

Index (BMI) was significantly associated with positive expenditures. Higher BMI was correlated with more positive expenditures. The most appropriate framework for the GLM was the Gamma distribution. The GLM showed that higher BMI was associated with greater expenditures. Age, gender, and marital status (separated and never married) were significantly associated with health care expenditures. Degree of education (Bachelor and Masters) was also significantly related but negatively correlated. **CONCLUSIONS:** Health care expenditures are significantly associated with BMI using a gamma distribution, where age, gender, marital status and education are also significant.

**POB2****COSTS OF PREMATURE DEATH ATTRIBUTED TO OBESITY IN SPAIN**

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**OBJECTIVES:** Obesity has become an important public health issue because of its link to high rates of avoidable and premature morbidity and mortality, especially due to its association with severe cardiovascular diseases and cancer. The objective of this study is to describe the mortality attributed to obesity in Spain in 2000 and its associated costs. **METHODS:** Mortality associated with obesity was obtained by combining mortality data for the general population and the PAR (Population Attributable Risk). Loss of potential productive life years attributable to obesity was estimated, based on activity rates of population under 65 years old. The costs associated to premature death were then obtained by multiplying by mean wage figures. **RESULTS:** 18.7% of all the deaths could be attributed to obesity. This mortality was similar in males and females (10.116 vs 11.537). The life years potentially lost attributable to obesity were 23,510, distributed as follows: 1015 for DM type 2, 422 for hypertension, 8925 for ischemic heart disease, 3854 for stroke, 61 for osteoarthritis, 3330 for colorectal cancer, 897 for ovarian cancer, 3649 for breast cancer, 1359 for vesicle cancer. The loss of productivity years, based on activity rates for population under 65 years was 12,309, meaning a loss of €294 million. **CONCLUSIONS:** This economic approach to premature death shows how deep is the impact of obesity on the productivity of our country. But obesity and its comorbidities increase with age, reaching its highest prevalence after 65 years old, meaning that the real impact of obesity in mortality in general is even more significant. Given that abdominal obesity has been proved to be a specific risk factor for cardiovascular events, and that its prevalence is higher than obesity itself, this analysis could be completed by including this parameter, once the data are available in the literature.

**POB3****COST-UTILITY ANALYSIS OF RIMONABANT IN THE TREATMENT OF OBESITY**

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**OBJECTIVES:** Rimonabant is a new agent currently seeking approval by the FDA for the indications of smoking cessation and treatment of obesity. This study estimates the cost-utility ratio of rimonabant for the treatment of obesity using data from two phase-III clinical trials. **METHODS:** Data from the Rimonabant in Obesity (RIO) Europe and RIO Lipids trials, two randomized, double-blinded, placebo-controlled, parallel group, fixed-dose, multicenter studies, were used to model utilities gained as increase in quality of life due to a temporary weight loss during a one-year treatment with rimonabant. In this study,

two separate analyses were conducted: first, treatment with rimonabant 20 mg/d plus dietary modification versus placebo plus dietary modification and second, comparison of treatment as above with a hypothetical no intervention group. The second analysis assumed no reduction in BMI [kg/m<sup>2</sup>] and zero costs for the no intervention group. The temporary weight loss for the treatment and placebo group was calculated assuming a weight regain to baseline within 3 years after treatment cessation. Costs included drug acquisition costs (estimated based on costs for comparable agents), physician office visits and dietary counseling. Efficacy estimates were discounted at 3%. **RESULTS:** Reduction in BMI was 2.395 and 0.601 for treatment and placebo, respectively. In the second analysis, comparison to no intervention, treatment resulted in a BMI reduction of 3.133. The incremental cost-utility ratio is \$38,884 per QALY comparing treatment to placebo and \$28,364 per QALY compared to no intervention. Sensitivity analysis revealed that the results are sensitive to variations in acquisition costs and sustainability of weight loss. **CONCLUSIONS:** Rimonabant is able to increase quality of life by reducing body weight. This benefit is achieved at considerable costs; however, the cost-utility ratios are well below the currently accepted thresholds.

