OBJECTIVE: Sibutramine, a serotonin and norepinephrine transporter inhibitor, is widely used as an adjunctive obesity treatment. There have been concerns that norepinephrine reuptake inhibition with sibutramine could exacerbate arterial hypertension. DESIGN: Combined analysis of two placebo-controlled trials. SUBJECTS: The combined data set consisted of 1336 patients. Of these patients, 966 were randomized to sibutramine and 370 were randomized to placebo. MEASUREMENTS: Body weight, blood pressure, heart rate (HR). RESULTS: Sibutramine reduced body weight regardless of basal blood pressure. In the complete set of patients, systolic blood pressure did not change with either intervention over the 48-week period (-0.1 +/- 15.5 mmHg with sibutramine, -0.2 +/- 15.2 mmHg with placebo, P=0.9). The change in diastolic blood pressure over the 48-week period was 0.3 +/- 9.5 mmHg with sibutramine and -0.8 +/- 9.2 mmHg with placebo (P=0.049). The blood pressure response was not exacerbated in patients with grade 1 or 2 hypertension or in patients with isolated systolic hypertension. Sibutramine treatment caused a slight increase in supine HR that was sustained throughout the studies. CONCLUSIONS: Sibutramine treatment is unlikely to elicit a critical increase in blood pressure even in hypertensive patients. However, blood pressure and HR should be monitored closely. In patients who experience a
clinically significant and sustained increase in blood pressure, the drug should probably be discontinued.