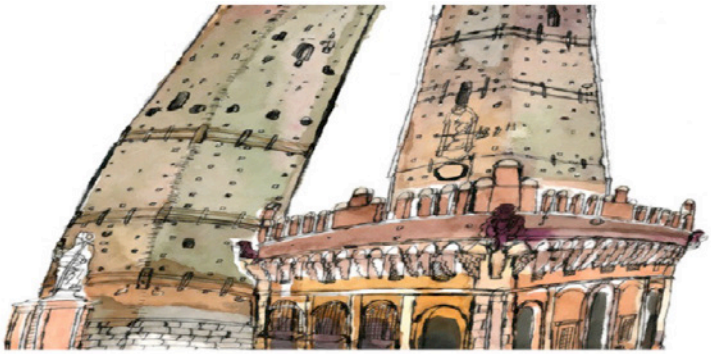


3° CONVEGNO DI ANTICOAGULAZIONE.it

ANTICOAGULAZIONE
Attualità cliniche e di laboratorio.
Aspetti sociali

BOLOGNA 25-26 GENNAIO 2018

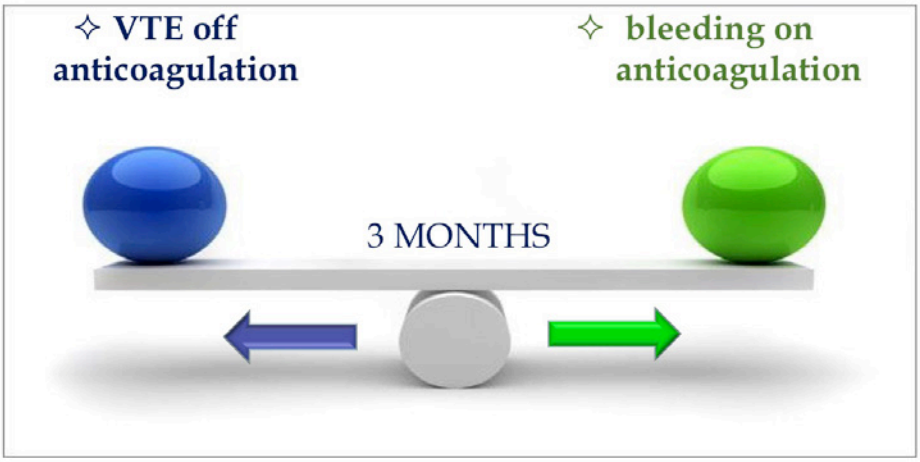
Come si applica ai pazienti dello START2-Registry lo score ACCP per il rischio emorragico nei pazienti con TEV

Emilia Antonucci, Daniela Mastroiacovo

fondazione arianna ANTICOAGULAZIONE

START REGISTRY

Duration of anticoagulant therapy for VTE : the clinical judgement regarding risk/benefit



Continue anticoagulant therapy based on the individualised assessment of risks and benefits

Risk factors for bleeding with anticoagulant therapy and categorisation of risk of bleeding (ACCP Guidelines)

Risk factors	
Age >65 years	Diabetes
Age >75 years	Anaemia
Previous bleeding	Antiplatelet therapy
Cancer	Poor anticoagulant control
Metastatic cancer	Comorbidity and reduced functional capacity
Renal failure	Recent surgery
Liver failure	Frequent falls
Thrombocytopenia	Alcohol abuse
Previous stroke	Non-steroidal anti-inflammatory drug

For the decision about whether to stop treatment at 3 months or to treat indefinitely ('extended treatment'), a patient's risk of bleeding on anticoagulant therapy was categorised as:

- ✓ **Low (no bleeding risk factors; 0.8% annualised risk of major bleeding)**
- ✓ **Moderate (one bleeding risk factor; 1.6% annualised risk of major bleeding)**
- ✓ **High (two or more bleeding risk factors; ≥6.5% annualised risk of major bleeding)**

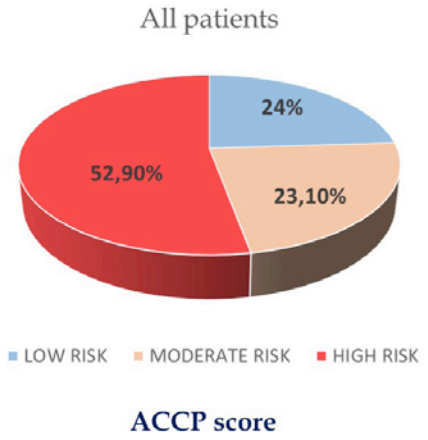
Kearon et al. 2016

ACCP score to assess the risk of bleeding during anticoagulation: application to real-life data from the START2-REGISTRY

Palareti G., Antonucci E., Mastroiacovo D., Ageno W., Pengo V., Poli D., Testa S., Tosetto A., Prandoni P.

