Biomarkers Of Thrombosis As Predictors Of Venous Thromboembolism In Cancer Patients: Preliminary Results From Fiit Project

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Background: Venous thromboembolism (VTE) is an important cause of morbimortality in cancer patients. Comprehensive management of VTE, includes not only its effective its treatment, but also identification of patients who will benefit from thromboprophylaxis. *Khorana* score is the main validated tool for VTE risk-stratification.

Aims: Develop a predictive model of VTE in ambulatory cancer patients, combining thrombosis biomarkers (*D*-dimers and thrombin generation potential) with *Khorana* model.

Methods: This is a prospective observational study that Includes patients with a cancer diagnosis, proposed for anti-tumour treatments (chemotherapy, immunotherapy or targeted therapies). Patients with major bleeding in the last 3 months, major surgery in the last 28 days, on anticoagulation/antithrombotic therapy were excluded. Patients' disease characteristics, blood count values and thrombosis biomarkers were collected at baseline. The primary endpoint is the occurrence of symptomatic or incidental VTE at 6 and 12 months. The study was approved by the local ethics committee. Informed consent was obtained prior to study inclusion.

Results: From April-December 2019, 211 patients were enrolled, 171 analysed (40 were excluded). Median age was 56 [21-81], 53% were female. The majority had breast (22%,n=38), colorectal (20%,n=34) and gastric/gastroesophagic (14%,n=24) malignancies, 68% had advanced disease (stage III-IV). The majority initiated chemotherapy+/-targeted therapies (95%,n=163). At 6 months, 9 patients (5.3%) were diagnosed with VTE (4 pulmonary embolisms, 3 catheter-related and 2 deep venous thrombosis), 56% (n=5) were incidental findings on exams. VTE was more frequent in metastatic or locally advanced solid cancers (78%,n=7), and in gastric/gastroesophagic/biliary (44%,n=4) and coloretal (22%,n=2). At 12 months VTE was present in 8.8% (n=15).

Conclusions: Recruitment achieved 74% by December 2020, lower than expected due to COVID-19 pandemics. This study is ongoing and will result in a comprehensive risk model adapted to new realities taking into account the diversity of anti-tumour treatments available.

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