Materials and Methods: We included all adult non-valvular AF patients who were new users of DOACs or VKA between 1 August 2012 and 31 June 2018. We focused on patients with a diagnosis of gastrointestinal or urological cancer identified from the Danish nationwide health registries. Patients were followed for up to one year to ascertain clinically relevant bleeding events and death. Bleeding events were defined as anemia, hemorrhagic stroke, gastrointestinal, lung, or urinary hemorrhage, hemothorax, or bleeding in the eye. We calculated crude bleeding rates per 100 person-years according to treatment regimen.
Results: The study included 5197 AF patients (23% women, median age 77 years) with gastrointestinal (n = 2,408) or urological (n = 2,917) cancer of which 128 patients had a record of both cancer types. There were 3,249 new users of DOAC and 1,948 new users of VKA. More VKA than DOAC users had comorbid hypertension (62% vs 57%), ischaemic heart disease (29% vs 25%), venous thromboembolism (9.0% vs 5.2%), and renal disease (12% vs 6.2%). Similarly, VKA users more often had dispensed prescriptions for calcium channel blockers (27% vs 21%), and diuretics (43% vs 33%) within 90 days before DOAC or VKA prescription. At one year, bleeding rates were of 6.86 (95% confidence interval (CI): 5.94–7.92) (n = 185) and 6.74 (95% CI 5.61–8.09) (n = 115) among DOAC and VKA users, respectively. Gastrointestinal bleeding rates were rate: 0.86 (95% CI 0.58–1.29) (n = 24) among DOAC users and 0.74 (95% CI 0.43–1.28) (n = 13) among VKA users.
Conclusions: Bleeding events were common among AF patients with gastrointestinal or urological cancer receiving oral anticoagulant treatment. We observed similar crude bleedings rates among patients receiving a DOAC and patients treated with a VKA.

PO-101
Management of direct oral anticoagulant (DOAC)-related bleeding with andexanet alpha or idarucizumab versus prothrombin complex concentrate (PCC) in patients with cancer: the MD Anderson experience

J.A. Ross, S. Lee, A. Zalpour, J.T. Henry, C.M. Rojas Hernandez
The University of Texas MD Anderson Cancer Center, TX, USA

Introduction: Many patients with cancer develop venous thromboembolism (VTE) and these events are associated with significant morbidity and mortality. DOACs, which inhibit factor Xa and/or thrombin and its propagation, have been shown in randomized clinical trials to be safe and effective for the treatment of VTE, including in patients with cancer. However, DOACs are associated with the risk for major bleeding. Andexanet alpha, a factor Xa inhibitor antidote, is approved for the reversal of anticoagulation in patients receiving rivaroxaban or apixaban. Idarucizumab is approved for patients with dabigatran-related bleeding. Other strategies are available for reversal, including four-factor PCC. Each of these pro-hemostatic therapies is associated with the risk for thrombosis. No prospective, randomized studies are completed or in progress comparing the safety and effectiveness of available strategies.
Aim: Our aim was to compare the safety and effectiveness of PCC with available antidotes in cancer patients with DOAC-relating major bleeding.
Materials and Methods: We performed a retrospective study of patients with major bleeding while receiving DOACs between January 2014 and September 2019. Bleeding severity and hemostasis were analyzed based International Society for Thrombosis and Haemostasis guidelines and the Sarode criteria, respectively. The rates of thrombosis and mortality at 30-days from the index bleeding event were analyzed. Outcomes were compared between groups by Chi-square test or Fisher exact test. All comparisons were performed with a test significance of 0.05.
Results: We identified 27 patients with DOAC-related major bleeding. All patients were treated for the bleeding event; 16 patients received four-factor PCC, 2 received idarucizumab, and 9 received andexanet alpha. The most common sites of bleeding were the GI tract (9 patients, 33%), brain (7 patients, 26%), and lungs (5 patients, 19%). In the PCC group, 12 patients (75%) were discharged alive and the median ICU stay was 3 days (min. 0, max. 11). In the idarucizumab/andexanet alpha group, 8 patients (73%) were discharged alive and the median ICU stay was 2 days (min. 0, max. 11). Effective hemostasis was achieved in 81% of patients receiving PCC compared to 73% of patients receiving idarucizumab/andexanet alpha. Re-bleeding events occurred in 3 patients (19%) receiving PCC and 2 patients (18%) receiving idarucizumab/andexanet alpha. 1 patient in each treatment group experienced a thrombotic event within 14 days. Thirty-day mortality was 31% in the PCC group compared to 27% in the idarucizumab/andexanet alpha group. There were no statistically-significant differences in the rate of hemostasis, thrombosis, re-bleeding, or mortality between the treatment groups.
Conclusions: The use of four-factor PCC had comparable safety and effectiveness to newer antidotes for oral factor Xa inhibitor-related major bleeding in patients with cancer. Prospective, randomized studies are needed in this area.

