

Secondary Prophylaxis of Venous Thromboembolism with Direct Oral Anticoagulants in Patients with Major Congenital Thrombophilia vs Non-thrombophilic Patients

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Abstract Number: PB1138

Meeting: [ISTH 2021 Congress](#)

Theme: [Venous Thromboembolism](#) » [Genetic Risk Factors of Thrombosis](#)

Background: Direct oral anticoagulants (DOACs) are widely used for the treatment and secondary prophylaxis of venous thromboembolism (VTE). Congenital thrombophilia is a condition that predisposes to a higher incidence of VTE, more frequent VTE recurrences, some also in atypical sites, and often require long-term anticoagulation for secondary prevention. It is less clear the efficacy of DOACs in patients with major thrombophilia.

Aims: The aim of our study was to evaluate the efficacy, in terms of VTE prevention, and safety, in terms of absence of bleeding complications, in patients with major thrombophilia compared to non-thrombophilic patients candidate to long-term anticoagulation for recurrent VTE.

Methods: We evaluated consecutive patients who required long-term anticoagulation for recurrent VTE, treated with DOACs, and compared the outcomes between patients affected by major thrombophilia and non-thrombophilic patients. All patients presented at least 2 thrombotic events. Major thrombophilia was defined as the presence of physiologic inhibitors deficiency (protein C, protein S and antithrombin; homozygous Factor V Leiden, homozygous Factor II G20210A, combined heterozygosity of these defects.

Table I. Population Characteristics

Patients under DOAC 167	Patients with thrombophilia	Control Patients	p value*
Number of patients	72	94	
Sex (Male/Female)	39/33	62/32	0.12
Body Mass Index (median)	24,6 (range 16.8-45)	27 (range 20-39)	0.007
Age at start of therapy (median years)	42,4 (range 18-91)	55,9 (range 18-94)	<0,0001
Platelets at start of therapy (Median10 ³ /mmc)	228 (range 148-380)	234 (range 130-600)	0.24
Creatinine at start of therapy (median mg/dl)	0,8 (range 0.2-1.50)	0.93 (range 0.2-1.53)	0.005
DOAC administered			
Rivaroxaban	29 (40.3%)	26 (27.7%)	
Edoxaban	7 (9.7%)	20 (21.3%)	
Apixaban	28 (38.9%)	43 (45.7%)	
Dabigatran	8 (11.1%)	5 (5.3%)	
Thrombophilia			
Protein C Deficiency	7 (9.6%)		
Protein S Deficiency	20 (27.4%)		
Antithrombin Deficiency	12 (16.4%)		
FV Leiden Homozygous Mutated	18 (24.7%)		
FII G20210A Homozygous Mutated	5 (6.8%)		
Double Heterozygous mutation	10 (13.7%)		

*When appropriate, Chi-square and Mann-Whitney tests were performed

Results:

DOAC= direct oral anticoagulants; FV= factor V; FII= factor II

Population's characteristics

The examined patients were 167: 72 (43.4%) with major thrombophilia and 94 (66.6%) non-thrombophilic. All patients' characteristics are specified in table 1. The median time of DOACS therapy was 32 months (range 6-90) in the group with major thrombophilia; 20 months (range 6-80) in the other group. No significant difference was observed in the 2 groups in the incidence of thrombotic events (p 0.4) and for the onset of hemorrhagic complications (p 0.14).

Conclusions: Although major thrombophilia predisposes to a higher incidence of VTE, our data suggest that in this setting of patients, DOACs are effective and safe, with comparable results to non-thrombophilic patients.

To cite this abstract in AMA style:

Serrao A, Assanto GM, Santoro C, Pallotta A, Chistolini A. Secondary Prophylaxis of Venous Thromboembolism with Direct Oral Anticoagulants in Patients with Major Congenital Thrombophilia vs Non-thrombophilic Patients [abstract]. *Res Pract Thromb Haemost.* 2021; 5 (Suppl 1). <https://abstracts.isth.org/abstract/secondary-prophylaxis-of-venous-thromboembolism-with-direct-oral-anticoagulants-in-patients-with-major-congenital-thrombophilia-vs-non-thrombophilic-patients/>. Accessed July 6, 2021.

ISTH Congress Abstracts - <https://abstracts.isth.org/abstract/secondary-prophylaxis-of-venous-thromboembolism-with-direct-oral-anticoagulants-in-patients-with-major-congenital-thrombophilia-vs-non-thrombophilic-patients/>