

# *Dal caso clinico alle nuove strategie terapeutiche:*

*confronto tra Cardiologi Ospedalieri  
e Medici di Medicina Generale*

Responsabili del Convegno:

Dott. Ferdinando Varbella, Dott. Riccardo Riccardi,  
Dott.ssa Maria Milano



rivolto a:

- Medici di Medicina Generale
- Cardiologi



**Sabato 23 Settembre 2017**

**IL MULINO DI PIOSSASCO**

**Sala Teatro**

Via Riva Po 9 - Piossasco (TO)

**6,4  
crediti  
ECM**

## Quale NAO per il signor Giuseppe?

**Dottor.ssa Maria Milano**

**Dottor. Emanuele Tizzani**



# Giuseppe

- 81 anni
- IRC di grado moderato (eGFR 45ml/min)
- Cardiopatia ipertensiva
  
- ECOCARDIO (sei mesi fa): lieve ipertrofia ventricolare sinistra, FE 65%, non vizi valvolari
  
- Poli-artrosi diffusa. Morbo di Parkinson. IPB.
  
- In terapia con:
  - Valsartan 160 mg 1 cpr/die
  - ASA 100 mg 1 cpr/die

# 15 settembre 2017, visita MMG

- Giuseppe viene in studio con l'ECG prescritto per il monitoraggio dell'ipertensione

## Diagnosi di FA ad esordio non databile

- Sintomi: lamenta dispnea da sforzo e tachicardia sintomatica
- ECG: FA con FC 110
- Alla visita: PAOS 140/82, FC 110 bpm, aritmico, restante nn

**In base alle caratteristiche del paziente quali NAO pensi che il cardiologo prescriverà e con quale posologia?**

**Televoto I**

1. Pradaxa 150 mg 1 cpr x 2 /die
2. Lixiana 60 mg 1 cpr/die
3. Xarelto 15 mg 1 cpr/die
4. Eliquis 5 mg 1 cpr x 2/die
5. No NAO prosegue l'ASA



# The NEW ENGLAND JOURNAL of MEDICINE

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## Dabigatran versus Warfarin in Patients with Atrial Fibrillation

Stuart J. Connolly, M.D., Michael D. Ezekowitz, M.B., Ch.B., D.Phil., Salim Yusuf, F.R.C.P.C., D.Phil., John Eikelboom, M.D., Jonas Oldgren, M.D., Ph.D., Amit Parekh, M.D., Janice Pogue, M.Sc., Paul A. Reilly, Ph.D., Ellison Themeles, B.A., Jeanne Varrone, M.D., Susan Wang, Ph.D., Marco Alings, M.D., Ph.D., Denis Xavier, M.D., Jun Zhu, M.D., Rafael Diaz, M.D., Basil S. Lewis, M.D., Harald Darius, M.D., Hans-Christoph Diener, M.D., Ph.D., Campbell D. Joyner, M.D., Lars Wallentin, M.D., Ph.D., and the RE-LY Steering Committee and Investigators\*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Apixaban versus Warfarin in Patients with Atrial Fibrillation

Christopher B. Granger, M.D., John H. Alexander, M.D., M.H.S., John J.V. McMurray, M.D., Renato D. Lopes, M.D., Ph.D., Elaine M. Hylek, M.D., M.P.H., Michael Hanna, M.D., Hussein R. Al-Khalidi, Ph.D., Jack Ansell, M.D., Dan Atar, M.D., Alvaro Avezum, M.D., Ph.D., M. Cecilia Bahit, M.D., Rafael Diaz, M.D., J. Donald Easton, M.D., Justin A. Ezekowitz, M.B., B.Ch., Greg Flaker, M.D., David Garcia, M.D., Margarida Geraldes, Ph.D., Bernard J. Gersh, M.D., Sergey Golitsyn, M.D., Ph.D., Shinya Goto, M.D., Antonio G. Hermosillo, M.D., Stefan H. Hohnloser, M.D., John Horowitz, M.D., Puneet Mohan, M.D., Ph.D., Petr Jansky, M.D., Basil S. Lewis, M.D., Jose Luis Lopez-Sendon, M.D., Prem Pais, M.D., Alexander Parkhomenko, M.D., Freek W.A. Verheugt, M.D., Ph.D., Jun Zhu, M.D., and Lars Wallentin, M.D., Ph.D., for the ARISTOTLE Committees and Investigators\*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation

Manesh R. Patel, M.D., Kenneth W. Mahaffey, M.D., Jyotsna Garg, M.S., Guohua Pan, Ph.D., Daniel E. Singer, M.D., Werner Hacke, M.D., Ph.D., Günter Breithardt, M.D., Jonathan L. Halperin, M.D., Graeme J. Hankey, M.D., Jonathan P. Piccini, M.D., Richard C. Becker, M.D., Christopher C. Nessel, M.D., John F. Paolini, M.D., Ph.D., Scott D. Berkowitz, M.D., Keith A.A. Fox, M.B., Ch.B., Robert M. Califf, M.D., and the ROCKET AF Steering Committee, for the ROCKET AF Investigators\*

