

**Sincope e cadute
nell'anziano:
sospendere o non
iniziare
l'anticoagulante?**

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Associazione Multidisciplinare
di Geriatria

2019

A Congresso Nazionale

**GERIATRIA E DINTORNI
UN VIAGGIO DI INCONTRI**

Presidente: Matteo Grezzana



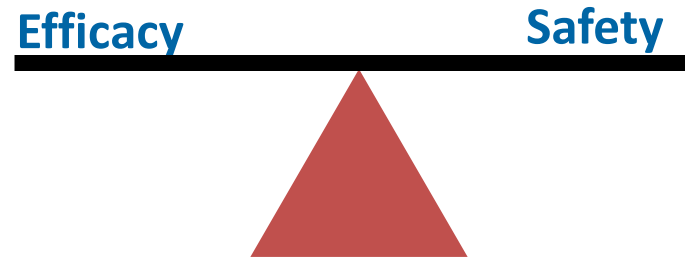
PROGRAMMA

VERONA

5 - 7 Dicembre 2019
Palazzo della Gran Guardia

L'anticoagulante ideale

- Somministrazione orale
- Dose fissa piuttosto che dosaggio stabilito in base ai risultati di test coagulativi
- Specificità farmacologica per evitare effetti inaspettati
- Rapido onset e offset
- Buona biodisponibilità
- Farmacocinetica e farmacodinamica prevedibili
- Buona efficacia
- Eccellente sicurezza (soprattutto in termini di rischio emorragico)
- Ampia finestra terapeutica
- Bassa interazione con il cibo e con altri farmaci
- Nessuna necessità di monitoraggio di laboratorio
- Disponibilità di un antidoto



Four randomized clinical trials of new oral anticoagulants in SPAF...

The NEW ENGLAND JOURNAL *of* MEDICINE

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ORIGINAL ARTICLE

Dabigatran versus Warfarin in Patients
with Atrial Fibrillation

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ORIGINAL ARTICLE

Rivaroxaban versus Warfarin in Nonvalvular
Atrial Fibrillation

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ORIGINAL ARTICLE

Apixaban versus Warfarin in Patients
with Atrial Fibrillation

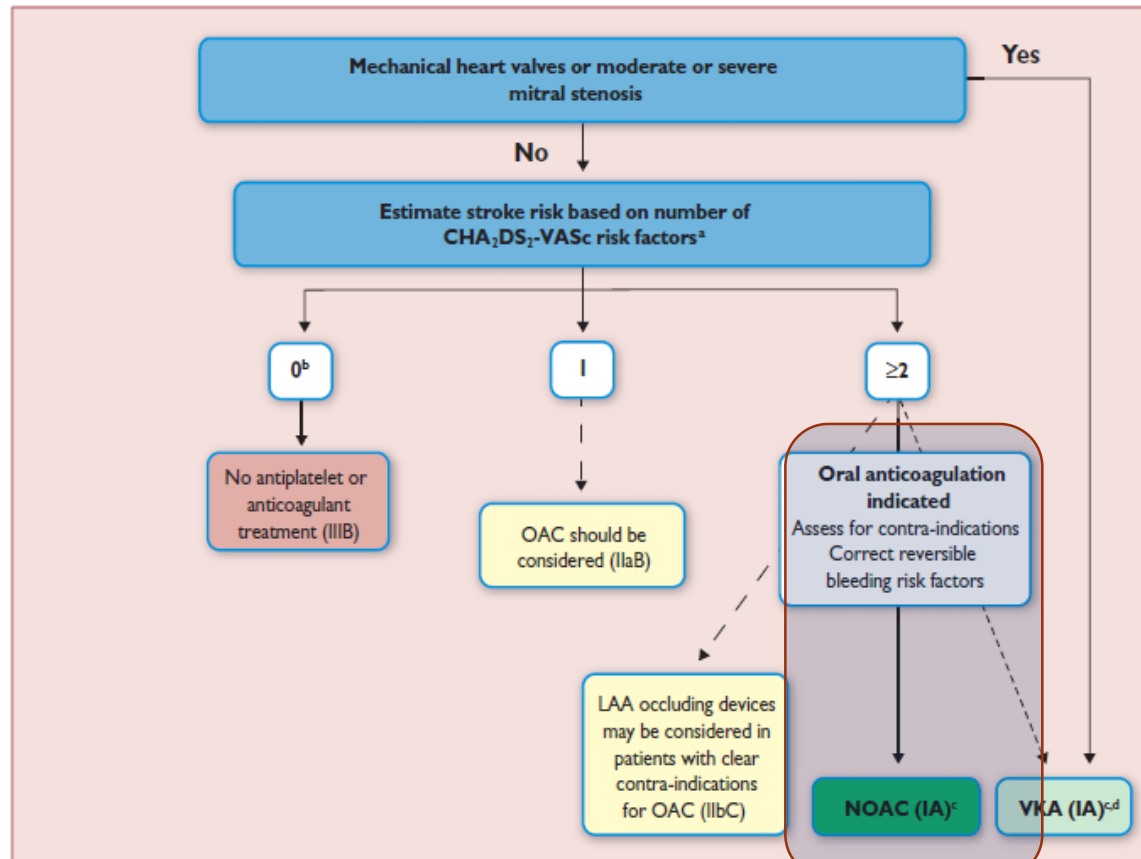
The NEW ENGLAND JOURNAL *of* MEDICINE

ORIGINAL ARTICLE

Edoxaban versus Warfarin in Patients
with Atrial Fibrillation

2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

The Task Force for the management of atrial fibrillation of the European Society of Cardiology (ESC)



AF = atrial fibrillation; LAA = left atrial appendage; NOAC = non-vitamin K antagonist oral anticoagulant; OAC = oral anticoagulation; VKA = vitamin K antagonist.

^aCongestive heart failure, Hypertension, Age ≥ 75 years (2 points), Diabetes, prior Stroke/TIA/embolus (2 points), Vascular disease, age 65–74 years, female Sex.

^bIncludes women without other stroke risk factors.

^cIIaB for women with only one additional stroke risk factor.

^dIB for patients with mechanical heart valves or mitral stenosis.

Figure 8 Stroke prevention in atrial fibrillation.

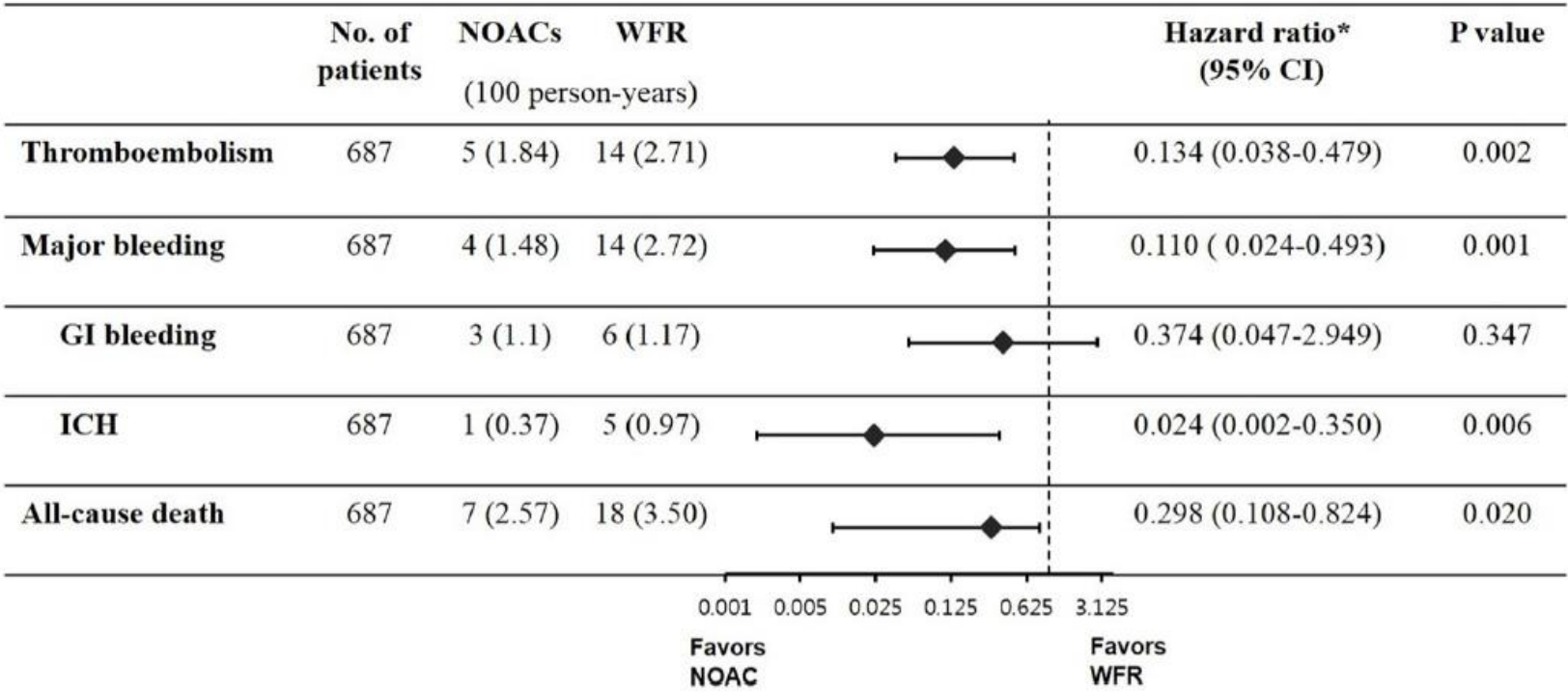
Gli anziani con NAO e
sincope o caduta sono
spesso i pazienti più
complessi e fragili

