

Identification of Patients at High Thrombotic Risk in a Large Prospective Cancer Patient Cohort Undergoing Anticancer Treatment

C. Verzeroli¹, M. Marchetti¹, S. Bolognini¹, S. Gamba¹, C. Giaccherini¹, L. Russo¹, C.J. Tartari¹, D. Spinelli², P. Malighetti², A. Santoro³, F. De Braud⁴, G. Gasparini⁵, M. Minelli⁶, C. Tondini⁷, R. Labianca⁸, F. Giuliani⁹, F. Petrelli¹⁰, S. Barni¹⁰, A. Falanga¹, A. D'Alessio¹¹

¹Immunohematology and Transfusion Medicine ASST Papa Giovanni XXIII, Bergamo, Italy, ²Human Factors and Technology in Healthcare, Università degli Studi di Bergamo, Bergamo, Italy, ³Medical Oncology, IRCCS, Humanitas Institute, Rozzano, Italy, ⁴Foundation IRCCS National Cancer Institute, Milan, Italy, ⁵Medical Oncology, Hospital San Filippo Neri, Rome, Italy, ⁶Oncology Unit, Hospital San Giovanni Addolorata, Rome, Italy, ⁷Medical Oncology, ASST Papa Giovanni XXIII, Bergamo, Italy, ⁸DIPO, ASST Papa Giovanni XXIII, Bergamo, Italy, ⁹Medical Oncology, IRCCS Cancer Institute Giovanni Paolo II, Bari, Italy, ¹⁰Medical Oncology, ASST Bergamo Ovest, Treviglio, Bergamo, Italy, ¹¹Medical Oncology, Policlinico San Marco, Bergamo, Italy

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Background: Anticancer therapies contribute to increase the patient risk of venous thromboembolism (VTE). Identifying subjects at highest risk, in whom anticoagulant thromboprophylaxis is justified, is a relevant issue. Risk assessment models (RAMs), involving clinical and biological parameters, are promising tools, although their ability to discriminate high versus low VTE risk is still suboptimal particularly in lung and colorectal cancer outpatients.

Aims: To estimate the role of thrombin generation (TG) assay and D-dimer together with cancer site in generating an accurate RAM for VTE risk in a large prospective cohort of outpatients with metastatic non-small cell-lung (NSCL), colorectal, gastric, or breast cancers, undergoing chemotherapy.

Methods: As of December 2019, 1,442 newly diagnosed metastatic cancer patients were prospectively enrolled in the HYPERCAN study. TG (5pM TF) and D-dimer levels were evaluated at baseline before starting chemotherapy. VTE events occurring within 6 months were included in the analysis. For RAM generation, patients were randomly split in derivation and validation cohorts (1:1).

Results: After a median time of 419 days, 130 VTE were recorded (10.3%, 95% CI: 8.5-12.1%) with the highest incidence in NSCL (12.8%), followed by colorectal (10.6%), gastric (9.9%), and breast (3.3%) cancers. In the derivation cohort, by multivariate analysis, pre-chemotherapy levels of TG-peak and D-dimer, and the cancer site of NSCL or colorectal were independently associated with VTE ($p < 0.05$). A specific RAM including these variables, with 3 VTE risk levels, was created. In the validation cohort the RAM significantly discriminated the 3 categories: “high” (HR: 3.4 vs low), “intermediate” (HR: 2.1 vs low) and “low” VTE risk. The validated Khorana score failed to significantly discriminate the 3 groups.

Conclusions: This internal validated model, enabled the identification of high risk patients among the commonest solid cancers including NSCL and colorectal, where other RAMs failed.

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