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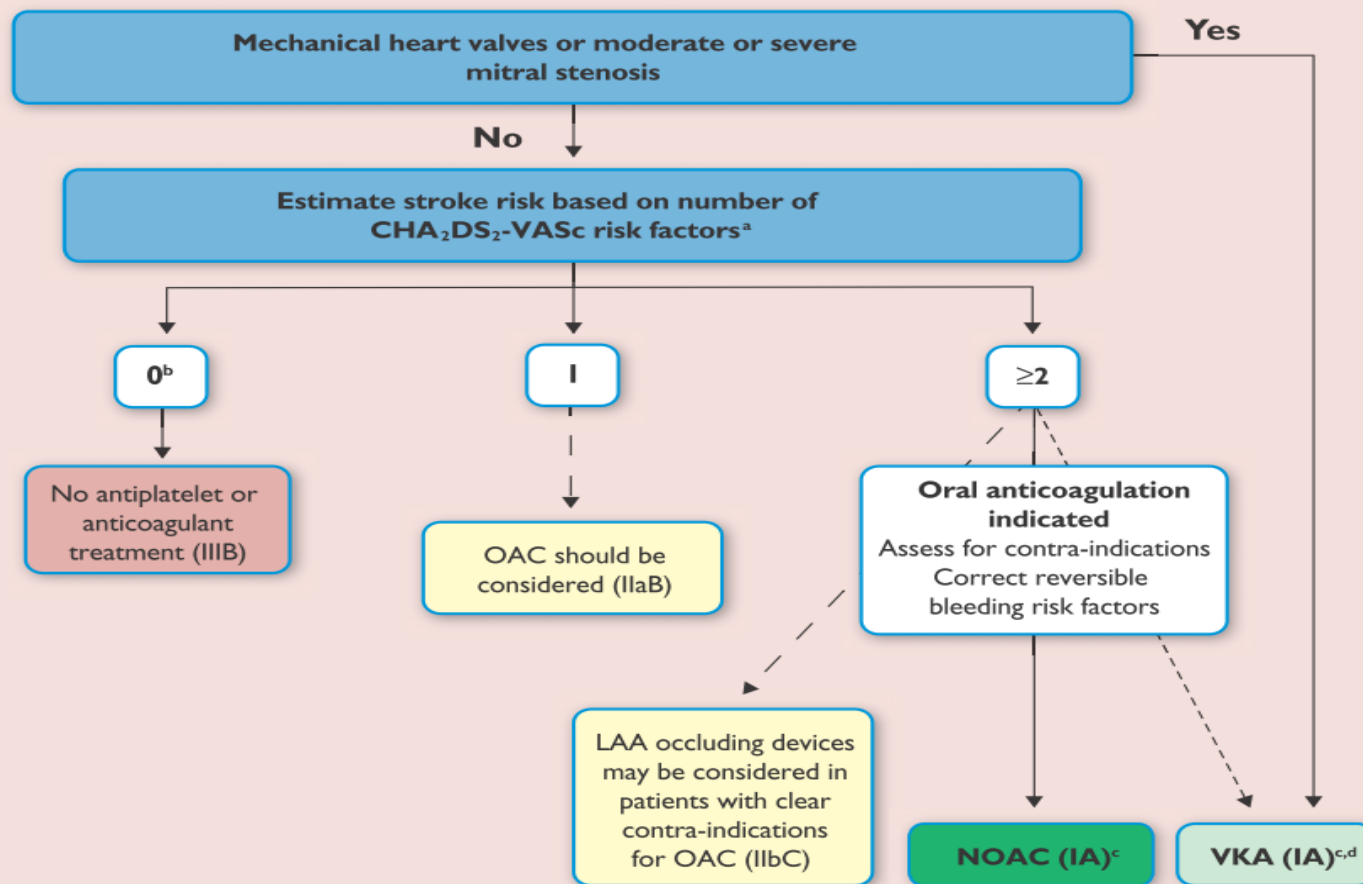
ORIGINAL ARTICLE

## Edoxaban versus Warfarin in Patients with Atrial Fibrillation

Robert P. Giugliano, M.D., Christian T. Ruff, M.D., M.P.H., Eugene Braunwald, M.D., Sabina A. Murphy, M.P.H., Stephen D. Wiviott, M.D., Jonathan L. Halperin, M.D., Albert L. Waldo, M.D., Michael D. Ezekowitz, M.D., D.Phil., Jeffrey I. Weitz, M.D., Jindřich Špinar, M.D., Witold Ruzyllo, M.D., Mikhail Ruda, M.D., Yukihiko Koretsune, M.D., Joshua Betcher, Ph.D., Minggao Shi, Ph.D., Laura T. Grip, A.B., Shirali P. Patel, B.S., Indravadan Patel, M.D., James J. Hanyok, Pharm.D., Michele Mercuri, M.D., and Elliott M. Antman, M.D., for the ENGAGE AF-TIMI 48 Investigators\*



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



# NAO ed età

## Età > 80 anni

Ridurre dabigatran a 110 mg 1 cpr x 2

Ridurre apixaban a 2,5 mg 1 cpr x 2 se presente oltre all'età un altro fattore (IRC di grado moderato, peso corporeo <60 kg)

