss pre-treatment, > 5% weight loss at 3 months). For non responders, Orlistat was stopped.
Population	Patients with a body mass index (BMI) of over 30 kg/m or over 28 kg/m with associated risk factors, who have already responded to a weight reducing regimen with a weight loss of at least 2,5 kg within 4 weeks.
Assumptions	1) 5 general practitioner visits would be required.
	2) Prescriptions are provided by general practitioners and not by more expensive hospital specialists
	3) No responders experienced no benefit
Data source for costs	PSSRU[8], Foxcroft[9, 10], Hoffmann-La Roche Ltd,
Cost items included	Prescription and general practitioner consultations costs. (Mildly hypocaloric diet costs not included)
Data source for outcomes	Three european trials : Sjöström[11], Finer[12], Rössner[13] provided by Hoffmann-La Roche Ltd /utility gains : Hakim[14].
Discounting	Not justified
Costs results	Total cost for 100 patients in the orlistat group : For NICE criteria : 22,744.8 £ / For EMEA criteria : 27,823.5 £
Outcomes results	QALYs gained for 100 patients : For NICE criteria : 0,931 / For EMEA criteria : 1,464
Cost-effectiveness	For NICE criteria : 24,431 £/QALY / For EMEA criteria : 19,005 £/QALY
Sensitivity analysis	Health benefit (QALY) and costs data were varied. As results : For NICE criteria : ICER ranged from 10,856 £/QALY to 77,197 £/QALY / For EMEA criteria : ICER ranged from 8,840 £/QALY to 57,798 £/QALY
Conclusion	The cost-utility of Orlistat treatment is improved when based on recent NICE guidance criteria in comparison with a previous model[10] and the less restrictive EMEA criteria should be considered in any future changes to the NICE criteria because of a better cost/Qaly ratio
Remarks	1) This model is limited to one year results, a possible rebond weight gain in the subsequent years and the long-term mortality and morbidity are thus not included. 2) Utility for weight loss is lower than in the previous model[10]. It is a conservative estimate. 3) The average one-year weight loss for all patients used in this model is similar with the results of a Cochrane systematic review[15]. 4) For non-responders patients, the costs are included in the model but the benefits not. 5) Results are extremely sensitive to health benefit and costs variations.

Author	Foxcroft DR, Milne R
Funding	Wessex Development and Evaluation Service
Year	Study year : 2000 / costs year : not specified (£)
Country	UK
Design	CUA
Perspective	Not clearly specified : NHS perspective ?
Time window	Not clearly specified : 2 years ?
Interventions	Orlistat 120 mg 3x/day + mildly hypocaloric diet versus placebo + mildly hypocaloric diet during maximum 2 years. For non responder patients (< 5% weight loss at 3 months), Orlistat was stopped.
Population	Patients with a body mass index (BMI) over 30 kg/m or over 28 kg/m with associated risk factors, who have already responded to a weight reducing regimen with a weight loss of at least 2,5 kg within 4 weeks
Assumptions	4 consultations per year Assumptions on costs and utilities
Data source for costs	Extracontractual referral tariffs and other less precise costs estimates, local NHS Trust
Cost items included	Outpatient appointments, general practitioner consultations and Orlitat costs
Data source for outcomes	Weight loss : 3 randomized clinical trial : Sjöstrom[11], Davidson[16], Hollander[2] / Quality of life :[17-24]
Discounting	Not specified
Costs results	Direct average cost for 100 patients treated for 2 years : £73,436
Outcomes results	QALYs gained for 100 patients treated for 2 years : 1.60
Cost-effectiveness	£45,881/QALY
Sensitivity analysis	Results range between £13,541 to £131,918 (parameter estimated not specified)
Conclusion	Orlistat may be effective for some obese people over 2 years as an adjunct to diet but further research is needed
Remarks	EMEA prescription indications for orlistat do not coincide with published trial used in the model. Results in the clinical pratice could thus be different. The study period is too short and long term results are uncertain. Cost data are not clear (sources ?, assumptions ? .) Estimation of QALYs is not clear. Variable tested in the sensitivity analysis are not clear and results are extremely sensitive to parameter variations. Population characteristics are not described (rate of patients with initial obesity-related co-morbidities and which co-morbidities?).

Author	Hertzman
Funding	Employed by Hoffmann-La Roche
Year	2005
Country	Sweden
Design	CUA
Perspective	Swedish healthcare payer
Time window	Not clear : 10 years
Interventions	1) a 12-month orlistat 120 mg 3x/day therapy + a 12-month diet versus placebo + a 12-month diet. For non-responders (< 5% weight loss at 3 months), orlistat was stopped after 3 months but diet was continued.
Population	Patients aged over 18 years, with a BMI over 30 kg/m , without diagnosed diabetes and who have already responded to a weight reducing regimen with a weight loss of at least 2,5 kg within 4 weeks.
Assumptions	1) For orlistat 'non responders', the 12 months weight-loss level was assumed to be the same as for patients in the placebo group
	2) the catch-up period to regain weight after therapy (= period of weight sustainability) is assumed to be of 3 years
	3) Temporary weight loss was assumed to reduce the risk of diabetes and thus the expected cost of treating and controlling patients diagnosed with diabetes
	4) It was assumed that all patients developing diabetes were immediately diagnosed and treated
	5) The number of outpatient physician visits was assumed to be the same in the two groups (4 doctors and 4 dieticians visits during a 12-month period)
Data source for costs	2003 public price in Sweden, Jönsson[25], Henriksson[26], Brandle[27]
Cost items included	Acquisition costs for orlistat, health care costs for visits to doctors and dieteticians diet programme and reduction in cost of controlling and treating diabetes
Data source for outcomes	1-year efficacy and safety of Orlistat : Rössner[13], Hauptman[28], Sjöström[11], Davidson[16], Finer[12] / Changes in Incidence of type 2 diabetes, hypertension and hyperlipidaemia : Field[29] / effect of a change of BMI on utility (QALY) : Hakim[14], Mathias[30]
Discounting	Costs : 3% / Outcomes : 3%
Costs results	Incremental cost of treatment : 444 € / Incremental cost of controlling and treating diabetes : -45 € / Total incremental cost/patient : 399 €
Outcomes results	Incremental QALY gain per patient : 0,0304
Cost-effectiveness	Incremental cost per QALY gained (ICER) : 13,125 €

Sensitivity analysis	Change in the period of weight sustainability period (1 year-5years) : ICER : 27,097 € - 8,527 €
	Change in the discount rate (0%-5%) : ICER : 12,413 € - 14,712 €
	Change in utility transformation (1.3-2.4) : ICER : 11,735 € - 16,352 €
	Change in doses per day (2.1-3.0) : 11,875 € - 17,500 €
	Change in BMI at baseline : 30-39 : 16,480 €-11,970 €
	Women's diabetes incidence (base-case male) : ICER : 14,033 €
	Women's diabetes incidence and women's weight-loss utility (base-case male) : ICER : 8,7536 €
	Additional utility loss 0.1 when experiencing diabetes : ICER : 10,962 €
	No diabetes incidence change related to temporary weight loss : ICER : 14,605 €
	No-diet comparator : ICER : 7,730 €
	No-diet comparator and for orlistat non-responders no weight change over study period and no drug and diet cost after 3 months : ICER : 9,744 €
	Diet only compared with no diet : ICER : 8,966 €
Conclusion	Treatment with orlistat and diet compared with diet only, using a responder criterion, gives an ICER comparable with many accepted healthcare interventions
Remarks	The assumption on the period of weight sustainability have an important impact on the result. It is thus crucial to better understand the long-term effect of orlistat on weight loss. It is also important to better understand the effect of orlistat on the prevention of diabetes and other long term morbidities
	The effect of weight loss on other co-morbidity and mortality was not included
	The effect of treatment complications on the withdrawal rate is not considered

Author	Malone DC, Raebel MA, Porter JA, Lanty FA, Conner DA, Gay EC, Merenich JA, Vogel EA
Funding	Knoll Pharmaceutical Company
Year	2005
Country	USA
Design	CEA
Perspective	a managed care organization perspective
Time window	1 year : 12 months after study enrollment compared with 12 month before study enrollment
Interventions	Sibutramine + structured weight management program (WMP) versus only structured WMP
Population	Patients aged over 18 years, with a BMI over 30 kg/m or a BMI of 27-29,9 kg/m with one or more comorbidities (diabetes, hypertension, and/or hyperlipidemia)
Assumptions	Drug costs used in the study are overstated (conservative estimates)
Data source for costs	Electronic medical records and administrative claim and clinical databases maintained and used by Kaiser Permanente of Colorado (KPCO) and center for Medicare services[31]
Cost items included	Outpatient visits, hospitalizations, professional services claims and prescription medications. For these units, obesity-related utilization and costs were also analyzed
Data source for outcomes	One prospective randomized 12-month study : Porter[32]
Discounting	Not justified
Costs results	Total health care expenditure costs differences between 12 months after and before enrollment : Sibutramine + WMP group : 1,279 $ (IC 95%: -2,399/131,090) WMP group : 271$ (IC 95%: -4,217/63,840) P-value = < 0,001 / Obesity-related total health care expenditure costs : Sibutramine + WMP group : 408$ (IC 95%: -6,077/4,868) WMP group : 31$ (IC 95%: -6,091/3,519) P-value : < 0,001
Outcomes results	Weight loss at 12 months : Sibutramine + WMP group : 13.7 +/- 15.5 pounds (range : -85 - +20) / WMP group : 5 +/- 13.2 pounds (range : -79/+20) P-value : < 0,001. The percentage change in weight : Sibutramine + WMP group : -6% / WMP group : -2.2% P-value : < 0,001
Cost-effectiveness	Incremental cost-effectiveness ratio (ICER) : 44$ per additional pound of weight loss (IC 95 % : 42-46) and 101$ per each additional percentage change in weight loss (IC 95% : 99-102)
Sensitivity analysis	When median costs and weight-loss values were used : ICER : 42$ per additional pound of weight loss
	When total costs instead of obesity-related costs only were used : ICER : 194 $ per additional pound of weight loss (IC 95 % : 188-200] and 399$ per each additional percentage change in weight loss (IC 95% : 391-406)
	When the cost of sibutramine was excluded : the mean obesity-related total costs was 19$ +/- 721$ for the sibutramine + WMP group and 54$ +/- 582 $ for the WMP group. (Sibutramine + WMP = dominant strategy)
	When the cost of clinic visits was increased by 50 % : ICER = 45 $ per additional pound of weight loss

Conclusion	ICER of sibutramine + WMP was 44$ per additional pound of weight loss compared with a WMP alone. This result is primarely due to the cost of sibutramine and the additional weight loss.
Remarks	1) This model is limited to one year results, a possible rebond weight gain in the subsequent years and the long-term mortality and morbidity are thus not included. 2) Subject were not blind to treatments 3) Drug costs used in the study are overstated (conservative estimates)

Author	Warren E, Brennan A, Akehurst R
Funding	Knoll Ltd
Year	2004
Country	UK
Design	CUA
Perspective	NHS perspective
Time window	5 years
Interventions	12 month of sibutramine + diet and lifestyle advice versus placebo + diet and lifestyle advice. For the sibutramine group : patients took 10 mg of sibutramine at the beginning. Non-responders (< 2kg weight loss at 1 month or < 5% weight loss at 3 months) took 15 mg of sibutramine for a further 3-month period and, if after this period, weight loss was < 5%, sibutramine was stopped.
Population	Patients aged between 18-65 years, with a BMI between 27 and 40 and without risk factors
Assumptions	When nonresponders were removed from sibutramine treatment, their weight were rose immediately to the natural history level and subsequent weight regain continued to follow the natural history rate
	The model assumed that all patients except non responders gained 0,385kg/month after treatment cessation until their weight reached a level consistent with the natural history growth rate (50 months for the sibutramine group and 18 months for the placebo group)
	UK MODEL : For the sibutramine group : the model assumed that 1 monthly general practitioner (GP) visit during the first year and 1 monthly nurse consultation in the subsequent 4 years were needed for the monitoring. This monitoring was stopped for non responders or when the group's weight regain reached natural history. For the placebo group : the model assumed that 1 monthly general practitioner (GP) visits during the first year and 1 monthly nurse consultation during the second year were needed (no monitoring costs after 2 years) / US MODEL : 1 GP visit each 3 months until the end of year 2. No nurse consultations included. The sibutramine and placebo patients received the same monitoring schedule.
	It was also assumed that patients with adverse events related to therapy incurred the cost of 1 GP consultation
	It was assumed that 33,33% of all CHD events were fatal
	It was assumed that males have the same incidence of diabetes than females from the study of Colditz
	The difference in incidence of diabetes between the sibutramine and placebo groups was assumed to narrow in proportion to weight regain
	A utility multiplier of 0,945 was used to represent the quality of life reduction associated with diabetes
Data source for costs	British national formulary[33] , Netten[34], Department of health : London[35], Pickin[36], Russel[37]
Cost items included	Drug costs, patient monitoring, saving associated with avoided coronary heart disease (CHD) and diabetes events
Data source for outcomes	Data on file Knoll-AG, data on file SAT trial / Weight-loss and weight regain : Smith[38], James[39], Heitman[40] / Utilities : Samsa[41], England and Wales life tables[42], United states life tables[43], Kind[44] / CHD : Anderson[45], Kuntz[46] / diabetes : Colditz[47], Sjostrom[48], de Grauw [49]
Discounting	UK MODEL : Costs : 6%, QALYs : 1,5% / US MODEL : costs and QALYs : 3%
Costs results	For the UK model : Total incremental cost for 1000 patients over 5 years = 281,791 £ / For the US model : Total incremental cost for 1000 patients over 5 years = 491,999 $

Outcomes results	Number of events avoided : in year 1 : 0.28 nonfatal CHD, 0.14 CHD-related deaths and 0.94 incident cases of diabetes / in subsequent 4 years : a further 0.36 nonfatal CHD, 0.18 CHD-related deaths and 0.60 incident cases of diabetes
	Total QALYs gained for 1000 patients over 5 years : For the UK model : 58.95 / For the US model : 52.91
Cost-effectiveness	Cost per QALY : For the UK model = 4,780 £ / For the US model : 9,299$
Sensitivity analysis	When excluding CHD and or diabetes benefits, ICER varied from 11,314 £ to 19,125 £ for the UK model and from 9,747 $ to 15,798 $ for the US model
	With a 10% mortality rate for CHD events instead of 33,33%, ICER was of 11,903 £ for the UK model and of 9,471 $ for the US model
	With a variation in the weight regain using the confidence interval (CI) limits : ICER varied from 10,155 £ to 10,886 £ for the UK model and from 8,700 $ to 9,852 $ for the US model
	With a variation in the utility per kilo lost using the confidence interval (CI) limits : ICER varied from 5,965 £ to 16,682 £ for the UK model and from 5,643 $ to 33,069 $ for the US model
	With a change in the frequency of monitoring, ICER varied from 8,897 £ to 19,899 £ for the UK model and from 10,473 $ to 17,187 $ for the US model
	With a change in the compliance rate from 30% to 75%, ICER varied from 14,271 £ to 34,905 £ for the UK model and from 12,599 $ to 22,045 $ for the US model
	With a discount rate for cost and QALY of 3 % , ICER was of 10,776 £ for the UK model
	When excluding adverse events, ICER was of 10,505 £ for the UK model and of 9,269 $ for the US model
	By considering all situations investigated : ICER varied from 5,809 £ to 34,260 £ for the UK model and from 5,242 $ to 61,758 $ for the US model
Conclusion	Sibutramine is a cost-effective treatment for obesity when combined with diet and lifestyle advice. This results is very sensitive to utility associated with weight loss and to the frequency of monitoring.
Remarks	1) It was assumed that adverse effects required 1 GP consultation but it is possible that an adverse effect requires more resources. With this model, sibutramine would become no longer cost-effective with side effects that cost 900 £ (1,487 $). 2) This model included only two comorbidities (CHD and diabetes). Hughes et al suggested that 10 comorbidities are commonly associated with obesity (hypertension, angina, hyperlipidaemia, cerebrovascular disease, digestive disease, osteoarthritis, cancer of the uterus and cancer of the colon. With the introduction of all of the comorbidities in the model, the ICER would be likely to decrease. 3) This model did not estimate the ICER for an obese population in which comorbidities are already prevalent. 4) No evidence was found in the literature relating to the diet and exercise monitoring costs of obese patients. However, results are fairly sensitive to this variables. Further research are thus needed. 5) CHD and diabetes benefits were estimated using a model and not a clinical trial. 6) Results are sensitive to the utility gained per kilo lost.

Author	Maetzel A, Ruof J, Covington M, Wolf A
Funding	Roche Pharmaceuticals
Year	2003
Country	USA
Design	CEA - markov model (with 1-year cycles)
Perspective	US healthcare provider
Time window	11 years
Interventions	Orlistat 120mg 3X/day during 1 year + adherence to guideline [ATG] care during 10 years versus ATG care alone during 11 years. ATG care = use of standard type 2 diabetes pharmacotherapy (sulphonylureas, metformin or insulin) and weight management (diet and physical activity) adherent to current standards of medical care for patients with diabetes.
Population	Obese patients with type 2 diabetes and without diabetes-related complications (male patients aged of 52 years)
Assumptions	1) A patient could experience no more than two-related complications during the lifetime of the model (11 years)
	2) HbA_{1c} reductions were directly translated into reductions of the incidence of diabetes-related complications
	3) Risk for complications and mortality returns to placebo values in function of weight catch-up over the 3 years after discontinuation of orlistat, thus after 4 years.
	4) The increase of complications with age was partially captured by an increase of HbA_{1c} value but no additional age effect was modelled. HbA_{1c} values increased over time
	5) Complications were not present at entry and increased linearly over time
	6) No gender effect was modelled
	7) No second course of orlistat was modelled during the 10-year follow-up period
Data source for costs	Hoerger TJ et al. (unpublished data), O'Brien[50], Costliest outpatient procedures[51], IMS Health[52]
Cost items included	Not specified

Data source for outcomes	Weight-loss : 1-year, randomized, placebo-controlled, double-blind comparative trials in obese patients with type 2 diabetes : Hollander[2], Hanefeld[53], Kelley[54], Miles[55]/ diabetic complications : UKPDS 35[56]
Discounting	Costs : 3% / effects : 3%
Costs results	Total incremental costs per patient : 1,122 US$
Outcomes results	Life-years gained by patient : 0,13 years
Cost-effectiveness	Incremental cost-effectiveness ratio (ICER) by patient : (euros per lifes-year gained) : 8,327 US$
Sensitivity analysis	95 % of the ICER ratios were of less than 20,000 US$. With the use of a raw annual HbA_{1c} instead of a mean updated HbA_{1c} and with a 1-year persistence of effect period instead of 3 years : The ICER ratio was of 23,574 US$
Conclusion	Adding orlistat to conventional diabetes pharmacological and weight management approaches for the treatment of obese patients with type 2 diabetes is cost-effective. Observational data to support long-term use of orlistat are needed to validate these results
Remarks	1) They did not directly assess the effect of weight loss on complications and death 2) They did not take into account possible reduction in lipid parameters or blood pressure and their additional impact on cardiovascular health 3) Other complications like end-stage renal disease, blindness or second amputations were not modelled 4) The costs for treating congestive heart failure were too low because subsequent hospitalizations costs, outpatient and physician services and pharmacological costs were not included 5) Results are sensitive to the period of treatment effects persistence and the long-term clinical impact of orlistat for this population is unknown 6) The results only apply to male patients with 52 years of age. With the inclusion of female patients the ICER ration would probably be higher since the rate of complications in females is half that in males 7) Costs item included in the model were not specified 8) The health-related quality of life was not calculated

Author	Ruof J, Golay A, Berne C, Collin C, Lentz J, Maetzel A
Funding	Employed by Roche
Year	costs : 2001 (€)
Country	Germany
Design	CUA / Model
Perspective	Not specified
Time window	11 years
Interventions	Orlistat 120 mg 3x/day therapy + weight program (diet + exercise) + standard antidiabetic drugs versus placebo + weight program (diet + exercise) + standard antidiabetic drugs during 1 year. For non responding patients (>= 5% weight loss at 12 weeks), orlistat was stopped.
Population	Overweight and obese patients with type 2 diabetes and with no diabetes-related complications. At baseline : Mean age : Orlistat group : 54.5 , Placebo group : 54.5 / BMI : Orlistat group : 34.6, Placebo group : 34.8
Assumptions	The treatment-related effect on HbA1C was lost in the 3 years after treatment The utility loss due to cataract is assumed to be -0.04 Outcomes results for no responding orlistat patients are assumed to be similar to those in no responding placebo patients
Data source for costs	Public sources (Sweden and Switzerland) / ICD 10 code
Cost items included	Medication costs (orlistat + antidiabetic drugs) and diabetes-related complications costs (Acute myocardial infarction, sichemic stroke, amputation, microvascular disease, heart failure and cataract
Data source for outcomes	Clinical data : 7 randomized controlled trials[2, 57, 58, 53-55, 59]/ diabetes related micro- and macrovascular complications and change in HbA1C : United Kingdom Prospective Diabetes Study (UKPDS 35)[56] / utilities changes due to decreases in BMI : Hakim[14], Hauptman[28]/ utilities associated with myocardial infarction : Mark[60], with stroke : Hiatt[61], with amputation : Sullivan[62], with microvascular disease : Churchill[63] and with Heart failure : Havranek[64]
Discounting	3% (for costs and QALYs?)
Costs results	Not specified
Outcomes results	Not specified
Cost-effectiveness	Sweden : 14,000 €/QALY / Switzerland : 13,600 €/QALY
Sensitivity analysis	Response definition : >= 3 % weight loss : Sweden : 11,500 €/QALY / Switzerland : 11,100 /QALY ; >= 0,6% reduction in HbA1c : Sweden : 15,500 €/QALY / Switzerland : 15,500 /QALY Persistence of HbA1C effect : 2 years : Sweden : 20,700 €/QALY / Switzerland : 21,300 /QALY ; 5 years : Sweden : 7,800 €/QALY / Switzerland : 7,000 /QALY Discount rate : 0% : Sweden : 13,300 €/QALY / Switzerland : 13,200 /QALY ; 5% : Sweden : 14,200 €/QALY / Switzerland : 14,100 /QALY Costs : Lower range : Sweden : 14,000 €/QALY / Switzerland : 14,000 /QALY; upper range : Sweden : 7,900 €/QALY / Switzerland : 7,500 /QALY Time horizon of model : 5 years : Sweden : 18,200 €/QALY / Switzerland : 18,300 /QALY Change in utility per 1 unit reduction in BMI : 0,0170 (base case 0,0285) : Sweden : 18,000/QALY / Switzerland : 17,900 /QALY

Conclusion	Orlistat is a cost-effective strategy for overweight and obese diabetic patients who respond to the treatment
Remarks	Cost data are not clear (direct costs or indirect costs ?, sources ?, results ?) Follow-up for weight-loss data is too short but diabetes related complications are based on a prospective study with a time of follow-up of 10 years Outcomes results are not specified Patients with other risk factors are not included (hypercholesterolemia, hypertension,…)

Author	Lacey LA, Wolf A, O'Shea D, Erny S, Ruof J
Funding	Employed by Roche
Year	costs : 2003 (€)
Country	Ireland
Design	CUA, model
Perspective	Irish health-care system
Time window	11 years
Interventions	Orlistat 120 mg 3x/day therapy + dietary programme versus placebo + dietary programme during 1 year. For non responding patients (>= 5% weight loss at 3 months), orlistat was stopped.
Population	Patients aged of >= 18 years, with a BMI >= 28kg/m , with no diagnosed type 2 diabetes and with > 2,5 kg weight loss pre-treatment. Initial BMI : Orlistat group : 36.4 (IC 95% : 36.0-36.5), Placebo group : 36.2 (IC 95% : 35,9-36.5)
Assumptions	A 10% reduction in BMI reduce the annual incidence of diabetes by 30% After 1 year, patients regain their original weight at a uniform rate over the following 3 years Diabetes-related savings are assumed to be null in the placebo group For no responding orlistat patients, weight loss is similar to weight loss in the placebo group
Data source for costs	Unit costs : Public prices, Medical publications in Ireland[65] / diabetes monitoring and treatment health-care costs : Clarke[66]
Cost items included	Cost of orlistat, cost of dietary programme and monitoring and treatment costs associated with type 2 diabetes
Data source for outcomes	Weight loss : 5 randomized clinical trials : Finer[12], Davidson[16], Sjostrom[11], Rossner[13], Hill[67]/ incidence of type 2 diabetes : Field[29]/ utilities : Hakim[14], Hauptman[28], Torrance[68]
Discounting	Costs and outcomes : 3%
Costs results	Incremental cost : €478
Outcomes results	Incremental percent of weight loss : 3,7% / Incremental QALY : 0,028
Cost-effectiveness	Incremental cost per QALY : €16,954/QALY
Sensitivity analysis	Sensitivity analysis was performed on 1-year effectiveness data using the most recent XENDOS study, on the number of years of sustained weight loss and on the daily dose of orlistat. Results range between €11,000 to €35,000
Conclusion	Orlistat is a cost-effective treatment in obese patients if the treatment is stopped for nonresponder patients after 3 months
Remarks	To short follow-up for weight loss data : 1 year Cost data are not clear (direct costs or indirect costs ?, sources ?) Other obesity complications are not included, which is a conservative assumption Utility loss due to the treatment are not included. Those data are actually unknown and it could be interesting to investigate them. Results are particularly sensitive to the assumption of the duration of sustained effect of orlistat on weight loss (3 years in the baseline) and to the daily dose (120 mg 3x/d in the baseline)

QUALITY ASSESSMENT CHECKLIST

	Lamotte	Foxcrott 2005	Foxcroft 2000	Hertzman	Malone	Warren	Maetzel	Ruof	Lacey
Study design									
The research question is stated	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
The economic importance of the research question is stated	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes
The viewpoints of the analysis are clearly stated and justified	Yes	No	No	Yes	Yes	Yes	Yes	No	No
The rationale for choosing the alternative programmes or interventions compared is stated	No	No	No	Yes	No	No	No	No	No
The alternatives being compared are clearly described	No	Yes	No	Yes	Yes	Yes	Yes	No	No
The form of economic evaluation used is stated	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
The choice of form of economic evaluation is justified in relation to the questions addressed	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes

	Lamotte	Foxcrott 2005	Foxcroft 2000	Hertzman	Malone	Warren	Maetzel	Ruof	Lacey
Data collection									
The sources of effectiveness estimates used are stated	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Details of the design and results of effectiveness study are given (if based on a single study)	Not for all	NA	NA	NA	Yes	Not for all	NA	NA	Yes
Details of the method of synthesis or meta-analysis of estimates are given (if based on an overview of a number of effectiveness studies)	NA	No	Not clear	No	NA	No	No	Yes	Yes
The primary outcome measure(s) for the economic evaluation are clearly stated	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Methods to value health states and other benefits are stated	Not clear	Yes	Not clear	Yes	Yes	Yes	Yes	Yes	Yes
Details of the subjects from whom evaluations were obtained are given	No	No	No	Yes	Yes	Yes	Few	Yes	Yes
Productivity changes (if included) are reported separately	NA	NA	NA	NA	NA	NA	NA	NA	NA
The relevance of productivity changes to the study question is discussed	NA	NA	NA	NA	NA	NA	NA	NA	NA
Quantities of resources are reported separately from their unit costs	No	Yes	No	No	Yes	No	No	No	Not clear
Methods for the estimation of quantities and unit costs are described	No	Yes	No	No	Yes	Yes	Yes	No	Not clear
Currency and price data are recorded	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Details of currency or price adjustments for inflation or currency conversion are given	Yes	NA	No	Yes	NA	Yes	Yes	Yes	Yes
Details of any model used are given	Yes	Not clear	No	Yes	NA	No	Yes	Yes	Yes
The choice of model used and the key parameters on which it is based are justified	Yes	Not clear	No	No	NA	No	Yes	Yes	Yes

	Lamotte	Foxcrott 2005	Foxcroft 2000	Hertzman	Malone	Warren	Maetzel	Ruof	Lacey
Analysis and interpretation of results									
Time horizon of costs and benefits is stated	Yes	Yes	Yes	Not clear	Yes	Not clear	Yes	Yes	Yes
The discount rate(s) is stated	Yes	NA	No	Yes	NA	Yes	Yes	Not clear	Yes
The choice of rate(s) is justified	No	NA	NA	No	NA	Yes	Yes	No	No
An explanation is given if costs or benefits are not discounted	Yes	NA	No	NA	NA	NA	NA	NA	NA
Details of statistical tests and confidence intervals are given for stochastic data	NA	NA	No	Not for all	No	NA	No	No	No
The approach to sensitivity analysis is given	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
The choice of variables for sensitivity analysis is justified	No	No	No	Yes	No	Yes	No	No	No
The ranges over which the variables are varied are stated	Yes	Yes	No	Yes	Yes	Yes	Not for all variables	Yes	Yes
Relevant alternatives are compared	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Incremental analysis is reported	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not for costs and outcomes	Yes
Major outcomes are presented in a disaggregated as well as aggregated form	No	Yes	No	Yes	Yes	Yes	No	No	No
The answer to the study question is given	Yes	Yes	NA	Yes	Yes	Yes	Yes	Yes	Yes
Conclusion follow from the data reported	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Conclusions are accompanied by the appropriate caveats	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

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APPENDIX CHAPTER 5: SAFETY AND CLINICAL EFFECTIVENESS OF SURGICAL TREATMENT

A: DESCRIPTION OF THE MOST RECENT HTAS ON OBESITY SURGERY

Alberta Heritage Foundation for Medical Research

Guo B, Harstall C. Laparoscopic Adjustable Gastric Banding for the Treatment of Clinically Severe (Morbid) Obesity in Adults: An Update. Edmonton,AB: : Alberta Heritage Foundation for Medical Research.(AHFMR); 2005 May 2005. Information paper. HTA. Available from: http://www.ahfmr.ab.ca/publications/
Research question: Is LAGB a safe and effective procedure compared with open and/or laparoscopic RYGB and VBG, especially in the longer term (five years), for adult patients with clinically severe obesity?
Search : Cochrane library, Centre for Review and Dissemination, Medline, Web of knowledge, Embase, CINAHL, relevant library collections, practice guidelines, evidence-based resources, other HTA agency resources. Up to March 2005.
Inclusion criteria: For HTA reports: (from 2000 onwards): comprehensive literature search, results for LAGB reported separately. For primary studies (from 2002 onwards): RCTs or non-randomized comparative studies comparing safety and/or efficacy of LAGB, RYGB and or VBG; case-series reporting long-term results of safety/efficacy of LAGB with RYGB and/or VBG (> 500 cases, follow-up>7years). Outcome measures included at least one of the following: mortality, morbidity, weight loss, changes in obesity-related co-morbidities, or QOL.
Results: 3 HTA (MSAC 2003; McGill 2004, BCBS 2003) and 18 primary studies included. Methodological limitations: lack of controlled studies (only one RCT that compared LAGB with LVBG), small sample sizes, short follow-up period and/or high loss to follow-up, inconsistent reporting for co-morbidity and quality of life.
Safety : comparing LAGB with LVBG or LRYGB : short-term mortality rates are similar, with lower post-operative complication rates and significantly higher long-term post-operative complications and associated re-operations *Loss of weight*: LAGB appears less effective than LRYGB and LVBG (mean %EWL around 50%) *Improvement of co-morbidities*: LABG resulted in improved diabetes and hypertension. LRYGB appears to yield more profound improvement of co-morbidities than LAGB *Quality of life*: patients treated on RYGB seems to report higher scores on QOL than did patients who received LABG
Conclusions : All bariatric surgeries are effective in the treatment of morbid obesity but differ in the degree of weight loss and range of complications. Greatest needs are studies that can better define *long-term* weight loss, improvement in co-morbidities, QOL, and complications. The main issue is to identify which patient group is most appropriate for which bariatric procedure

Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC).

Chen J, McGregor M. The Gastric Banding Procedure: An Evaluation. Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC). 2004 April 27, 2004. Available from: http://www.mcgill.ca/tau/publications/2004/
Research question: Is LAGB an effective and reasonably safe procedure (compared with RYGB)?
Search : 1) meta-analysis and systematic reviews : searched major databases (Cochrane library, DARE, DEC reports, Trip database, Medscape, NHS, NICE) and > 20 HTA websites. 2) primary studies from 2001 onwards: search Pubmed + manual search of certain journals.
Exclusion criteria: For primary studies: case-series reporting on less than 100 cases
Results:
8 reviews / HTA studies found: Cochrane review 2003[1] NICE 2002[2], AHMR 2000[3], NHS CRD 1997[4], SBU 2002[5] , SAGES guidelines 2000[6],CCOHTA pre-assessment 2003[7]. The study is based on the most recent at the time: ASERNIP-S 2002[8, 9]. Primary studies: 19 , published between June 2001 and February 2004 Pooled analysis made on >110000 cases)
Methodological limitations: there are no randomized comparison of LAGB vs RYGB. Very high loss to follow-up (> 90%) for long-term data on effectiveness, strong bias is very possible
Safety LAGB: average short-term mortality rate 0.11%; morbidity 13.5% (both figures weighted average, > 11.000 cases)
Weight loss : % EWL at year 1,2,3,4,5 : 41%, 50%, 50%, 55%, 56% (weighted average, 18 studies)
Improvement of co-morbidities: improvement reported for a wide range of co-morbidities (diabetes, hypertension, hypelipidemia…)
Quality of life: almost all studies report significant and sustained improvement
Costs: LAGB more expensive than RYGB, mainly due to the high cost of device (4000 Canadian dollars)
Conclusion : - There is sufficient evidence to support that LAGB is an effective procedure with an adequate safety report up to 5 years - Weight loss and the rates of mortality and morbidity associated with LAGB are fairly comparable, or possibly lower than, that of RYGB - There is insufficient evidence to determine whether LAGB is a superior procedure or not

Medical Advisory Secretariat - Ontario Ministry of Health and Long-Term Care

Medical Advisory Secretariat - Ontario Ministry of Health and Long-Term Care Bariatric Surgery:Health Technology Literature Review. 2005. Available from: http://www.health.gov.on.ca/english/providers/program/mas/reviews/review_baria_0105.html
Research questions: - Do patients maintain weight loss in the short and long term after bariatric surgery? - Do comorbid conditions (e.g., diabetes, hypertension) improve in the short and long term after bariatric surgery? - Is the newer adjustable gastric banding procedure more effective than other commonly used bariatric procedures? - Is any one type of bariatric surgery more effective than any other type? - What, if any, adverse effects are associated with each type of bariatric surgery?
Search : Cochrane database of systematic reviews, ACP Journal Club, DARE, INAHTA, EMBASE, Medline, reference sections from reviews and extracted articles. Up to September 2004
Exclusion criteria: - -
Results:
- 15 international HTA or systematic reviews found, and results discussed + update search up to Sept 2004 HTAs: ECRI 2004[10] , AHRQ 2004 [11], BCBS2003 [12], MSAC 2003[13], CMS 2004[14], NHS 2002[2], ASERNIP-S 2002[8] , AHTMR 2000, COCHTA 2003[7], ANAES 2001 [15] Buchwald Meta-analysis[16],
Methodological limitations: Conclusions on long-term effectiveness (weight loss, co-morbid conditions) based on level 3a evidence (prospective cohort, non randomized, SOS study). There are no published prospective, long-term, direct comparisons of surgical techniques.
Findings and conclusions - Bariatric surgery generally is effective for sustained weight loss of about 16% for people with BMIs of at least 40 kg/m2 or at least 35 kg/m2 with co-morbid conditions (including diabetes, high lipid levels, and hypertension). - It also is effective at resolving the associated co-morbid conditions. - There is evidence that malabsorptive techniques are better than other banding techniques for weight loss and resolution of comorbid illnesses.

Agency for Health care Research and Quality (AHRQ)

Shekelle P, Morton S, MA M, Suttorp M, Tu W, Li S, et al. Pharmacological and Surgical Treatment of Obesity. Southern California-RAND Evidenced-Based Practice Center; 2004. Agency for Healthcare Research and Quality Evidence Reports (Evidence Report/Technology Assessment No. 103. AHRQ Publication No. 04-E028-2) Available from: http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat1a.chapter.19289. same study as : *Maggard MA, Shugarman LR, Suttorp M, Maglione M, Sugarman HJ, Livingston EH, et al. Meta-analysis: surgical treatment of obesity. Ann Intern Med. 2005;142(7):547-59.*
Research questions: (non-surgical treatment) and What is the safety and efficacy of surgical therapies, such as stomach stapling and bypass surgeries, as interventions for morbid obesity?
Search : Cochrane Controlled Clinical Trials Register Database, Medline, Embase, systematic reviews
Inclusion criteria: - Comparative studies + case-studies > 10 patients
Results: 147 studies assessed. Meta-analysis of various outcomes by procedures
Methodological limitations: No RCT comparing surgical and non-surgical treatment. Conclusions on long-term effectiveness (weight loss, co-morbid conditions) mainly based on one prospective cohort, non randomized, SOS study). There are no published prospective, long-term, direct comparisons of surgical techniques. Case series are limited by incomplete reporting of data
Findings and conclusions
Surgery is more effective than non-surgical treatment for weight loss and control of some co-morbid conditions in patients with BMI>= 40 -more data are needed for less severely obese people Procedures differ in efficacy and incidence of complications

Blue Cross Blue Shield (BCBS)

Lefevre F. Newer Techniques in Bariatric Surgery for Morbid Obesity: Laparoscopic Adjustable Gastric Banding, Biliopancreatic Diversion, and Long-Limb Gastric Bypass. Technology Assessment Center. Blue Cross Blue Shield (BCBS).; 2005 August 2005. (Volume 20, No. 5) Available from: http://www.bcbs.com/tec/vol20/20_05.html This is an update of *:* *Lefevre F. Newer Techniques in Bariatric Surgery for Morbid Obesity:. Technology Assessment Program. Blue Cross Blue Shield (BCBS); 2003 September 2003. (Volume 18, No. 10) Available from: http://www.bcbs.com/tec/vol18/18_10.html*
***Research questions**: 2003, updated 2005* 1) Are outcomes of laparoscopic adjustable gastric banding as good as outcomes of open gastric bypass for patients with morbid obesity? 2) Are outcomes of biliopancreatic diversion as good as outcomes of open gastric bypass for patients with super-obesity? 3) Are outcomes of long-limb Roux-en-Y gastric bypass as good as outcomes of open gastric bypass for patients with super-obesity ***Research questions**: 2003 only* 1) Are outcomes of laparoscopic gastric bypass as good as outcomes for open gastric bypass for patients with morbid obesity? *Outcomes* are weight loss and adverse events
Search : Medline, manual reviews of bibliographies of selected references, Cochrane. Up to July 2005 (for 2005 study).
Inclusion criteria: Patient population with BMI > 40, or BMI > 35 with co-morbidity. Comparative studies, or case-studies with a least 100 cases per procedure evaluated
***Results**:* 65 studies (2005 study)
***Methodological limitations**:* No high-quality trial that directly compares outcomes between different procedures. Lack of standardisation in reporting outcomes in particular adverse effects. Inability to determine rates of long-term complications
Findings and conclusions
- (2003) the evidence is not sufficient to form conclusions about the relative efficacy and morbidity of laparoscopic vs open gastric by-pass - (2005 update) LAGB results in less weight loss at 1 year compared to GBY. This difference may lessen by years 2 to 3, but appears to remain substantial. Short-term complications and mortality are low. The frequency of long-term complications is higher than short-term complications but cannot be reliably determined from the available data. At the moment the evidence is not sufficient to form conclusions on the benefit/risk ratio of LAGB compared to gastric bypass. - The evidence is not sufficient to support conclusions on the benefit/risk ratio for Bilio-Pancreatic diversion compared with gastric bypass., nor long-limb gastric Bypass

B: ADVERSE EVENTS OF BARIATRIC PROCEDURES

Table 1. Abbreviations used in tables on adverse events of bariatric procedures

Anas	complication at one of the anastomotic sites, either stenosis/stricture, leak, or staple-line failure
Bleed	bleeding complications
Cardio	cardiopulmonary complications, e.g. MI, CHF, pneumonia, respiratory failure
Conv	conversion from laparoscopic to open procedure
Death	death within 30 days of operation
Eros	erosion of adjustable band through esophageal/stomach wall, or erosion into other visceral organ
Esoph	oesophageal abnormalities
GERD	Gastro-oesophegal Reflux Disease
Hern	abdominal wall hernia at incision or port site
Infect	Infection resulting from device, other than wound infection(s)
N/V	chronic nausea and/or vomiting, moderate or severe
Nutr	nutritional deficiencies, including vitamin deficiencies,
Obstr	bowel obstruction resulting from procedure
Perf	perforation of bowel and/or visceral organ, including splenic injury
Port	complications at the port access site, including infection, dysfunction, and/or revisions
Reop	reoperation resulting from a complication of the original procedure
Sl/Dil	slippage of adjustable band or dilation of proximal GI tract
Throm	thromboembolic complication
Ulcer	mucosal ulceration occurring at or near site of procedure
Wound	wound complications, including infection and dehiscence

RYGB ADVERSE OUTCOMES

Table 2. Laparoscopic and open RYGB - short term adverse outcomes

	Death	Perforation	Leak	Bleed	Obstruction	Thromb	Card	Wound
Open RYGB[17]								
BCBS - comparative studies (N=11).Range [17]	0-5%	0-3%	0-3%	-	-	0.3%	-	0-10%
Systematic review. Mean (N = 7)[8]	0.5%	1.0%	0.4%	1.1%	0.2%	0.4%	0.4%	4.5%
Podnos - case-series[18] (8/2771)	0.87	-	1.68%	0.60%	nr			
Laparoscopic RYGB								
BCBS - single-arm studies (N=8). Range[19]. Conversion: 1-7%	0-1%	0-4%	1-6%	1-3%	0-10%	0-1%	0-2%	0-9%
Podnos[18] (10/3464)	0.23%		2.05%	1.93	1.73			

Table 3. Laparoscopic and open RYGB. Long-term adverse outcomes

	Re-op	Sten	Obstr	Ulcer	Nutr	N/V	Hern	Chol
Open RYGB[17]								
Comparative studies (N=11) Range [17]	0-35%	0-0%	-	3-9.5%	-	-	2-9%	-
Systematic review (N = 7 single-arm studies)[8]	1.4%-16.2%	4.8%	1.0%	4.1%	6.0%	NR	0.3%	1.7%
Podnos - case-series[18] (8/2771)		0.67%	2.11%				8.58%	
Laparoscopic RYGB[12]								
Systematic review, single arm studies, range (N=8)	2-9%	2-7%	0-3%	0-5%	2-4%	1-2%	1-4%	1-2%
Podnos[18] (10/3464)	-	4.73%	3.15%	-	-	-	0.47%	-

LAGB ADVERSE OUTCOMES

Table 4. Overall follow-up in studies of LAGB that report Follow-up data [17]

	Baseline	1y	2y	3y	4y	5y
N studies/N patients (% tot patients)	18/7295 (100%)	18/4603 (63%)	16/2992 (41%)	13/1999 (27%)	5/802 (11%)	4/359 (4,9%)

Table 5. LAGB short term adverse outcomes[17]

	Death	Perforation	Conversion	Thromboembolic	Cardio-p	Bleeding	Wound
Pooled percentage	0.1% 17/12,433	0.6% 74/12,788	1.6% 189/11,602	0.3% 20/7,689	0.6% 46/7,896	0.8% 45/5,594	1.5% 85/5,792
Median	0	0.6%	1.7%	0.2%	0.5%	0.5%	0.6%
Range	0-0.8%	0.1-3.3%	0-5.3%	0-2.4%	0-8.1%	0.1-4.6%	0-14.0%

Table 6. LAGB long-term adverse outcomes[17]

	Re-op	Removal	Sl/dil	Erosion	Esoph	Obstr	Port	Hern	GERD
Pooled percentage	8.6% 1,081/12,633	3.4% 425/12,319	7,7% 1,101/14,362	1.2 135/11,618	2.3 84/3,691	5.3 63,1,199	5.0 625/12,421	0.7 28/3,981	33% 188/570
Median	7.8%	2.3%	8.0%	0.8%	1.3%	2.7%	3.2%	0.3%	34.0%
Range	2.0-52%	0.6-32.5%	1.3-24%	0-8.9%	0.2-10.0%	2.2-14.0%	0.7-29%	0-5.4%	29.3-34.0%

LAGB VS LRGBY : ADVERSE OUTCOMES IN 2 COMPARATIVE STUDIES

Source : [20, 21], adapted from a compilation by[17]

Table 7. Short-term adverse outcomes

	Death	Perforation	Conversion	Thromboembolic	Cardio-p	Bleeding	Wound
Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) – 569 patients							
Pooled percentage Range	0.3% 0-0.4%	1.6% 1.3%-2.9%	1.8% 1.0%-2.0%	0.9% 0.9-1.0	0.2% 0-0.02	0.9% 0.7-1.9	1.4% 0-8%
Laparoscopic Adjustable Gastric banding (LAGB) - 908 patients							
Pooled percentage Range	0% 0%	0.1% 0-0.1%	2.6% 0-3.0%	0.2% 0-0.2%	1.0% 0-1.0%	0.3% 0.2-1.0%	1.9% 0-6%

Table 8. Long-term adverse outcomes

	Re-op	Remov	Slip/dilat	Erosion	Esoph	Obstr	Port	Hern	GERD
LRYGB % (n/N patients evaluated)									
Pooled % Range	14.6% (15/103) 14.6%	NR	NA	NA	NA	1.8% (10/569) 1.1-4.9%	NA	0.7%(4/569) 0.2-2.9%	NR
LAGB (n/N patients evaluated)									
Pooled % Range	25.2% (26/103) 25.2%	NR	5.3% (48/908) 1.4%-36%	0.66% (6/908) 0.5-1.9%	3.7% (24/908) 2.8%-24.3%	0% (0/908) 0	2.8% (25/908) 1.9-2.9%	0.3%(3/908)	NR

C: REVIEW OF GUIDELINES ON BARIATRIC SURGERY

Table 9. Clinical criteria for bariatric surgery – from selected guidelines

So	Year	Criteria for bariaric surgery	Comments / definition of co-morbidities.
National scientific bodies			
National Institute of Health[22]	1992	BMI > =40 BMI >= 35 + *high risk* co-morbidity OR obesity-induced physical problem interfering with lifestyle	These were the first recommendations on bariatric surgery, and a reference for the majority of more recent recommendations Co-morbidity: high-risk defined as '*life-theatening*' . Non exhaustive list including type 2 diabetes, severe sleep apnea, Pickwickian syndrome, obesity – induced physical problems interfering with normal lifestyle and body size problems precluding or severely interfering with employment, family function and ambulation
National Institute of Health [23]	2000	BMI > =40 BMI >= 35 + co-morbidities	Non – exhaustive list of co-morbidities ('such as').
NICE [24]	2002	BMI > =40 BMI >= 35 + co-morbidities	Cardiovascular disease, hypertension, type 2 diabetes, cancer, musculo-skeletal disease, reproductive disorders and respiratory disorders
SIGN [25]	1996	BMI >= 40 OR >=35 + co-morbidities	Co-morbidities : a) coronary heart disease, b) stroke, c) diabetes mellitus, d) gallstones, e) infertility, menstrual, disorders, f) arthritis, g) respiratory disease, sleep apnoea, h) endocrine disease

Professional associations			
European Association for Endoscopic Surgery[26]	2005	BMI >=40 OR >=35+ obesity-associated co-morbidity	Co-morbidities: non-exhaustive list, including some vaguely defined such as 'obesity-related hypertension' or 'hyperlipidemia' or 'low back pain' Contra-indications: patients who do not understand or comply with strict FU schedule, Only absolute contra-indication is severe mental disease NB : BMI 30-35 + 'substantial' co-morbidity should undergo surgery only in the context of controlled clinical trials
American College of Physicians[27]	2005	BMI>=40 + co-morbidity	Non-exhaustive list ('such as…') , some vaguely defined
Association française d'études et recherches sur l'obésité, Association de langue française pour l'étude du diabétique et des maladies métaboliques et Société française de nutrition [28]	2003	BMI>=40 OR BMI>=35 + life threatening or functional co-morbidities	Co-morbidities : Cardiovascular disease, - respiratory disease, - metabolic disease, - reproductive disorders, -liver disorders, - osteo – articular disorders

American Society for bariatric surgery[29]	2004	BMI >= 40 BMI >= 35 + *high risk* co-morbidity OR obesity-induced physical problem interfering with lifestyle	Same as NIH 1992 Extension of bariatric surgery to patients with Class I obesity (BMI 30-34,9) with a condition that can be cured or markedly improved by substantial and sustained weight loss. More data and long-term risk-to-benefit analysis is needed.

Table 10. Bariatric surgery: recommendations for after care - selected guidelines

So	Year	Long-term after care	Comment
National Institute of Health[22]	1992	Lifelong medical surveillance after surgery is a necessity	
European Association for Endoscopic Surgery[26]	2005	Consensus-based timing of post-operative FU visits (according to type of surgery) is proposed	
American College of Physicians[27]	2005	None	
American society for bariatric surgery [29]	2004	Consensus based timing of post – operative FU visits according to the type of surgery	

D: REFUNDING WEIGHT LOSS INTERVENTIONS IN BELGIUM AND SOME WESTERN COUNTRIES

1.1 BELGIUM

1.1.1 Life style interventions

Since 2002 the assistance due to revalidation provided by dieticians is reimbursed (ZIV wet art. 34 7 quater). There's however no definition of the term "revalidation" in the law. Consequently the question rises what can be regarded as revalidation in the scope of bariatric surgery. One could argue that assistance by dieticians provided immediately after bariatric surgery can be reimbursed, but it can be presumed that lifelong assistance by a dietician in order to maintain weight loss doesn't cover the notion of revalidation.

Today there is no legal basis for reimbursement for preventive lifestyle interventions. Therefore a specific draft bill on the reimbursement of all interventions with regard to obesity provided by homologated dieticians has been formulated[1]. In that scope a recommendation by the Belgian WVVH suggests that the reimbursement of the consults of the dietician should be linked to certain conditions such as sufficient motivation, a weight loss of 5 à 10 % in 6 months and the willingness to maintain follow-up for at least 1 year[2].

Moreover there has been a draft bill with regard to the reimbursement of costs concerning the medical counselling and treatment of overweight and obesity of minors and adults[3]. The draft bill aims at food advice (not necessarily by homologated dieticians) and coached lifestyle programs.

1.1.2 Surgery and materials

Bariatric surgery and materials used for bariatric surgery are not at such reimbursed by the Belgian Social Security. However, bariatric surgery is done in large numbers and has been up to now billed with codes non specific to bariatric surgery.

A pre-draft of royal decree has been created with regard to the reimbursement of some bariatric interventions linked to several conditions[4]. It is waiting for approval.

It includes 5 different codes :

- Reducing gastroplastie (Mason, Sleeve) (to treat morbid obesity) by laparotomie
- Reducing gastroplastie (Mason, Sleeve) (to treat morbid obesity) by laparoscopie
- Reducing gastroplastie by placement of an adjustable band (« gastric banding ») (to treat morbid obesity), by laparoscopie
- Reducing gastroplastie with bileopancreatic or gastro-jejunale diversion (Scopinaro, « gastric bypass », duodenal switch) (to treat morbic obesity), by laparotomie
- Reducing gastroplastie with bileopancreatic or gastro-jejunale diversion (Scopinaro, gastric bypass, duodenal switch) (to treat morbid obesity), by laparoscopie

If the following conditions have been met:

- «BMI» $\geq$ 40

1 Wetsvoorstel tot invoeging in de Ziekteverzekeringswet van de terugbetaling van verstrekkingen door erkende diëtisten ter bestrijding van obesitas, *Parl. St.* Kamer 2004 – 2005, 1652/001

2 http://www.wvvh.be/files/obesitas_AB.pdf

3 Wetsvoorstel tot aanvulling van artikel 34 van de Ziekteverzekeringswet van 14 juli 1994 om de terugbetaling mogelijk te maken van de kosten inzake de medische begeleiding en behandeling van overgewicht en obesitas, Senaat, 3- 831/1

4 http://users.pandora.be/asgb/BijlBer05_4_051c.doc

- from the age of 18 to 60
- Having followed a documented dietary treatment without success for at least 1 year
- A multidisciplinary bariatric debate with the participation of a bariatric surgeon, an endocrinologist, a psychiatrist or a clinical psychologist has taken place.

The criteria set in the draft royal decree are very severe, especially the BMI level. In most international guidelines the cut off point for surgical intervention is BMI>=40 or BMI>=35 +comorbidities. Reimbursement for bariatric surgery is based on these cut-off points in other countries. There has been a discussion in the commission however with regard to the BMI level but no decision to insert the criterion BMI >= 35 + co-morbidities has been made yet.

In the draft royal decree there's nothing about the reimbursement of the surgical devices needed for the different types of bariatric surgery. A proposal for the reimbursement of material however is being prepared in the "technische raad voor implantaten". Today material used in bariatric surgery is in theory integrated in the patient-day price. Consequently it's prohibited for hospitals to charge it to the patient. Nevertheless this is common practice.

1.2 FRANCE

Types of reimbursable bariatric surgery[5]:
Scopinaro , Gastrectomie with biliopancreatic or intestinal short- circuit by laparoscopie

- BMI > 50
- If no other technique works
- In exceptional cases
- Complications should be taken into account
- The preliminary approval of the health insurance is needed

Gastric Bypass by laparoscopie or laparotomie

- If clinical practice guidelines are followed
- The preliminary approval of the health insurance is needed

Vertical Gastroplasty by laparoscopye or laparotomy

- The preliminary approval of the health insurance is needed

Gastric banding by laparoscopy or laparotomy

- BMI >=40 or >35 + life – treatening or functional co-morbidity such as cardiopulmonary problems, severe sleep apnoea, obesity-related heart disease, There is no exhaustive list.
- Moreover patients needs to have followed specialised medical treatment (diet, physical activity, psychological treatment, treatment of complications,) during at least 1 year.
- Furthermore the patient has to commit himself to follow a follow-up treatment.

[5] www.codage.ext.cnamts.fr

- The preliminary approval of the health insurance is needed

Types of non reimbursable bariatric surgery
Intragastric balloon by oeso – gastro-duodenoscopie

Reimbursed devices/ materials
Different types of adjustable and non adjustable bands are reimbursed.
The following conditions have to be met:

- BMI >=40 or >35 + life – treatening or functional such as cardiopulmonary problems, severe sleep apnoea, obesity-related heart disease, … There is no exhaustive list.
- Moreover the patients needs to have followed specialised medical treatment (diet, physical activity, psychological treatment, treatment of complications,..) during at least 1 year.
- Furthermore the patient has to commit himself to follow a follow-up treatment.

Prices for adjustable bands start from 900 to 1100 euro. For non adjustable bands prices vary between 500 and 700 euro.

1.3 THE UNITED KINGDOM

In the United Kingdom the National Health Service (NHS) is provided free at the point of delivery, not through a reimbursement system. Treatments are provided on the basis of medical need.
Surgery for patients with severe obesity is available through the NHS, although there are some restrictions. A body mass index above 40 indicates that a person is severely obese and therefore a candidate for surgery. Surgery also may be an option for people with a BMI between 35 and 40 + co- morbidities. As co-morbidities are considered for example life-threatening cardiopulmonary problems, severe sleep apnoea, obesity-related heart disease or diabetes. There is however no exhaustive list.

1.4 THE NETHERLANDS[6]

In the Netherlands medical intervention are solely eligible for reimbursement if they are evidence based.
Besides this general criterion the following conditions have to be fulfilled:
- BMI ≥ 40 or > 35 + co-morbidities. There no definition of "co-morbidities".
- The patient needs the intervention from the point of view of "effective provision of health care". The lap band and bariatric surgery in general is a common intervention but with a restrictive effectiveness. To comply with the condition of "effective provision of health care" a multidisciplinary diagnosis, a pre- operative traject and a commitment to good after care is needed.
- Absence of contra-indications for bariatric surgery. There is however no sound definition of what can be considered as a contra-indication.
- Preliminary approval from the health insurance.

[6] Information provided by an advisor of the "college voor zorgverzekeringen" -http://www.cvz.nl/

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APPENDIX CHAPTER 6: COST-EFFECTIVENESS OF SURGICAL TREATMENT

LITTERATURE REVIEW ON COST-EFFECTIVENESS

See appendix chapter 4

DATA EXTRACTION FORM

Author	van Mastrigt G, van Dielen F, Severens J, Voss G, Greve J.
Funding	grant from the Health Care Insurance Board of the Netherlands
Year	Data collection : 1999-2002 / costs : 1999 (€)
Country	Netherlands
Design	CEA -- CUA alongside a randomized clinical trial
Perspective	Societal perspective
Time window	1 year
Interventions	Vertical banded gastroplasty (VBG) versus laparoscopic adjustable gastric banding (Lap-Band)
Population	Patients with a BMI > 40 or between 35-40 with a significant co-morbidity, aged between 18 to 60 years and without previous upper abdominal surgery and psychological contra-indications
Assumptions	The costs for one-minute surgery = 2,96 €/min
Data source for costs	Hospital billing system, observation study and cost-diary (real costs)
Cost items included	Direct medical costs (inpatient days, clinical procedures, surgery, outpatient clinics, dietician consult, general practitioner consult, prescribed medication and expenses made by patients in relation to their health situation) and indirect non-medical costs (unpaid help and productivity losses)
Data source for outcomes	a prospective randomized trial : van Dielen[1]
Discounting	Not justified
Costs results	Hospitalization costs per patient : VBG : 6,679 € / Lap-Band : 5,857 € / Incremental hospitalization costs: 822 € (IC 95% : -1,767-+4,014 €) P-Value > 0,05.
	Medical costs per patient (Follow-up) : VBG : 1,426 € / Lap-Band : 1,479 € / Incremental medical costs: -53 € (IC 95% : -386 - ? €) P-Value < 0,05.
	Non-medical costs per patient (Follow-up) : VBG : 5,080 € / Lap-Band : 3,963 € Incremental non-medical costs: 1,117 € (IC 95% : -1,139 - +3,330 €) P-Value > 0,05.
	Total costs per patient : VBG : 13,185 € / Lap-Band : 11,299 € / Incremental total cost : 1,886 € (IC 95% : -1,765 - +5,999 €) P-Value > 0,05.
Outcomes results	% excess weight loss (EWL) : VBG : 71,69 +/- 20,79 / Lap-Band : 53,87 +/- 20,64 Incremental %EWL : 17,82 (IC 95 % : 9,60 - 26,05) P-Value : 0,001
	Quality-adjusted life-year (QALY) : VBG : 0,76 +/- 0,20 / Lap-band : 0,81 +/- 0,13 Incremental QALY : -0,05 (IC 95% : -0,117 - +0,016) P-value : 0,138
Cost-effectiveness	Incremental cost per %EWL : 105.83 € (1,885.91 € / 17.82)
	Incremental cost per QALY : Lap-band = dominant strategy

Sensitivity analysis	Tested : suppression of non-medical costs, a variation of surgery personal cost per minute (2,66-3,56 €) and a variation of inpatient days (232-432 days). If non-medical costs were not included (payer perspective), the results would show more uncertainty about the outcome.
Conclusion	The costs and QALY at 1 year were found to be equal. A long-term cost-effectiveness analysis should be performed.
Remarks	1) Short-term follow-up : With Lap-band, patients lose weight more slowly because adjustments are needed before to reach the proper weight loss. With a longer period, the differences in %EWL is expected to be reduced. Furthermore, events like re-operations or the fact of re-entering the labour market can occur after 12 months and could have also an important impact on the study outcomes.
	2) Limited number of patients in this trial : A bootstrap analysis (= a large number of simulations) showed uncertainty of the cost-effectiveness estimates.

Author	Craig MG, Tseng DS
Funding	Agency for Healthcare Research and Quality
Year	costs : 2001 (US $)
Country	USA
Design	CUA - Model
Perspective	Payer perspective
Time window	Life time
Interventions	Gastric bypass vs no treatment
Population	Patient aged between 35 to 55 years, with a BMI >= 40 kg/m who did not have cardiovascular disease and in whom conservative therapies had been unsuccessful
Assumptions	5 years after initial surgery, weight loss of successful patients stabilized
	Patients gone to a general practitioner and a dietitian 3x/year for 3 years if surgery was successful and for 1 year if the procedure was reversed
	Quality of life was reduced by 200 % during hospitalization and by 50% during recovery time
	Patients who had lost weight had the same quality of life as did those who had always been at the lower weight
Data source for costs	Healthcare Cost and Utilization Project Database (ICD-9-CM Code)[2], Thompson[3], Atkinson[4]
Cost items included	Initial surgery, treatment of complications, follow-up care and treatment of obesity-related morbidities (coronary heart disease, stroke, type 2 diabetes, hypercholesterolemia and hypertension)
Data source for outcomes	Rate of abdominoplasty and reversal surgery : 1 randomized clinical trial : Hall[5]/ Weight loss and complication rate : a cohort study : Pories[6]/ Venous thromboembolism complication : International Bariatric Surgery Registry : Mason[7] and Wu[8]/ Life expectancy : Thompson[3]/ Quality of life : National Health Interview survey[9]
Discounting	Costs and QALYs : 3%
Costs results	Direct cost : Men : $21,800 – $30,100 / Women : $12,900 – $23,700
Outcomes results	QALYs : Men : 0.84-2.04 / Women : 1.32-2.85
Cost-effectiveness	Incremental cost per quality adjusted life-year : Men :$10,700-$35,600 / Women : $5,400-$16,100
Sensitivity analysis	1) Lower bound of percentage loss of excess weight to 38% 2) Variation of the reimbursement rate 3) Variation of the effect of obesity on quality of life 4) Variation of the mortality and complications rates 5) Variation of the discount rate => Results were not changed, except for older, less obese men (> US $ 50,000 for some parameter variation)
Conclusion	Gastric bypass is not cost-saving from the payer perspective but the quality of life is improved. Gastric bypass is a cost-effective alternative in comparison with no treatment, especially among women and younger, more obese men.

Remarks	Patients with initial co-morbidities are not included The alternative hypothesis is not clearly described The model is based on a lot of assumptions and especially on the fact that weight loss is stabilized after 5 years. More long-term follow-up on safety and effectiveness are needed Societal costs (like decreased productivity) are not included A conservative estimate of weight loss is used as base case and a much reduced loss of excess weight estimated is tested in the sensitivity analysis

Author	van Gemert WG, Adang EMM, Kop M, Vos G, Greve JWM, Soeters PB
Funding	Not specified
Year	Publication year : 1999 costs and data collection years not specified
Country	Netherlands
Design	CUA (based on a retrospective study)
Perspective	society perspective
Time window	Follow-up : 2 years / costs and QALYs : lifelong
Interventions	VBG vs no treatment
Population	Mean age (years): 33.1 +/- 8.4 / Female ratio : 1:20 / Mean BMI (kg/m) : 47.22 +/- 7.15 / Mean weight (kg) : 125.6 +/- 25.8
Assumptions	The productivity status 2 years after surgery is assumed to be stable and is extrapolated to the age of retirement Prevalence of morbid obesity is assumed to be 0,25% or 1%
Data source for costs	Institute of Public Health Care of the Netherlands
Cost items included	(real prices) Direct costs : surgical treatment (pre- and postoperative diagnostic, operation costs, revisional surgery, surgical complications, hospitalization, outpatient visits, overhead costs), lifelong costs-of-illness (treatment of co-morbidities). Indirect costs : productivity losses
Data source for outcomes	A retrospective study performed during this study. Life expectancy were provided by vital statistics tables : Statistical yearbook[10]
Discounting	Costs and QALYs : 5%
Costs results	Incremental direct cost : with a prevalence of morbid obesity of 0,25 % : - $ 2,164 / with a prevalence of morbid obesity of 1 % : - $ 1,253 Incremental indirect cost : - $ 45,879 Total incremental cost : with a prevalence of morbid obesity of 0,25 % : - $ 48,043 / with a prevalence of morbid obesity of 1 % : - $ 47,132
Outcomes results	Weight loss 2 years after VBG : 18,05 kg Lifelong QALY gained : 12
Cost-effectiveness	Dominant strategy : from 3,928 to 4,004 $/QALY saved
Sensitivity analysis	Variation on the prevalence of obesity and on the complication rate did not change significantly the results
Conclusion	VBG results in QALYs gained and less costs in a societal perspective. VBG is thus a dominant strategy.
Remarks	A limited number of patients (21 patients) The productivity status is assumed to be stable after 2 years and is extrapolated to a lifelong period Costs in charge of the patients are not included Comorbidities such as heart failure, liver steatosis and pulmonary disease are not included. The costs attributable to morbid obesity is thus underestimated Lifelong costs-of-illness was estimated from an assumption on the prevalence of morbid obesity and not from assessed values, the prevalence of morbid obesity being not exactly know

