Sitagliptin Associated Pancreatic Carcinoma: a Review of the FDA AERS Database

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Abstract
Purpose: Sitagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor used in the treatment of type 2 diabetes mellitus in adults, as adjunct to diet and exercise to improve glycemic control. During phase III studies, sitagliptin was shown to cause toxicity to the pancreas, including pancreatitis. To date there is limited information available regarding its association with pancreatic carcinoma. Our goal was to qualitatively and quantitatively review available information in the AERS database in order to provide clinicians with a general understanding of the comparative occurrence of sitagliptin use and pancreatic carcinoma and any clinically relevant characteristics that may be useful in identifying patients at risk.

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Purpose
Sitagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor used in the treatment of type 2 diabetes mellitus in adults, as adjunct to diet and exercise to improve glycemic control. During phase III studies, sitagliptin was shown to cause toxicity to the pancreas, including pancreatitis. To date there is limited information available regarding its association with pancreatic carcinoma. Our goal was to qualitatively and quantitatively review available information in the AERS database in order to provide clinicians with a general understanding of the comparative occurrence of sitagliptin use and pancreatic carcinoma and any clinically relevant characteristics that may be useful in identifying patients at risk.

Methods
We used Empirica Signal software to query AERS from November 1968 to December 31, 2013. The software was used to calculate a disproportionality statistic, namely the Empirical Bayesian Geometric Mean (EBGM), for reports of sitagliptin-associated pancreatic carcinoma. The FDA considers an EBGM significant if the 5th percentile of the distribution is at least two (EB05 > 2.0). With use of a disproportionality analysis, sitagliptin was compared with all agents listed in AERS. The disproportionality analysis was also performed on other medications classified as DPP-4 inhibitor and other oral hypoglycemic agents.

Results
One hundred cases of pancreatic carcinoma were reported in patients who were receiving sitagliptin. Overall 39% of the cases reported in patients receiving treatment with oral hypoglycemic agents occurred in patients receiving sitagliptin. An EB05 of 10.3 was determined for sitagliptin compared to all other agents included in AERS. All but one medication classified as a DPP-4 inhibitor were determined have an EB05 > 2.0. Glimepiride and pioglitazone were also determined to have an EB05 > 2.0, but the findings were not consistent within their associated medication classes.

Conclusions
There appears to be a statistical association between sitagliptin use and pancreatic carcinoma. Additional clinical studies are needed to further explore this statistical association.