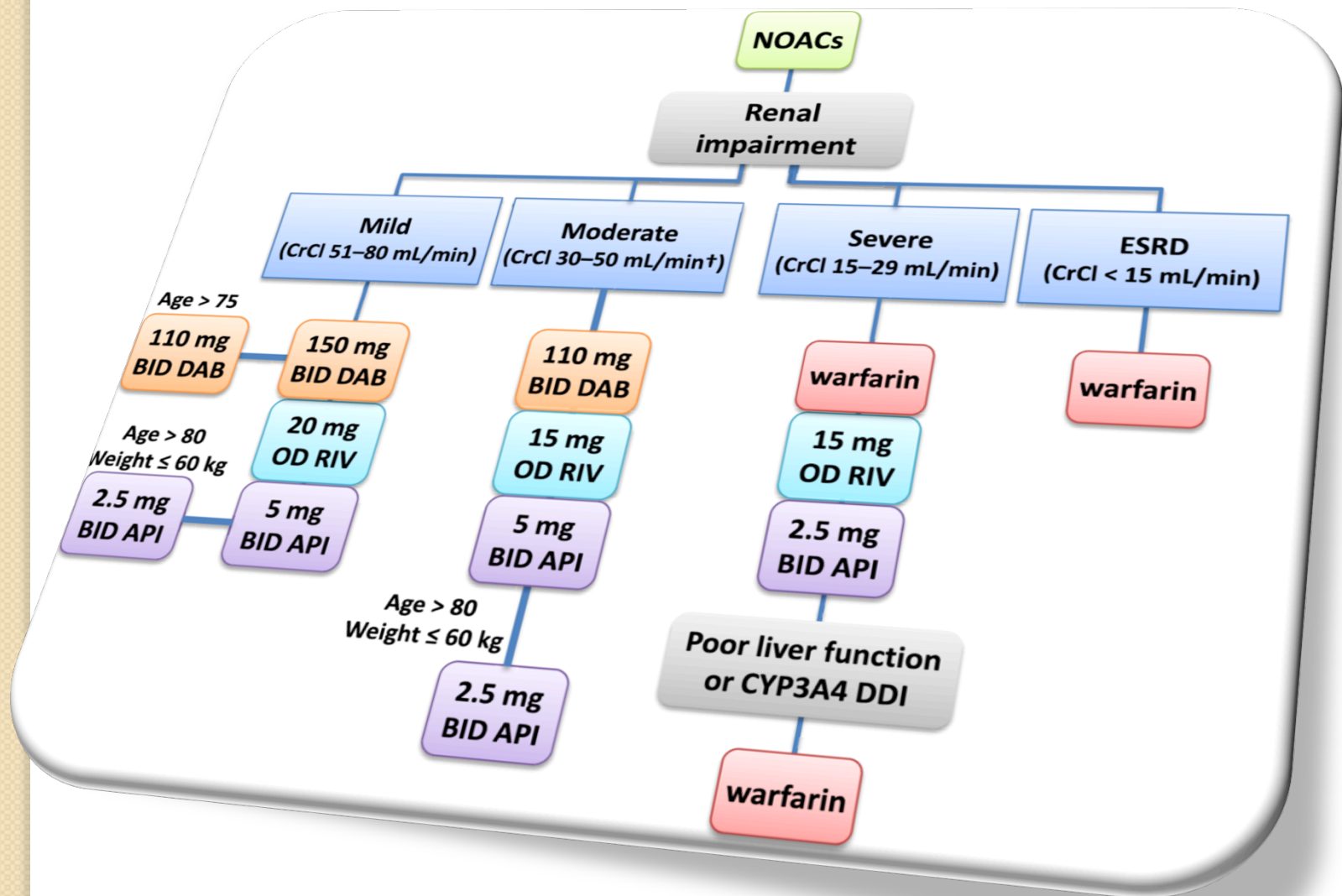
Non riduzione per l'età di rivaroxaban ed edoxaban



# DOAC e IRC

	Dabigatran	Apixaban	Edoxaban <sup>a</sup>	Rivaroxaban
Fraction renally excreted of absorbed dose	80%	27%	50% <sup>9</sup>	35%
Bio-availability	3–7%	50%	62% <sup>17</sup>	66% without food Almost 100% with food
Fraction renally excreted of administered dose	4%	14%	37% <sup>9</sup>	33%
Approved for CrCl ≥ ...	≥ 30 ml/min	≥ 15 ml/min	Not available	≥ 15 ml/min
Dosing recommendation	CrCl ≥ 50 ml/min: no adjustment (i.e. 150 mg bid)	Serum creatinine ≥ 1.5 mg/dl: no adjustment (i.e. 5 mg bid)	Not available	CrCl ≥ 50 ml/min: no adjustment (i.e. 20 mg qd)
Dosing if CKD	When CrCl 30–49 ml/min, 150 mg bid is possible (SmPC) but 110 mg bid if 'high risk of bleeding' (SmPC) or 'recommended' (GL update) <sup>2</sup> Note: 75 mg bid approved in US only: <sup>b</sup> <ul style="list-style-type: none"> <li>• if CrCl 15–30 ml/min</li> <li>• if CrCl 30–49 ml/min and other orange factor Table 5 (e.g. verapamil)</li> </ul>	CrCl 15–29 ml/min: 2.5 mg bid Serum creatinine ≥ 1.5 mg/dl in combination with age ≥ 80 years or weight ≤ 60 kg, <sup>SmPC</sup> or with other 'yellow' factor (Table 5): 2.5 mg bid	Not available	15 mg qd when CrCl 15–49 ml/min
Not recommended if	CrCl < 30 ml/min	CrCl < 15 ml/min	Not available	CrCl < 15 ml/min

# Importance of Pharmacokinetic Profile and Variability as Determinants of Dose and Response to Dabigatran, Rivaroxaban, and Apixaban



# Edoxaban: dosaggio raccomandato

## Riassunto della posologia nella FANV e nel TEV (TVP ed EP)

### Guida riassuntiva per la somministrazione

Dose raccomandata		60 mg una volta al giorno
<b>Raccomandazione sulla dose per i pazienti con uno o più dei seguenti fattori clinici</b>		
Compromissione renale	Moderata o severa (CrCl 15-50 ml/min)	
Basso peso corporeo	≤60 kg	30 mg una volta al giorno
Inibitori della P-gp	Ciclosporina, dronedarone, eritromicina, ketoconazolo	

Risk factors include:

- Previous stroke, transient ischaemic attack, or systemic embolism
- Left ventricular ejection fraction  $\leq 40$
- Symptomatic heart failure  $\geq$  NYHA class 2
- Age  $\geq 75$  years
- Age  $\geq 65$  years and with one of the following: diabetes mellitus, coronary artery disease, or hypertension

— Recommended dose  
- - - Dose can be considered

Patient has risk factors for stroke

Estimated CrCl

<30 mL/min

30–50 mL/min

>50 mL/min

Contraindicated in the EU (<75 mg BID dose in USA if CrCL 30–50 mL/min)

High bleeding risk

Age <75 years

Age 75–80 years

Age >80 years

High bleeding risk

110 mg BID

150 mg BID

150 mg BID

110 mg BID

150 mg BID

110 mg BID

BID = twice daily; CrCl = creatinine clearance; NYHA = New York Heart Association