**L'anziano che
cade o ha una
sincope? Come
comportarsi**

**Perché i NAO nell'anziano
fragile?**

Effectiveness and safety of non-vitamin K antagonist oral anticoagulants in octogenarian patients with non-valvular atrial fibrillation

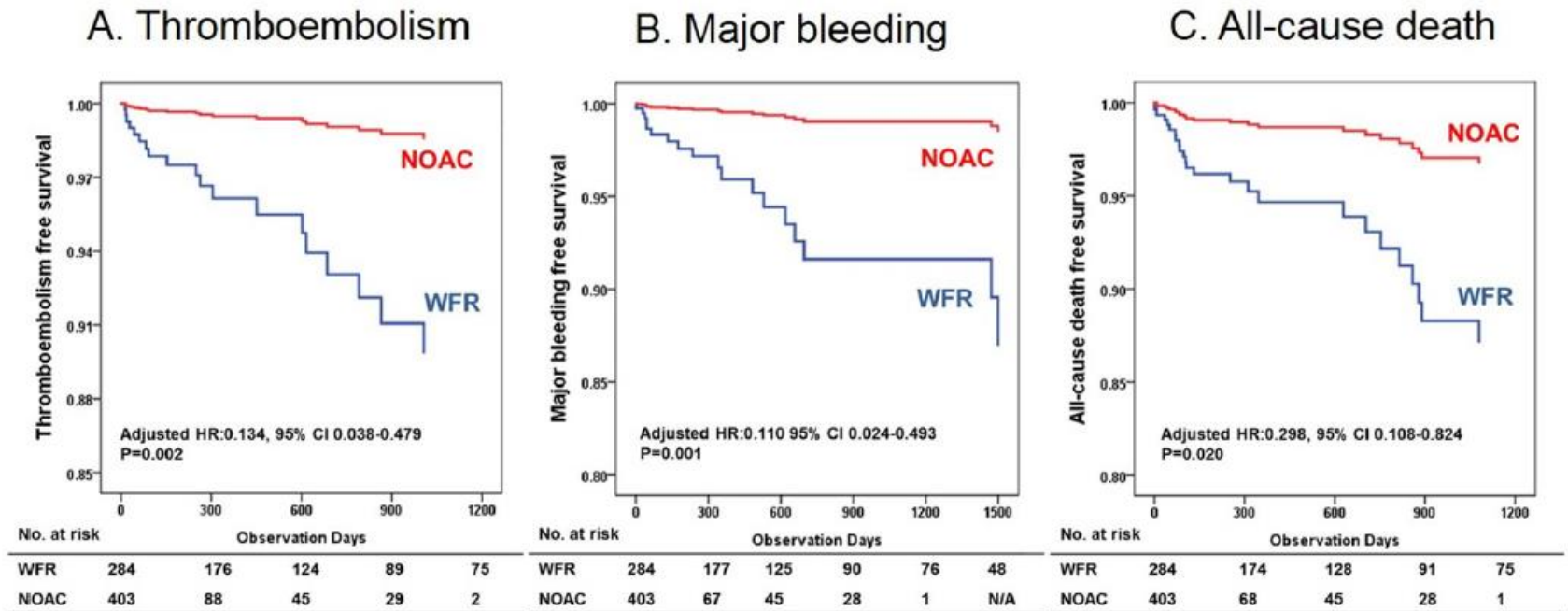
Hye Mee Kim^{1,2}, Eue-Keun Choi^{1*}, Chan Soon Park¹, Myung-Jin Cha¹, Seo-Young Lee¹, Joon-Myung Kwon³, Seil Oh¹



Effectiveness and safety of non-vitamin K antagonist oral anticoagulants in octogenarian patients with non-valvular atrial fibrillation

PLOS ONE | <https://doi.org/10.1371/journal.pone.0211766> March 7, 2019

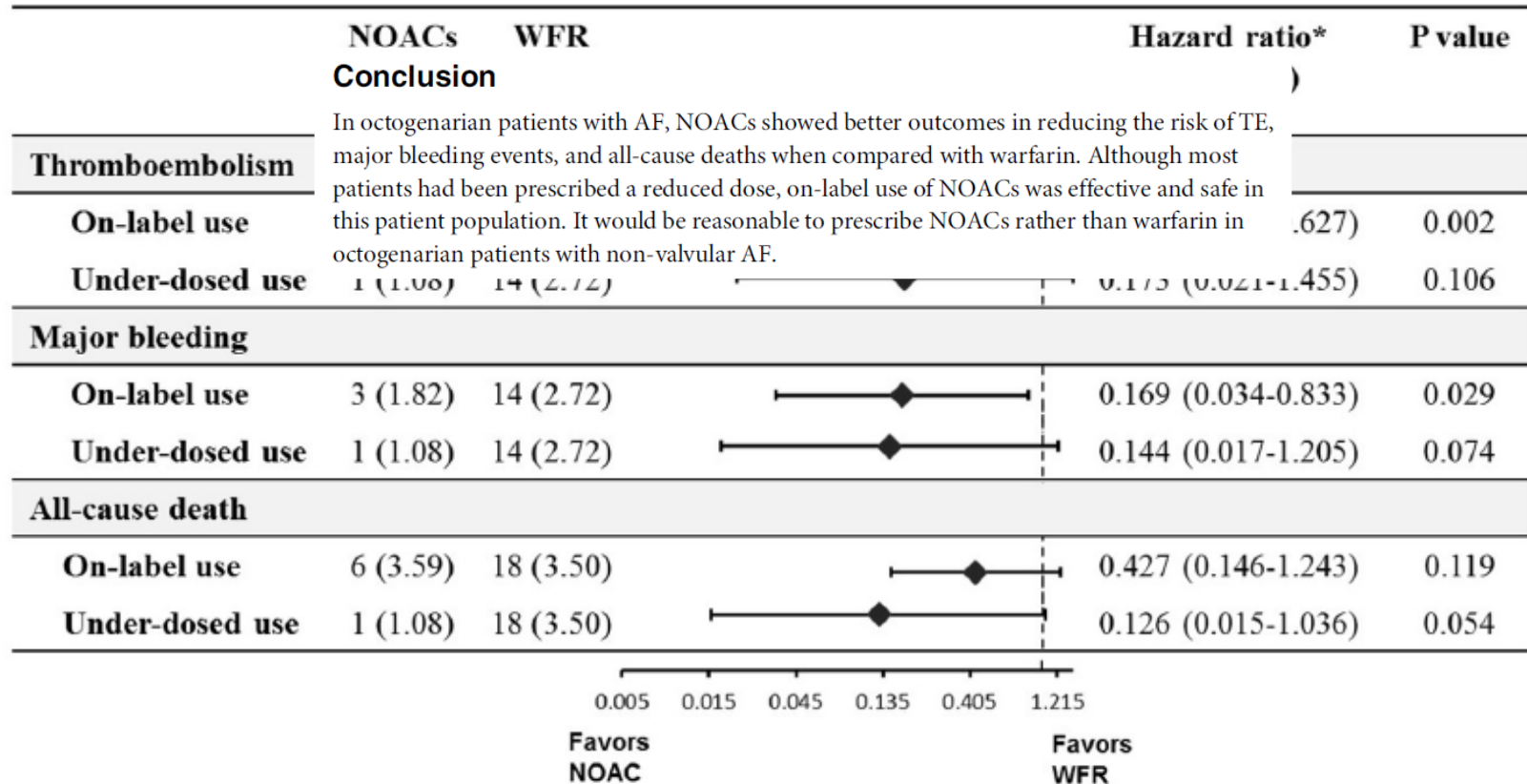
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Effectiveness and safety of non-vitamin K antagonist oral anticoagulants in octogenarian patients with non-valvular atrial fibrillation