**OBESITY—Methods and Concepts****POB4****USE OF GROWTH CURVE ANALYSES FOR DISCRETE EVENT SIMULATION: A CASE STUDY OF POOLED CLINICAL TRIALS OF THE EFFECTS OF RIMONABANT ON CARDIOMETABOLIC RISK FACTORS IN OBESE PATIENTS**

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**OBJECTIVE:** To predict effects over time on cardiometabolic risk factors of adding rimonabant to diet and exercise in overweight/obese patients. Both weight-dependent and weight-independent effects of treatment were examined in order to carry out a Discrete Event Simulation (DES). The DES predicts the time-dependent course of individual patients' data according to treatment. **METHODS:** Data were taken from 4 RIO trials in over 6600 overweight/obese patients who received once-daily rimonabant 20 mg (or placebo) on top of diet and exercise. Time-dependent functions of individual changes in weight, waist circumference, cholesterol, HDL-cholesterol, triglycerides, HbA<sub>1c</sub>, fasting glucose, and blood pressure were required for the DES. Change over time was analyzed in pooled trial data using a two-step process: 1) Logistic regressions predicted whether the parameter would decrease, and 2) fractional polynomials predicted change as a function of time and other factors. Random-effects were included to account for within and between patient variance. **RESULTS:** One year of treatment induced cardiometabolic improvements following a curvilinear course with steep initial changes and subsequent stabilization after six to nine months. To properly reflect these time-dependent changes, several time parameters were required in each equation. The degree of change over time depended on baseline levels and other patient characteristics and on weight changes, but rimonabant 20 mg provided an additional, weight-independent, statistically-significant, effect (OR for worsening 0.36–0.88 depending on outcome considered). **CONCLUSIONS:** Multivariate time-dependent analytic techniques can provide the detailed estimates required for discrete event simulation. Growth curves enable estimation of the course of each simulated individual over time by providing for realistic modeling of risks and facilitate probabilistic sensitivity analyses. These analyses provided a detailed, accurate reflection

of rimonabant's effects, showing that its beneficial impact is present even when accounting for any reductions in weight, suggesting that there is an effect beyond weight loss.

### OBESITY—Patient Reported Outcomes

#### THE IMPACT OF BODY MASS INDEX ON HEALTH-RELATED QUALITY OF LIFE AMONG US ADULTS

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**OBJECTIVES:** To test the impact of body mass index (BMI) on health-related quality of life (HRQOL) in overweight and obese individuals. **METHODS:** Data were obtained from the 2002 Medical Expenditure Panel Survey (MEPS). MEPS collects data on health care use, insurance, access, and satisfaction, along with basic demographic and health status information for a representative sample of the US civilian non-institutionalized population. Our weighted sample consists of 207,969,360 adults. Regression analyses were used to detect independent effects of HRQOL (using EQ-5D US valuation and EQ VAS) on overweight and obese individuals. **RESULTS:** After adjusting for com-morbidities, smoking status, and socio-demographic variables, respondents with a self-reported BMI >25.0 kg/m<sup>2</sup> reported impaired quality of life. Health-related quality of life diminished with each increasing level of BMI ( $p < 0.01$ ). Additionally, HRQOL significantly diminished with increasing age ( $p < 0.01$ ). **CONCLUSIONS:** Our findings suggest a significant impact of BMI on changes in HRQOL that is independent of co-morbidities and socio-demographic variables.

