

of some drugs in addition to the omission of potential indicated medication.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

#### 5PSQ-087 EVALUATION OF THE EFFECTIVENESS OF LAMIVUDINE IN THE PROPHYLAXIS OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS WITH HAEMATOLOGICAL DISEASES

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**Background and Importance** The use of lamivudine as prophylactic treatment in patients with past hepatitis B virus (HBV) infection and on treatment with drugs considered at high risk of reactivation has been associated with a higher likelihood of reactivation compared to the use of other antivirals.

**Aim and Objectives** To evaluate the effectiveness of lamivudine in the prophylaxis of HBV reactivation in patients with haematological disease, undergoing immunosuppressive or chemotherapy treatment and presenting positive serology for HBV.

**Material and Methods** Observational and retrospective study including all haematological patients over 18 years of age who started HBV prophylaxis between January 2018 and December 2020 in a tertiary hospital. Follow-up was performed from the start of treatment until December 2021 to observe whether HBV reactivation occurred.

Electronic medical records were reviewed and the following variables were collected: demographic data (age and sex), haematological diagnosis, immunosuppressive or chemotherapy treatment received, analytical data (HBsAg, HBeAg, HBeAc, HBV DNA, transaminases) and HBV prophylactic treatment.

**Results** In the study period, 65 patients started HBV prophylaxis, of which 3 patients were excluded due to false positive. Sixty-two patients (33 women) were reviewed, with a median age (range) of 70 years (20-91). Diagnoses were lymphomas (26 patients), monoclonal gammopathies (13), chronic lymphoproliferative syndromes (7), autoimmune diseases (6), acute leukemias (5), chronic myeloproliferative syndromes (4) and bone marrow aplasia (1).

Out of the 62 patients, 60 patients were HBsAg negative and anti-HBc positive at the initial serological control. All of which received lamivudine prophylaxis. The other 2 patients had chronic HBV infection at the start of prophylaxis, with positive HBsAg, positive anti-HBe and undetectable HBV DNA. One of them started prophylaxis with tenofovir, and the other received lamivudine as prophylaxis.

Of the patients who started lamivudine prophylaxis, 60.7% were being treated with drugs considered at high risk of reactivation (rituximab, doxorubicin or idarubicin).

No patient had either clinical reactivation or detectable HBV viral load during the study period. Fourteen patients died during follow-up due to non-HBV causes.

**Conclusion and Relevance** In our patients, 60.7% of whom received high-risk drugs, no reactivation event occurred. Lamivudine has proven to be effective in the prophylaxis of HBV reactivation in our study population.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

#### 5PSQ-091 TRIFECTA™ BIOPROSTHESES : EVALUATION OF THE SAFETY BASED ON THE STUDY OF DEGENERATIONS ACCORDING TO THE VARC-3 CLASSIFICATION

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**Background and Importance** In 2021, cardiologists reported to the medical-devices-vigilance sector serious incidents in four patients with a first-generation Trifecta™ bioprosthesis that resulted in three aortic valve replacement (AVR) and one death. The question of degeneration of their bioprosthesis arose.

**Aim and Objectives** The aim was to evaluate the intrinsic imputability of Trifecta™ for dysfunction in patients implanted and to reassess their referencing in our centre.

**Material and Methods** A retrospective, single-centre and observational study of computerised patient records (CPR) was conducted between 02/04/2011, date of our centre's first implantation, and 12/31/2016 to have 5 years of follow-up per patient.

Trifecta™ valves and data related to the implantation were extracted from the traceability software. The collection of echographic and clinical follow-up data was based on the CPR with an extended follow-up period until 03/31/2022.

Dysfunctions were classified according to the VARC-3 classification criteria : structural valve deterioration (SVD), non-structural valve dysfunction (NSVD), thrombosis and endocarditis.

The study was approved by our local research department. **Results** A total of 382 bioprostheses was implanted in 378 patients, mean age 73.0 years and 60.7% male. Data were missing for 253 bioprostheses and 15 patients died perioperatively. Among the 114 bioprostheses with conclusive data, 50 functioned properly (mean follow-up time of 6.6 years) and 64 presented dysfunctions : 34 SVD, 10 NSVD (8 paravalvular regurgitation, 2 prosthesis-patient mismatches) and 20 endocarditis. AVR occurred for 20 patients following SVD and for 11 patients following endocarditis (4 of whom had a second Trifecta™) within a mean time of 6.7 years and 3.4 years, respectively.

**Conclusion and Relevance** The classification of failures according to VARC-3 allowed us to confirm the intrinsic imputability of the Trifecta™ bioprostheses regarding to the number of SVD-type dysfunctions. Although this study has limitations, it shows the understatement of medical-devices-vigilance cases by the medical staff. The 64 files with dysfunctions will be transmitted to the national health authority. The patients will be reviewed to complete the data and perform an echographic follow-up. According to the manufacturer, degenerations could be related to the expansion system that was improved in the second-generation Trifecta™ marketed in 2016. Since this study, the Trifecta™ has been removed from the hospital formulary.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest