Venous thromboembolism: secondary prevention with dabigatran vs. acenocumarol in patients with paraneoplastic deep vein thrombosis. Results from a small prospective study in Romania

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Background: Secondary prevention of thromboembolic disease in cancer patients with oral anticoagulants is a challenging issue, due to the particular liver biology in this high-risk category of subjects.

Aim: To compare novel oral anticoagulant dabigatran vs acenocumarol administered in patients with malignant disease and deep vein thrombosis.

Method. We randomized 46 patients with paraneoplastic deep vein thrombosis in two groups, matched by age, sex, cancer type and Khorana score in 2 groups: first group (n=23) assigned to bid fixed-dose dabigatran (according to individual creatinine clearance), and second group (n=23) assigned to qd adjusted-dose acenocumarol (according to individual INR determined monthly). Patients were followed-up 6 months.

Results: 6 patients from the dabigatran group (13.95%) experienced an adverse outcome (major bleeding or recurrent thrombosis), vs. 12 patients (52.817%) from acenocumarol group, showing a significant difference (P=0.0349; 95%CI=0.2266-1.103). No patient developed pulmonary thromboembolism. There was one death due to major bleeding in the acenocumarol group vs. none in dabigatran group. No difference in the progression of underlying cancer was noticed between the two studied groups (4 deaths in dabigatran group vs 5 deaths in acenocumarol group, OR= 0.7579; 95% CI= 0.1752-3.279; P=0.3551). Patients in the dabigatran group reported a better QOL due to the fact that there was no need for monthly blood tests as in acenocumarol group.

Conclusion: In our study dabigatran was associated with a smaller rate of complications and may be safer in cancer patients with venous thromboembolism. Larger studies are needed, but difficult to be performed in this specific class of patients.