POB5

#### SELF-IMAGE SCALE: A PRAGMATIC EVALUATION

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**OBJECTIVES:** To evaluate the self-image of women suffering from overweight, using a validated questionnaire. **METHODS:** Pharmacists who took part in this project gave 3 questionnaires to all their customers who had purchased a cartane oil (80% conjugated linoleic acids) treatment, explaining that the first questionnaire had to be filled in immediately after having bought the product and the others, after 6 and 10 weeks of treatment. Once completed, the questionnaire had to be mailed in its prepaid envelop by the subject. Questionnaire were then collected, typed in then analyzed anonymously. Self-image was evaluated by BISS scale. The hereby analysis was obtained from the first 118 filled in and returned questionnaires (inclusion, 6 & 10 weeks). The population was entirely made up of women with an mean age of 43.5 years, mean weight of 67.6 kg and average height of 162 cm. The BMI calculated using the two latter variables was of 25.5. **RESULTS:** For the SF-12 scale, mean scores upon inclusion were respectively of 47.2 and 40.6 for the physical and mental dimension. Six weeks later, these same scores were respectively of 45.6 and 45.6. Improvement is significant for the mental dimension. For the <<Self-image>> scale (BISS), scores were 22.8 upon inclusion and 28.46 weeks later. The difference was significant, hence putting forward an improvement in the body's image. After 10 weeks of treatment with cartane oil the effect is sustained, self-image is significantly improved (33.1). **CONCLUSIONS:** This result is confirmed through the significant improvement of the physical & mental dimension of the SF-12. mean scores were respectively of 52.9 and 44.4 for the physical and mental dimension.

POB6

### OBESITY AND QUALITY OF LIFE IN THE UNITED STATES:

2000–2002

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**OBJECTIVES:** To assess the impact of overweight/obesity on health-related quality of life (HRQL) and health utility in the U.S. **METHODS:** Adults (age  $\geq 18$ ) in the 2000 and 2002 Medical Expenditure Panel Survey (MEPS) were classified as underweight (BMI < 18.5), normal weight (BMI: 18.5–24.9), overweight (BMI: 25–29.9), obese (BMI: 30–39.9), and extreme obese (BMI:  $\geq 40$ ). HRQL was measured using the SF-12 mental score and physical score. Underweight adults were excluded from the analyses. Health utility was measured using EQ-5D index score and visual analogue scale (EQ-VAS). A stratified matching method was used to compare overweight, obese, and extreme obese samples with the corresponding normal weight samples matched by age, gender, race, current smoking status, and physical activity level. Effect sizes (ES) were estimated. Bonferroni method was used to adjust for multiple comparisons. MEPS individual weights were applied to achieve nationally representative statistics. **RESULTS:** Of the 36,897 adults in the study sample, 13,521 were with normal weight, 13,631 overweight, 8435 obese, and 1310 extremely obese. Descriptive results showed that normal weight sample had the highest average scores in all the HRQL and health utility measures. These findings were further supported by the results using the stratified matching method. Compared to matching normal weight adults, overweight adults had similar SF-12 mental scores and EQ-VAS scores, but significantly lower SF-12 physical scores (ES = 6.24,  $p < 0.01$ ) and EQ-5D index (ES = 3.72,  $p < 0.01$ ). On average, both obese and extremely obese adults had lower SF-12 mental score (ES = 5.25 and 17.23, respectively), SF-12 physical score (ES = 23.78 and 60.04, respectively), EQ-5D index (ES = 16.92 and 49.99, respectively), and EQ-VAS score (ES = 19.17 and 45.33, respectively). All differences were significant at 1%. **CONCLUSIONS:** Our study showed that obesity is a condition associated with significant reduction of physical and mental HRQL and health utility among adults in the United States. Overweight had a negative impact on physical HRQL and health utility.

POB7

#### IMPACT OF ABDOMINAL OBESITY ON QUALITY OF LIFE

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**OBJECTIVES:** To compare health-related quality of life (HRQOL) using the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) questionnaire in subjects with or without abdominal obesity (AO definition: waist circumference >102/88 cm for men/women, respectively). **METHODS:** Prospective Obesity Cohort of Economic Evaluation and Determinants (PROCEED) is an ongoing international, Internet-based, longitudinal, observational cohort of overweight/obese subjects [body mass index (BMI)  $> \text{or} = 25 \text{ kg/m}^2$ ], aged 35–75, intending to lose weight. The IWQOL-Lite is a validated 31-item self-reported questionnaire, specifically designed for HRQOL assessment in obesity, and comprises 5 domains (Physical Function, Self-esteem, Sexual Life, Public Distress, Work) and a total score. Using two-sample *t*-tests, baseline IWQOL scores for USA subjects were compared between AO groups overall; between genders within the sub-

POB8