Author	Chevallier JM, Daoud F, Szwarcensztein K, Volcot MF, Rupprecht MF
Funding	Johnson & Johnson
Year	For costs : 2004 (€)
Country	France
Design	CUA-CEA
Perspective	Health care payer
Time window	5 years
Interventions	Swedish adjustable gastric banding (SAGB) versus conventional treatment (CT)
Population	Patients with a BMI >= 40 kg/m or with a BMI >= 35 kg/m and co-morbidity
Assumptions	Resources consumptions are assessed by expert and are supposed to be based on conservative assumptions
	After 2 years, reduction in BMI is assumed to be null for the CT group (according to previous studies[11-20]
	QALYs are based on weight loss and are assessed by a regression model which is supposed to be linear. Reduction in BMI after SAGB is assumed to be the same for patients without complications and for patients with obesity related complication
Data source for costs	Unitary cost : "Nomenclature générale des actes professionnels" (NAGP) and "taux de prise en charge pour la sécurité sociale" / Type 2 diabetes : Code II study[21] / Use of resources based on expert opinion ?
Cost items included	Direct costs : Initial surgery, treatment of complications, follow-up care and treatment of obesity-related morbidities (type 2 diabetes and sleep apnea)
Data source for outcomes	Not clear : Weight-loss : For the SAGB group :[13, 18-20]/ For the CT group :[11, 12, 14-17] / Type II diabetes :[22-25, 18, 20]/ Sleep apnea :[26-29, 20]
Discounting	outcomes and costs : 3,5%
Costs results	Cost-effectiveness study : For patients without co-morbidity : Incremental cost : 350 € For patients with type 2 diabetes : Incremental cost : -2,396 € For patients with sleep apnea : Incremental cost : -1,221 €
	Cost-utility study : For patients with a BMI >= 40 with or without type 2 diabetes : Incremental cost : -3 € For patients with a BMI >= 35 and with type 2 diabetes : Incremental cost : -2,448 € Cumulated budgetary impact in the private sector at 5 years (SAGB-CT) : -108,632 € Cumulated budgetary impact in the public sector at 5 years (SAGB-CT): 772,439 €
Outcomes results	Cost-effectiveness study : For patients without co-morbidity : Incremental BMI loss : 56.2 kg/m For patients with type 2 diabetes : Incremental BMI loss : 56.2 kg/m For patients with sleep apnea : Incremental BMI loss : 56.2 kg/m Cost-utility study : For patients with a BMI >= 40 with or without type 2 diabetes : Incremental QALY : 0.79 For patients with a BMI >= 35 and with type 2 diabetes : Incremental cost : 1.06
Cost-effectiveness	Cost-effectiveness study : For patients without co-morbidity : Incremental cost / BMI loss : 6.2 € For patients with type 2 diabetes : Dominant strategy For patients with sleep apnea : Dominant strategy Cost-utility study : For patients with a BMI >= 40 with or without type 2 diabetes : Dominant strategy For patients with a BMI >= 35 and with type 2 diabetes : Dominant strategy
Sensitivity analysis	Not performed

Conclusion	SAGB is a cost-effective strategy, especially for patients with type 2 diabetes and obstructive sleep apnea (less expensive and more effective in terms of loss of BMI and QALY in comparison with the CT group)
Remarks	Choices concerning the estimations of resources consumption is not clearly justified Sources for outcomes are not clear Sensitivity analysis is not performed QALYs are based on weight loss and are assessed by a regression model which is supposed to be linear. The effects of surgical complications on the quality of life are not included After 2 years, reduction in BMI is assumed to be null for the CT group Reduction in BMI after SAGB is assumed to be the same for patients without complications and for patients with obesity related complication BMI losses are cumulated and discounted for each year

Author	Clegg A, Colquitt J, Sidhu M, Royle P, Walker A
Funding	NHS R&D HTA Programme
Year	Year for costs : 2000 (£)
Country	UK
Design	CUA
Perspective	National Health Service (NHS) perspective
Time window	20 years
Interventions	Three surgical interventions were considered : vertical banded gastroplasty (VBG), silicone adjustable gastric banding (SAGB) and gastric bypass (GB). Each intervention was compared with the others interventions and with non-surgical treatment.
Population	Patients with a mean age of 40 years, a mean BMI of 45 kg/m , a baseline weight of 135 kg, a life expectancy of 20 years and with a majority of women (90%).
Assumptions	Percent of weight loss : for GB : 36% in the first year and maintened over time / for VBG : 25% in the first year but -2% each subsequent year / for AGB : 20 % in the first year, 33% after 5 years and after, the weight is stabilized Effectiveness of non-surgical treatment was null Prevalence of diabetes under morbidely obese patients : 10% Resources consumptions are assessed by expert
Data source for costs	Unitary cost : NHS[30]and Netten[31]/ Type 2 diabetes : Williams[32]/ Use of resources based on expert opinion
Cost items included	preoperative care costs, operative care costs, treatment-related complications costs, revisions and additional procedures costs and follow-up costs
Data source for outcomes	Weight loss data : 17 randomized clinical trials and 1 cohort study with matched controls (SOS study)[33-38_39-67]Utility values :[68]
Discounting	Costs : 6% / QALYs : 1.5%.
Costs results	Incremental cost for 100 patients : GB vs no surgery : £ 280,020 VBG vs no surgery : £ 266,275 SAGB vs no surgery : £ 383,102 GB vs VBG : £ 13,745 SAGB vs VBG : £ 116,826 SAGB vs GB : £ 103,082
Outcomes results	Incremental QALY for 100 patients: GB vs no surgery : 45 VBG vs no surgery : 26 SAGB vs no surgery : 45 GB vs VBG : 19 SAGB vs VBG : 19 SAGB vs GB : 0,4
Cost-effectiveness	Incremental cost/QALY : GB vs no surgery : £6,289 VBG vs no surgery : £10,237 SAGB vs no surgery : £8,527 GB vs VBG : £742 SAGB vs VBG : £6,176 SAGB vs GB : £256,856
Sensitivity analysis	Sensitivity analysis was performed on a range of factors (hospital length of stay, surgery costs, surgeon experience, diabetes cost, utility gains from weight reduction and use of effectiveness data rather than efficacy data). For all factors, surgery is a cost-effective alternative to non-surgical treatment.

Conclusion	Surgery led to a greater weight loss than non-surgical treatment and consequently to improved quality of life and co-morbidity rates.
Remarks	The only assessed co-morbidity was diabetes because long-term impact of weight-loss on other co-morbidities was less evident.
	Reduction in BMI is assumed to be null for the non-surgical treatment group. For the surgical treatments groups, few studies assessed outcomes beyond 5 years and patients were thus assumed to stabilized their weight after 5 years. Concerning the comparison of the different types of surgery, they were too much uncertainty to make a conclusion. Choices concerning the estimations of resources consumption is not clearly justified. Outcomes selected in the analysis are not clear.

QUALITY ASSESSMENT CHECKLIST

	Van Mastrigt	Craig	Chevallier	Clegg	van Gemert
Study design					
The research question is stated	Yes	Yes	Yes	Yes	Yes
The economic importance of the research question is stated	Yes	No	Yes	Yes	Yes
The viewpoints of the analysis are clearly stated and justified	Yes	Not justified	Yes	No	Yes
The rationale for choosing the alternative programmes or interventions compared is stated	Yes	No	Yes	No	No
The alternatives being compared are clearly described	Yes	No	No	No	Yes
The form of economic evaluation used is stated	Yes	Yes	Yes	Yes	Yes
The choice of form of economic evaluation is justified in relation to the questions addressed	Yes	Yes	Yes	Yes	Yes
Data collection					
The sources of effectiveness estimates used are stated	Yes	Yes	Not clear	Not clear	Yes
Details of the design and results of effectiveness study are given (if based on a single study)	Yes	Yes	No	Yes	Yes
Details of the method of synthesis or meta-analysis of estimates are given (if based on an overview of a number of effectiveness studies)	NA	NA	No	No	NA
The primary outcome measure(s) for the economic evaluation are clearly stated	Yes	Yes	Yes	Yes	Yes
Methods to value health states and other benefits are stated	Yes	Yes	Yes	Not clear	Yes
Details of the subjects from whom evaluations were obtained are given	Yes	No	No	Yes	Yes
Productivity changes (if included) are reported separately	Yes	NA	NA	NA	NA
The relevance of productivity changes to the study question is discussed	Yes	NA	NA	NA	NA
Quantities of resources are reported separately from their unit costs	No	No	Yes	Yes	No
Methods for the estimation of quantities and unit costs are described	Yes	Yes	No	No	Yes
Currency and price data are recorded	Yes	Yes	Yes	Yes	Yes
Details of currency or price adjustments for inflation or currency conversion are given	Yes	Yes	Yes	No	No
Details of any model used are given	NA	Yes	No	Yes	NA
The choice of model used and the key parameters on which it is based are justified	NA	Yes	No	No	NA

Analysis and interpretation of results					
Time horizon of costs and benefits is stated	Yes	Yes	Yes	Yes	Yes
The discount rate(s) is stated	NA	Yes	Yes	Yes	Yes
The choice of rate(s) is justified	NA	No	No	No	No
An explanation is given if costs or benefits are not discounted	Yes	NA	NA	NA	NA
Details of statistical tests and confidence intervals are given for stochastic data	Yes	NA	NA	NA	No
The approach to sensitivity analysis is given	Yes	Yes	No	Yes	Yes
The choice of variables for sensitivity analysis is justified	No	Yes	NA	Yes	No
The ranges over which the variables are varied are stated	Yes	Yes	NA	Yes	No
Relevant alternatives are compared	No	No	No	No	No
Incremental analysis is reported	Yes	Yes	Yes	Yes	Yes
Major outcomes are presented in a disaggregated as well as aggregated form	Yes	No	Yes	No	Not all outcomes
The answer to the study question is given	Yes	Yes	Yes	Yes	Yes
Conclusion follow from the data reported	Yes	Yes	Yes	No	Yes
Conclusions are accompanied by the appropriate caveats	Yes	Yes	No	Yes	Yes

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APPENDIX CHAPTER 7

A: REPORT OF A VISIT TO SINT BLASIUS DENDERMONDE – SURGICAL TREATMENT OF OBESITY

Imgard Vinck, visit of 23th of March 2006

Dr. J. Himpens (surgeon), Mevr. Christine D'Haese (Co-ordinating Officer), Mevr. Katrien Van Nuffel(date manager-master in Law)

SCOPE

Nowadays foreign patients come to Belgium to an increasing extent to undergo all kinds of surgery, also bariatric surgery. The centers where doctor Himpens works are popular because of his experience. He performed over 1000 lap Roux and Y gastric bypass operations, over 700 sleeve gastrectomies and over 400 duodenal switch operations.

SETTING

Dr. Himpens, accredited at St. Blasius in Dendermonde, The Universtity Hospital of St Pierre in Brussels and chief of the Obesity Center in Cavell Hospital routinely carries out Duodenal Switch, Gastric Banding and Roux-en-Y procedures, all laparoscopically. He also carries out Sleeve Gastrectomy and Pacemaker procedures. His staff comprises 2 surgeons, 4 nurses, the obesity coordinator and an admitting officer. There are approximately 1200 patients per year undergoing bariatric surgery in his services, 1/3 of them are foreign patients. St Blasius in Dendermonde offers 24 beds for bariatric surgery, St. Pierre some 15 beds and Cavell hospital 10 beds. All hospitals are specially equipped to perform operations for patients with high BMI (special operation table, stockings, beds, wheelchairs, …)

PATIENTS

Patients come from all over Europe (UK, the Netherlands, Portugal, Norway, Romania, …) and America. Most of them come on their own initiative to the surgical department to request surgery. They are often referred by information provided by patient organisations on the internet (for instance: http://www.wlsinfo.org.uk, www.jacqueshimpens.com, www.obesitycenteratcavell.com).

PATIENTS' MANAGEMENT

Pre-operative contact and information

Standardised protocols have been developed for most steps of patient's management. The first contact with foreign patients mostly occurs by phone or by e-mail. On request of the patient a questionnaire (see annex 1) is sent to the patient. Based on that questionnaire the team of dr. Himpens decide what the best treatment option is for this particular patient. Often the questionnaire however is insufficient to decide about the right option. Therefore patients usually are requested to come over to Belgium for pre-examinations and consults or they are requested to be examined in their home country and to send the

results (often Americans). Depending on the patients' wish, patients are referred to the psychologist (some patients are already following treatment in their home country or are refusing treatment).

Dutch patients mostly come to the hospital for an intake before being operated. This intake comprises a psychological test, a consultation with the co-ordinating officer where all possible interventions are shown in a film and a consultation with the surgeon. Since Dutch insurers need of motivation letter from the surgeon before patients are eligible for reimbursement they need to see the surgeon before the decision making.

Patient selection criteria

To be eligible for bariatric surgery the patient must meet the following criteria:

- BMI >35 + Co-morbidities (f.e. diabetes, apnea, asthma, hyperlipidemia,…)
- BMI >40

Informed consent

A written consent form set up by the hospital (see annex 2) is submitted to the patient. The consent form states that the patient is entirely informed about the possible complications linked to the intervention and consents to the operation. Moreover the consent form declares that information is given about the fact that a life long follow up is needed.

There is also a clause of non-responsibility stating that if another hospital is involved in the follow – up of the patient, without the consent of the Sint-Blasius obesity centre, one can not blame the obesity centre for possible follow-up problems.

Follow-up

For foreign patients a hospital stay of 4-5 days is anticipated. Furthermore the patient is required to stay in a hotel nearby the hospital until the 7th post-operative day. Upon discharge information is given about what symptoms can be regarded as normal and what are not after the operation in order for the patient to recognize complications. The patient receives a diet sheet and is encouraged to work with a dietician (see attachment 3).

The follow – up after care following the hospital stay will be performed by the physician in the home country of the patient and consists of blood lab checks on defined intervals after the surgery. The tests are performed in order to detect any deficiency that may occur after weight loss operations. The patient is requested to make sure that these results are sent to dr. Himpens and the team. Dutch patients are requested to return to Sint Blasius for a check up with a blood analysis after 1, 3, 6 and 9 and 12 months during the first year after the operation and afterwards once every 6 months. Other foreigners are suggested to have a blood test every three months the first year, every six months the second and the third year and every year after that.

In case of emergency the department offers a 24 hours permanence, 7 days a week. There is a phone number with permanence of Christine (+32 497 36 00 03) This can be reached 24 hours/24, 7 days a week (also for Belgians). The Obesitas Centre has many addresses and contacts in the home country of the patient. Hence patients are often referred to one of these hospitals if a complication occurs.

COSTS OF PRIMARY PROCEDURES

The cost of the DS procedure is currently

-9,250 Euro in Dendermonde

-10.500 Euro in Cavell

The cost of the RNY gastric bypass procedure is currently

-9,250 Euro in Dendermonde

-9500 Euro in Cavell

The cost of the Adjustable Gastric Banding procedure is currently 4,100 Euro.

Foreign patients are offered a package deal for their specific operation. This package includes all costs during a hospital stay up to five days (see annex 4):

- Hospital stay in regular room
- All nursing and paramedical care, including physiotherapy
- The complete doctors' fees of surgeon, anaesthetic and other doctors
- All bandages and surgical material, medication
- No additional doctors' fees will be charged in case of complications occurring within 31 days after the initial surgical procedure and provided the complications are treated at the Sint Blasius/Cavell facility. After 30 days all costs are charged.

In case of complications necessitating a longer hospital stay, the condition the patient is in will generate additional costs. These costs when generated in the hospital will be billed on a non – profit basis, which means that the patient will not have to pay additional doctors' fees. Every additional day beyond the patients' stay covered by the package deal costs some 250 euro in a regular ward or 1000 euro in the intensive care unit. The medical condition may require special treatment at additional charge on top of this.

Complications generated by the initial operation and treated in the hospital where the initial operation was performed one month or more after the surgery will be charged according to the rates of the Belgian National Health Services.

INFORMATION REGISTRATION

The Obesity Centre keeps a registry containing the name, sex, pre-operative weight, height, BMI, date of operation, date of discharge and the post – operative development. If complications occur the type and the date of occurrence are also registered.

All operations are video taped and kept on file.

B : TRAITEMENT DE L'OBÉSITÉ CHEZ L'ADULTE – UCL-ST LUC

Service : **Service d'Endocrinologie et de Nutrition, Cliniques Universitaires St-Luc à Bruxelles**

Interlocuteur(s) : Prof Jean-Paul Thissen

Date d'entrevue : 27 mars 2006

Objectifs de la visite :

Description de la prise en charge ambulatoire des patients obèses adultes au sein des Cliniques Universitaires St-Luc de Bruxelles.

Structure et organisation du service :

- Type de patients et critères d'admission

Patients obèses (BMI 30) ou présentant un surpoids (BMI 25)

- Prestataires engagés pour le traitement étudié

Un médecin endocrinologue nutritionniste
Trois diététiciennes (1,5 ETP)
Une psychologue (4/5 temps) et un psychiatre (1/2 temps)
Un médecin de médecine physique
Un kinésithérapeute
Deux chirurgiens digestifs

Le traitement : Itinéraire du patient

- Le patient
  - Origine médicale – qui réfère ?