PO-102
Bleeding management challenges in rare cancer-associated thrombosis: a case report of inferior vena cava thrombus in a patient with testicular germ cell tumour

J. Gramaça[a], D.D. Machado[a], T. Ponte[b], I. Pina[a]
[a]*Department of Medical Oncology, Centro Hospitalar Barreiro Montijo, Barreiro, Portugal,* [b]*Department of Internal Medicine, Centro Hospitalar Barreiro Montijo, Barreiro, Portugal*

Introduction: Germ cell tumours (GCT) represent a rare malignancy. Cancer associated thrombosis (CAT) is unusual in this tumour type, namely involvement of the inferior vena cava (IVC).
Aim: Report a case of IVC and bilateral pulmonary embolism (EP) in a patient with testicular GCT with a bleeding complication.
Materials and Methods: Patient's clinical process analysis and consultation of published case reports using PubMed research database using the keywords "germ cell tumours", "cancer associated thrombosis", "inferior vena cava"and "bleeding".
Results: A 44-year-old male patient presented with pleuritic left chest pain for 1 week; the chest x-ray showed several nodular lesions in both lungs. The lab tests showed increased beta-HCG (26.6 mUI/mL), alfa-fetoprotein (10591.1 ng/mL) and LDH (385 UI/L); D dimer 477 ng /mL. He underwent a thoraco-abdomino-pelvic computerized tomography (CT) which showed pulmonary and retroperitoneal nodules and extensive IVC thrombus from the iliac veins to renal veins confluence; the chest angio-CT showed segmentary bilateral pulmonary embolism and the lower limb venous Doppler ultrasound showed no evidence of deep venous thrombosis. The patient was started on therapeutic hypocoagulation with low molecular weight heparin (LMWH), namely enoxaparin 1 mg/kg bid. Regarding diagnosis the testicular ultrasound showed a right testicular nodule and the patient was submitted to a diagnostic right orchiectomy; the nodule was found to be a non-seminomatous GCT. Despite adequate suspension and reintroduction of LMWH 24 hours later the patient developed a right scrotal haematoma 72 hours after surgery. Lab tests showed minor coagulation tests alterations (APTT/control 1.28, INR 1.22). In spite of this, LMWH was maintained and at day 5 after surgery there was not any haematoma increase; at day 7 there was a de novo abdominal wall haematoma with 17 cm of greater axis and documented by CT, coincident with a slight deterioration in coagulation tests (INR 1.52, aPTT/control 1.33) and a significative haemoglobin decrease with blood transfusion

needed. The LMWH was suspended and the patient was treated with protamine, with normalization of coagulation tests in the following 48h. The haematomas reabsorbed in the following 4 weeks without LMWH, being the patient subjected to a tight clinical surveillance; an imaging re-evaluation described a stable IVC thrombus. Four weeks after the bleeding event the patient was started on chemotherapy (bleomycin, etoposide and cisplatin) and LMWH was restarted with the same dosage, without new events at the 30-day follow-up.

Conclusions: Due to the rarity of these clinical cases, and adding to it a treatment-related bleeding event, it is necessary to share the experiences with managing these very particular situations in order to refine our approach.