

DIFFERENCES IN BASELINE CHARACTERISTICS BETWEEN TYPE 2 DIABETES MELLITUS PATIENTS TREATED WITH DIPEPTIDYL PEPTIDASE-4 INHIBITORS IN RANDOMIZED CONTROLLED TRIALS AND THOSE RECEIVING THE SAME TREATMENT IN REAL-WORLD SETTINGS

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AIMS

The goal was to analyze differences between the baseline characteristics of type 2 diabetes mellitus (T2DM) patients treated with dipeptidyl peptidase-4 (DPP-4) inhibitors in three randomized clinical trials (RCTs) and those receiving the same treatment in a German real-world setting.

MATERIALS AND METHODS

Details of the baseline characteristics of subjects with T2DM from three RCTs focusing on DPP-4 inhibitors were obtained. The present study also included T2DM patients receiving prescriptions for DPP-4 inhibitors who were followed between April 2007 and December 2016 in 1,246 general and diabetologist practices in Germany. Three different DPP-4 inhibitors were considered in the subsequent statistical analyses: sitagliptin, vildagliptin, and saxagliptin. The first outcome was the difference in baseline characteristics between patients in RCTs and those included in the real-world study for the three drugs. The second outcome was the proportion of real-world patients who met exclusion criteria and who could not have been included in RCTs.

RESULTS

Patients being prescribed DPP-4 inhibitors were younger in RCTs than in the real-world setting. RCT participants receiving sitagliptin were also more likely to be men than the patients from the real-world study, whereas the opposite was observed for vildagliptin and saxagliptin. The share of real-world patients who met the exclusion criteria ranged from 20.7% for vildagliptin to 38.1% for sitagliptin. In the case of the proportion of people potentially not included in RCTs, figures ranged from 61.9% for sitagliptin to 79.3% for vildagliptin.

CONCLUSION

Real-world studies should be included in the evaluation of new drugs in the future

Published in: *Int J Clin Pharmacol Ther.* 2018 Sep;56(9):411-416. doi: 10.5414/CP203285.



If you would like to read any of the studies in its entirety, please, contact us to obtain the full version of a publication. Also, our research director is at your disposal if you have any further questions.

Thank you for your interest!