Le patient vient dans 50% des cas de lui-même à la consultation. Dans les autres cas, il est référé par son médecin généraliste ou par un spécialiste de St-Luc.

  - Origine géographique – catchment area

Bruxelles, Brabant Wallon, Hainaut (principalement)
Namur, Luxembourg et Liège (dans une moindre mesure)

  - Statut de santé (BMI, co-morbidités ?)

Une grande proportion des patients présente une obésité vraie, voire morbide.

- Le programme
  - Comment le programme est-il élaboré ? Se base-t-il sur des guidelines ?

Le programme se base sur les guidelines internationaux (NIH(1)) et les recommandations nationales du BASO, l'association belge pour l'étude de l'obésité, ainsi que sur l'expérience clinique.

- Quels sont les intervenants / prestataires ?

Le médecin, la diététicienne, la psychologue ou le psychiatre, le médecin de médecine physique et le chirurgien digestif

- Quels types d'intervention/traitement ?

La prise en charge est individuelle. Le patient est suivi en consultation par les différents intervenants. Le patient rencontre le médecin tous les trois mois et la diététicienne tous les mois.

Un suivi par le psychologue ou le psychiatre est proposé si l'obésité est liée à une problématique psychologique (de 2 à 6 fois par an)

Le traitement consiste essentiellement en une modification de l'alimentation et la réalisation d'activités physiques.

Le patient est vu en consultation par le médecin de médecine physique qui vérifie s'il n'existe pas de contre-indications à l'activité physique et qui peut prescrire des séances de kinésithérapie. Le patient a aussi l'occasion de suivre en groupe deux séances de kinésithérapie par semaine pendant trois mois au centre sportif.

Les médicaments sont proposés aux patients lorsqu'ils ont déjà adapté leur alimentation et modifié leur style de vie. Le médicament est arrêté s'il n'y a pas de perte de poids supplémentaire après 3 mois.

L'équipe se réunit deux fois par mois : une réunion avec le chirurgien pour discuter d'éventuels cas chirurgicaux et une autre réunion avec le psychologue et le psychiatre pour discuter des cas de troubles alimentaires.

- Quel est le paradigme dominant ?

Perte de 10% du poids et maintenir ensuite le poids atteint.

- Combien de temps le programme est-il prévu ?

Aussi longtemps que le patient reste motivé.

- Taux d'abandon en cours de traitement : plus de 50 % (le risque d'abandon est plus faible chez les patients présentant des complications médicales)

- Raisons d'abandon :

Le manque de motivation du patient, son inaptitude à changer d'hygiène de vie et de comportements, un régime trop difficile à suivre, etc.

Accessibilité pour le patient

- Coût

Seules les consultations des médecins sont remboursées (interniste, spécialiste en médecine physique, psychiatre et chirurgien)
La consultation de la diététicienne revient à 35 € pour la première visite et ensuite à 15 € par consultation.

- Listes d'attente : 3 à 4 mois

Améliorations à apporter

1. Motiver le patient à long terme
2. Responsabiliser le patient par un contrat
3. Améliorer la prise en charge financière du traitement

Reference List

(1) NHLBI Obesity Education Initiative. The practical guide: identification, evaluation and treatment of overweight and obesity in adults. National Institutes of Health. 1998.

C: REPORT OF A VISIT TO UZ GENT – SURGICAL TREATMENT OF OBESITY

ML Lambert, 27/11/06

Pr P.Pattyn (surgeon), Dr Baerdemaeker (anesthesist), Dr Giri (endocrinologist), Mevr Geirnaert (dietician)

SETTING

Abdominal surgery department in a teaching hospital. Bariatric surgery started in the early 1990' and the team has accumulated considerable experience (1800 patients' files will be computerised this year). Apart from training their own students, team members are also involved in industry-sponsored training of foreign surgeons.

There is no psychologist attached to the department; the physiotherapists and the dietician are 'transversal' (dietician is based in the endocrinology unit). Surgeons work in close collaboration with the specialised obesity clinic (endocrinology).

Although demand for bariatric surgery is high, the offer is voluntarily limited out of a concern to keep enough beds available in the ward for other patients (mainly oncology). The ward also accommodate patients hospitalised for complications of bariatric surgery performed elsewhere. This is perceived as a serious problem, in terms of quality of care.

PATIENTS

Patients come from all over Flanders. Most come from their own initiative directly to the surgical outpatient department to request surgery, or they are referred by their general practitioners. Another category of patients (mainly diabetics) are sent by the endocrinologist after being advised and persuaded that they should consider surgery. A minority of patients are not Belgian residents (not entitled to Belgian social security coverage). These are mainly Dutch, being treated within the terms of a contract between their insurance and the hospital; others are sent by commercial health organisation such as EuroSurgery. If found eligible for surgery and operated, they will be billed the 'full' cost of their care.

PATIENTS' MANAGEMENT

Standardised protocols have been developed for most steps of patient's management. To be eligible for bariatric surgery the patient must meet the following criteria:

- Various failed attempts at loosing weight + medical criteria (BMI > 35 + at least 2 co-morbidities, or BMI >= 40). These are strictly applied, although there can be some exceptions on a case-to-case basis (example was given of a patient with BMI 33, and cardiomyopathy);
- Eating behaviour assessed by a dietician. Binge eaters are referred to a psychiatrist. Costs of the dietician (32 Euros for the first session, 16 for follow-up sessions) are usually borne by the patients (unless they meet some conditions, such as diabetics); psychological evaluation (if necessary), in particular of motivation and 'skills' to comply with the diet requirements following surgery (+/- 40 Euros/session, paid by the patient).

- Two visits to the surgeon in the out-patient department. The patients are given information on surgery and after care.

The decision is ultimately taken by a multidisciplinary team, written informed consent is obtained.

Choice of type of surgery: the default used to be LAGB if no counter-indication was found (sweet-eaters). The rationale was that LAGB adverse events, even if frequent, were almost never life-threatening, unlike RYGB's. Patients with extreme obesity (BMI > 60) would be considered for RYGB, and those with BMI > 80 for a Scopinaro. The later are truly exceptional cases; Scopinaro is considered in UZ Gent as an obsolete method. Duodenal switch is hardly ever used.

The trend however is towards an increased use of RYGB, based on the observation of weight regain after a few years, and difficult compliance with the diet in some patients with LAGB. If RYGB is chosen, the protocol requires a consultation with the endocrinologist; waiting time is 6 months. For a consultation with the surgeon, waiting time is 3 months. The choice of open vs laparoscopic RYGB is also done after careful evaluation of the patient.

Surgery : average length-of-stay is 2 days for LAGB and 6 days for RYGB. Special protocols for anaesthesia in this high-risk population have been developed by the team. Post-op care for super-obese will be done in the intensive care unit. Conversion rate (LRYGB => open procedure) is low – 2%- attributed to careful patient selection. In UZ Gent, length-of-stay is similar for patients operated with open and laparoscopic RYGB.

Costs to the patients are higher for LAGB than for RYGB because of the cost of the device (+/-1700 Euros for a Swedish Band).

Children: for ethical reasons the team is reluctant to operate children. Restrictive (and reversible) procedure such as LAGB are poorly tolerated by children, and obese children are often sweet eaters. As much as possible, the operation should be postponed until the child is at least 18.

Follow-up : first consultation is scheduled 6 weeks after LAGB (band adjustment if needed). The standard protocol then includes consultations with each member of the team (surgeon, dietician) every 6 months until weight is stable and then yearly.

Reconstructive surgery - often needed after an important weight loss – would be very expensive. Indeed the corresponding 'nomenclature' code is not used and fees for reconstructive surgery are in effect set by the reconstructive surgeon and entirely borne by the patients (+/- 1500 Euros in UZ Gent).

HEALTH INFORMATION SYSTEM

A register for bariatric surgery has been recently implemented in Belgium. This is an industry-sponsored initiative (software, human resources). Design and contents were adapted by Belgian bariatric surgeons. Use of the register is a condition for being a member of the Association for Bariatric Surgery (Belgium, Holland, Luxembourg). A pilot study for registry is going on in UZA, Stuyvenberg and UZ Gent: all consecutive patients (retro and prospective) will be included. In UZ Gent retrospective computerisation of all patients files is foreseen.

CONCLUSIONS, KEY POINTS

- Tertiary care setting, considerable experience in bariatric surgery.
- Patients hospitalised for complications of bariatric surgery performed elsewhere raise concerns as regards quality of care provided in some setting
- Demand for bariatric surgery is high, offer is voluntarily limited (to keep beds available for other patients)
- Assessment of eligibility for surgery, surgery itself, and after-care are standardised in protocols; multidisciplinary approach is emphasised.
- At present, bariatric surgery entails high costs to the patients
- A register for bariatric surgery is now being implemented in Belgium. It is at the moment industry-sponsored for lack of other financing mechanism

APPENDIX CHAPTER 8: TREATMENT OF OBESITY IN CHILDREN

A: REVIEW OF STUDIES ON BARIATRIC SURGERY IN SHOOL-AGED CHILDREN

Table 1. Bariatric surgery in children and adolescents: studies reviewed

Study	N	Mean age in years (range)	Mean BMI (range)	Mean follow-up in years (range)	Data on :		
					Adverse events	Weight loss	Co-morbidities
Rand[1]?	34	17 (11-19)	47 (38-66)	6 (2-13)	Limited	yes	no
Breaux[2]	22	14 (8-18)	68 (52-105)	Na (6-131 mo	Limited	yes	Limited
Mason[3]	47	18.1 (8-20)	48.4 (SD: 6.9)	5-10 yrs	Limited	yes	no
Sugerman[4]	33	16 (12-18)	52 (38-91)	1-14 yrs	Limited	yes	Limited
Kalra [5]	34 (19 with sleep apnea)	17.5 (na)	57 (48-87)	Mean: 5.1 mo	no	yes	Only sleep apnea
Angresani[6]	58	18 (15-19)	46 (35-67)	1-7 yrs	Limited	yes	no

Table 2. Studies contributing to evaluation of weight loss

	Technique	Follow-up	N evaluated/ Total eligible (%)	N (%) with > 50% EWL	Other indicators
Rand[1]	RYGB (30) VBG (4)	Mean: 6 years	34/39 (87%)	na	Mean % EWL (SD) : 66 (26) ; range 0-100% Mean BMI (SD): 32 (22-48)
Angresani[6]	LAGB	1y	48/52 (92%)	na	Mean BMI (SD): 36 (8)
		5y	25/33 (76%)	na	Mean BMI (SD): 35 (12) 5/25 (20%) with less than 25% EWL
		7y	10/10 (100%)	na	Mean BMI (SD): 30 (5)
Sugerman[4]	RYGB 17/33; LL GBP 10/33.	1 y	31/32	na	Mean EWL 58%. Mean BMI:36
		5 y	20/24	na	Mean EWL: 63%. Mean BMI: 33 5/20 (25%) regained all lost weight
		10 y	14/18	na	Mean EWL: 58 % . Mean BMI: 34 5/14 (35%) regained all lost weight
		14 y	6/9	na	Mean EWL: 33% . Mean BMI: 38
Mason[3]?	VBG	5 y	25/34 (74%)	na	7/23 (26 %) patients with less than 25% EWL. Mean BMI 36.2 (SD 5.0)
		10y	14/19 (74%)	na	Mean EWL 38.5 %. Mean BMI 39.2 (SD 7.1)
Breaux[2]	VBG:4, RYGB:14, BPD:4	?	?	na	Mean EWL : 45% in patients with sleep apnea (N=9) and 59% in patients without sleep apnea (N=11)I
Kalra [5]	(L)RYGB	?	?	Na	Mean BMI post chirurgical (?): 41.6(9.5)

Table 3. Studies contributing to evaluation of adverse events

	Technique	Follow-up	N evaluated/ eligible (%)	Adverse event
Rand[1]	RYGB (30) VBG (4)	Mean: 6 years	34/39 (87%)	No major post-operative complication. 4 insufficient weight loss (indications for revisional surgery), 4 cholecystectomies. Only 4/30 (13%) patients with RYGB reported taking their nutritional supplements as instructed.
Mason[3]	VBG	'operation-related'	47/47 (100%)	No death, no leaks, no peritonitis
		> 5 years	?	4 revisions
Breaux[2]	VBG:4/22, RYGB:14/22, BPD:4/22	'post-op complications'	22/22 (100%)	Nutritional deficiency (5/22, 23%), Incisional hernia (1/22 5%) , other 3/22; 15%) 1 revision surgery (5%) 1 early death (5%) , 2 late deaths (10%). Deaths thought to be unrelated to surgery.
Sugerman[4]	RYGB (17/33) LL GBP (10/33).	'Early'	33/33	No death. 1 pulmonary embolism, 1 major and 4 minor wound infection, 3 stoma stenoses, 4 marginal ulcers.
		?	?	1 severe protein-calorie malnutrition , Late complication requiring additional surgery in 21% of the patients (including 2 late conversions, one small bowel obstruction, 6 incisional hernias). 2 deaths (thought to be unrelated)
Angrisani[6]	LAGB	'Post-op'	58/58	6/58 (10%) : 1 band slippage, 2 pouch dilatations, 3 intragastric migrations requiring removal
		?	?	No death. Overall removal rate 6/58 (10%), re-operation 8 /58 (14%)

Table 4. Studies contributing to evaluation of co-morbidities

			N with co-morbidy pre-op/total operated vs N with co-morbidity post-op/total evaluated			
	FU	N evaluated/ Total at risk (%)	Diabetis	Hypertension	DJD	Sleep apnea
Breaux[2]	'long-term'	9/11 (82%)	na	na	na	11/11 vs 9/9
Sugerman[4]	1 y	31/32	2/31 vs 0/31	11/31 vs 7/31	11/31 vs 2/31	6/31 vs 0/31
Kalra [5]		10/19 (53%)	na	na	na	All subject showed significant improvement of apnea-hypopnea index

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B : TRAITEMENT AMBULATOIRE DE L'OBÉSITÉ CHEZ L'ENFANT – UCL – ST LUC

Service : **Unité d'Endocrinologie Pédiatrique – Cliniques Universitaires St-Luc à Bruxelles**

Date d'entrevue : 24 mars 2006

Interlocuteur(s) :Dr V. Beauloye

Objectifs de la visite

Description de la prise en charge multidisciplinaire des enfants obèses au sein du service de Pédiatrie des Cliniques Universitaires St-Luc de Bruxelles.

Historique du service

La prise en charge de type multidisciplinaire a été introduite en 1982 par le Prof Malvaux avec l'aide du Dr Maes et de Mme Siméon, psychologue(1). L'objectif était de créer un cadre psychosomatique favorisant une approche intégrée du patient et pallier ainsi aux échecs observés par la seule prise en charge médicale des patients obèses.

Structure et organisation du service

- Type de patients et critères d'admission

Enfants obèses (BMI 30)
Enfants en surpoids (BMI 25) présentant des complications médicales ou des indications psychologiques

- Sources de financement (dont convention)

Pas de convention INAMI
Les différents intervenants sont salariés et payés par l'hôpital universitaire.

- Prestataires engagés pour le traitement étudié:

1 pédiatre endocrinologue (1 jour/semaine)
1 psychologue (1 jour/semaine) (prestation non remboursée)
1 diététicienne (1 jour/semaine) (prestation remboursée partiellement suivant les mutuelles)

Le traitement : Itinéraire du patient

- **Le patient**
  - Origine médicale – qui réfère ?

La demande de suivi vient des parents, du centre de médecine scolaire, du médecin traitant, du pédiatre, ou du nutritionniste (médecin ou diététicien)

- Origine géographique – catchment area
-

Les patients viennent du sud de la Belgique, d'Arlon à Tournai (excepté la région de Liège)

- Caractéristiques socio-démographiques

Le service de pédiatrie accueille des enfants de toutes origines sociales. Le prix des consultations est adapté dans le cas de difficultés sociales des parents.

- Statut de santé (BMI, co-morbidités ?)

Evaluation en cours (mémoire de Mme C. Bila)

- **Le programme**

  - Comment le programme est-il élaboré ?

Le programme se base sur les 25 années d'expérience du service et sur les guidelines. Plusieurs modifications ont été apportées au programme initial du Prof Malvaux notamment la suppression de l'hospitalisation des enfants et adolescents. Ceux-ci étaient mis au régime et suivaient une heure de kinésithérapie par jour durant leur séjour à l'hôpital. L'hospitalisation est par ailleurs indiquée en cas de complications (par exemple pour un test du sommeil)

  - Se base-t-il sur des guidelines ?