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Effectiveness and safety of non-vitamin K antagonist oral anticoagulants in octogenarian patients with non-valvular atrial fibrillation

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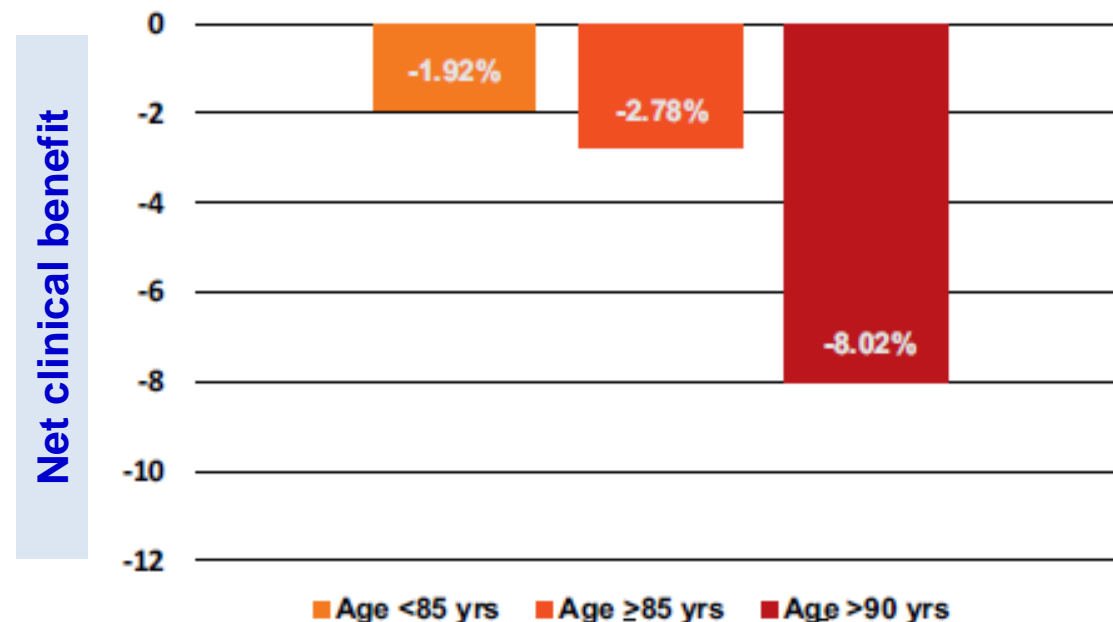
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Conclusion

In octogenarian patients with AF, NOACs showed better outcomes in reducing the risk of TE, major bleeding events, and all-cause deaths when compared with warfarin. Although most patients had been prescribed a reduced dose, on-label use of NOACs was effective and safe in this patient population. It would be reasonable to prescribe NOACs rather than warfarin in octogenarian patients with non-valvular AF.

The safety and efficacy of non-vitamin K antagonist oral anticoagulants in atrial fibrillation in the elderly

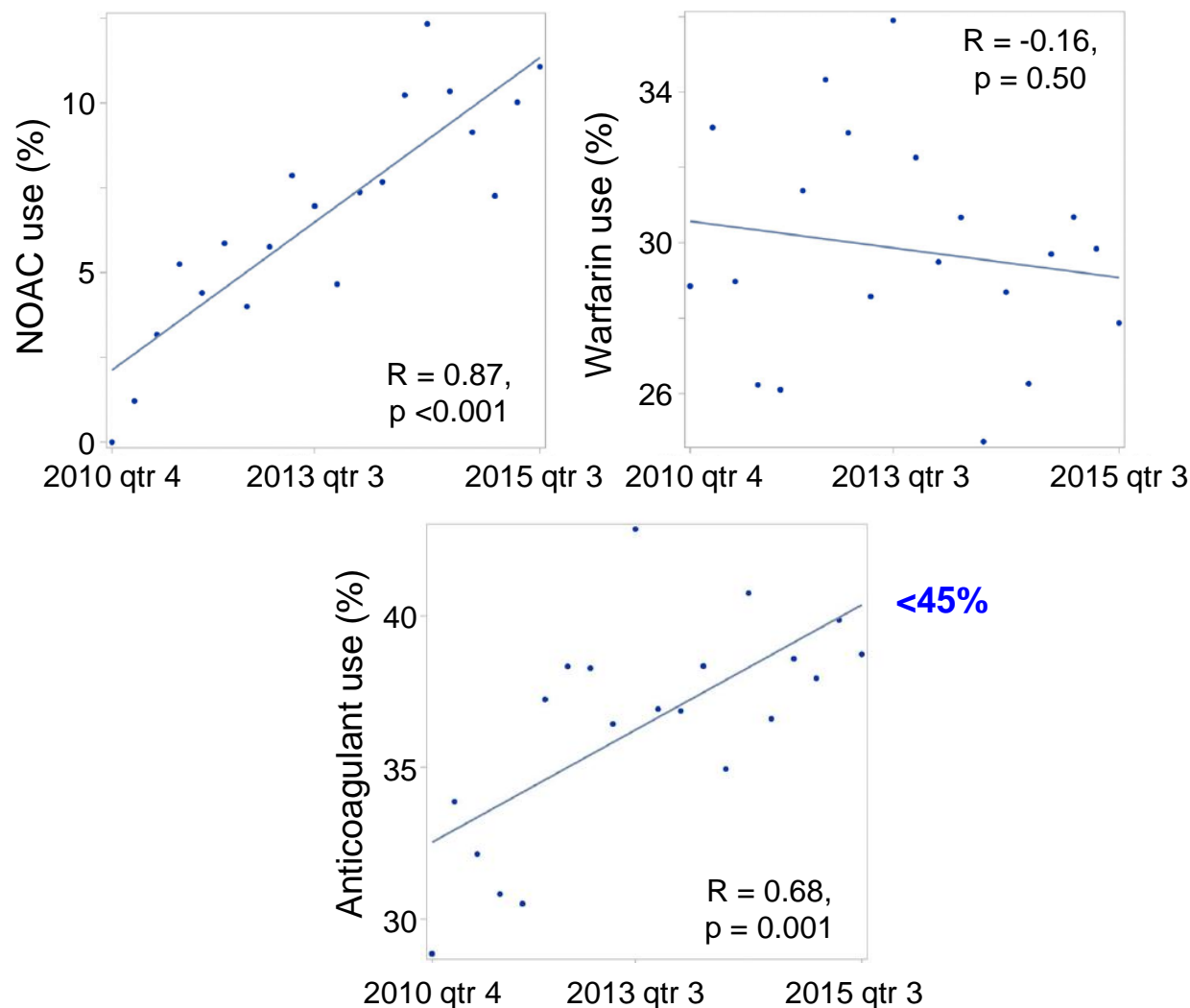
Net clinical benefit, adjusted for the risk of subsequent death, of OACs vs no OACs according to different age groups (the PREFER in AF)



VKAs or NOACs led to a 36% risk reduction of TE events vs. antiplatelet or no treatment; notably, OACs did not increase the risk of major bleeding compared to antiplatelet therapy

Effect of New Oral Anticoagulants on Prescribing Practices for Atrial Fibrillation in Older Adults

Quarterly trend in anticoagulants use (N=6568; age ≥ 75 years)
(the Clinical Investigation Data Exploration Repository - CIDER, Washington University)



