BSH 2020 VIRTUAL
9 -14 NOVEMBER
British Society for Haematology
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60 1960–2020

Observational study of outcomes in patients with antiphospholipid syndrome anticoagulated with Rivaroxaban

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INTRODUCTION

- The management of antiphospholipid syndrome (APS) has changed recently as a result of the Medicines and Healthcare products Regulatory Agency (MHRA) interpretation of the TRAPS.
- The RAPS study, 2016, suggested little difference in the surrogate end point of thrombin generation when rivaroxaban and warfarin were compared in the management of patients with APS with prior venous thromboembolism (VTE). Based on this clinicians started to use rivaroxaban in APS patients with VTE.
- Following review of TRAPS the MHRA stated that DOACs should not be used in patients with APS. This decision surprised some as the criteria for inclusion in the TRAPS study included triple positivity for the antiphospholipid antibodies; lupus anticoagulant (LA), anticardiolipin (ACA) and anti-beta 2 glycoprotein 1 (anti-beta-2GP1), whereas most patients with APS are diagnosed on the basis of persistent positivity of a single abnormal test.

AIM

- The purpose of our retrospective study is to determine the outcomes of thrombotic and haemorrhagic events in patients with APS and VTE receiving rivaroxaban in our centre.

METHOD

- Patients newly diagnosed with APS without prior exposure to warfarin between November 2016 and August 2019 and treated with rivaroxaban were included.
- APS was diagnosed based on persistent positivity of LA and/or ACA Ig over a 12-week period.
- We reviewed clinical records for evidence of thrombotic and haemorrhagic events whilst on rivaroxaban with reference to ISTH criteria of thrombosis and major, clinically relevant non-major bleeding (CRNMB) and minor bleeding episodes.

RESULTS

- 31 cases were identified. 30 cases were single positive, 1 double positive.
- Amongst 30 single positives, the presenting clinical feature was DVT in 53.3% (n=16), PE in 36.6 % (n=11) both PE and DVT in 6.6 % (n=2) and ischaemic stroke in 3.3 % (n=1).
- Median treatment duration with rivaroxaban was 723 days and total follow up period was 21,691 patient days.
- No new venous or arterial thrombotic events were reported throughout the study period.
- No major bleeding occurred, 6.6 % (n=2) patients reported CRNMB.
- Rate CRNMB was approximately 1 in 10,000 days.

CONCLUSIONS

- Our study shows that no new thrombotic events occurred in 21,691 days of treatment in our cohort of patients with newly diagnosed non-triple positive APS treated with rivaroxaban.
- The incidence of new/recurrent thromboembolism in the TRAPS cohort was 12% in 59 patients followed for median 569 days.
- The incidence of major bleeding and CRNMB was also lower than reported in the TRAPS study.
- Many clinicians have been surprised at the MHRA response to the TRAPS data and the extrapolation that this decision should pertain to all cases of APS.
- This small retrospective study suggests that the event rate in non-triple positive APS patients on rivaroxaban is less than that seen in TRAPS.
- Our results suggest further large prospective studies are required to address whether the TRAPS data is generalisable to non-triple positive APS.

REFERENCES

1. Pengo V, Denas G, Zoppellaro G, Jose SP, Hoxha A, Ruffatti A, et al. Rivaroxaban vs warfarin in high-risk patients with antiphospholipid syndrome. Blood. 2018;132(13):1365-71.

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BSH2020-PO-174