MONITORING ADVERSE EVENT BY IPOGLYCEMIC DRUGS IN CALABRIA REGION

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Introduction: The prevalence of diabetes has progressively increased over time and today 415million people worldwide are estimated to be affected. Diabetes is a complex metabolic disorder, that predisposes patients to several complications profoundly impacting quality of life and expenses for the healthcare system in terms of both hospitalizations and outpatient visits. During the last 10 years, despite new emerging therapies, glycemic control remains an elusive goal in many patients. However, adherence to antihyperglycemic medications is often suboptimal and this can contribute to poor glycemic control, increased hospitalization, and the development of diabetic complications. Furthermore, onset of adverse drug reactions (ADRs) can lead to a perceived lack of therapy effectiveness and subsequent suboptimal adherence.

Materials and methods: We conducted a prospective observational study to identify ADRs by hypoglycemic drugs and to evaluate continuity/adherence to chronic therapies. Prior informed consent, we enrolled diabetic patients' afferent to the Internal Medicine units of the "Mater Domini" University Hospital, "Pugliese-Ciaccio" Hospital of Catanzaro, and Hospital of Lamezia Terme, between 1August 2018and 1March 2019. Reported ADRs were categorized based on MedDRA coding. To evaluate/measure therapeutic adherence, the Italian version of Morisky's Eight-Item (MMAS-8) scale was used, that is a self-reported measure of drug intake behavior, based on a series of 8simple questions, previously validated by our group.

Results: The study involved 270 patients (48% female). Mean age was 64years (age range: 12-93years old) and me dian duration of diabetes 11.5years (range: 1-52). The mean age at the start of antidiabetic therapy was 48.32years (range: 5-86). Most patients were affected by hypertension and dyslipidemia (33.7%). 26.3% of patients were treated with metformin in monotherapy whereas metformin in polytherapy was used in 38.2% of patients. We encountered 231ADRs, the most frequently ADRs identified were related to gastrointestinal disorders (43%), followed by hypoglycemia or hyperglycemia (26.3%), change in bodyweight (8.3%), renal failure (2.2%) incontinence and polyuria (2.2%). Most of gastrointestinal's ADRs (54) were associated with metformin use in monotherapy (46.3%) and in combination (53.7%). By analysis of Morisky's Eight-Item (MMAS-8) questionnaires, we observed that about 45% of patients were adherent to treatment, 36% showed medium adherence and 19% were non-adherent to therapy. The gastrointestinal ADRs were responsible for poorer adhesion in 5.5% of patients. There were 36therapeutic switches mostly due to hypoglycemia (31.42%) followed by diarrhea (25.71%).

Discussion and conclusions: This study aims to highlight the importance of active pharmacovigilance and post-marketing surveillance of drugs. The management of adherence and tolerability of antidiabetic therapies in patients with diabetes has a great clinical relevance and could improve the outcome of patients' health beyond the costs of the long-term health system. In this regard, clinicians should actively urge the reporting of ADRs by their patients in order to identify early the link between ADR and poor adherence and to prevent their deterrent consequences on long-term clinical efficacy.