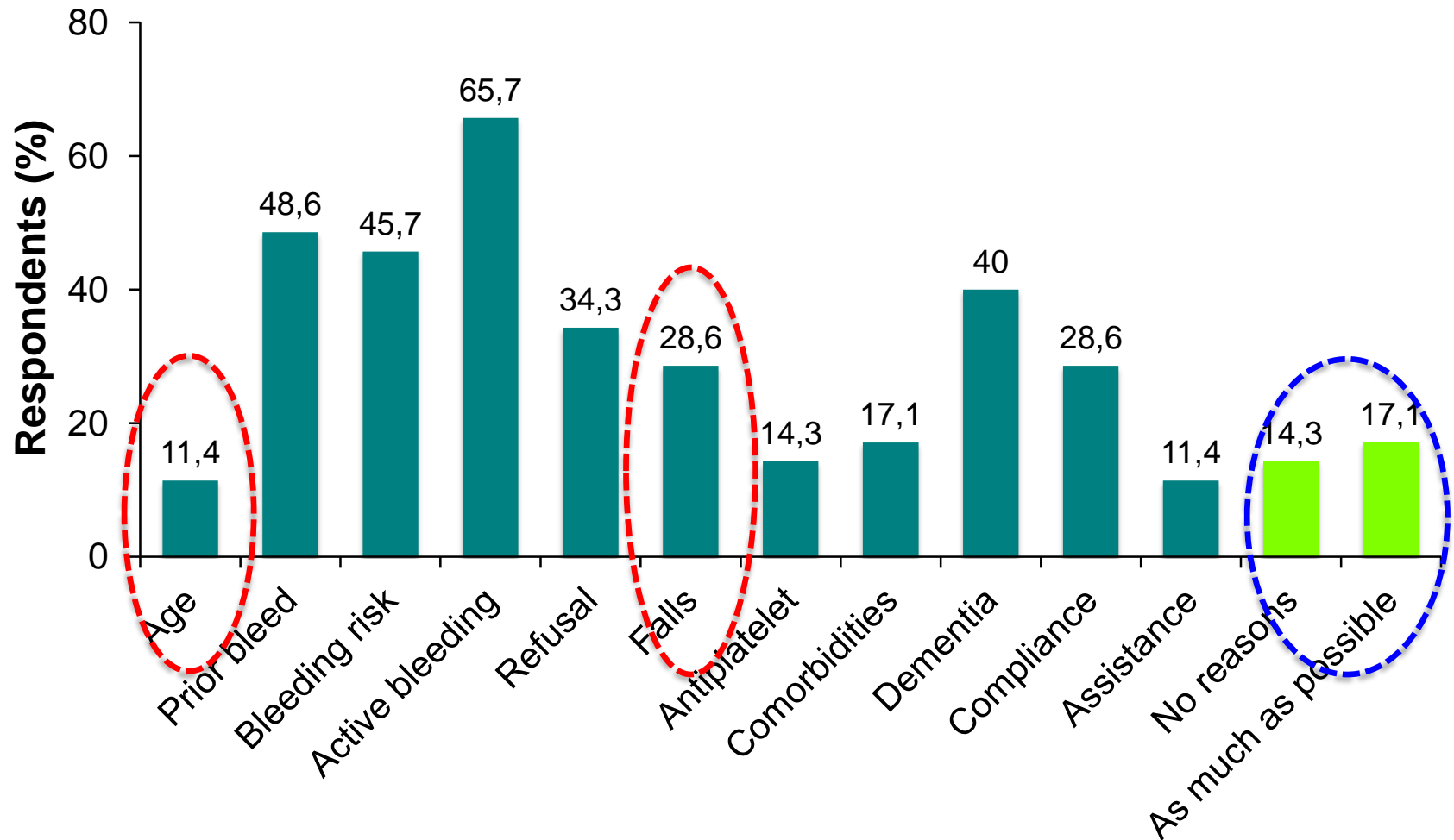
**L'anziano che
cade o ha una
sincope? Come
comportarsi**

E se cade?

Frailty syndrome: an emerging clinical problem in the everyday management of clinical arrhythmias: results of the European Heart Rhythm Association survey

Fumagalli S et Al.,
EP Europace 2017

Reasons not to prescribe OAs to a frail patient with AF (light green bars indicate responses that are in favour of the use of Oas)

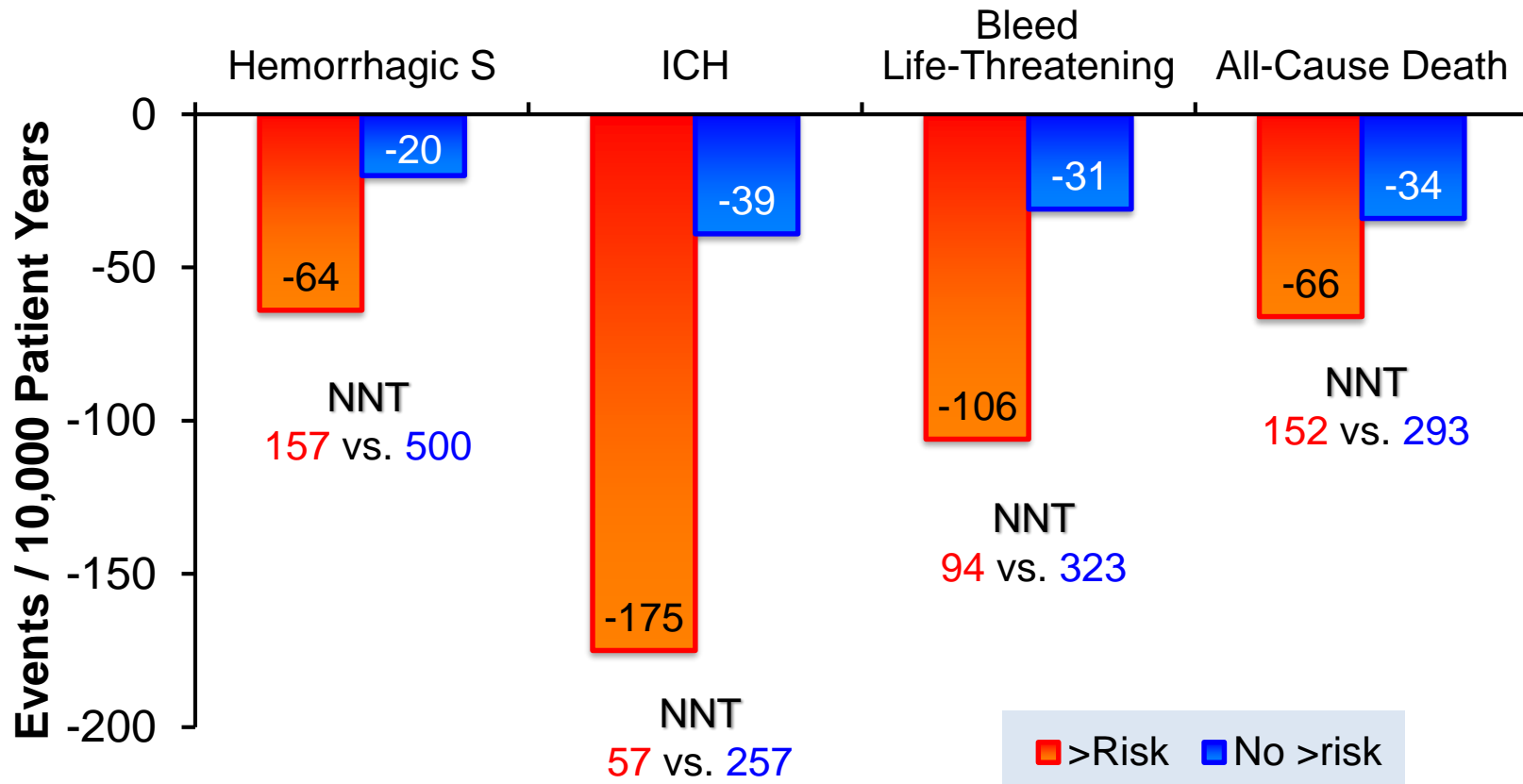


Edoxaban Versus Warfarin in Atrial Fibrillation Patients at Risk of Falling

ENGAGE AF-TIMI 48 Analysis



Absolute Risk Reduction of HD Edoxaban Regimen Compared With Warfarin in Patients at Increased Versus Not at Increased Fall Risk



Clinical Outcomes and History of Fall in Patients with Atrial Fibrillation Treated with Oral Anticoagulation: Insights From the ARISTOTLE Trial

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753 patients with vs 15738 without history of falling

Characteristics	Fall(s) Within 1 Year		P-Value
	Yes (n = 753)	No (n = 15,738)	
Age, median (25th, 75th), years	75 (67, 79)	70 (63, 76)	< .0001
Age ≥75 years, n (%)	379 (50.3%)	4787 (30.4%)	< .0001
Female sex, n (%)	357 (47.4%)	5438 (34.6%)	< .0001
BMI, median (25th, 75th), kg/m ²	29.1 (25.6, 33.8)	28.4 (25.2, 32.4)	< .001
CHA2DS2-VASC score, mean (SD)	4.19 (1.65)	3.43 (1.51)	<.001
Prior stroke, TIA, SE	28.3%	20.9%	<.001
Prior bleeding	35.1%	16.0%	<.001

