Weight reduction by sibutramine in obese subjects in primary care medicine: the SAT Study.

BACKGROUND: Sibutramine is a selective serotonin and noradrenaline reuptake inhibitor that is known to reduce body weight. The efficacy of this drug in primary care medicine is currently unknown. OBJECTIVE: To study, in a primary healthcare setting, the effect of a standardized non-pharmacological treatment program and 15 mg sibutramine or placebo on long-term weight reduction in obese subjects with a body mass index $\geq 30$ and $< 40$ kg/m$^2$.

DESIGN: A multicentre, double-blind, placebo-controlled, randomized, parallel group comparison over 54 weeks of continuous therapy.

SETTING: 33 general practitioners in Germany.

SUBJECTS: 389 obese patients were recruited of whom 362 were randomized.

MEASUREMENTS: Primary measure was weight reduction at week 54; others included reduction in BMI, waist circumference, waist-hip ratio, blood pressure and blood lipids.

RESULTS: 348 obese subjects were analyzed using an intention-to-treat analysis. Mean weight loss in the sibutramine (S) group was 8.1 +/- 8.2 kg vs. 5.1 +/- 6.5 kg in the placebo (P) group (p< 0.001; Intent-to-treat analysis). More subjects lost more than 5 % and 10 % of initial weight with sibutramine than with placebo (5 %, S: 62.6 %, P: 41.4 %, p< 0.001; 10 %, S: 40.8, P: 19.0 %, p< 0.001). Weight loss was accompanied by an improvement in the lipid profile, in particular, an increase in HDL-cholesterol and a decrease in
fasting triglycerides. In both groups, systolic and diastolic blood pressure decreased in those with moderate hypertension and remained unchanged in those with normal blood pressure at baseline. There was a modest increase in heart rate in S (1.9 beats/min) vs. P (- 0.9 beats/min) (p< 0.05).

CONCLUSIONS: Under primary care conditions, sibutramine 15 mg daily proved to be a safe and effective drug for additional weight loss in obese subjects undergoing a comprehensive weight reduction program.

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