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Direct Oral Anticoagulants – the real story of their side effect profile

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INTRODUCTION

Dabigatran was the first direct oral anticoagulant (DOAC) licensed for use in 2008, followed by apixaban, rivaroxaban and edoxaban. The trials carried out highlighted the side effect profiles of the drugs, but with increasing use in clinical practice new data is emerging with regards to their safety profile.In Whipps Cross Hospital we have been collecting data on our DOAC patients since June 2016.

AIM

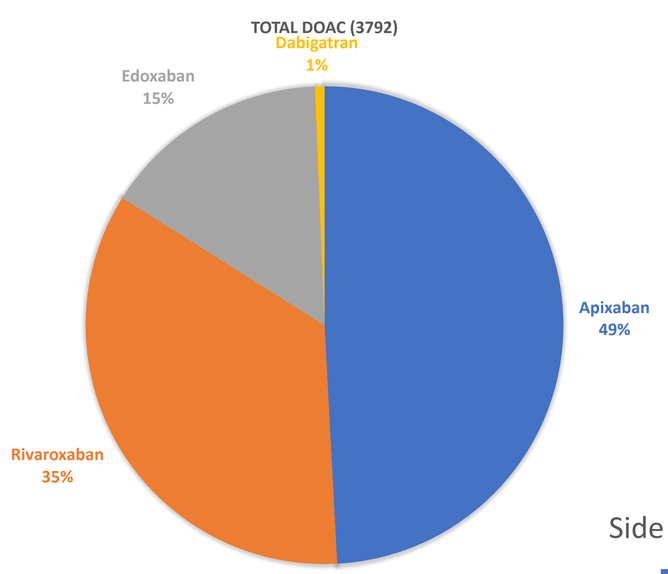
Our aim was to ensure that we are counselling our patients appropriately with regards to their side effects as well as improving our understanding of these drugs. By looking at the side effects our patient population were experiencing we could determine if this was in line with those reported from initial studies, and if not, ensure we are providing adequate information to our patients, many of whom are elderly with multiple co-morbidities.

