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Review Article

SAFETY PROFILE OF METFORMIN

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ABSTRACT

Pharmacovigilance heavily focuses on adverse drug reactions, or ADRs, and SADR which are defined as any response to a drug which is noxious and unintended, including lack of efficacy, which occurs at doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function. Medication errors such as overdose, and misuse and abuse of a drug, are also of interest because they may result in an ADR. (*Gupta*, 2001). Metformin an oral antidiabetic drug in the biguanide class. It is the first line drug of choice for the treatment of type-2 diabetes. Its main use is in overweight patients, particular those are normal kidney function. In the present study 133 cases were studied with the help of Argus safety data base in which 188 adverse drug reactions occurred. Out of 188 adverse drug reactions 100 were found in Females and 88 ADR's were occurred in Males.

Keywords: Pharmacovigilance, Safety profile, Adverse drug reaction, Metformin.

INTRODUCTION

Pharmacovigilance is used to establish the safety profile of drugs in humans. Information received from patients and healthcare providers, as well as other sources such as the medical literature plays a critical role in providing the data necessary for pharmacovigilance to take place. (Mann and Andrews, 2002) In fact, in order to market or to test a pharmaceutical product in most countries, adverse event data received by the license holder (usually a pharmaceutical company) must be submitted to the local drug regulatory authority. Ultimately, pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients. Pharmacovigilance is concerned with the detection of adverse effects that are previously either unknown or poorly understood. Its purpose is to contribute to a scientific understanding of safety profile of drugs.

METHODOLOGY

The study was conducted at Panacea Biotec Ltd New Delhi; a total no. of 133 cases was analyzed obtained from Argus Safety Database. Prepare a line listing of all possible ADR, SADR, in Patients. A detailed study were done on various parameters like Gender wise adverse drug reaction, age wise adverse drug reaction, yearly adverse drug reaction, their outcomes in male and female, Indication wise use in gender, Soc wise gender distribution. Microsoft excel pivot tables were used to carry out analysis of different parameters. MedDRA (Medical Dictionary for Regulatory Activities) is use to code Indication, ADR, and SADR.

KEYWORDS

MedDRA

RESULT

Descriptive and inferential statistics was used to analyse and interpret the obtained data. The

summery of the findings of the study is given below.

1. *Findings on Gender wise Adverse Drug Reaction distribution by use of Metformin:*
   The total number of 188 adverse drug reactions occurred in Male and Female by the use of Metformin; Gender wise 100 in female and 88 in males. Among which major adverse drug reactions were lactic acidosis.
2. *Findings on Gender Wise Indication Distribution:*
   The total numbers of 134 Indications were found in male and female by use of Metformin. In males a total of 65 cases were occurred among which maximum 57 cases of Type 2 Diabetes reported. While in females a total number of 69 cases was observed among which maximum 51 cases of Type 2 Diabetes.
3. *Gender Wise Serious Adverse Drug Reaction Distribution:*
   A total number of 162 SADR occurred by the use of Metformin. Among which 85 SADR cases were reported in female. And 77 cases of SADR were reported in male.
4. *Gender wise System Organ Class distribution:*
   Metabolism and nutritional disorders system organ class belongs to maximum no. of ADR, then Renal and urinary disorders along with Hepatobiliary disorders, General disorders and administration site conditions, and Gastrointestinal disorders respectively.
5. *Yearly distribution of ADR by Metformin:*
   There were many adverse drug reactions occurred between the year 2002 to 2013, among which maximum cases of ADR's were found in 2011 and 2012.

DISCUSSION

On the basis of detailed study on safety profile of Metformin, we come to know that by the use of Metformin there were lot of possible Adverse drug reactions, Serious adverse drug reaction occurs among which Lactic acidosis, acute renal failure, hepatotoxicity and acute pancreatitis are the prominent adverse drug reaction. In the light of results our study indicates that Metformin is a first line choice of drug for type-2 diabetes but it exhibits significant adverse drug reactions, serious adverse drug reactions in all age group of population. Guo PY *et al.*, (2006) also reported a 53-year-old man who ingested 50 g of Metformin presented with severe lactic acidosis. He was placed on hemodialysis as a continuous therapy for 21 hours. His hospital course was complicated by acute renal failure requiring a period of intermittent hemodialysis. He has subsequently made a complete recovery.

In the presence study out of 188 adverse drug reactions lactic acidosis, acute renal failure, hepatotoxicity and acute pancreatitis were found significantly high and fatal. And the study conducted by Correia and Bronander (2012) also found that in a 69-year-old male admitted in psychiatric ward with a history of depression, coronary artery disease, diabetes mellitus, and dyslipidemia. Laboratory investigations revealed the developed hyperkalemia and acidosis. After surgery the patient's condition continued to deteriorate. And he died. It was determined that the patient died of severe Metformin-associated lactic acidosis.

CONCLUSION

It is evident that although Metformin is a first line drug of choice for Diabetes and other medical conditions but the prescriber, distributor and consumer should take precaution and be vigilant with dosage for adverse reactions. These results are limited by the data available in an administrative, healthcare database.

REFERENCES

1. Gupta, SK (2011), "***A Text Book of Pharmacovigilance***", Jaypee brother's medical publisher, 21-27.
2. Mann and Andrews (2002), "***Test Book of Pharmacovigilance***", John Wiley & Sons Ltd, Chichester, 317.
3. Guo, PY; Storsley, LJ and Finkle, SN (2006), "Severe lactic acidosis treated with prolonged hemodialysis: recovery

after massive overdoses of Metformin", ***Semin Dial***. Vol. 19, Issue 1, 80-3.

4. Correia and Bronander (2012), "Metformin-associated lactic acidosis masquerading as ischemic bowel", ***American Journal of Medicine***, Vol. 125, Issue 5, E9.

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