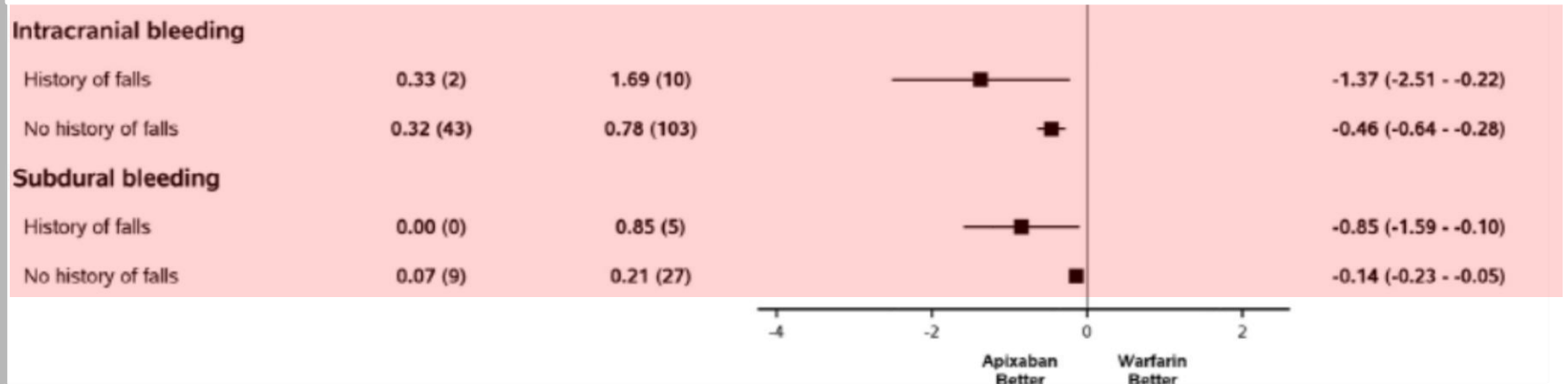
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Effectiveness and Safety of Apixaban, Dabigatran, and Rivaroxaban Versus Warfarin in Frail Patients With Nonvalvular Atrial Fibrillation

Brandon K. Martinez, PharmD; Nitesh A. Sood, MD; Thomas J. Bunz, PharmD, PhD; Craig I. Coleman, PharmD

(J Am Heart Assoc. 2018;7:e008643.

What Are the Clinical Implications?

- Our study results suggest direct-acting oral anticoagulants are reasonable alternatives to warfarin for stroke prevention in frail patients with nonvalvular atrial fibrillation managed in routine practice.

Conclusion

Our study found rivaroxaban but not apixaban or dabigatran to be associated with reduced SSE versus warfarin in frail NVAF patients at 2-years follow-up.

No DOAC demonstrated a significant difference in bleeding versus warfarin. The relative effectiveness and safety of DOACs compared with warfarin appears maintained in frail NVAF patients treated in routine US clinical practice.

Direct oral anticoagulants do not worsen traumatic brain injury after low-level falls in the elderly

Madelyn Batey, PharmD^a, Jason Hecht, PharmD^b, Cherise Callahan, PharmD^b, Wendy Wahl, MD, FACS, FCCM^{b,*}

Table 1
Demographic characteristics of older trauma patients presenting with low-level falls on anticoagulants.

	<i>No Anticoagulant (N = 523)</i>	<i>Warfarin (N = 141)</i>	<i>DOAC (N = 36)</i>	<i>P</i>
Age (y)	81 ± 9	81 ± 8	81 ± 7	NS
65–79, N (%)	237 (76)	59 (19)	17 (5)	
80+, N (%)	286 (74)	82 (21)	19 (5)	
Sex (% female)	55	53	53	NS
Admission GCS	13.8 ± 2.6	14 ± 2.4	15 ± 1*	* <i>P</i>
Admission comorbidities, N (%)				
Cardiac	361 (69)	123 (87)*	34 (94)*	** <i>P</i>
Pulmonary	71 (14)	40 (28)*,†	2 (6)	** <i>P</i> , † <i>P</i>
Gastrointestinal	9 (2)	8 (6)*	3 (8)	* <i>P</i>
Clotting disorder	1 (0.2)	3 (2.1)	0	NS
Cancer	22 (4)	10 (7)	4 (11)	NS
Diabetes mellitus	120 (23)	40 (28)	7 (19)	NS
Renal	61 (12)	23 (16)	7 (19)	NS
Neurologic	128 (25)	32 (23)	12 (33)	NS

NS = nonsignificant

Direct oral anticoagulants do not worsen traumatic brain injury after low-level falls in the elderly

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Table 4

GCS and outcomes for traumatic brain injuries with intracranial hemorrhage and/or contusion.

	No Anticoagulant N = 446	Warfarin N = 137	DOAC N = 29	P
Admission GCS	13.7 ± 2.7	14 ± 2.4	15 ± 1	NS
Hospital days	3.7 ± 4.0	5.4 ± 5.3*	4 ± 2	P < .001 versus No-AC*
ICU days	2.1 ± 3.2	3.2 ± 4.2*	2 ± 2	P < .01 versus No-AC*
Ventilator days	0.3 ± 1.5	0.3 ± 1.2	0	NS
Combined mortality, N (%)	63 (14)	17 (13)	2 (7)	NS
Discharge home, N (%)	193 (43)	45 (33)	15 (52)	NS

Direct oral anticoagulants do not worsen traumatic brain injury after low-level falls in the elderly

Madelyn Batey, PharmD^a, Jason Hecht, PharmD^b, Cherise Callahan, PharmD^b, Wendy Wahl, MD, FACS, FCCM^{b,*}

Table 5
Outcomes for traumatic brain injury requiring neurosurgical intervention.

	No Anticoagulant N = 55 (11%)	Warfarin N = 26 (18%)	DOAC N = 1 (3%)	P
Admission GCS	13 ± 3	13 ± 3	15	NS
Hospital days	7 ± 6	8 ± 6*	6.0	<i>P</i> < .001 versus No-AC*
ICU days	5 ± 6	6 ± 6*†	3.0	<i>P</i> < .001 versus No-AC,* <i>P</i> = .04 versus DOAC†
Ventilator days	5 ± 6	4 ± 2	0	NS
Combined mortality, N (%)	10 (18)	5 (19)	0	NS
Discharge home, N (%)	17 (31)	4 (15)*	0	<i>P</i> = .015 versus No-AC*

Conclusion: Older direct oral anticoagulant patients with **traumatic brain injury after low-level fall did not have increased morbidity or mortality** compared with those treated with warfarin or who were not treated with anticoagulants.

Safety and effectiveness of oral factor Xa inhibitors versus warfarin in nonvalvular atrial fibrillation patients at high-risk for falls

Benjamin Miao¹ · Mark J. Alberts² · Thomas J. Bunz³ · Craig I. Coleman¹ 

Variable	Oral factor Xa inhibitors N = 13,027 %	Warfarin N = 12,117 %	Absolute standardized dif- ference
Oral factor Xa inhibitors			
Apixaban	48.9	0	–
Edoxaban	0.4	0	–
Rivaroxaban	50.7	0	–
Demographics			
Age, years (median, 25%, 75% range)	83 (47, 87)	83 (47, 87)	0.00
Male sex	59.0	59.1	0.00

Safety and effectiveness of oral factor Xa inhibitors versus warfarin in nonvalvular atrial fibrillation patients at high-risk for falls


Benjamin Miao¹ · Mark J. Alberts² · Thomas J. Bunz³ · Craig I. Coleman¹ 

Table 2 Incidence and Hazard Ratios for the Comparison of Oral Factor Xa Inhibitors and Warfarin

	Incidence rate (events/100 person-years)		HR (95% CI)
	Oral factor Xa inhibitor	Warfarin	
Any oral factor Xa inhibitor versus warfarin			
Intracranial hemorrhage	0.28	0.48	0.57 (0.35–0.95)
Stroke or systemic embolism	1.19	1.51	0.86 (0.66–1.11)

Safety and effectiveness of oral factor Xa inhibitors versus warfarin in nonvalvular atrial fibrillation patients at **high-risk for falls**

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In conclusion, as a class, oral factor Xa inhibitors reduced patients' risk of intracranial hemorrhage and were at least as effective in preventing stroke or systemic embolism as warfarin in nonvalvular atrial fibrillation patients at high-risk for falls. No evidence of a statistical interaction between individual oral factor Xa inhibitors was observed for intracranial hemorrhage or stroke or systemic embolism. Based on their ability to decrease risk of intracranial hemorrhage, oral factor Xa inhibitors should strongly be considered as alternatives to warfarin in patients deemed at higher than average risk for falls.

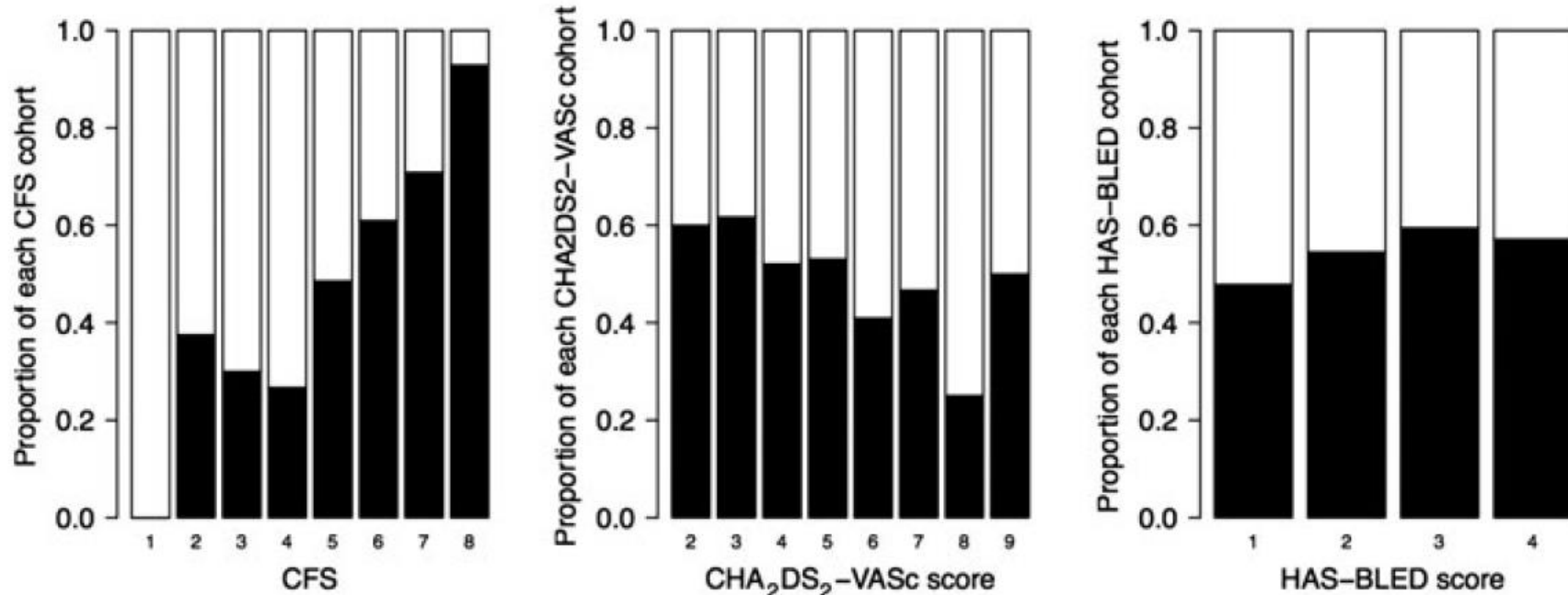
**L'anziano che
cade o ha una
sincope? Come
comportarsi**

**Come ci comportiamo
nell'anziano fragile?**

Clinical frailty is independently associated with non-prescription of anticoagulants in older patients with atrial fibrillation

Induruwa I et Al,
Geriatr Gerontol Int 2017

The proportion of individuals not taking anticoagulants (*black*) compared with those taking anticoagulants (*white*), by Clinical Frailty Scale, CHA₂DS₂-VASc and HAS-BLED scores (N=419; anticoagulated No/Yes: 215/204)



Anticoagulated
Yes – Frailty: 52.5%
No – Frailty: 81.4%
P<0.001

Anticoagulated
Yes – CHA₂DS₂-VASc: 5
No – CHA₂DS₂-VASc: 4
P<0.001

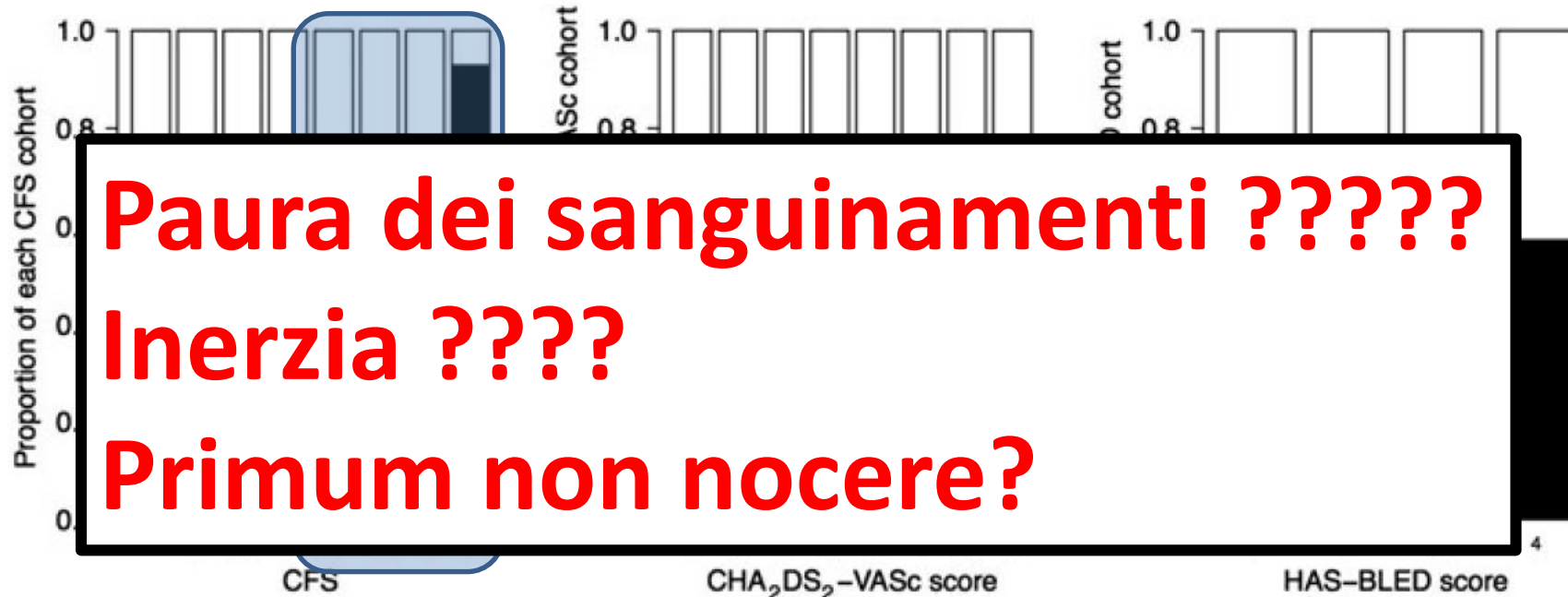
Anticoagulated
Yes – Age: 83
No – Age: 87
P<0.001

Multivariate predictors
OR_{Frailty} = 0.77, p<0.001
OR_{Bleeding Risk} = 0.85, p=0.02
OR_{Age} = 0.98, p<0.001

Clinical frailty is independently associated with non-prescription of anticoagulants in older patients with atrial fibrillation

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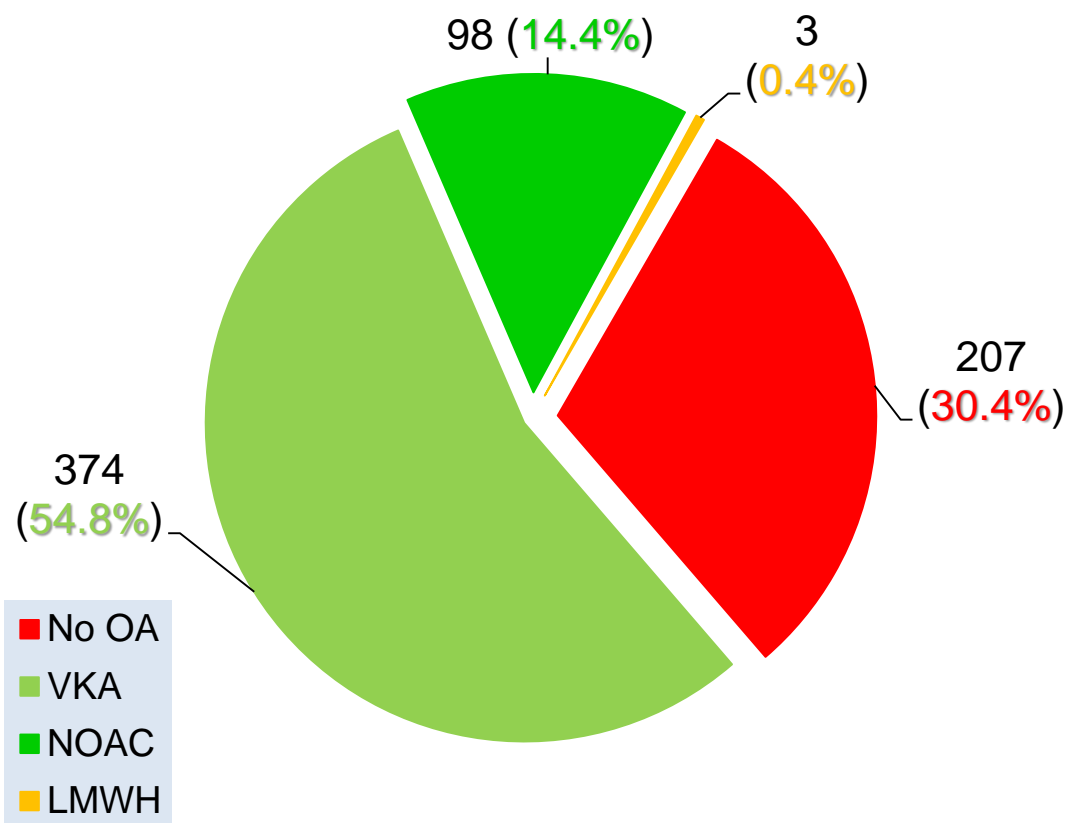
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OR_{Age} = 0.98, p<0.001