Le programme se base sur les recommandations de Barlow(2), du Consensus de 2005 du JCEM(3), des Obesity Reviews de l'International Obesity TaskForce (IOTF)(4;5) et des recommandations nationales du BASO, l'association belge pour l'étude de l'obésité.

  - Quels sont les intervenants / prestataires ?

Un pédiatre endocrinologue, une psychologue et une diététicienne

  - Quels types d'intervention/traitement ?

Le traitement proposé aux enfants obèses est une prise en charge ambulatoire individuelle, visant des changements du mode de vie à long terme.
L'enfant est vu tous les 3 à 4 mois par l'équipe pluridisciplinaire et cela pendant au minimum 1 an. L'enfant est suivi plus régulièrement s'il présente des complications médicales ou psychologiques importantes.

La prise en charge consiste en une *consultation intégrée* d'une demi-heure à trois quarts d'heure où l'enfant est vu en même temps par le pédiatre et la psychologue. Cette consultation permet de confronter le diagnostic médical et le diagnostic psychologique et de restituer le symptôme, c'est-à-dire l'obésité, dans son contexte.

Peu de médicaments sont prescrits (sauf en cas de complications)

L'enfant est ensuite vu le même jour pendant une demi-heure par la diététicienne.

L'approche *intégrée* permet la communication entre les différents intervenants. Des réunions de travail en interne sont prévues avant et après les consultations.

Des séances individuelles de kinésithérapie sont parfois prévues pour permettre à l'enfant de pouvoir réintégrer un club sportif. L'objectif de ces séances est d'aider l'enfant à reprendre confiance en son corps et à retrouver le plaisir de faire du sport.

- Quel est le paradigme dominant ?

L'objectif principal est la modification des habitudes de vie de l'enfant.

- Combien de temps le programme est-il prévu ?

C'est une prise en charge à long terme, entre 1 et 3 ans.

- Evaluation des résultats ?

Evaluation en cours (mémoire de Mme C. Bila)

- Lien avec la scolarité ?

L'équipe rencontre parfois l'école (PMS ou éducateur) si le jeune y rencontre des problèmes (moqueries, problèmes d'insertion sociale) ou s'il vit en internat (adaptation du régime alimentaire)

- La place des parents ?

Sont impliqués à chaque consultation : les parents ou toute autre personne s'occupant de l'éducation de l'enfant. Par exemple, si les grands-parents accueillent l'enfant après l'école et lui préparent à manger, ils seront aussi invités à la consultation. Si les parents sont divorcés, l'équipe reçoit le père et la mère séparément une fois sur deux.

Les parents sont impliqués dans le processus de modification des habitudes de vie de leur enfant (cuisine, recherche d'activités pour leur enfant, etc.)

- Critères de fin de traitement ?

Le traitement s'arrête lorsque le jeune a modifié son style de vie et qu'il n'y a plus de problèmes psychologiques observés et ceci quel que soit le poids atteint.

- Taux d'abandon en cours de traitement

Evaluation en cours (mémoire de Mme C. Bila)

- Raisons d'abandon

Evaluation en cours (mémoire de Mme C. Bila)

Manque de motivation des enfants et des parents, le délai trop long entre les rendez-vous (si les parents ne sont pas organisés dans leur prise de rendez-vous, ils doivent attendre 6 mois entre chaque consultation)

Travail en réseau ?

Un travail en réseau est effectué. Dans certains cas, des contacts sont pris avec une psychologue dans la région de la famille pour permettre un suivi plus proche du domicile.

Accessibilité pour le patient

- Coût

Seule est remboursée la consultation du pédiatre

Coût (€) par consultation		
Intervenant	**Coût total**	**À charge des parents**
Pédiatre	29	9
Psychologue	20	20 (5 si difficultés sociales)
Diététicienne	18	Remboursement partiel suivant l'organisme de mutuelle et la région

- Liste d'attente : 6 mois

Rapport d'activité

Evaluation en cours (mémoire de Mme C. Bila)

Difficultés rencontrées et améliorations possibles

- Liste d'attente trop longue avec comme conséquence la diminution de la motivation des familles.
- Manque d'une secrétaire pour l'organisation des rendez-vous. Il est très utile de retéléphoner aux familles 15 jours avant leur rendez-vous. Ceci permet de diminuer de manière importante le nombre de désistements. Ce travail permet par exemple de rencontrer 6 enfants par après-midi sur les 7 rendez-vous prévus. Si aucun rappel téléphonique n'est réalisé, seulement 3 rendez-vous sur 7 sont honorés.
- Manque d'une assistante sociale pour le relais avec l'école et le domicile. Les familles ont parfois beaucoup de mal à organiser leur quotidien. Il faut dans certains cas les aider à rechercher des activités pour leur enfant dans leur région.
- Dans le travail en réseau avec des diététiciennes des autres régions : la formation des diététiciennes n'est pas toujours *up to date,* les traitements diététiques ne sont pas toujours adaptés aux enfants.
- Une demande de convention de la part de plusieurs centres de prise en charge des enfants obèses a déjà été introduite auprès du Ministère de la Santé. Cette source de financement permettrait de diminuer la liste d'attente, d'augmenter la durée et la fréquence des consultations pour pouvoir ainsi répondre correctement à la forte demande des familles.

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C : TRAITEMENT RESIDENTIEL DE L'OBÉSITÉ CHEZ L'ENFANT – L. PORINIOT

Service : Centre médico-pédiatrique L.Poriniot – Biez

Interlocuteur(s) : Dr Melika, Médecin Directeur ; Dr Nizet (Pédiatre) ; Dr Picard (Pédopsychiatre)

Date d'entrevue : 21 mars 2006

Présents KCE : L. Kohn

Objectif de la visite :

Décrire le service en relation avec la prise en charge des enfants obèses

Description du service :

Le centre est un ancien sanatorium-preventorium et est géré par les mutualités neutres. Il s'agit d'une reconversion de lits pour malades avec pathologie pulmonaire.

- Volume patient : 28 patients obèses sur 38 lits occupés. En effet, la convention finance 30 lits et donc autorise l'occupation de 30 lits 365 jours par an. Etant donné que les enfants sont régulièrement en vacances ou en week-end, il est possible d'accepter 40 enfants qui ne seront pas présents les 365 jours, pris en charge durant une année scolaire environ renouvelable. Le centre est accessible à tous les jeunes, pas seulement aux affiliés des mutualités neutres.
- Les jeunes obèses côtoient au quotidien les autres enfants et adolescents traités en intra-muros pour d'autres pathologies chroniques. Ils sont répartis dans le bâtiment selon l'âge et le sexe mais pas en regard de leur pathologie.

L'existence d'une liste d'attente n'est pas claire.

- Sources de financement :

Les financements des journées d'hospitalisation proviennent de l'unique convention 'maladies chroniques' qui lie le centre à l'INAMI (pour 30 lits).
Le traitement de l'obésité intervient dans le cadre de cette convention.
Tous les patients obèses sont internes, il n'y a pas de prise en charge en ambulatoire à L.Poriniot pour cette pathologie.
Les parents participent financièrement pour la somme de 1,45€ par jour. Certaines factures restent cependant impayées.

- Ressources humaines

Une équipe de soins prend en charge les patients obèses. La composition de l'équipe est définie par la convention INAMI. Elle est constituée de plusieurs médecins dont au minimum 1 pédiatre et 1 pédopsychiatre), 1 diététicienne, 1 logopède, 1 ergothérapeute, une infirmière, 1 kinésithérapeute, 1 psychologue et une assistante sociale et une infirmière sociale une équipe éducative et du staff administratif.

- Infrastructure spécifique : salle de fitness + piscine + école primaire et maternelle de type 5 – discussion sur l'utilité et la pertinence d'un enseignement secondaire sur place

Description des patients

- Origine :

Les jeunes patients sont toujours envoyés suite à une prescription médicale.
Le centre étant relié aux mutualités neutres, les patients sont informé de l'existence du centre par ce biais.
En général, les enfants arrivent au centre suite à un constat d'échec de la prise en charge en ambulatoire. Ils proviennent de toute la Communauté française. Des demandes de l'étranger ont été effectuées au centre.

- Caractéristiques socio-démographiques et statut socio-économique :

Une majorité de filles adolescentes sont traitées pour obésité dans le centre.

Il semblerait que les enfants de L. Poriniot proviennent de milieux défavorisés. Ce constat repose uniquement sur l'impression des intervenants car il n'y a pas de collecte de données systématique pour le moment.

- Indications médicales :

Les enfants sont admis en fonction des critères d'admission repris dans la convention avec l'INAMI. Ils présentent une série de co-morbidités associées telles que hypertension artérielle, diabète (et autres pathologies endocriniennes), pathologies ostéo-articulaires, hypercholestérolémies, pathologies dermatologiques et psychologiques. D'après le pédopsychiatre uniquement, des problèmes d'abus sexuels seraient présents chez au moins 50% des patients.
Avant d'être admis pour un traitement dans le centre, l'enfant et ses parents passent 1 ou 2 entretiens de pré admission, éventuellement, une journée dans le centre et une période d'essai de 3 semaines. Cette période d'essai a pour but de réaliser une anamnèse médicale pédiatrique, une anamnèse psychologique, une anamnèse diététique et évaluer la motivation de l'enfant et de sa famille. De ce bilan dépendra l'admission ou non de l'enfant dans le centre, et ce après décision de l'équipe de soins.
L'enfant sera pris en charge au cours de l'année scolaire suivante avec comme objectif l'atteinte d'un poids idéal individuel (réaliste et défini en 2 étapes) qui est différent du poids idéal médical.

Traitement :

- Type de soins : prise en charge multidisciplinaire, traduite en environs 4 réunions sur le séjour, principalement médicale : équilibre calorique, adoption d'une alimentation équilibrée et variée et dépense d'énergie. Pas de recours médicamenteux ni chirurgical pour le traitement de l'obésité

- Programme de traitement :

Le traitement est individuel avec des prises en charges individuelles et en groupe.
Le programme comporte :

  - de la kiné au quotidien à la disposition du jeune (fitness, natation, psychomotricité, activités sportives à l'extérieur comme du vélo dans le parc ou des entraînements football) dont certaines séances sont « contractuelles » : le jeune s'est engagé à en suivre un minimum. Ces séances sont fixées au cours de la période d'observation ;
  - de la diététique comprenant des entretiens individuels, des ateliers cuisine, des cours d'éducation nutritionnelle ;
  - de la logopédie et cours d'orthographe et de lecture si nécessaire ;
  - de l'ergothérapie si nécessaire ;
  - des séances de psychothérapies collectives (groupes de parole) et/ou individuelles ;
  - des activités avec les éducateurs : ballades, visites de musées, apprentissage de nouveaux sports, activités culinaires,…

La prise en charge des enfants a lieu après l'école pour les enfants en secondaire. La scolarité est poursuivie soit dans l'école primaire rattachée au centre soit dans un établissement secondaire à l'extérieur du centre. Les enfants rentrent dans leur famille en moyenne un week-end sur deux, parfois pour respecter les conditions de la convention (83 jours maximum en dehors du centre). Le traitement s'étale a priori sur une année scolaire avec parfois des retours précipités par des facteurs extérieurs (familiaux).
A sa sortie, l'enfant sera pris en charge par un réseau mis sur pied au cours de son internat.

Les parents sont invités à rencontrer les intervenants de chacune des disciplines pour suivre l'évolution de leur enfant. L'infirmière sociale effectue des visites au domicile des parents. L'éloignement géographique est un frein à une participation plus active des parents.

- Les abandons s'élèvent à 2/38 pour cette année.

- Suivi des patients après la sortie : Cette mission ne fait pas partie de la convention. Le seul 'suivi' se produit lorsque l'enfant se présente pour un éventuel deuxième séjour (soit 5 enfants sur 38).

Données collectées :
Des données standardisées mais non informatisées sont collectées dans le cadre du dossier médical des enfants. Elles n'ont pour le moment pas fait l'objet d'analyses ni d'un rapport.
La convention liant L.Poriniot à l'INAMI ne comporte pas d'exigence d'évaluation et de collecte de données.

Conclusion et messages-clés :

- La prise en charge de patients se prépare quelques mois avant l'admission avec une « période d'observation » qui dure 3 semaines ;
- Les patients semblent issus de familles socio-économiquement plutôt défavorisées.
- Prise en charge multidisciplinaire avec un accent mis sur l'équilibre calorique et la dépense d'énergie. Pas de recours aux médicaments ni à la chirurgie pour le traitement de l'obésité
- Pas de collecte de données informatisées ni rapport d'activité pour le moment

D : TRAITEMENT RESIDENTIEL DE L'OBÉSITÉ CHEZ L'ENFANT - CLAIRS VALLONS

Service : Centre médico-pédiatrique Clairs Vallons – Ottignies

Interlocuteur(s) : Dr De Buck, Médecin Directeur

Date d'entrevue : 17 mars 2006

Présents KCE : ML. Lambert – L. Kohn

Objectif de la visite :

Décrire le service en relation avec la prise en charge des enfants obèses

Description du service :

- Sources de financement :

Le centre est orgnaisé en ASBL dirigé par un CA composé de membres des Mutualités socialistes. Il est aux patients de toutes les mutualités.
Les financements proviennent uniquement des conventions qui lient le centre à l'INAMI. Le prix de la journée est fixé par ces conventions.
Elles sont au nombre de 3 :

- la convention médico-psycho-sociale
- la convention mère-bébé
- la convention maladies chroniques.

Le traitement de l'obésité intervient dans le cadre de la convention 'maladies chroniques'. Le centre traite des patients obèses depuis 5-6 ans, depuis qu'une convention finance ce type de prise en charge.
Les parents participent financièrement pour une modique somme par jour (4.64 euros) augmentée de certains frais extraordinaires (activités sportives à l'extérieur par exemple)

- volume des patients : 46 patients pris en charge pour la plupart durant une année scolaire environ.

Tous les patients sont internes, il n'y a pas de prise en charge en ambulatoire à Clairs Vallons pour cette pathologie.

- ressources humaines

Les enfants sont répartis dans différents pavillons (2 pour le traitement de l'obésité). A chaque pavillon est allouée une équipe de soins constituée d'un médecin (pédiatre), 2 psychologues, 1 diététicienne, 1 logopède, un assistant social, une équipe de kiné, un pédopsychiatre et une équipe éducative.

- Infrastructure spécifique : 2 salles de fitness – école primaire de type 5 – école secondaire en projet, ouverture en septembre 2006.

Description des patients

- Origine :

Les jeunes patients nous sont adressés obligatoirement sur prescription médicale, qu'elle soit de l'initiative du médecin soit de la leur.
En général, les enfants arrivent au centre suite à un constat d'échec de la prise en charge en ambulatoire. Ils proviennent de toute la Communauté française.

- Caractéristique socio démographiques et SES :

Un plus grand nombre de filles sont traitées à Clairs-Vallons, elles représentent 62% des patients. Les enfants sont âgés de 6 à 18 ans dont plus de la moitié ont entre 12 et 15 ans. Il semblerait que les enfants de Clairs Vallons ne proviennent pas de milieux particulièrement défavorisés. Les parents sont moins nombreux à être sans emploi et plus instruits en moyenne par rapport aux moyennes nationales. D'un point de vue médical, on constate une surreprésentation de parents obèses ayant eu recours à la chirurgie en comparaison avec la prévalence de cette maladie dans la population générale ainsi qu'une plus grande prévalence de troubles mentaux associés dans la famille.

- Indications médicales :

Les enfants sont admis après évaluation en fonction des critères repris dans la convention avec l'INAMI. Ils présentaient en 2004-2005 un BMI variant de 25.77 à 55.90. Les critères de BMI ne concernent que les enfants de plus de 17 ans. Jusque 16 ans, BMI> ou = 97ème percentile, selon les courbes de l'INSERM.
Leur pathologie est évaluée comme sévère ou modérée afin d'affiner le financement lié à leur séjour et dépend de l'intensivité des prises en charge nécessaires en fonction des pathologies associées. On constate une grande prévalence de pathologies médicales associées à l'obésité : 79% en ont au moins 1 dont plus de la moitié, plus d'une. De même, 95% présentent des troubles psychologiques ou psychiatriques associés.