Adapted from: Huisman M et al. Thromb Haemost doi:10.1160/TH11-10-0718

# NAO e peso corporeo

## Peso corporeo < 60 kg

Ridurre edoxaban a 30 mg/die

Ridurre apixaban a 2,5 mg 1 cpr x 2 se presente oltre al basso peso un altro fattore (IRC di grado moderato, età >80 anni)

Non riduzione per basso peso corporeo per dabigatran e rivaroxaban

# Interazioni farmacologiche NAO

Farmaco	Dabigratan	Rivaroxaban	Apixaban
Atorvastatina	possibile	possibile	non studiata
Digossina	possibile	possibile	possibile
Verapamil	Possibile con riduzione di dosaggio a 110 mg e assunzione simultanea	possibile con cautela	non studiata
Diltiazem	possibile	possibile con cautela	possibile con cautela
Chinidina	possibile con cautela	possibile con cautela	non studiata
Amiodarone	possibile con cautela	possibile	non studiata
Dronedarone	no	no	non studiata
Itraconazolo	no	no	no
Fluconazolo	non studiata	possibile con cautela	non studiata
Ciclosporina, tacrolimus	no	possibile con cautela	non studiata
Claritromicina, eritromicina	possibile con cautela	possibile con cautela	non studiata
Inibitori proteasi HIV	no	no	no
Rifampicina, Erba di S. Giovanni, carbamazepima, fenitoina, Fenobarbital	no	possibile con cautela	no
Gastroprotettori (IPP e antiH2)	possibile	possibile	non studiata

	Via	Dabigatran	Apixaban	Edoxaban <sup>a</sup>	Rivaroxaban
Atorvastatin	P-gp competition and CYP3A4 inhibition	+18% <sup>29</sup>	No data yet	No effect <sup>30</sup>	No effect <sup>27,31</sup>
Digoxin	P-gp competition	No effect <sup>32</sup>	No data yet	No effect <sup>30</sup>	No effect <sup>27,33</sup>
Verapamil	P-gp competition (and weak CYP3A4 inhibition)	+12–180% <sup>24</sup> (reduce dose and take simultaneously)	No data yet	+53% (SR) <sup>30</sup> (reduce dose by 50%) <sup>a</sup>	Minor effect (use with caution if CrCl 15–50 ml/min)
Diltiazem	P-gp competition and weak CYP3A4 inhibition	No effect <sup>24</sup>	+40% <sup>SmPC</sup>	No data yet	Minor effect (use with caution if CrCl 15–50 ml/min)
Quinidine	P-gp competition	+50%	No data yet	+80% <sup>30</sup> (reduce dose by 50%) <sup>b</sup>	+50%
Amiodarone	P-gp competition	+12–60% <sup>24</sup>	No data yet	No effect <sup>30</sup>	Minor effect (use with caution if CrCl 15–50 ml/min)
Dronedarone	P-gp and CYP3A4 inhibitor	+70–100% (US: 2 × 75 mg)	No data yet	+85% (reduce dose by 50%) <sup>c</sup>	No data yet
Ketoconazole; itraconazole; voriconazole; posaconazole	P-gp and BCRP competition; CYP3A4 inhibition	+140–150% (US: 2 × 75 mg)	+100% <sup>SmPC</sup>	No data yet	Up to +160% <sup>27</sup>
Fluconazole	Moderate CYP3A4 inhibition	No data yet	No data yet	No data yet	+42% (if systemically administered) <sup>27</sup>
Cyclosporin; tacrolimus	P-gp competition	No data yet	No data yet	No data yet	+50%
Clarithromycin; erythromycin	P-gp competition and CYP3A4 inhibition	+15–20%	No data yet	No data yet	+30–54% <sup>26,27</sup>
HIV protease inhibitors (e.g. ritonavir)	P-gp and BCRP competition or inducer; CYP3A4 inhibition	No data yet	Strong increase <sup>SmPC</sup>	No data yet	Up to +153% <sup>27</sup>
Rifampicin; St John's wort; carbamazepine; phenytoin; phenobarbital	P-gp/ BCRP and CYP3A4/CYP2J2 inducers	–66% <sup>34</sup>	–54% <sup>SmPC</sup>	–35%	Up to –50%
Antacids (H2B; PPI; Al-Mg-hydroxide)	GI absorption	–12–30% <sup>22–24</sup>	No data yet	No effect	No effect <sup>21,25</sup>

**Un mese dopo Giuseppe torna in studio con il referto della visita urologica: sospetto k prostatico con necessità di biopsia.**

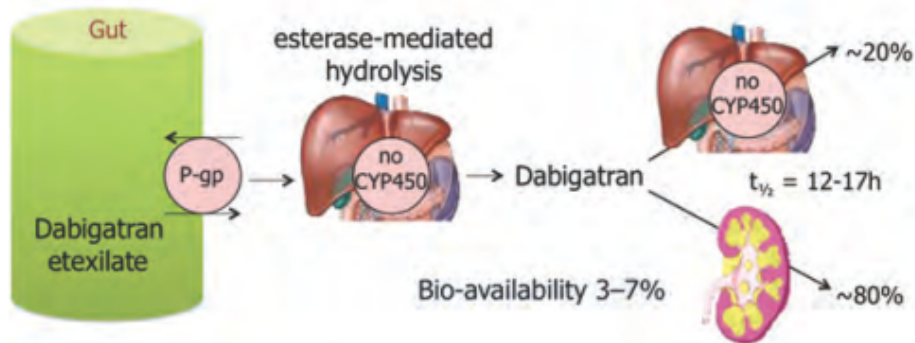
**Sta assumendo Xarelto 15 mg 1 cpr/die: cosa gli prescrivete in previsione della biopsia?**

