events was similar between denosumab and zoledronate (19.4 vs. 20.0 per 1000 patient years) which yielded a hazard ratio of 0.97 (95% CI 0.68 to 1.39).

Conclusion and relevance Denosumab and zoledronate had similar risks for cardiovascular events in the Asian elderly population with osteoporosis. Further large scale studies are suggested to confirm our findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-201 EFFECT OF SACUBITRIL/VALSARTAN ON GLYCAEMIC CONTROL AND RENAL FUNCTION IN PATIENTS WITH DIABETES AND HEART FAILURE: A MULTI-INSTITUTIONAL COHORT STUDY IN TAIWAN

[1]YH Chen*, [1]SC Shao, [2]ECC Lai. *[1]Keelung Chang Gung Memorial Hospital, Department of Pharmacy, Keelung, Taiwan ROC; [2]National Cheng Kung University, Institute of Clinical Pharmacy and Pharmaceutical Sciences, Tainan, Taiwan ROC*

10.1136/ejhpharm-2021-eahpconf.320

Background and importance A well known trial, PARADIGM-HF, has demonstrated that sacubitril/valsartan could affect glycaemic control (HbA1c −0.3%) and renal function (eGFR −1.7 mL/min/1.73 m^2) in patients with diabetes and heart failure with reduced ejection fraction (HFrEF). However, the effects have not been evaluated using real world data.

Aim and objectives To assess the effect of sacubitril/valsartan on glycaemic control and renal function in patients with diabetes and heart failure, by evaluating the changes in HbA1c and eGFR, respectively.

Material and methods We analysed the multi-institutional electronic health records database, Chang Gung Research Database, covering 1.3 million individuals from seven hospitals in Taiwan (6% of the national population) for this study. We selected a cohort of patients with diabetes and HFrEF (ie, left ventricular ejection fraction ≤40%) newly initiating sacubitril/valsartan during 2016–2018. Study outcomes were changes in HbA1c and eGFR values from baseline to 1 year after the initiation of sacubitril/valsartan. We used a two tailed paired t test to compare the differences in HbA1c and eGFR before and after sacubitril/valsartan treatment.

Results We identified 511 patients with diabetes and HFrEF receiving sacubitril/valsartan. Mean age was 64.1 (SD 13.2) years and 24.9% were women. At baseline, mean HbA1c and eGFR were 7.5 (SD 1.6)% and 62.6 (SD 31.7) mL/min/1.73 m^2, respectively. After 1 year of sacubitril/valsartan treatment, the mean differences in HbA1c and eGFR were −0.16% (95% CI −0.29 to −0.03; p=0.014) and −4.45 mL/min/1.73 m^2 (95% CI −6.27 to −2.63; p<0.001), respectively.

Conclusion and relevance Consistent with the PARADIGM-HF trial, our findings indicated the use of sacubitril/valsartan affected glycaemic control and renal function in patients with diabetes and heart failure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-202 BIOSIMILARS IN THE REAL WORLD: RESULTS FROM AN ACTIVE PHARMACOVIGILANCE PROGRAMME IN A PORTUGUESE ONCOLOGY HOSPITAL

[1,2]G Rigueiro*, [2,3]D Mendes, [2,3]J Abrantes, [1]AF Pais, [2,3]A Penedones, [2,3,4]C Alves, [2,3,4]F Batel-Marques. *[1]IPO-C–Instituto Português De Oncologia De Coimbra Francisco Gentil-EPE, Ipo-C–Instituto Português De Oncologia De Coimbra Francisco Gentil-EPE, Coimbra, Portugal; [2]Drug Safety and Effectiveness Research Network, Drug Safety and Effectiveness Research Network, Coimbra, Portugal; [3]UFC–Coimbra Regional Pharmacovigilance Unit, Ufc–Coimbra Regional Pharmacovigilance Unit, Coimbra, Portugal; [4]Laboratory of Social Pharmacy and Public Health, School of Pharmacy-University of Coimbra, Coimbra, Portugal*

10.1136/ejhpharm-2021-eahpconf.321

Background and importance The use of biologics is essential in the management of several types of cancer. When patents of reference biologics expired, biosimilars emerged, widening the patient's access to biological therapy and providing cost savings to healthcare systems. The hospital pharmacist stands in a privileged position, structuring post-marketing surveillance and implementing active pharmacovigilance programmes to monitor the safety of these technologies.

Aim and objectives The aim of this study was to evaluate the safety profiles of two biosimilar medicines (rituximab and trastuzumab) in the treatment of cancer patients within a Portuguese oncology hospital using an intensive monitoring programme.

Material and methods This hospital based prospective observational study followed a cohort event monitoring approach focused on signalling suspected adverse drug reactions (ADRs). Patients undergoing treatment with rituximab biosimilar CT-P10 (Truxima) or trastuzumab biosimilar CT-P6 (Herzuma) were recruited over an 11 month and a 6 month period (from 1 November 2018 and 1 April 2019, respectively, until 30 November 2019). A paper based ADR reporting form was developed for each biosimilar medicine and completed by clinicians. Clinical secretariats sent the reports through an electronic platform to the pharmacovigilance department for analysis of seriousness, expectedness and causality of suspected ADRs.

Results 94 patients received biosimilar medicines (rituximab, n=35; trastuzumab, n=59). Of these, 4 (11.4%) experienced 16 ADRs with rituximab and 1 patient (1.7%) experienced 5 ADRs with trastuzumab. All case reports contained serious and expected ADRs that were at least probably related to the biosimilar medicines under study. Based on the MedDRA PT coding, the most reported ADR for rituximab CT-P10 (Truxima) was chest discomfort (n=4; 19.1%), followed by odynophagia (n=2; 9.5%). Trastuzumab CT-P6 (Herzuma) was associated with back pain, headache, pain in extremity, tachypnoea and tremor (each, n=1; 4.8%).

Conclusion and relevance The results of this study suggest that in the real world setting, the biosimilar rituximab and biosimilar trastuzumab to treat cancer patients were associated with acceptable safety profiles. No new safety problems were identified. Also, the results of this study showed that carrying out active pharmacovigilance programmes in oncology pharmacy practice is feasible and that such activities contribute to better characterisation of the safety profiles of medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest