



START-Eventi

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IM - ORIGINAL



Management of major bleeding and outcomes in patients treated with direct oral anticoagulants: results from the START-Event registry

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Testa S, Int Em Med 2018





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Bleeding events: Main clinical characteristics



Major bleeding events, n (%)	224
Cerebral	111 (49.5)
Gastrointestinal	83 (37.1)
Other	30 (13.4)
Fatal, 11 Cerebral; 6 GIB	25 (11.0)
Males, n (%)	132;59
Median Age (IQR range) years	80 (75-85)
Median Cr Cl mL/min	66 (33-72)
Indication to anticoagulation, n (%)	
Non Valvular AF	192 (86)
Venous thromboembolism	32 (14)
Anticoagulant drugs, n (%)	
Apixaban	71 (31.7)
Dabigatran	49 (21.9)
Edoxaban	16 (7.1)
Rivaroxaban	88 (39.3)
Antiplatelet drugs, n (%)	32 (14.2%)
DOAC low dose, n (%)	98 (43.8%)
Overall mortality	



Outcomes at hospital discharge and after 6 months



Outcome at hospital discharge (n;%)	224
- Complete resolution	153 (63)
- Disability (for ICH)	46/111 (41.4)
- Death	25 /224 (11)
Outcome within 6 months (n; %)	199
- Complete resolution	156/199 (78)
- Disability (for ICH)	43/65 (66)
- Death	7 (3.5)
- Lost at follow-up	2(1.0)

Overall mortality rate 14.3%



Thrombotic events: Main Clinical Characteristics



Patients	110
Males, n (%)	65 (60)
Median Age (IQR range) years	71 (64,84)
Median time (IQR range) [min-max] from starting DOAC and Thrombotic Events, days	230 (72;585)* [4-1755]
Indication to anticoagulation, n (%)	
Non Valvular AF	70 (64)
Venous thromboembolism	40 (36)
Anticoagulant drugs, n (%)	
Apixaban	26 (23)
Dabigatran	23 (21)
Edoxaban	7(6)
Rivaroxaban	54 (50)
Low dose DOACs	34* (31)
Low dose according guidelines	19** (17)
Antiplatelet drugs	10 (9.1)



Characteristics of thrombotic events



Thrombotic events	All 110	AF 70	VTE 40
Deep vein thrombosis	21	4	17
DVT+PE	9	2	7
Isolated PE	11	3	8
TVS	4	1	3
Stroke	49	46	3
TIA (positive imaging)	6	5	1
Peripheral embolism	6	6	-
Acute myocardial infarction	3	2	1
Retinal Vein Occlusion	1	1	-



n	DVT 21	DVT+EP 9	PE 11	TVS 4
Nessuna Terapia	-	-	-	-
Sospensione DOAC	21	9	11	4
Terapia Acuta				
LMWH	20	6	11	4
Fondaparinux	1	2		
Procedura invasiva*	-	-	1	
Terapia post-evento				
LMWH	2	3	1	1
Fondaparinux	-	-	-	-
Stesso DOAC	11	2	6	-
Stesso DOAC dose +	1	-	-	1
Altro DOAC	5	1	2	-
VKA	2	3	2	2

*trombectomia



n	TIA 6	STROKE 49	Periph Emb 6	AMI 3
Nessuna Terapia	1	7	1	-
Sospensione DOAC	5	34	-	1
Terapia Acuta				
LMWH	-	17	1	1
Fondaparinux	-	-	-	-
LMWH+ASA	1	14	-	-
ASA	2	8	-	2
Procedura invasiva*		5	4	1
Terapia post-evento				
LMWH	-	-	-	-
Fondaparinux	-	-	-	-
ASA	-	-	-	-
Stesso DOAC	4	10	2	2
Stesso DOAC dose +	1	6	-	-
Altro DOAC	-	13	2	-
DOAC+ASA	1	6	-	-
Altro DOAC+ASA	-	4	1	-
VKA	-	6	1	1

*trombolisi, trombectomia, PTCA+Stent



OUTCOMES

at hospital discharge and within 6 months

Patients	110
Outcome at discharge	110
Complete resolution	82 (74.5)
Disability (for patients with stroke)	24 (57)
Death	4# (3.6)
Outcome within six months	106
Complete resolution	95 (90.4)
Disability (for patients with stroke)	7 (16.2)
Death	3§ (2.8)
Lost at follow-up	1 (0.9)

Overall mortality rate 6.4%



Laboratory testing

Test (n° of patients)	Before intervention	Post intervention
	Median (IQR)	-
PT INR (70)	1.3 (1.2,7.4)	-
aPTT ratio (58)	1.1 (1.0,1.2)	-
Hemoglobin (101)	13.4 (9.8,14.1)	-
Platelet count (98)	221 (167,281)	-
Cr Cl mL/min (77)	67 (47.5,92.5)	-
Dabigatran DTT (ng/ml) (11/23) (median; range)	52 (14-154)	-
Apixaban aXa (ng/ml) (7/26) (median; range)	87 (42-262)	-
Rivaroxaban aXa activity (17/54) (median; range)	97 (9-167)	-

70-80 %

25%



Conclusioni

- La mortalità degli eventi trombotici è **significativamente più bassa** se confrontata con gli eventi emorragici
- Nei pazienti **fibrillanti** sono più **frequenti** gli eventi **arteriosi** rispetto a quelli venosi
- Maggiore utilizzo antidoti nelle ICH
- Il **dosaggio** dei **DOAC** è richiesto molto raramente
- L'interpretazione **dei livelli di antiXa** è difficoltosa in quanto la maggior parte dei pazienti sono trattati anche con **LMWH**
- Importante **estendere l'arruolamento**



Participants



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<http://www.start-register.org>



Start₂-Registry

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