**Televoto II**

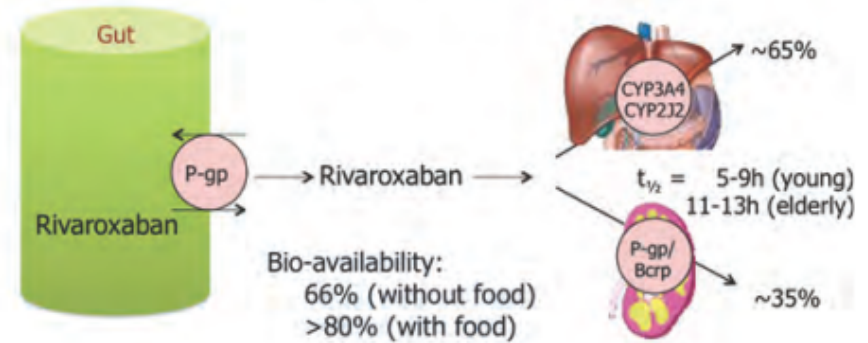
1. Brigde therapy con EBPM
2. Sospensione dello Xarelto 24-48 ore prima
3. Sospensione dello Xarelto 48-72 ore prima
4. Sospensione dello Xarelto 1 settimana prima



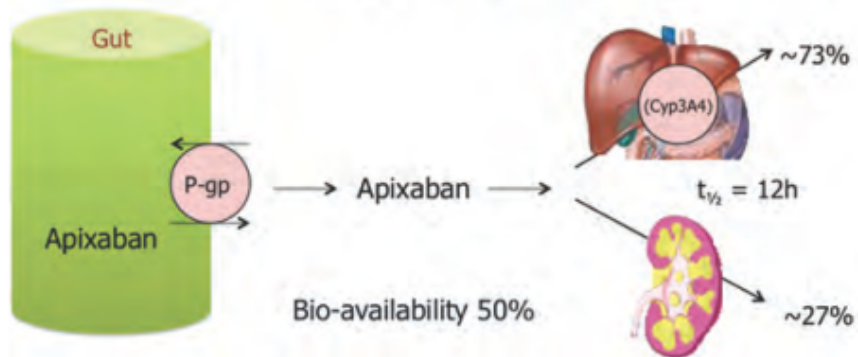
## Dabigatran



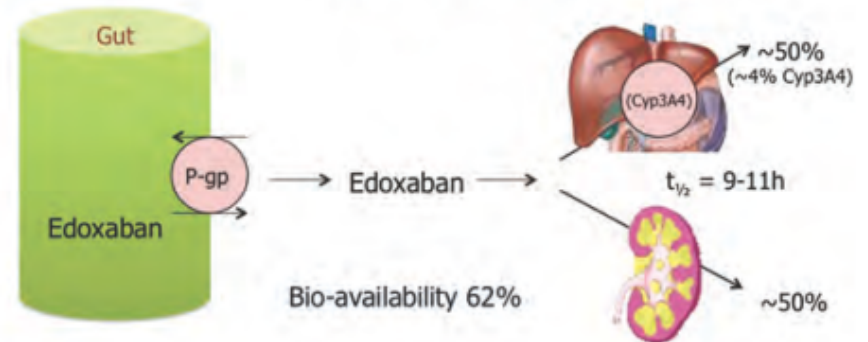
## Rivaroxaban



## Apixaban

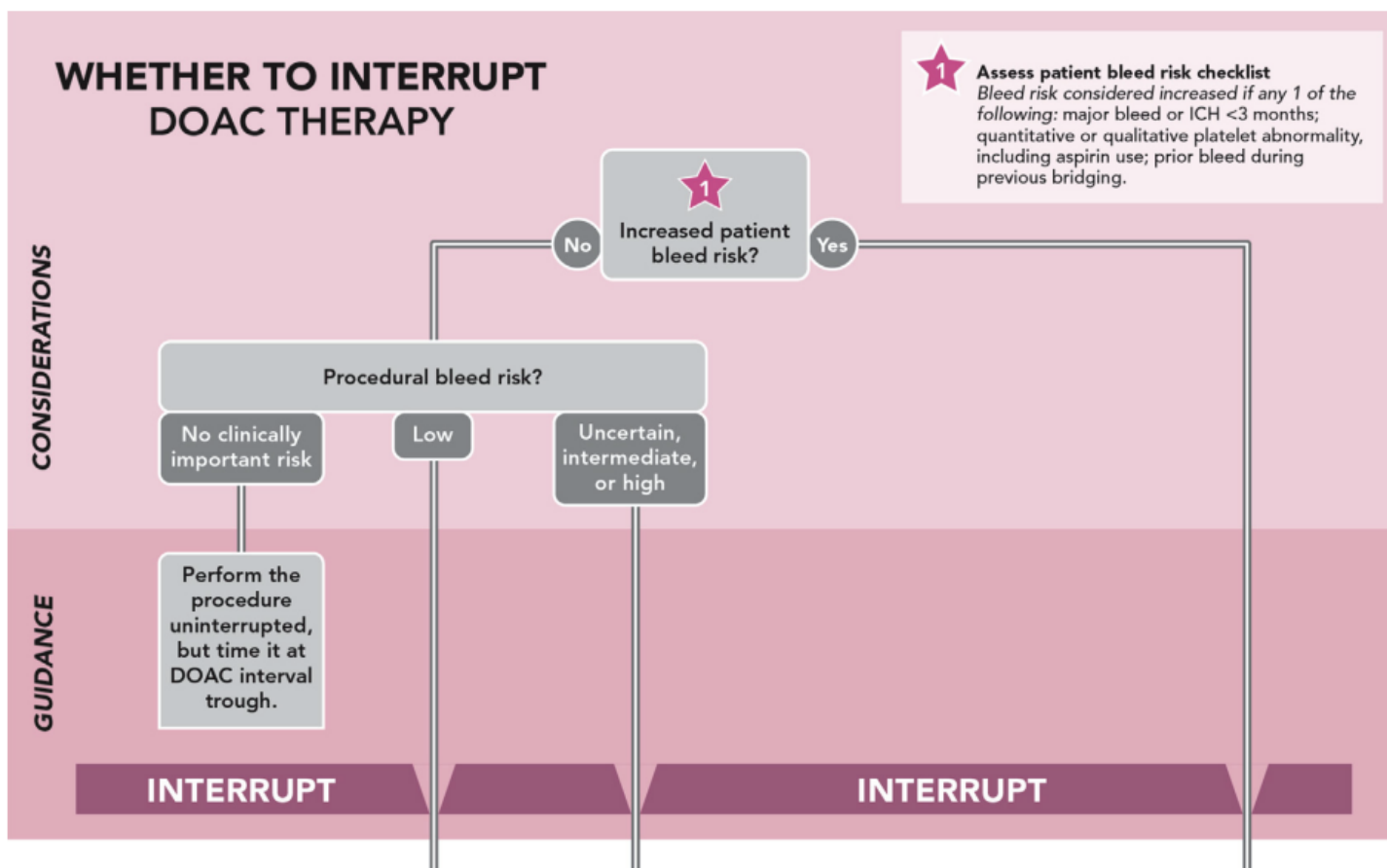


## Edoxaban



# 2017 ACC Expert Consensus Decision Pathway for Periprocedural Management of Anticoagulation in Patients With Nonvalvular Atrial Fibrillation

**FIGURE 3** Detailed Algorithm: Whether to Interrupt, and How to Interrupt for DOACs





## Updated European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist anticoagulants in patients with non-valvular atrial fibrillation

**Table 1 | Classification of elective surgical interventions according to bleeding risk**

Interventions not necessarily requiring discontinuation of anticoagulation

Dental interventions

Extraction of one to three teeth

Paradental surgery

Incision of abscess

Implant positioning

Ophthalmology

Cataract or glaucoma intervention

Endoscopy without surgery