ACCP score to assess the risk of bleeding during anticoagulation: application to real-life data from the START2-REGISTRY

- Luglio 2017: 2263 pazienti



BASELINE CHARACTERSTICS	n (%)
Males	1160 (51.3)
Median age (IQR) years	67(51,77)
Age ≤65 y	1041(46.0)
Age 66-75 y	559 (24.7)
Age >75 y	663 (29.3)
Site and type of index event n. (%)	
DVT	1282 (56.6)
DVT+PE	472 (20.9)
Isolated PE	460 (20.3)
Recurrent SVT	49 (2.2)
Unprovoked	1543 (68.2)
Follow-up (patient-years)	2216
Type of anticoagulant treatment n. (%)	
VKA	1522 (67.3)
DOACs	741 (32.7)

ACCP score to assess the risk of bleeding during anticoagulation: application to real-life data from the START2-REGISTRY

- Follow up: 3130 anni/paziente
- 48 emorragie registrate (2.2%; 1.53%/y):
  - 28 emorragie maggiori
  - 20 emorragie non maggiori clinicamente rilevanti

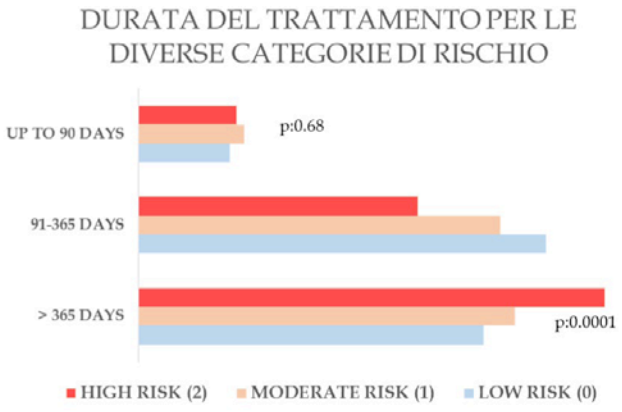
✓ Pazienti con emorragia più anziani [età mediana 74 anni (IQR 63,81) vs 64 (51.,77); p = 0.02]

✓ Emorragie più frequenti nelle donne [2.2% vs. 0.9%/y, RR 2.5 (95%CI 1.2-5.1) p=0.003].

ACCP score to assess the risk of bleeding during anticoagulation: application to real-life data from the START2-REGISTRY

	Low risk (0 points) n=543	Moderate Risk (1 point) n=522	High Risk (=> 2 points) n=1198	High vs Low risk Chi-squared p
Females n. (%)	220 (36.8)	227 (43.5)	656 (54.7)	0.0001
Total follow-up during treatment y	628	665	1828	0.0001
Duration of treatment				
Up to 90 days	59 (10.8)	65 (12.5)	139 (11.6)	0.68
91-365 days	262 (48.3)	224 (42.9)	397 (33.1)	0.0001
>365 days	222 (40.9)	233 (44.6)	662 (55.3)	0.0001
Lost to follow-up	4	4	10	
Dead patients (*) n. (%)	1 (0.4)	10 (0.4)	118 (9.8)	0.0001
Type of index event				
Provoked (n. 720) n. (%)	164 (22.8)	173 (24.0)	383 (53.2)	0.4
Unprovoked (n. 1543) n. (%)	379 (24.6)	349 (22.6)	815 (52.8)	0.4
Type of anticoagulant drug n. (%)				
VKAs	256 (16.8)	336 (22.1)	930 (61.1) ††	0.0001
DOACs	287 (38.7) †	186 (25.2)	268 (36.2)	0.3

(*) All deaths were due to causes different than bleeding complications during anticoagulant treatment

