BACKGROUND

Diabetes mellitus (DM) is regarded as a risk equivalent for cardiovascular (CV) disease.1

CONCLUSIONS

Safety

Analysis of this observational, real-world data in patients with diabetes mellitus suggest that PCSK9i is associated with significant, intensive and predictable reductions in atherogenic cholesterol, as demonstrated in previously reported clinical trials. Importantly, the use of these classes of medications demonstrated a significant reduction in both LDL-C and non-HDL-C of 33% and 46% (p < 0.001), respectively, each of which is considered to be atherogenic and primary targets for therapeutic action.1,2,3

Overall, PCSK9i were well tolerated and associated with a side effect profile as demonstrated in previously reported clinical trials. These medications offers a novel, efficacious and potentially safer approach to significantly lower atherogenic cholesterol in patients with diabetes mellitus.

METHODS AND STATISTICAL ANALYSIS

This is a prospective, observational, Institutional Review Board approved study involving patients with DM referred to a pharmacist-managed PCSK9i clinic. Upon referral, the following data were collected: patient demographic information, indication for referral, history of prior antilipemic therapy, notably statin use, and adverse medication events related to previous therapies. Following data were collected: patient demographic information, indication for referral, history of prior antilipemic therapy, notably statin use, and adverse medication events related to previous therapies. Upon inclusion in the study, PCSK9i are initiated with Alirocumab (Praluent) or Evolocumab (Repatha), which are both fully human monoclonal antibodies directed against PCSK9. PCSK9 is a chaperone protein, PCSK9, as illustrated in Figure 1. Elevated levels of PCSK9 results in increased LDL-C levels, which, if uncontrolled, increases the risk of developing atherosclerotic disease and ultimately CV disease.4

RESULTS

Table 1: Baseline demographic characteristics of the study population

Table 2: Baseline lab data ± standard deviation

Table 3: Change from baseline to final labs (n=28)

Figure 1: Lipid profiles at baseline and four-week follow-up

Figure 2: A comparison of the percent change from baseline for each lipid parameter for all patients and subgroups. There were no statistically significant differences for any lipid parameter between either agent.

Alirocumab: LDL-C, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), non-HDL-C, triglycerides (TG), and other atherogenic lipoproteins, many patients with DM fail to achieve desirable lipid results with first-line agents.5

RESULTS (Continued)

REFERENCES

1. Reference for background.

DISCLOSURES

Dr. Robert S. Busch serves on the Speakers Bureau for Amgen, Inc. and Regeneron Pharmaceuticals, manufacturer of Repatha and Praluent. Dr. Styler, Kane and Hamilton have nothing to disclose.