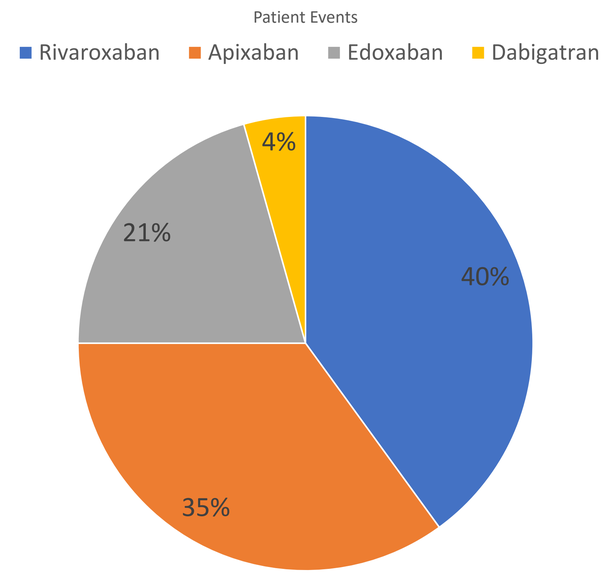
METHOD

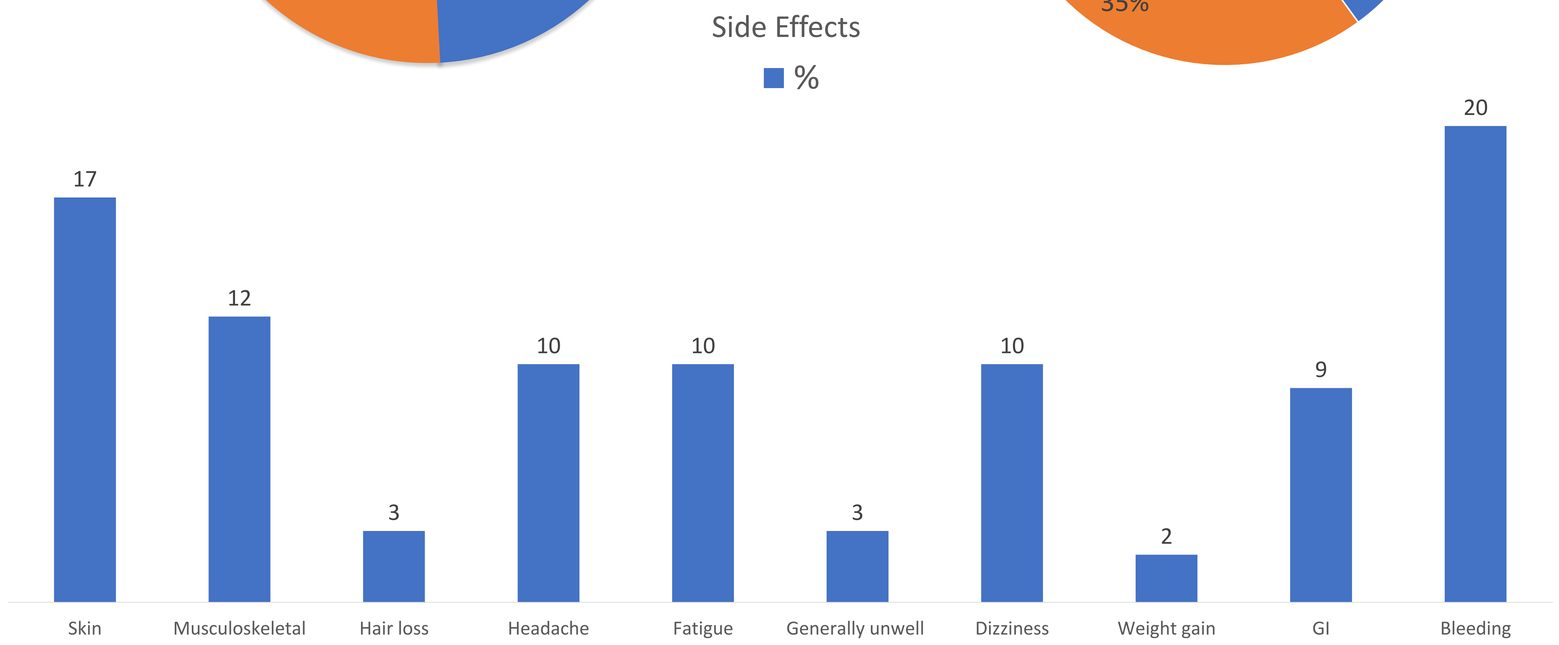
We used our database and warfarin dosing tool, DAWN 7.9, to access data collected on all patients on DOACs between June 2016 and May 2019. Using the events documentation tool and noting patients who have had their DOAC switched, we were able to collect data on all patients who had reported side effects on a DOAC.

RESULTS

The total number of patients was 3786 of which 64% were on a DOAC for atrial fibrillation and 36% for venous thromboembolism. Of these 49% were on apixaban, 35% on rivaroxaban, 15% edoxaban and 1% on dabigatran. There were 160 patient events reported. Of these, rivaroxaban had 64 events, 40% of the total events but 5% of the rivaroxaban patients. For patients on apixaban there were 56 events, 35% of the total events but 3% of the apixaban patients. For patients on edoxaban there were 33 events, 21% of the total events but 6% of the edoxaban patients and finally for dabigatran there were 7 events, 4% of the total events but 18% of dabigatran patients had an event.The majority of the events were related to bleeding. We found 35 events due to bleeding complications and 123 due to all other side effects. For 2 of the events there was no documentation.







DISCUSSION

RocketAF reported bleeding events of 20.7% (major and non-major clinically relevant bleeding) and other side effects of 81%. Aristotle reported bleeding rates of 4.3% for major haemorrhage and any bleeding of around 26% and other side effects of 81%. Engage-AF reported bleeding at around 30% and other side effects of 84.3%. RE-LY reported bleeding at 33% and other side effects at 93%.We report an overall 4.2% event rate in our patient group most of which happened with rivaroxaban. The most common side effects were bleeding, skin reactions, musculoskeletal, dizziness, fatigue, headache and gastrointestinal. We noted side effects that have not been reported in the BNF including hair loss and weight gain. In conclusion, we have reported much lower events than within the trials. This could be related to over reporting within the study population of which many side effects may not have been directly related to the DOAC. The studies were also done in a significantly larger population. We have however found that in general, these agents are well tolerated and easier to take by most patients when compared to Vitamin K antagonists. Moving forward we need to ensure we are counselling patients appropriately and we have updated our counselling checklist to reflect this. We have reported side effects not previously reported in the BNF and will continue to collect data as more patients are being started on or switched to DOACs.

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