Superficial surgery (e.g. abscess incision, small dermatologic excisions, etc.)

Interventions with minor bleeding risk (i.e. infrequent or with low clinical impact)

Endoscopy with biopsy

Prostate or bladder biopsy

Electrophysiological study or catheter ablation for right-sided supraventricular tachycardia

Non-coronary angiography (for coronary angiography and ACS: see 'Patient with atrial fibrillation and coronary artery disease' section)

Pacemaker or ICD implantation (unless complex anatomical setting, e.g. congenital heart disease)

Interventions with major bleeding risk (i.e. frequent and/or with high impact)

Catheter ablation of simple left-sided supraventricular tachycardia (e.g. WPW)

Spinal or epidural anaesthesia; lumbar diagnostic puncture

Thoracic surgery

Abdominal surgery

Major orthopaedic surgery

Liver biopsy

Transurethral prostate resection

Kidney biopsy

Extracorporeal shockwave lithotripsy (ESWL)

Interventions with major bleeding risk AND increased thrombo-embolic risk<sup>a</sup>

Complex left-sided ablation (PVI; some VT ablations)



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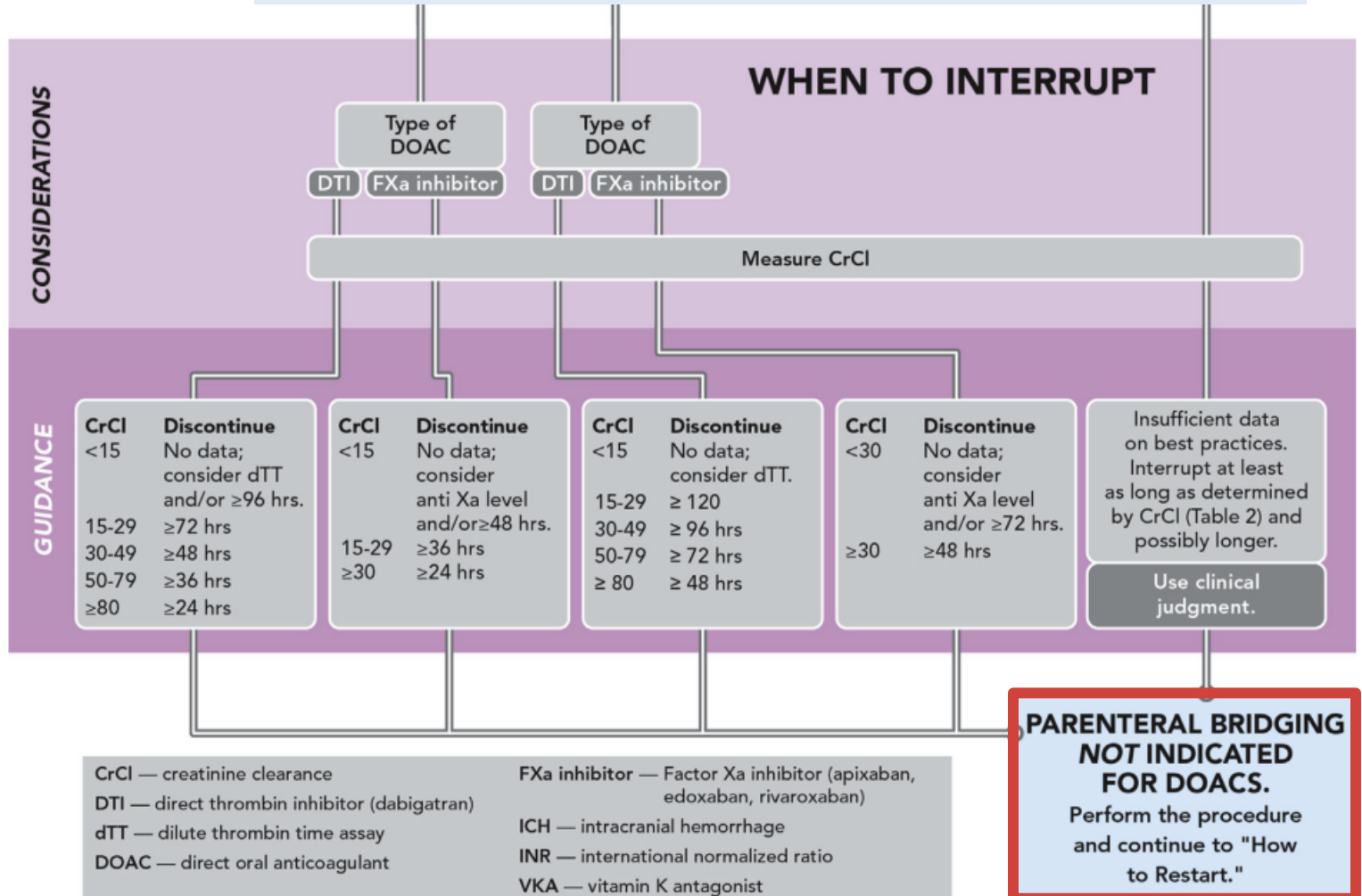
TABLE 2

