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Original Article

Adverse events associated with antidiabetics: An analysis of Vigiflow data

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Abstract

The use of Antidiabetics has been increasing. However, sporadic reports of serious adverse effects associated with the use of these products have become a source of concern. Spontaneous adverse event reporting may be used to monitor the safety of these drugs. **Objective-** The objectives of this study is to analyze and describe the patterns of adverse events associated with the use of Antidiabetics in the Indian Pharmacovigilance database (VigiFlow) from 2010 to 06/07/2012 and to highlight areas of safety concerns. Methods- Adverse events associated with Anti diabetics reported in Indian Pharmacovigilance database (VigiFlow) for the period 2010-06/07/2012 were analyzed. The informations which extracted and collated were: patient demographics, type of antidiabetics, system-organ class affected, seriousness of the adverse event, hospitalization status, outcome of adverse event, and profession of the reporter. **Results-** In the period 2010-2012, 466 cases of adverse events due to antidiabetics were reported. Average onset age (mean±SEM) of male patients was 51.0±0.72 & female patients 50.433± 0.72. It was found that 40% of ADR related to antidiabetics were occurred in female where as 60 percent in counterpart. Twenty six percent cases were found to be of the serious, Metabolic and nutritional disorders constituted 13%, Gastro-intestinal system disorders constituted 5% and central nervous system disorders constituted 4%. Two cases of hypoglycaemia were responsible for the life threading condition during this period. One case of metformin induced encephalopathy without metabolic syndrome was found which is the unexpected. In most of cases reporter was doctor. **Discussion-**In conclusion, 465 adverse event reports associated antidiabetics had been successfully analyzed and described. They constituted ~0.60% of the total number of adverse events reported from 2010-06/07/2012. One case of metformin induced encephalopathy without metabolic syndrome was found which is the unexpected. Further work to confirm the metformin induced encephalopathy without metabolic syndrome is warranted. Reporting of suspected adverse events is strongly encouraged even if the causality is not confirmed because any signs of clustering will allow rapid regulatory actions to be taken. The analysis of spontaneously reported adverse events is important in monitoring the safety of antidiabetics and helps in the understanding of the benefits and risks associated with the use of such products.

Keywords: Adverse events, Adulteration, Hypoglycemia, Hepatotoxicity, Pharmacovigilance.

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