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Sitagliptin as combination therapy in the treatment of inadequately controlled type 2 diabetes

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Background & Aim: The purpose of this study was to evaluate the effects of sitagliptin 100 mg in the treatment of participants with type 2 diabetes mellitus who have inadequate glycemic control on metformin ≥1500 mg/day.

Materials & Methods: Outpatients aged 52-72 years with type 2 diabetes. Patients were on metformin monotherapy (≥1500 mg/day) for ≥8 weeks with an A1C ≥7.5% and ≤11.0% before treatment with sitagliptin. Glycemic efficacy endpoints were included the changes from baseline in A1C and FPG at week 26 and also percentage of participants achieving an HbA1c of <7%. Other efficacy endpoints that were assessed include changes from baseline at week 26 in body weight, and some safety endpoints such as hepatic safety tests ALT and AST, total and direct bilirubin, and renal failure tests - serum creatinite calculated using the CKD-EPI formula, urinary albumin/creatinine ratio. The efficacy and safety were retrospectively evaluated by comparison of laboratory values before and after the administration of sitagliptin and by review of adverse events after treatment.

Results: Target HbA1c (<7%) was achieved in 83.3% overall with no incidence of hypoglycemic episodes (and some other side-effects (25%-female genital mycotic infection). 26 weeks after the initiation of sitagliptin, participants' hemoglobin A1c was significantly decreased by 13.99% ± 0.8% (mean HbA1c before administration was 8.76% ± 0.8%). Furthermore, sitagliptin was well tolerated in the group. On logistic regression analysis, baseline HbA1c was the strongest contributing factor for achieving target HbA1c; baseline body mass index and duration of diabetes were also significant factors. Significant decreases of the liver transaminases were observed after 26 weeks of treatment with sitagliptin alanin aminotransferase - 22.0% ± 2.0%; Aspartate Aminotransferase – 14.9% ± 1.7%; total bilirubin – 23.5% ± 3.2%. At study end, sitagliptin treatment produced a significant reduction in GFR by 6.4% ± 2.0, urinary albumin/creatinine ratio was significantly decreased by - 106.8% ± 1.6 (mean albumin/creatinine ratio before administration was 4.08 ± 6.1%, maximum - 18.1mg/mmol). An interesting finding was the significant decrease in uric acid levels – 17.4% ± 1.7, the increase of which is an independent predictor of occurrence of cardiovascular diseases in patient with diabetes.

Conclusion: In this study, not only the parameters of diabetes, but also those of liver and kidney tests, uric acid level as an independent predictor of occurrence of cardiovascular diseases were improved by the treatment with sitagliptin. Sitagliptin was effective and safe as combination therapy with metformin in type 2 diabetes patients.

Biography

Klitsunova Yuliia, PhD, is Assistant Professor of State Institution "Zaporizhia Medical Academy of Post-Graduate Education Ministry of Health of Ukraine", Zaporizhzhia, Ukraine, where she covers endocrinology and cardiology projects. She holds BS and MS degrees in Medicine from the Zaporizhzhia State Medical University. She is a member of EASD (reg.# 360234) and has more than 9 years of experience in medicine. She is the author of more than 35 scientific articles and 1 guidelines for daily monitoring of blood pressure.

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