The Effect of Bleeding Risk and Frailty Status on Anticoagulation Patterns in Octogenarians With Atrial Fibrillation: The FRAIL-AF Study

Anticoagulant use in 682 hospitalized patients ≥ 80 years with AF/AFI (Age: 85.9; 3 academic hospitals; Montreal, Quebec; 2012-2013)



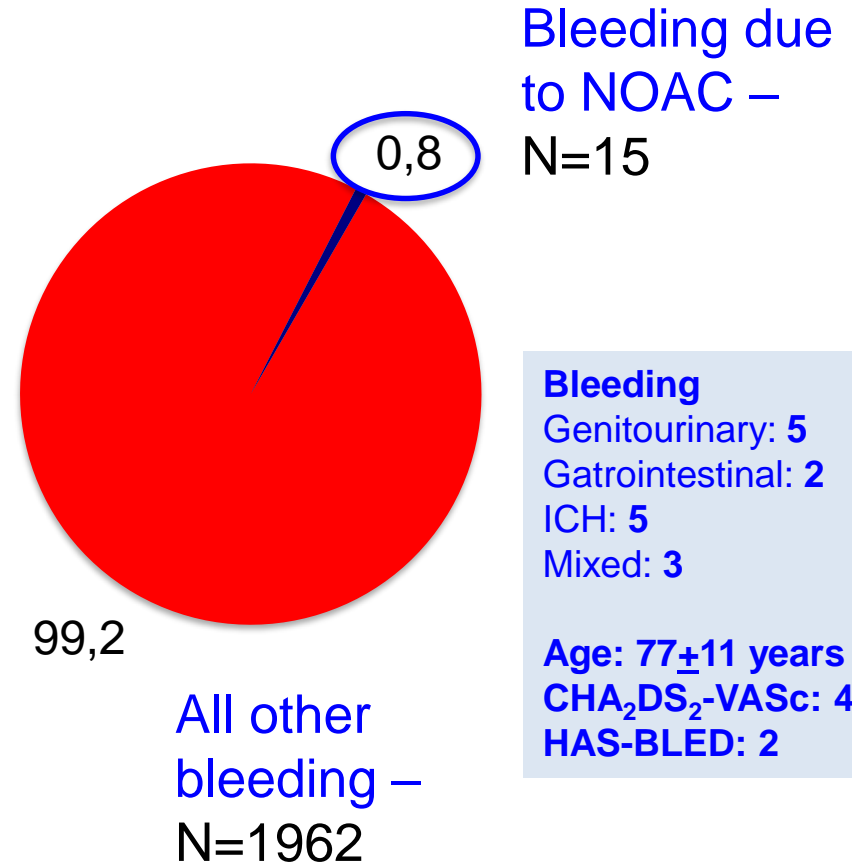
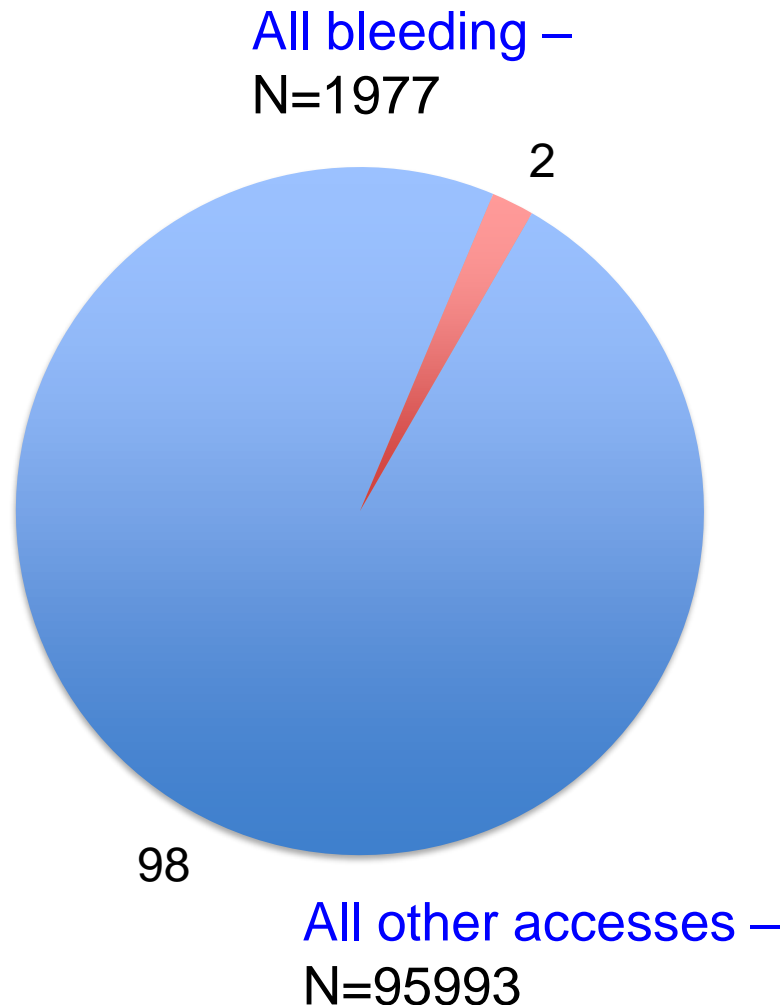
The most common reasons for not prescribing an OA:

1. Hx of bleeding (15.5%)
2. Active bleeding (15.5%)
3. Risk of falls (14%)
4. Patient refusal (8.7%)
5. No justification provided (15%)

Bleeding related to non-vitamin K antagonist oral anticoagulants in emergency department: A “Real-world” snapshot from Southern Italy
On behalf of MIRC-NOAC study group

Salzano A,
Eur J Intern Med 2017

Clinical characteristics of patients with bleeding (year 2015; people potentially referring to the ED: N=3.000.000)



Bleeding
Genitourinary: 5
Gastrointestinal: 2
ICH: 5
Mixed: 3

Age: 77 \pm 11 years
CHA₂DS₂-VASc: 4
HAS-BLED: 2

Hospitalization – N=11/15 (73%)
Mortality – 3/15 (20%)

Appropriateness of oral anticoagulant therapy prescription and its associated factors in hospitalized older people with atrial fibrillation

Carlotta Franchi^{1,†} , Stefania Antoniazzi^{2,3,†}, Marco Proietti⁴, Alessandro Nobili⁴, Pier Mannuccio Mannucci⁴ and on behalf of the SIM-AF Collaborators*

	Patients with OAC N (%)	Patients without OAC N (%)
Overall	221	107
APPROPRIATE	153 (69.2)	19 (18)
a) CHA₂DS₂-VASc ≥1 (men) and ≥2 (women) but with contraindication for OAC	–	19
b) Dose	153	–
Dabigatran	11	–
Rivaroxaban	13	–
Apixaban	22	–
Edoxaban	8	–
Warfarin	93	–
Acenocoumarol	6	–

Appropriateness of oral anticoagulant therapy prescription and its associated factors in hospitalized older people with atrial fibrillation

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Table 3

Results from univariate and multivariable logistic regression analyses for the appropriateness of oral anticoagulant prescribing

	OR	95% CI	P-value
<i>Univariate analysis</i>			
Age (year)	0.97	0.94–1.00	0.030
History of falls	0.50	0.28–0.89	0.018
BMI (kg m⁻²)	1.07	1.01–1.12	0.020
BMI categories			
Underweight	0.29	0.06–1.47	0.136
Normal weight (ref.)	–	–	–
Overweight	1.69	1.02–2.82	0.043
Obesity	1.79	0.87–3.66	0.114

What is the Impact of Frailty on Prescription of Anticoagulation in Elderly Patients with Atrial Fibrillation? A Systematic Review and Meta-Analysis

