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Analysis of the all Russia observational studies: Reduxine® (Sibutramine) safety monitoring in patients with alimentary obesity and comorbidities

As in many other developed nations, the problem of obesity is acute in Russia, where it's prevalent in 24.1% of the population (28 million people). In Russia, Sibutramine (Reduxine) and a combination of Sibutramine and Metformin (ReduxineMet) are authorized to reduce weight in patients with obesity and type-2 diabetes mellitus or prediabetes. Since the administration of central-acting drugs as pharmacotherapy of obesity is the most pathogenetically justified treatment, the issue of safety of Sibutramine therapy is very important. In order to implement the principles of active monitoring of the efficacy and safety of Sibutramine in the current clinical practice and to develop an algorithm of it's reasonable prescribing the observation studies "Vesna", "Primavera" and "Aurora" were conducted in 2011-2017 under the auspices of Endocrinology Research Centre and the Russian Association of Endocrinologists. The programs were attended by 4,874 doctors of various specialties and 139,305 patients. In "Vesna" study it was shown that Sibutramine therapy is effective in weight loss, changing eating behavior and promotes positive changes in LDL, HDL, TG and fasting glucose. In the "Primavera" study the body mass reducing dynamics during 3, 6, 12 months was 9.5 ± 4.28 kg, 15.0 ± 6.22 kg, 20.0 ± 8.62 kg respectively. Moreover, it was shown that Reduxine therapy under the supervision of a physician was associated with decreased levels of systolic and diastolic blood pressure and had no effect on heart rate. Reduxine® Met in "Aurora" study was being added to the diabetes therapy, that was chosen by the attending physician, prior to the patient's participation in the program. The average fasting plasma glucose and HbA1c reduction were 2 ± 1.6 mmol/l and $1.2 \pm 1.1\%$ respectively. Current studies show, that Sibutramine therapy of obesity according to approved indications is safe and effective for long-term treatment in regards to weight loss, regulation of lipemic index, glucose profile and quality of life.

Biography

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