

Lay summary

Venous thromboembolism (VTE), comprising deep-vein thrombosis and pulmonary embolism, is a frequent problem in patients with cancer. Over the last few years, with the introduction of direct oral anticoagulants (DOACs), more treatment options have emerged. However, regardless of type of anticoagulation, patients with cancer-associated VTE still have a high risk of recurrence in the first 6 months. Furthermore, cancer patients treated with anticoagulation are at higher risk of bleeding compared to patients without cancer.

Decisions about the optimal intensity and duration of anticoagulant treatment could be guided by risk assessment tools, which assess the risk of recurrent VTE or bleeding in cancer patients. For example, such tools could be used to decide in which patients a dose reduction to 75% after one month should be avoided because of high risk of recurrent VTE. On the other hand, bleeding risk scores could aid in the decision making of treatment duration in patients with a high risk of bleeding. One such score for recurrent VTE is the Ottawa score which was derived in 543 patients with cancer and VTE who were diagnosed at the Thrombosis Unit of the Ottawa Hospital between 2002 and 2008 and validated in 819 patients from two RCTs which compared VKA to LMWH in the treatment of cancer-associated VTE. For this score, five variables are used for which either negative points (breast cancer=-1, TNM stage I=-2) or positive points (female= +1, lung cancer +1, previous VTE +1) are awarded, which produces a score sum, ranging from -3 to 3. In this risk prediction, a score of ≤ 0 corresponds with a low risk of recurrence and a score of ≥ 1 corresponds with a high risk of recurrence. However, several studies demonstrated that the discriminatory performance of this score is poor, making it unfit for adequate prediction of recurrent VTE. Furthermore, even though tumour type is known to be very predictive for recurrent VTE, only five different tumour categories were chosen to derivate the model (lung, breast, gastrointestinal, other, hematologic), combining tumour types with a high incidence of VTE (e.g. gynaecological or pancreatic tumours) to tumour types with a lower incidence of VTE (e.g. prostatic or colorectal tumours). To date, no risk prediction scores for bleeding in cancer patients are developed. Therefore, the aim of this study is to derivate and validate a new prediction model for recurrent VTE and a risk prediction model for bleeding in cancer patients. These models should aid clinicians in predicting recurrent VTE and bleeding in a more accurate way than previously was possible. This could help patients, for example, by preventing long-term anticoagulation and subsequent bleeding risk in those who are at the lowest risk of recurrent VTE.

Data from several large trials on the efficacy and safety of different types of anticoagulation will be combined to construct these new models. A large amount of clinical variables will be collected from all studies. The variables that are most predictive for recurrence of bleeding will be added to the model. Afterwards these candidate models will be tested within the complete study population. Finally we aim to have a model for both outcomes with variables that are generally available for all cancer patients and which is easy to use. These results will be published in a major cardiovascular journal.