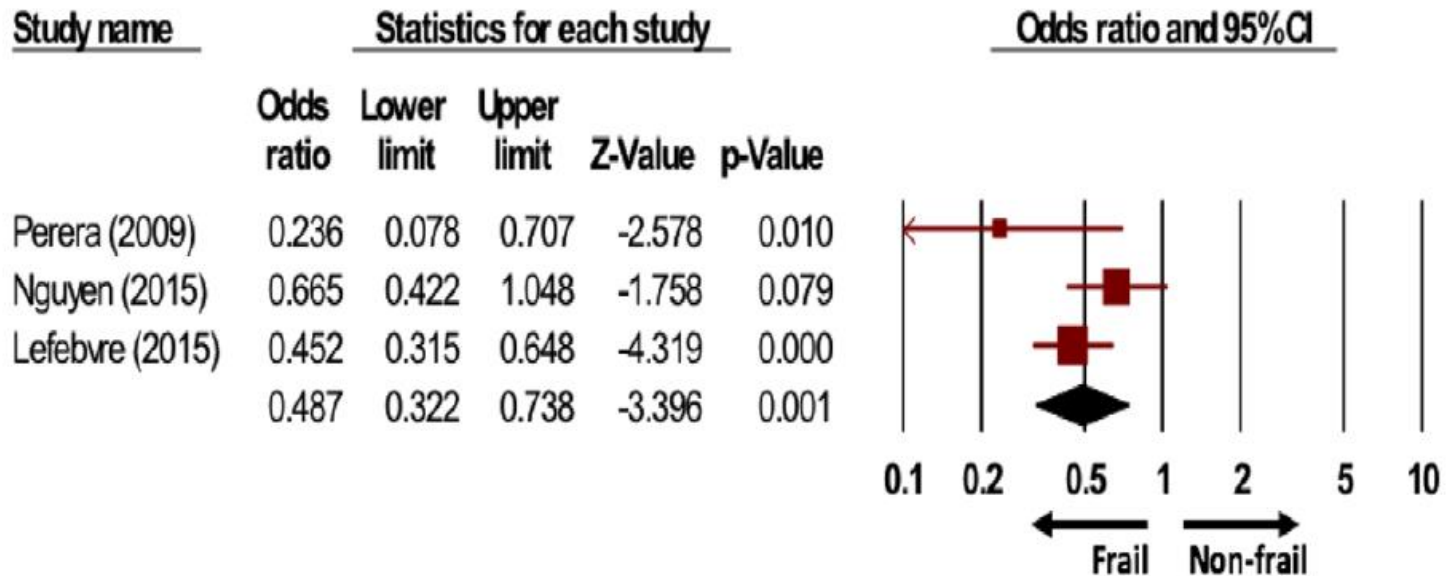
Zardasht Oqab¹, Payam Pournazari¹, Robert S Sheldon¹

Table 1: Characteristics of studies included in the meta-analysis

First author, Year	Perera, 2009	Nguyen, 2015	Lefebvre, 2015
Study design	Prospective observational	Prospective observational	Cross-sectional
Frailty instrument	Edmonton Frail Scale	Edmonton Frail Scale	Clinical Frailty Scale
Sample size	207	302	682
Age in Years, Mean \pm SD	82.7 \pm 6.3	84.7 \pm 7.1	85.0 \pm 4.4
Male %	46	50	40
Frail n (%)	64	53	25*
% anticoagulated	50	55.7	70
# of medications \pm SD	8.0 \pm 3.4	11.3 \pm 4.0	13.5 \pm 4.5

What is the Impact of Frailty on Prescription of Anticoagulation in Elderly Patients with Atrial Fibrillation? A Systematic Review and Meta-Analysis

Zardasht Oqab¹, Payam Pournazari¹, Robert S Sheldon¹



Conclusions: The **prevalence** of **frailty** in hospitalized elderly patients with AF **is high**, and the **use** of OAC **is low** in these patients. Frail elderly are significantly less likely to receive OAC.

Documento di consenso di Esperti con Metodo Delphi GIMSI-AcEMC

Anticoagulation therapy in older patients at syncopal or non syncopal fall risk and/or frailty

Steering Committee:

Ivo Casagrande, Andrea Ungar, Michele Brignole

Membri del Delphi

Medicina di emergenza-urgenza	Roberto Lerza, Pier Michele Diamanti
Geriatrics	Chiara Mussi, Stefano Fumagalli
Cardiologia	Filippo Rabajoli, Roberto Maggi
FCSA	Sophie Testa
Medicina interna	Raffaello Furlan
Tossicologia clinica	Carlo Locatelli
Neurologia	Alessandra Fanciulli
Medicina generale	Sergio Baglioni
Syncope Unit	Pasquale Abete, Attilio Del Rosso, Filippo Numeroso, Marco Tomaino

IL PROCESSO PER RAGGIUNGERE IL CONSENSO

The process to reach consensus

DELPHI



DELPHI

Delphi è una metodologia di sondaggio qualitativa, è iterativa e basata su input forniti da esperti selezionati nell'ambito-oggetto in questione.

È ideale per negoziare quando non c'è accordo e per la definizione di scenari condivisi.

Ciclo Delphi

- 1) Nomina del panel**
- 2) Stesura iniziale del documento (questionario)**
- 3) Invio del documento al panel**
- 4) Analisi delle risposte e creazione del nuovo documento per il consenso**
- 5) Nuovo inoltro al panel per 2 o 3 volte**
- 6) Stesura del documento finale**

Anticoagulation therapy in older patients at syncopal or non syncopal fall risk and/or frailty

Patients over 75 with **medium** cognitive impairment who need anticoagulation therapy

	1	2	3	4	5
1. Not prescribe OAT *	10	4	1	0	0
%	93		7		
2. Prescribe VKA	3	7	4	1	0
%	67		33		
3. Prescribe DOACs *	1	0	4	5	5
%	7		93		
4. Prescribe low-dose DOACs	8	2	3	2	0
%	67		33		
5. Prescribe aspirin *	11	4	0	0	0
%	100		0		
6. No therapy *	9	5	0	0	1
%	93		7		
7. I don't know					

Anticoagulation therapy in older patients at syncopal or non syncopal fall risk and/or frailty

Patients over 75 with **severe** cognitive impairment who need anticoagulation therapy

1. Not prescribe OAT	4	6	2		3
%	67		33		
2. Prescribe VKA ***	5	9	1	0	0
%	93		7		
3. Prescribe DOACs***	3	0	5	7	0
%	20		80		
4. Prescribe low-dose DOACs	6	5	3	1	0
%	73		27		
5. Prescribe aspirin *	10	4	0	1	0
%	93		7		
6. No therapy ***	1	2	9	1	2
%	20		80		
7. I don't know					

Anticoagulation therapy in older patients at syncopal or non syncopal fall risk and/or frailty

Patients over 75 without caregiver and with a **poor therapy compliance**

	1	2	3	4	5
1. Not prescribe OAT	1	9	4	1	0
%	67		33		
2. Prescribe VKA	7	4	3	1	0
%	73		27		
3. Prescribe DOACs	2	4	7	2	0
%	40		60		
4. Prescribe low-dose DOACs *	8	6	1	0	0
%	93		7		
5. Prescribe aspirin **	10	4	1	0	0
%	93		7		
6. No therapy	2	5	6	2	0
%	47		53		
7. I don't know					

Anticoagulation therapy in older patients at syncopal or non syncopal fall risk and/or frailty

“**Frail**” patients over 75 with non valvular AF and CHADS₂- VASc score ≥ 3

	1	2	3	4	5
1. Not prescribe OAT *	7	7	1	0	0
%	93		7		
2. Prescribe VKA	0	11	3	1	0
%	73		27		
3. Prescribe DOACs **	0	1	4	7	3
%	7		93		
4. Prescribe low-dose DOACs	2	6	3	4	0
%	53		47		
5. Prescribe aspirin *	11	3	1	0	0
%	93		7		
6. No therapy *	8	7	0	0	0
%	100		0		
7. I don't know					

Anticoagulation therapy in older patients at syncopal or non syncopal fall risk and/or frailty

Patients over 75 with **previous falls** in the last year

	1	2	3	4	5
1. <u>Not prescribe OAT</u> ***	5	7	2	1	0
%	80		20		
2. <u>Prescribe VKA</u> ***	4	9	2	0	0
%	87		13		
3. <u>Prescribe DOACs</u> **	1	1	8	5	0
%	13		87		
4. <u>Prescribe low-dose DOACs</u> ***	2	11	1	1	
%	87		13		
5. <u>Prescribe aspirin</u>**	12	2	0	1	0
%	93		7		
6. <u>No therapy</u>	3	6	5	1	0
%	60		40		
Non so					

** Consensus obtained in the second round;

*** Consensus obtained in the third round

Documento di consenso di Esperti con Metodo Delphi GIMSI-AcEMC

Anticoagulation therapy in older patients at syncopal or non syncopal fall risk and/or frailty

Steering Committee:

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Si agli anticoagulanti, in particolare si ai DOACs

**Grazie per la vostra
attenzione**