Avant d'être admis pour un traitement dans le centre, l'enfant et ses parents passent 2 ou 3 entretiens préalables avec le psychologue, le coordonnateur de l'équipe éducative et le médecin au cours de l'année précédent l'entrée. Ces entretiens ont pour but de présenter le projet et de réaliser une anamnèse quant au fonctionnement familial ainsi qu'une anamnèse pédiatrique et diététique et de s'assurer de l'adéquation du projet pour le patient.
L'enfant sera pris en charge au cours de l'année scolaire suivante. Cependant, des entrées en cours d'années scolaires sont possibles en fonction des disponibilités. Un 2ème séjour est possible, si accord du médecin-conseil

Traitement :

- type de soins : prise en charge multidisciplinaire de type rééducation fonctionnelle avec chaque semaine, une réunion pluridisciplinaire : par semaine., une réunion éducative et une réunion thérapeutique :

    - pas de restriction calorique (2500Kcal/ jour)
    - basée sur la dépense d'énergie et l'adoption d'une alimentation équilibrée et variée
    - prise en charge psychologique
    - Pas de recours médicamenteux ni chirurgical pour le traitement de l'obésité décidée par l'équipe soignante

- programme de traitement :

Le traitement multidisciplinaire est individuel avec des prises en charges individuelles et en groupe.
Le programme comporte :

- de la psychothérapie individuelle, familiale et groupale ;
- de la kiné au quotidien (fitness, natation, aérobic, psychomotricité)
- de la diététique comprenant des entretiens individuels et en groupe, des ateliers cuisine, des visites de supermarché pour apprendre à lire les étiquettes entre autres.
- de la logopédie ;
- l'école des devoirs : un certain nombre d'enfants sont en situation de décrochage scolaire

Les parents sont invités régulièrement à rencontrer les intervenants pour suivre l'évolution de leur enfant, participer aux entretiens de psychothérapie et diététique familiaux et préparer le retour en famille. Les parents participent également à des groupes de parole.

Les enfants en primaire sont inscrits à l'école Clairs-Vallons (type 5).Les enfants en âge de scolarité secondaire suivent leur scolarité à l'extérieur du centre.
La prise en charge des enfants a lieu après l'école après 15h30 et un week-end sur deux (retour en famille l'autre week-end). Il s'étale a priori sur une année scolaire.
A sa sortie, l'enfant sera pris en charge par un réseau identifié au cours de son séjour résidentiel.

Le travail se fait en collaboration avec le centre sportif du Blocry afin de préparer la poursuite d'activités sportives à la sortie.

- Le nombre d'abandon est de 5/46 cette année.

- suivi des patients après la sortie : cette mission ne fait pas partie de la convention et n'est donc pas financée. Quelques entretiens de suivis et de follow-up sont cependant prévus à raison de 3 séances systématiquement proposées.

Données collectées :
Un système d'information sanitaire de recueil de données de routines a été mis en place : des données standardisées et informatisées sont collectées dans le cadre du dossier des enfants. Elles comportent des informations de type médical mais également psycho-social et familial.
Une analyse fouillée de ces informations a été réalisée dans le cadre de l'évaluation de la convention demandée par l'INAMI et les résultats présentés dans le rapport d'activité.
Par exemple, on y observe une bonne à très bonne compliance au traitement pour plus de la moitié des patients et pour un tiers de leur famille. Les enfants perdent en moyenne 9 points de BMI au cours de leur hospitalisation. De plus la majorité d'entre eux ne présentera plus de pathologie médicale associée à l'obésité (21% à l'entrée pour 67.5% à la sortie) et 7.5% présenteront encore plus d'une pathologie (contre 41.6% à l'entrée).
Exceptionnellement, un mi-temps psychologue a été alloué à la collecte des données et à la rédaction du rapport d'activités ; des fonds propres ont été réservés aux analyses. Toutefois, il ne s'avère pas possible de poursuivre cette démarche sans financement complémentaire. Pour cette même raison, une étude de follow up à des fins de recherche n'est pas envisageable.

Conclusion et messages-clés :

- La prise en charge de patients se prépare un an à l'avance
- Prise en charge multidisciplinaire de rééducation fonctionnelle : psychologique et basée sur le comportement alimentaire et la dépense d'énergie, sans restriction calorique spécifique. Il n'y a pas de recours aux médicaments ni à la chirurgie pour le traitement de l'obésité
- Evaluation des activités et production d'un rapport d'activité (requis par la convention) avec analyses fouillées

E: RESIDENTIAL TREATMENT OF OBESITY IN CHILDREN - THE ZEEPREVENTORIUM IN DE HAAN

Report of visit to the Zee Preventorium, De Haan, 23-08-2008, by Luc Bonneux and Marie-Laurence Lambert

This former sanatorium adjusted to changing patterns of diseases and care. It was the staff's own decision to focus on obese youths (3-18 years) to whom the Zeepreventorium started to offer specialised care in 1994. Only in 2000 was the 'obesity' specificity officially included in the INAMI/RIZIV convention through which the Zeepreventorium is financed. An all-inclusive lump sum of +/- 180 Euros per patient/day is paid by INAMI to the Zeepreventorium.

Out of 200 beds, 120 are now exclusively dedicated to obese children (other beds accommodate children with other chronic diseases like severe asthma, and atopic eczema, chronic fatigue syndrome, and metabolic diseases).

The obese patients

Official criteria for admission for obesity treatment are:

- >=16 y.o. : BMI over 97e percentile (INSERM tables)
- 17-18 y.o. : BMI >= 35

These criteria can be lowered BMI > 30 in case of co-morbidity, which is extremely frequent. Particularly prevalent are mental health problems, like depression, anxiety, and low self-esteem.

A 'typical' patient would arrive after several failed attempts at loosing weight, often having dropped out of school. Tensions and communications problems with the family are also frequent. Patients come from all over Belgium.

Adolescent girls are the most represented group. There is a waiting list of up to 6 months for younger children (< 12 years) and up to 12 months (even longer for girls) for older children.

As reported by the staff, trends seem to be towards increasingly severe obesity, and co-morbidity on admission.

The care package

This was the first initiative of its kind in Belgium, and apparently in an European Country. There was no similar experience to build upon and the care package has been developed on an empirical basis.

Length of stay is variable, but youths typically stay between 10 and 12 months. They spend week-ends at home. A school is annexed to the Zeepreventorium.

The approach is multidisciplinary. The staff includes physiotherapists, psychologists, dieticians, social workers, educators, and medical doctors,

- The diet provides 1600 calories/day. It is usually not individualized. The programme includes cooking lessons, even 'food shopping' lessons for the eldest
- Sports (4 hours/week) and physiotherapy (4 hours per week) under the supervision of a physiotherapist
- Cognitive therapy: individual and group therapy, as well as family therapy.
- Medical assessment is done on admission and every 2 weeks. No drugs are given to enhance weight loss.

In-patient care is felt to be a necessary condition to the package (being away from the family and usual environment)

The stay in the Zeepreventorium overall is extremely structured and demanding for the patients, but motivation seems to be high. Average drop-out is hardly 1%.

The '*dominant paradigm'* of this care package is as much psycho-social as bio-medical.

Follow-up after discharge

This is not 'officially' part of the Preventorium mission; on the other hand patients come from all over Belgium, and follow-up would need to be decentralised anyway.

A serious problem is therefore the lack of a specialised reference network. It is not clear either what this 'specialised reference' should be. A multidisciplinary, hospital-based team? A dietician? A therapist trained in systemic therapy? A general practitioner?

Monitoring and evaluation

There is no systematic data collection of outcomes as clinical files are not computerised. No resources in the Zeepreventorium are ear-marked for monitoring and evaluation. Weight loss is usually important at discharge, but improvements in 'socio-psychological' functioning are equally important outcomes.

The Zeepreventorium maintains close contact with academic teams from various universities (like faculty of psychology in Ghent). Research is conducted by the academic teams on an 'ad hoc' basis, depending on the availability of funds and students. This applies also to the study of long-term outcomes after discharge.

Work is underway with a university team to design a computerised health information system that could help both in clinical management and in compiling and analysing relevant data.

- Main conclusions and key points
- the Zeepreventorium is building a unique expertise in the care of obese youths and is obviously responding to a high demand.
- The 'dominant paradigm' of this innovative care package is psycho-social as much as bio-medical.
- This experimental approach deserves to be better monitored, evaluated, and researched (particularly long-term results), so that it could benefit others. Additional resources should be made available to the Preventorium for this purpose.
- A major problem is the lack of a structured referral care network after discharge.

APPENDIX CHAPTER 9: LEGAL ASPECT OF WEIGHT LOSS INTERVENTIONS

CONFLICT OF LAW AND JURISDICTION

1.1 COMPETENT COURT

1.1.1 Contractual liability[1]

According to European legislation competent courts are those from the country where the obligation (=the object of the contract) was performed[2]. The European legislation has been transposed into Belgian law.

According to the Belgian law, Belgian courts are competent if

a) parties contracted in Belgium or

b) if the contract is carried out or has to be carried out in Belgium

If for instance a British patient comes on his own initiative to Belgium and contracts with a Belgium hospital to have a gastric band, the Belgian courts will probably be competent.

There is however a special protection for consumers contracts that can also apply to some cross border bariatric surgery contracts[3]. This protection applies a.o. to contracts

- for the supply of services which in the State of the consumer's domicile the conclusion of the contract was preceded by a specific invitation addressed to him or by advertising and
- the consumer took in that State the steps necessary for the conclusion of the contract.

If these conditions are met a consumer may bring proceedings against the other party to a contract either in the courts of the contracting State in which that party is domiciled or in the courts of the contracting State in which he is himself domiciled[4].

If for instance a Belgian organisation advertises on bariatric surgery performed in Belgium in an English magazine and the patient contracted in England with a branch where information is given and preliminary medical examination are performed, the consumers' protection will probably apply. Consequently the patient will be able to choose to bring proceedings in Belgium or in England.

1.1.2 Tort liability

According to the European legislation the courts of the place where the harmful event occurred are competent[5].

According to the Belgian law the Belgian court is competent[6] if a) the act that caused the damage occurred partly or entirely in Belgium or is likely to occur in Belgium

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1 art. 96 van 16 juli 2004 houdende het wetboek van international privaatrecht, *B.S.* 27 juli 2004 (after this Wet internationaal privaatrecht)

2 art. 5.1 Brussels Convention on jurisdiction and the enforcement of judgments in civil and commercial matters, http://www.jura.uni-sb.de/convention-bruxelles/en/c-textes/brux-idx.htmhttp://www.curia.eu.int/common/recdoc/convention/en/c-textes/brux-idx.htm

3 art. 13, 14 en 15 Brussels Convention

4 It should be noted that the protection specifically addresses to the "passive" consumer (or patient) that has been recruited by advertisement. Patients going abroad on their own initiative are consequently not protected

5 art. 5.3 Brussels Convention

6 art. 96 Wet International Privaatrecht, *B.S.* 27 juli 2004

or

b) if the damage occurred in Belgium or is likely to occur in Belgium.

This implies that if damage results from a medical mishap occurred in Belgium the Belgian courts will be competent.

1.2 APPLICABLE LAW

1.2.1 Contractual liability

There is a set of EU rules[7] relating to contractual obligations. The Belgian law explicitly refers to the Rome convention.

a) Liberty of choice but safeguard for consumers' contracts

In principle contract parties are free to choose which legislation will be applicable to the contract[8]. However, patient contracts will sometimes be standard contracts which patients cannot negotiate and are compelled to take or leave. Therefore some safeguards should be provided. There is a special protection for "consumers' contracts" which in specific circumstances can also apply to patient contracts in the scope of cross border health services:

Notwithstanding the fact that a choice is made by a contract party, that choice shall not have the result of depriving the consumer of the protection afforded to him by the mandatory rules (= all regulations aiming at the protection of the consumer[1]) of the law of the country in which he has his habitual residence:

i) if in that country the conclusion of the contract was preceded by a specific invitation addressed to him or by advertising, and he had taken in that country all the steps necessary on his part for the conclusion of the contract, or

ii) if the other party or his agent received the consumer's order in that country, or…

It is conceivable that some cross border contracts with regard to bariatric surgery meet the criteria mentioned in i) or ii).

The protection however doesn't apply to a contract for the supply of services where the services are to be supplied to the consumer exclusively in a country other than that in which he has his habitual residence. Cross border contracts with regard to bariatric surgery offered by organisations (packages) often offer services in the country in which the patient has his residual residence. For instance the counselling, the provided information or the preliminary checks by the GP can occur in the home country of the patient… Consequently, in similar circumstances, the consumers' protection can probably be applied.

There is a proposal for a new regulation on the law applicable to contractual obligations, mainly adapting the regulations to the development of new forms of marketing (for instance via the internet) and distribution[9]. The new Regulation[10] provides the automatic application of the law of the consumers' country of residence if the business directs its activities towards the consumer.

This protection will however not apply for the supply of services where the services are to be supplied to the consumer exclusively in a country other than that in which he has his residual residence (art. 5 § 3). Consequently it can be questioned to what extent the consumers'

7Rome Convention 1980 http://www.jus.uio.no/lm/ec.applicable.law.contracts.1980/doc.html#26

8 art. 3 Rome Convention

9 http://europa.eu.int/servlet/portail/RenderServlet?search=DocNumber&lg=en&nb_docs=25&domain=Preparatory&in_force=NO&an_doc=2002&nu_doc=654&type_doc=COMfinal

10 http://europa.eu.int/servlet/portail/RenderServlet?search=DocNumber&lg=en&nb_docs=25&domain=Preparatory&in_force=NO&an_doc=2002&nu_doc=654&type_doc=COMfinal

protection still applies to bariatric surgery tourism contracts in the scope of this new regulation. This all depends on the question if bariatric surgery can be presumed as a service that has been supplied exclusively in the foreign country. As aftercare should be part of the surgery and often is provided in the home country of the patient, one could argue that bariatric surgery is not exclusively performed in the foreign county and that consequently the consumers' protection still applies.

b) If no choice has been made

To the extent that the law applicable to the contract has not been chosen, the contract shall be governed by the law of the country with which it is most closely connected[11] . It shall be presumed that the contract is most closely connected with the country where the party who has to perform the act that characterises the contract has, at the time of conclusion of the contract, his habitual residence or in case the other party is an organisation, has its central administration.

If it appears from the circumstances as a whole that the contract is more closely connected with another country the law of that country will be applicable[12].

If for instance there was a contract between a Belgian physician and a British patient, the act which is characteristic for the contract is the operation. If the surgeon has his/her habitual residence in Belgium the Belgian law will apply to the contract.

1.2.2 Tort liability

With regard to the applicable law on liability issues, the Rome II convention which is transposed into Belgian law applies.

The general rule states that the law of the place where the direct damage arises or is likely to arise applies (lex loci delicti commissi). The application of this rule however if often problematic in cases where the harmful event and the place where the loss is sustained are spread over several countries. Imagine for example the case of complications after bariatric surgery due to a medical mishap. The place where the direct damage arises can be interpreted in two ways: the place where the patient got the surgery or the place where the complications occurred. Solutions emerge from the decisions of the courts but often remain uncertain.

There are variations between national laws[13] as regards the practical impact of the 'lex loci delicti commissi' rule. The Belgian law states that the law of the country where the act that caused the damage and the damage have arisen entirely or are likely to arise is applicable[14]. It is however possible that the surgery performed in Belgium can cause damage that arises in another country. In that case the court can decide to apply the law of the country that is closest linked to the obligation (=the operation). In case of medical negligence with regard to bariatric surgery performed in Belgium, the Belgian law will probably apply. In order to facilitate things and to respects the autonomy parties freedom of choice of the applicable law after the dispute has arisen could offer a solution.

There is however a proposal for a regulation of the European Parliament and the council of the law applicable to non – contractual obligations[15] offering the freedom of choice of the applicable law after the dispute arose in order to respect the intentions of parties. As a general rule for "double locality cases" (i.e. cases where the act complained of happened and the place of damage are located in different countries) that the applicable law is that of the country where the loss is sustained. In particular the basic rule of the draft Regulation leads in many cases leads to the application of the laws of the country of the victim's residence.

11 art. 4

12 art. 4, 5

13 The Rome II convention has been transposed to the national legislation of the member states that signed the convention

14 artikel 99 wet international privaatrecht

15 http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2006/com2006_0083en01.pdf

The exceptions to the general rule, lead to the application of the law of the parties' common habitual residence or of the law of the country with which the situation presents a "substantially closer connection".

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Legale depot : D/2006/10.273/31

KCE reports

34 Trastuzumab in Early Stage Breast Cancer. D/2006/10.273/25.
36 Pharmacological and surgical treatment of obesity. Residential care for severely obese children in Belgium. D/2006/10.273/30.

Note: All KCE reports are available with a Dutch or French executive summary. Scientific summaries are often written in English.