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What Is the Acute and Post Acute Risk of VTE in Acute Medically Ill Patients?

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Dr. Spyropoulos:
Hello. I'm Dr. Alex Spyropoulos, professor of medicine at the Zucker School of Medicine at Hofstra/Northwell, and professor of the Institute of Health System Science at the Feinstein Institutes for Medical Research in New York. I will be discussing thromboprophylaxis in medically ill patients.

Now, what is the scope of the problem of venous thromboembolism, or VTE, in hospitalized medical patients. Well, there are an estimated 20 million acutely ill medical patients at risk of VTE that are hospitalized each year in the United States and European Union alone, although these likely represent underestimates from older data. There continues to be a significant unmet medical need for VTE prevention in this population, including both the in-hospital as well as the immediate post-hospital discharge settings. The majority of symptomatic VTEs and up to 80% of fatal pulmonary embolic events occur in acute medically ill nonsurgical patients, especially in those at high VTE risk. Also, hospitalized medical patients tend to have more severe forms of VTE than their younger, less comorbid surgical counterparts and more VTE-related deaths likely due to their more limited cardiopulmonary reserve. Now, the typical patient profile of an acutely ill medical patient is an elderly patient, mean age 70 years. They tend to present with acute exacerbations of underlying cardiopulmonary disease, such as congestive heart failure or respiratory failure, COPD, or other disease, say, such as acute infection, stroke, and acute rheumatic arthritic disorders, as well as inflammatory bowel disease exacerbations.

Risk factors for VTE are now well established in this population. Patients with a prior history of VTE, disease states such as acute infection malignancy, are at high risk of VTE. Also, advanced age, the presence of congestive heart failure, stroke, immobility, and stay in the intensive care unit are also markers of high risk of a VTE. More recently, a relatively novel biomarker D-dimer that's elevated is also able to predict high risk of VTE in this population.

There are also 2 well-validated VTE risk models in medically ill patients: the Padua model that we see on the left, and the IMPROVE model that we see on the right. Both models include clinical risk factors that are weighted and scored from 1 to 3 points. And using established cutoffs, are able to predict patients at low, intermediate, or high VTE risk. More recently, the IMPROVE model incorporated elevated D-dimers to improve model discrimination.

Now, landmark placebo-controlled randomized trials of inpatient thromboprophylaxis by using either low-molecular-weight heparin, such as once-daily enoxaparin or dalteparin, or the pentasaccharide fondaparinux, were able to establish that these agents led to a 50% to 60% reduction of total VTE in medically ill patients, with the rates in the placebo arm varied from about 5% to 15%.

However, this is during the time that the average duration of hospitalization was 7 to 14 days in this population. These same landmark trials established that inpatient thromboprophylaxis, usually with heparins, were also able to decrease fatal pulmonary embolic events by about 60% during the inpatient period. It is because of the consistency and high quality of this data that multiple antithrombotic guideline

recommendations, including most recently the updated 2024 International Consensus Statement Guidelines which represent the most up-to-date and comprehensive guidelines on the topic, give a strong recommendation based on high level of evidence that, for acutely ill medical patients with high individual risk factors as described for VTE, or who establish minimum score threshold using validated VTE risk scores, such as those of the Padou and IMPROVE tool, low-molecular-weight heparin and enoxaparin or dalteparin once daily is recommended. If low-molecular-weight heparin is not available, then the use of low-dose unfractionated heparin 5000 units twice or thrice daily is recommended. Single daily doses of fondaparinux over rivaroxaban, which is approved for use in the United States, are also recommended as second-line agents, although these are moderate recommendations based on results from single randomized trials.

Now, the practice of hospital-based medicine for treating these patients has changed dramatically in the last 20 years or so. In this very large quality-improvement project conducted in 35 Michigan area hospitals, there was no difference in VTE-free survival by the use of in-hospital-only thromboprophylaxis, despite the fact that the rates of pharmacologic prophylaxis between the low- and high-performing hospitals varied by as much as 30% absolutely. And one potential reason of this was the very low median length of stay, which is now reduced to 4 days for this patient population. When we coupled with the fact that there are very low rates of post-discharge prophylaxis in these patients, less than 4%, it is now easy to see that if we concentrate all our efforts on VTE prevention on the in-hospital setting without looking at the immediate post-discharge setting, we will do very little to reduce the disease burden of hospital-acquired thrombosis.

So to conclude, we are reaching what I think is a new paradigm in medically ill thromboprophylaxis, what I'd like to call an individualized patient-level, risk-adapted approach. We know that the acute hospitalization period represents the highest thrombotic risk period for medically ill patients, and we now can appreciate that many of these events occur in the post-discharge setting. We should still formalize VTE risk assessment and admission but move away from intuitive or universal practices of VTE risk assessment and move towards more evidence-derived practices using either high individual risk factors as described – advanced age, prior history of VTE, cancer, thrombophilia – or better yet, using validated risk scores such as the Padua and IMPROVE using established score cutoffs.

And if patients meet these established score cutoffs and do not have high bleed risk criteria, either through individual high bleed risk factors, or better yet using validated VTE risk tools such as the IMPROVE Bleed, they should be offered inpatient prophylaxis with unfractionated heparin, or better yet, low-molecular-weight heparin. Second-line agents include fondaparinux or rivaroxaban 10 mg, which is approved in the United States.

Thank you.

Announcer:
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