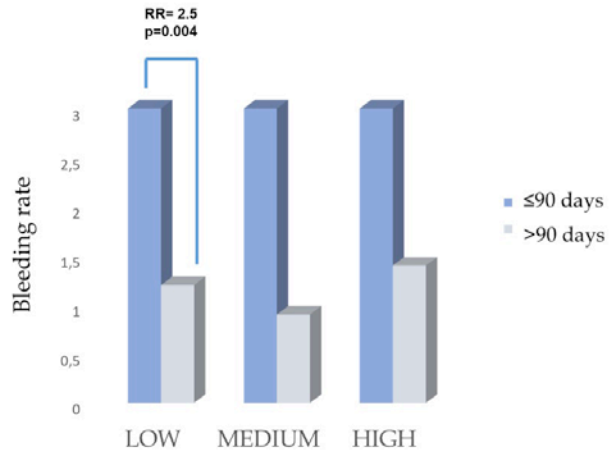


† Low-risk DOACS vs low-risk VKAs: p=0.0001

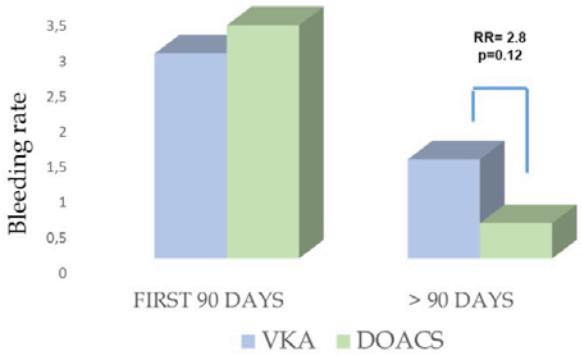
†† High-risk DOACs vs high-risk VKAs: p=0.0001

ACCP score to assess the risk of bleeding during anticoagulation: application to real-life data from the START2-REGISTRY

Incidence of bleeding events in the different timing of treatment in different ACCP Score Risk class (rate)

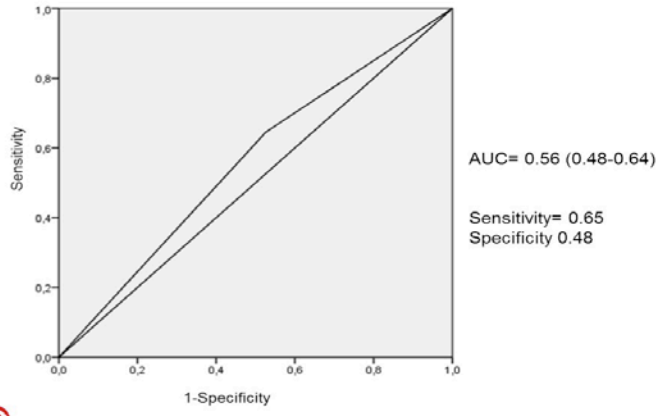


... and in patients who received VKAs or NOACs

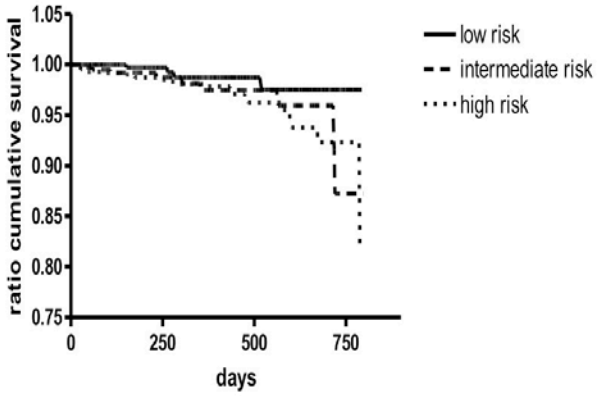


ACCP score to assess the risk of bleeding during anticoagulation: application to real-life data from the START2-REGISTRY

Receiver operating characteristics curve of ACCP score for the prediction of bleeding complications during anticoagulant treatment (high-risk versus low/moderate-risk categories)



Bleeding-free survival probability for the three risk categories in the first 24 months from anticoagulation inception



ACCP score to assess the risk of bleeding during anticoagulation: application to real-life data from the START2-REGISTRY

Conclusioni:

- ✓ Più della metà dei pazienti arruolati nel registro START sarebbero classificati ad alto rischio emorragico secondo lo score ACCP e dovrebbero essere esclusi dal trattamento esteso. Nella pratica clinica, tuttavia, la maggiorparte di essi riceve un trattamento esteso.
- ✓ Dopo i primi 90 giorni di terapia, abbiamo osservato una bassa incidenza di eventi emorragici, anche nei pazienti considerati ad alto rischio di sanguinamento
- ✓ L'incidenza di emorragie nella fase estesa di terapia sembra essere minore nei pazienti trattati con DOACs
- ✓ Lo score proposto dall'ACCP sembra avere un basso valore predittivo nell'identificare i pazienti che dovrebbero essere esclusi da un trattamento esteso o candidati ad esso

Prospettive future:

- ✓ Individuare nuovi strumenti in grado di identificare pazienti ad alto rischio emorragico, applicabili anche a pazienti trattati con i DOACs

ACCP score to assess the risk of bleeding during anticoagulation: application to real-life data from the START2-REGISTRY

Palareti G., Antonucci E., Mastroiacovo D., Ageno W., Pengo V., Poli D., Testa S., Tosetto A., Prandoni P.

Grazie