Recommended Durations for Withholding DOACs Based on Procedural Bleed Risk and Estimated CrCl When There Are No Increased Patient Bleed Risk Factors

CrCl, mL/min	Dabigatran					6-15	Apixaban, Edoxaban, or Rivaroxaban		
	≥80	50-79	30-49	15-29	<15		≥30	15-29	<15
Estimated drug half-life, h	13	15	18	27	30 (off dialysis)	6-15	Apixaban: 17 Edoxaban: 17 Rivaroxaban: 9	Apixaban: 17 (off dialysis) Edoxaban: 10-17 (off dialysis) Rivaroxaban: 13 (off dialysis)	
<b>Procedural bleed risk</b>									
Low	≥24 h	≥36 h	≥48 h	≥72 h	No data. Consider measuring dTT and/or withholding ≥96 h.	≥24 h	≥36 h	No data. Consider measuring agent-specific anti Xa level and/or withholding ≥48 h	
Uncertain, intermediate, or high	≥48 h	≥72 h	≥96 h	≥120 h	No data. Consider measuring dTT.	≥48 h	No data. Consider measuring agent-specific anti Xa level and/or withholding ≥72 h.		



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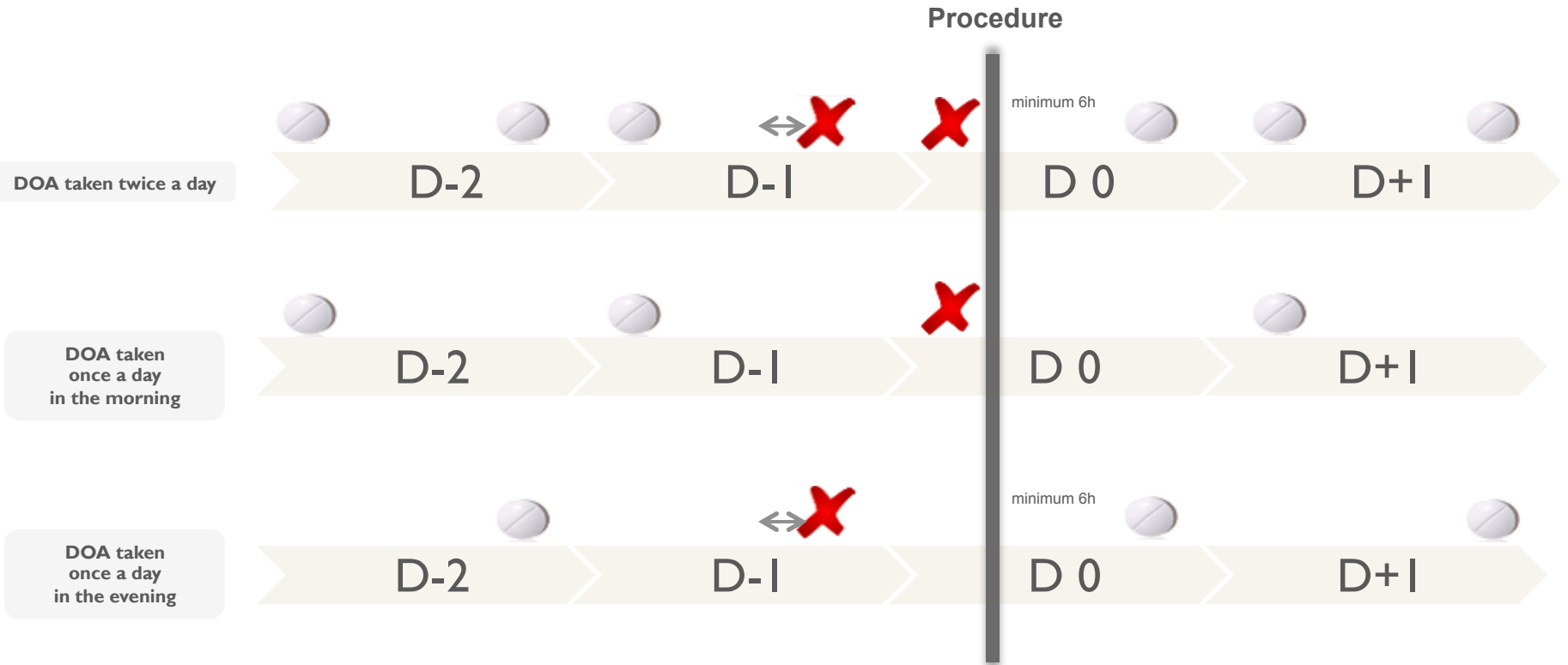
## Perioperative Bridging Anticoagulation in Patients with Atrial Fibrillation

