

## **MONITORING SAFETY AND USE OF OLD AND NEW THERAPIES FOR TYPE 2 DIABETIC PATIENTS IN CALABRIA: A TWO-YEAR (2013-2016) ANALYSIS**

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The number of diabetic patients is continuously increasing, and the burden of the costs of their treatment is hard on the budget of all countries; accordingly, the World Health Organization has included diabetes among the pathologies requiring more investment for both prevention and management (1). Lifestyle changes are crucial to achieve a stable glycemic control. However, most type 2 diabetic patients need also medications for long-term management of their clinical condition (2,3). Unfortunately, despite new emerging therapies for type 2 diabetes mellitus (T2DM), glycemic control remains an elusive target in many patients. On the other hand, other factors beyond drug effectiveness should be considered. Indeed, the complexity of the diabetic patient significantly affects the pharmacological treatment, leading to the need for multiple drugs administered chronically. This entails the risk of increasing patient's fragility and exposing him/her to hazardous adverse drug interactions (4). Lack of adherence is another risk related to polytherapy (5,6). Moreover, adverse drug reactions (ADRs) can lead to a perceived lack of therapy effectiveness and subsequent suboptimal adherence. Noteworthy, it has been recently suggested that the careful assessment of the bidirectional causal relationship between medication non-adherence and ADRs occurrence by healthcare professionals is crucial to improve the effectiveness of pharmacological interventions (7).

Based on this background, we compared patients' and physicians' perceptions regarding effectiveness and tolerability of non-insulin hypoglycemic drugs in an Italian cohort of T2DM patients. We also tried to verify whether a tridimensional link between effectiveness, tolerability and adherence exists and influences long-term therapeutic outcomes.

A two-year retrospective/prospective observational study was performed including 1389 T2DM patients consecutively enrolled between 1 August 2013 and 31 January 2014. Two care settings were involved: general practitioner clinics and Diabetes Centers both of Calabria region in Italy. Inclusion criteria were predefined as follows: (a) diagnosis of T2DM, (b) first drug therapy or change of the current antidiabetic treatment. The start/change of treatment was defined as "time zero". Six follow-ups were carried out at the 1st, 3rd, 6th, 12th, 18th, 24th months after time zero.

A decimal scale and the Italian version of the Eight-Item Morisky Medication Adherence Scale (MMAS-8) (8) were used, respectively, to assess effectiveness and tolerability perceptions, and medication adherence. Total score on the MMAS-8 ranges from 0 to 8: highly adherent patients (score = 8), medium adherents (score: 6 to <8), low adherents (score <6) (8).

Physicians perceived therapy as more efficacious compared to their patients: perceived effectiveness was steady for physicians during the study while it declined not significantly in patients (mean score from >8 to  $7.84 \pm 1.69$ ). Physicians assigned higher tolerability scores

compared to patients but only at the beginning of the study; at the last follow-up no difference between the two groups was observed. Interestingly, physicians' tolerability perception was poorer than patients' perception at the last follow-up (mean score =  $7.57 \pm 1.40$  vs.  $7.88 \pm 1.84$ ). Incretins positively drove patients' overall perceptions regarding effectiveness and tolerability across the study. Patients showed medium adherence (mean score  $\sim 6.5$ ) during the study.

More favorable (score  $>7$ ) patients' perceptions about treatment effectiveness and tolerability were significantly associated with higher levels of adherence.

Our findings demonstrate a tridimensional link between clinical effectiveness, tolerability, and adherence all influencing each other, significantly impacting the clinical management of diabetic patients. A careful monitoring of this link by clinicians appears therefore necessary to improve long-term health outcomes in these patients.

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