A Prospective Study on the Evaluation of Statins Usage on HbA1c Control among Type 2 Diabetes Mellitus in an Outpatients Setting

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Abstract : Medication safety is always an issue. In 2015, the National Pharmaceutical Control Bureau released a statement requesting all statins manufacturers in Malaysia to include the risk of diabetes information in the drug information leaflet in response to United States Food and Drug Administration (U.S. FDA) report. However, the data regarding this warning label in Malaysia is limited, so there is still some uncertainty whether such risk can also be observed in the Malaysian population or not. The study aims to determine the effect of statins on HbA1c% in type 2 diabetic outpatients in endocrine clinics at Hospital Pulau Pinang between June 2015 and May 2016 in Malaysia. In a prospective cohort study, records of 400 type 2 diabetic patients (control group 104 patients not using statin and treatment group 296 patients using statin) were reviewed to identify demographic criteria and lab tests. The prevalence of glycemic control (Glycated hemoglobin, HbA1C $\leq$ 7% for patient < 65 years, and < 8% for patient $\geq$ 65 years) was estimated, according to American Diabetes Association guidelines 2015. The results were presented as descriptive statistics. From 296 patients with Type 2 diabetes using statins cohort with a mean age of 57.52 $\pm$ 12.2 years, only 81 (27.4%) cases had controlled glycemia, and 215 (72.6%) had uncontrolled glycemia, CI: 95% (6.3–11.1). While the control group 104 diabetic patients had a mean age 46.1 $\pm$ 18 years and distributed among 59 (56.7%) patients with controlled diabetes and 45 (43.3%) cases, had uncontrolled glycemia, CI: 95% (5.2–10.3). The relative risk (RR) of uncontrolled glycemia in diabetic patients used statins was 1.68, and the excessive relative risk (ERR) was 68%. The absolute risk (AR) was 29.3%, and the number needed to harm (NNH) was 4. Diabetic patients using statins have more risk of uncontrolled glycemia than the patients with Type 2 diabetes non-using statins.

Keywords : diabetes mellitus, HbA1c, Malaysia, outpatients, statin, type 2, uncontrolled glycemia