who have difficulty achieving a target INR despite compliance with warfarin. EULAR recommendations indicate that rivaroxaban should not be used in APS patients with triple APAbs positivity. However, there is an ongoing need for a prospective evaluation of DOACs versus VKA inhibitors in patients with provoked venous thromboembolism, particularly in those without triple positive disease. The ongoing RISAPs study (NCT03634564) is comparing patients with APS with single/double positivity only for APAbs, who have a history of ischaemic stroke or other brain ischaemic injury. The endpoint is the rate of change in brain white matter hyperintensity volume between baseline and 24 months follow-up assessed on magnetic resonance imaging as a surrogate marker of ischaemic damage.

In summary DOACS are not dead…… but their ‘existence’ in APS/systemic lupus erythematosus is threatened!

REFERENCES

Learning Objectives
• Explain that while widely used VKAs, notably warfarin, while often effective, have major drawbacks in terms of requirement for regular blood tests, and the avoidance of many types of food and drugs
• Describe how the TRAPS study demonstrated the comparative effectiveness of rivaroxaban compared to warfarin in treatment with venous thromboembolic disease with a target INR of 2–3
• Describe how the TRAPS and later studies identified a risk of thromboembolic disease in patients on DOACs compared to warfarin in triple APAb positive patients, although earlier studies demonstrated that there is an increased risk (about 3% per annum) of recurrent thromboembolic risks on warfarin
• Explain, whilst the current advice from the MHRA and EULAR is to avoid DOACs in the treatment of triple positive APS patients, there remains a desperate need for clinical trials to compare the effectiveness of DOACs with VKAs in single and double positive antiphospholipid antibody APS

09 COVID-19 VACCINE IN LUPUS PATIENTS
Eloisa Bonfá. University of São Paulo Medical School, São Paulo, Brazil
10.1136/lupus-2022-la.9

CoronaVac (SARS-CoV-2 inactivated vaccine) has been largely used as the main immunogen for COVID-19 in several countries; however, its immunogenicity, antibody decay and booster dose response in immunocompromised individuals had not been established. 1–3

This Phase 4 prospective controlled study of 910 patients with adult autoimmune rheumatic diseases (ARD) and 182 age- and sex-controlled group (CG) subjects who received two doses of CoronaVac in a 28-day interval. The primary outcome was assessed by anti-SARS-Cov-2 IgG and neutralizing antibodies 6 weeks after the second dose. Secondary outcomes included immunogenicity at different time points, antibody decay, booster dose response and vaccine safety.

Pre-specified endpoints were met, with lower anti-SARS-Cov-2 IgG seroconversion (70.4% versus 95.5%, p<0.001) and frequency of neutralizing antibodies (56.3% versus 79.3%, p<0.001) in patients with ARD compared to the CG. 1 A significant decline in the number of COVID-19 cases (p<0.0001) was observed 10 days after the second dose, with a predominant P1 variant. Six months after the 2nd dose of CoronaVac, anti-S1/S2IgG positivity reduced 23.8% in patients with ARD (p<0.001) and 20% in the CG (p<0.001). A concomitant decrease of COVID-19 cases (from 27.7 to 8/100 person-years; p<0.001) occurred during this period. The booster dose after 6-months resulted in a significant increase in anti-S1/S2 IgG rates (60% versus 93%, p<0.0001), neutralising antibody positivity (38% versus 81.4%, p<0.0001), GMT (25.3 versus 140.5 AU/mL, p<0.001) and NAb activity (69.7% versus 90.1%, p<0.001). Safety analysis revealed no moderate/severe adverse events. Multivariate analysis revealed that drugs were the major factors influencing immunogenicity, antibody decay and third dose response.

In conclusion, CoronaVac has an excellent safety profile and reasonable rates of quantitative serology/neutralisation in ARD patients. A moderate antibody waning occurred over six months with a decline in cases despite the Delta variant spread. Booster dose at six months induced a robust response. Our data suggest that CoronaVac vaccine is an excellent alternative treatment for COVID-19 in immunocompromised patients. [clinicaltrial.gov #NCT04754698 (CoronavRheum); Funded by FAPESP, CNPq and B3 - Bolsa de Valores do Brasil].

REFERENCES

Learning Objectives
• Discuss Covid-19 vaccine immunogenicity in ARD patients
• Identify the risk factors for reduced COVID-19 vaccine response
• Define vaccine antibody waning in ARD patients and their risk factors
• Manage the third dose of COVID-19 vaccine in ARD patients

10 NOVEL CONCEPTS IN SLE: IS IT TIME FOR A NEW TAXONOMY?
Ronald van Vollenhoven. Amsterdam University Medical Centers, and Amsterdam Rheumatology and Immunology Center, The Netherlands
10.1136/lupus-2022-la.10