

Pharmacovigilance 2020: Pancreatic and Thyroid Cancer Related to Exenatide and Liraglutide Treatment: A Post-marketing Analysis of Spontaneous Cases Reported in EudraVigilance Database-Ghanshyam Mali-Sun Pharmaceutical Industries Ltd.

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Abstract:

The use of glucagon-like peptide-1 (GLP-1) analogues has been linked with the risk of pancreatic and thyroid cancer. Exenatide and liraglutide carry a boxed warning in their pack insert regarding the possible association with medullary thyroid cancer and caution regarding acute pancreatitis. Our objective was to detect from EudraVigilance database, a signal of pancreatic and thyroid cancer with exenatide and liraglutide treatments in patients with diabetes. EudraVigilance (European Union Drug Regulating Authorities Pharmacovigilance) is the European data processing network and management system for reporting and evaluation of suspected adverse reactions to medicines which have been authorised or being studied in clinical trials in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the European Union (EU) medicines regulatory network.

The European EudraVigilance system deals with the: Electronic exchange of Individual Case Safety Reports, EudraVigilance Clinical Trial Module (EVCTM) for reporting Suspected Unexpected Serious Adverse Reactions (SUSARs), EudraVigilance Post-Authorisation Module (EVPM) for post-authorisation ICSRs, Early detection of possible safety signals from marketed drugs for human use, Continuous monitoring and evaluation of potential safety issues in relation to reported adverse reactions, Decision-making process, based on a broader knowledge of the adverse reaction profile of drugs.

Methods:

Herein, we analyzed all spontaneous cases of pancreatic and thyroid cancer reported with exenatide and liraglutide in EudraVigilance database from their inception till 30th January 2020. A case/noncase method was used to detect the association, calculating proportional reporting ratios (PRRs) and their 95% confidence interval (CI) as a measure of disproportionality.

Results:

There were 4349 cases of pancreatic cancer and 1697 cases of thyroid cancer in the 6,665,794 reports recorded in EudraVigilance during the study period. From the

inception of exenatide and liraglutide, the total numbers of pancreatic cancer cases identified with them in EudraVigilance database were 222 and 313, respectively, and the total numbers of thyroid cancer cases were 36 and 53, respectively. Significant disproportionality was observed between pancreatic cancer and exenatide and liraglutide with PRR of 36.4 (95% CI, 31.8-41.7) and 42.4 (95% CI, 37.7- 47.6), respectively. Disproportionality was also observed between thyroid cancer and exenatide and liraglutide with PRR of 14.7 (95% CI, 10.5-20.4) and 17.6 (95% CI, 13.4-23.2), respectively.

Conclusions:

This study based on EudraVigilance database further confirms signals for both thyroid and pancreatic cancer with exenatide and liraglutide.

Biography:

Ghanshyam Mali has completed his Master of Pharmacy at the age of 24 years from Manipal University Karnataka, India and currently pursuing his PhD from Jamia Hamdard, deemed to be University, New Delhi. He has more than 5 years of experience in Medical Writing in Pharmaceutical Organization. He has published 3 papers in reputed journals.