Clinical and Translational Oncology (2020) 22:1423–1424
https://doi.org/10.1007/s12094-019-02265-x

CORRESPONDENCE

# TESEO, cancer-associated thrombosis registry from the Spanish Society of Medical Oncology (SEOM)

**A. J. Muñoz Martín[1] · P. Jiménez-Fonseca[2] · A. Carmona-Bayonas[3] · E. Martínez de Castro[4] · J. Muñoz Langa[5] · P. Pérez Segura[6] · A. Rodríguez Lescure[7] · R. Vera García[8] on behalf of Cancer and Thrombosis Section, Spanish Society of Medical Oncology (SEOM)**

Received: 11 September 2019 / Accepted: 8 December 2019 / Published online: 23 December 2019


**Keywords** Bleeding · Cancer · Complication · Thrombosis · Real world evidence · Registry

Venous thromboembolism (VTE) is considered as a major cause of preventable mortality and morbidity in cancer patients [1]. In recent years, there has been a marked increase in the diagnosis associated with a significant rise in the research and awareness of specialists who care for cancer patients [2]. However, only a few randomized clinical trials (RCTs) have been published in the last 2 decades regarding cancer-associated thrombosis (CAT), and this trend is unlikely to change. Multiple and important clinical questions associated with the approach to CAT remain unanswered such as long-term and recurrence treatment, and probably future RCTs will not address these dilemmas. Real-world evidence (RWE) and big data are emerging as new tools that can improve patient outcomes and eventually change our clinical practice and cancer registries are an example of this. The multinational, prospective RIETE registry has become the largest registry of VTE in the world with more than 82,000 patients included and has offered an extraordinary amount of evidence [3]. It is not a specific registry of CAT and does not consider cancer-specific variables with significant impact on VTE. For example, ALK-rearranged non-small-cell lung cancer (NSCLC) is associated with a very high rate of VTE ranging from 30 to 47%, much higher than other NSCLC and with a profound impact on overall survival [4]. Furthermore, chemotherapy has been considered an independent risk factor for VTE, however, the risk of VTE is not homogenous among different cytostatic agents, even inside the same drug category [5]. The alkylating agent cisplatin has been associated with the highest risk of thrombosis [6]. A direct comparison of advanced gastroesophageal cancer between cisplatin and oxaliplatin showed a significantly higher incidence of VTE in patients receiving cisplatin (15.1% versus 7.6%; $p=0.0003$) that remained in the multivariate analysis (hazard ratio 0.51; $p=0.001$) [7]. A recent study based on data from a gastric cancer registry found that multiple covariates have significant time-varying effects on the cumulative incidence of CAT such as cisplatin-containing regimen, Khorana score, secondary thromboprophylaxis, high tumor burden, and cisplatin-containing regimen, whereas other predictors exerted a constant effect (signet ring cells and primary thromboprophylaxis) [8]. CAT has a cumulative and late effect in elderly patients with cardiovascular disease receiving cisplatin regimens [8]. With all this evidence, we can no longer consider chemotherapy, type of cancer or other variables as single and homogenous risk factors for CAT. Therefore, it is necessary to discover a

✉ P. Jiménez-Fonseca
palucaji@hotmail.com

1 Medical Oncology Department, Hospital Universitario Gregorio Marañon, Madrid, Spain

2 Medical Oncology Department, Hospital Universitario Central de Asturias, Avenida Roma, 33011 Oviedo, Spain

3 Hematology and Medical Oncology Department, Hospital Universitario Morales Meseguer, University of Murcia, IMIB, Murcia, Spain

4 Medical Oncology Department, Hospital Universitario Marqués de Valdecilla, IDIVAL, Santander, Spain

5 Medical Oncology Department, Hospital Universitario Clínico de Valencia, Valencia, Spain

6 Medical Oncology Department, Hospital Universitario Clínico San Carlos, Madrid, Spain

7 Medical Oncology Department, Grupo Español de Investigación en Cáncer de Mama (GEICAM), Hospital General Universitario de Elche, Elche, Spain

8 Medical Oncology Department, Complejo Hospitalario de Navarra, Pamplona, Spain

specific approach and a more detailed analysis of the risk of VTE in cancer patients.

Cancer & Thrombosis Section of the Spanish Society of Medical Oncology (SEOM) launched a specific clinical registry of CAT in June 2018. In the 1st year, 636 patients were included in 34 centers and since then the register has also been opened in hospitals of Portugal. In 51% of the cases, the VTE was pulmonary and in 54.24% the event was incidental, finding it in a computed tomography scan performed to assess the treatment response. The most frequent cancers were colorectal (21%) and lung (20%) and the most common stage was IV (73%). Treatment of thrombosis was ambulatory in 48.2% and was based on low-molecular-weight heparin (95.1%). This registry, in addition to the usual variables of thrombosis, includes other special characteristics of CAT such as variables associated with renal function, platelet count, risk of bleeding, molecular profiles, systemic oncological treatments with antitarget, antiangiogenic and immunotherapy drugs. In the current series, 58% of patients who developed a VTE were receiving chemotherapy, 25% immunotherapy and 8% an antiangiogenic agent. In the first 3 months after thrombosis, 6% had bleeding, 4% a rethrombosis and 21.8% had died with cancer being the cause in more than half and thrombosis in 27%. These data highlight the severity and particularities of thrombosis in cancer patients. In this way, the registry will provide information on clinical practice situations that are underrepresented in RCTs and will collect molecular, treatment and specific cancer clinical variables. Our group has opted for a research approach based on personalized medicine [9], and the next challenging step is to collect biological specimens from both, patient and tumor to perform a translational approach.

To sum up, the TESEO registry of CAT is an example of RWE that aims not only to generate high-quality evidence, but also to improve patient outcomes by answering questions that have not been addressed in the RCTs.

**Acknowledgements** The authors want to express their gratitude to: (1) Sanofi for supporting TESEO registry with an unrestricted educational grant, (2) Cancer & Thrombosis Section, Spanish Society of Medical Oncology (SEOM) for promoting this registry and (3) all the researchers and centers for their inclusion of cases.

**Author contributions** Conception, design, article writing and final approval of manuscript: all authors.

## Compliance with ethical standards

**Conflict of interest** AJMM declares consulting or advisory role: Celgene, Sanofi, Pfizer, Bristol-Myers Squibb, LEO Pharma, Daiichi Sankyo, Bayer, Halozyme; speakers' bureau: Rovi; research funding: Sanofi, LEO Pharma and patents, royalties, other intellectual property: risk assessment model in venous thromboembolism in patients with cancer. PJF has participated as speaker in meetings sponsored by Leo Pharma and Rovi, all without the scope of this project. ACB has participated as a speaker in meetings sponsored by Rovi and Leo Pharma, all without the scope of this project. EMC declares consulting or advisory role: Pfizer; speakers' bureau: Celgene, Rovi, Leo Pharma, Roche, Sanofi, Shire. JML: no conflict of interest. PPS declares consulting or advisory role: Leo Pharma. ARL declares no conflict of interest. RVG declares consulting or advisory role: Roche Amgen, Merck and Sanofi.

**Ethical approval** The study has been performed in accordance with the ethical standards of the Declaration of Helsinki and its later amendments. This study is an observational, non-interventionist trial.

**Informed consent** Signed informed consent was obtained from all patients.

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