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Tatiana Romantsova

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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±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

Tatiana Romantsova is currently working as a Professor at Department of Endocrinology in Sechenov University, Moscow. He is the author of 215 scientific articles.

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Jeffry Beta Tenggara

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Necrotizing fasciitis as a rare documented side effect of Docetaxel

Introduction: Docetaxel was frequently used to treat solid tumors, primarily breast cancer by disrupting microtubule function to inhibit cell division. Although this agent was known to cause myalgia, arthralgia and neuropathy, there are few reports since 2005 that published the myositis complication of this agent. We presented a case report of necrotizing fasciitis as a continuing myositis condition that happened after Docetaxel treatment.

Case Report: A 44 years old female diagnosed with stage-IIIB ductal invasive breast carcinoma (ER/PR+ HER-). She underwent chemotherapy with Docetaxel and Doxorubicin following the surgical treatment. After 6th chemotherapy cycle, the patient had pain at both thighs especially the left side. The symptom progressed until blisters seen on the skin and ulcer developed. Physical examination showed normal vital signs, ulceration at posterior left thigh with minimal purulent discharge, stiff and tender on palpation. Laboratory result showed elevated CRP and ESR with no elevated WBC and shifting of differential count. Doppler ultrasound showed soft tissue edema with no sign of DVT or thrombus, contrast MRI showed thickening and edema of the thigh muscle, enhancement of adductor brevis, semitendinosus, gluteus maximus and lateral vastus muscle, which consistent with myositis necroticans. PET- CT revealed necrotic irregular pattern on subcutaneous tissue including muscles at both posterior thigh compartment, with left domination. The result was different than previous PET- CT study which conducted before administration of Docetaxel. She was suspected with myositis complicated with secondary infection and planned to undergone surgical debridement. At intraoperative procedure, the surgeon found necrotic muscular tissue with no sign of primary infection. The tissues were sent for pathology examination. Pathology examination revealed necrotic tissues with gas inclusion, inflammatory cells (PMN and lymphocyte) and necrotic vascular tissues, these findings consistent with necrotizing fasciitis. In 1990s, reports of Docetaxel side effect began to revealed myopathy condition with unexplained pathophysiology. Documented cases of acute inflammatory myositis in patients treated with Docetaxel began to publish since 2005. Until 2015 there are less than 10 cases reported the myositis side effect of Docetaxel. The proposed theory linking this effect were direct myotoxicity, systemic leakage of protein in the interstitial space, increased cytokine levels (primarily IL-6, IL-8, IL-10), indirect muscle damage through hypocalcaemia and hyperthermia and accumulation of acid phosphatase in muscle lysosome. Although Docetaxel induced myositis was an exclusion diagnosis, this rare side effect must be considered to prevent further deteriorating condition.

Discussion: Myositis and necrotizing fasciitis is a rare side effect of Docetaxel that only few of reports documented since 2005. There are several proposed mechanisms linking this condition. Consideration and early recognition of this condition were needed to prevent further deterioration.

Biography

Jeffry Beta Tenggara has 8 years' experience in treating oncology patients. He currently works in MRCCC Siloam Hospital Jakarta, a cancer hospital, as a medical oncologist and a member of Internal Medicine Department. In addition to his medical practice, he is a member of the Indonesian Society of Internal Medicine, Indonesian Society of Oncology, and Indonesian Medical Association.

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