James D. Douketis, M.D., Alex C. Spyropoulos, M.D., Scott Kaatz, D.O., Richard C. Becker, M.D., Joseph A. Caprini, M.D., Andrew S. Dunn, M.D., David A. Garcia, M.D., Alan Jacobson, M.D., Amir K. Jaffer, M.D., M.B.A., David F. Kong, M.D., Sam Schulman, M.D., Ph.D., Alexander G.G. Turpie, M.B., Vic Hasselblad, Ph.D., and Thomas L. Ortel, M.D., Ph.D.,  
for the BRIDGE Investigators\*

**Table 3. Study Outcomes.**

Outcome	No Bridging (N = 918) <i>number of patients (percent)</i>	Bridging (N = 895) <i>number of patients (percent)</i>	P Value
<b>Primary</b>			
Arterial thromboembolism	4 (0.4)	3 (0.3)	0.01*, 0.73†
Stroke	2 (0.2)	3 (0.3)	
Transient ischemic attack	2 (0.2)	0	
Systemic embolism	0	0	
Major bleeding	12 (1.3)	29 (3.2)	0.005†
<b>Secondary</b>			
Death	5 (0.5)	4 (0.4)	0.88†
Myocardial infarction	7 (0.8)	14 (1.6)	0.10†
Deep-vein thrombosis	0	1 (0.1)	0.25†
Pulmonary embolism	0	1 (0.1)	0.25†
Minor bleeding	110 (12.0)	187 (20.9)	<0.001†

# Invasive procedures with low hemorrhagic risk



**La biopsia di Giuseppe è negativa. Deve effettuare una estrazione dentale: come vi comportate con l'anticoagulante?**

**Televoto III**

1. Sospensione dello Xarelto 24-48 ore prima
2. Sospensione dello Xarelto e ripresa di ASA
3. Proseguire Xarelto 15 mg/die
4. Dimezza la dose di Xarelto
5. Sospende Xarelto alcuni giorni prima ed inizio eparina bpm





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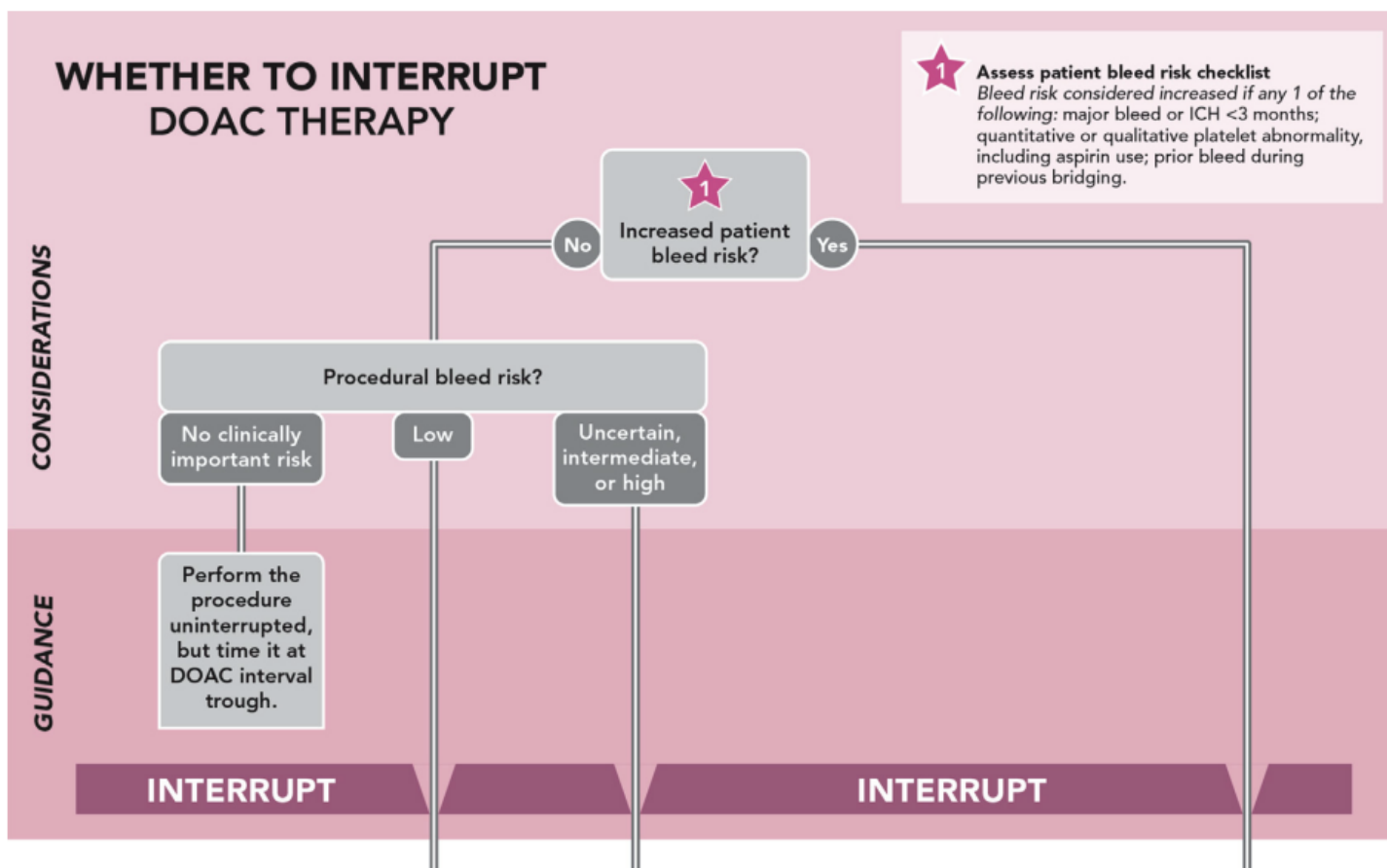
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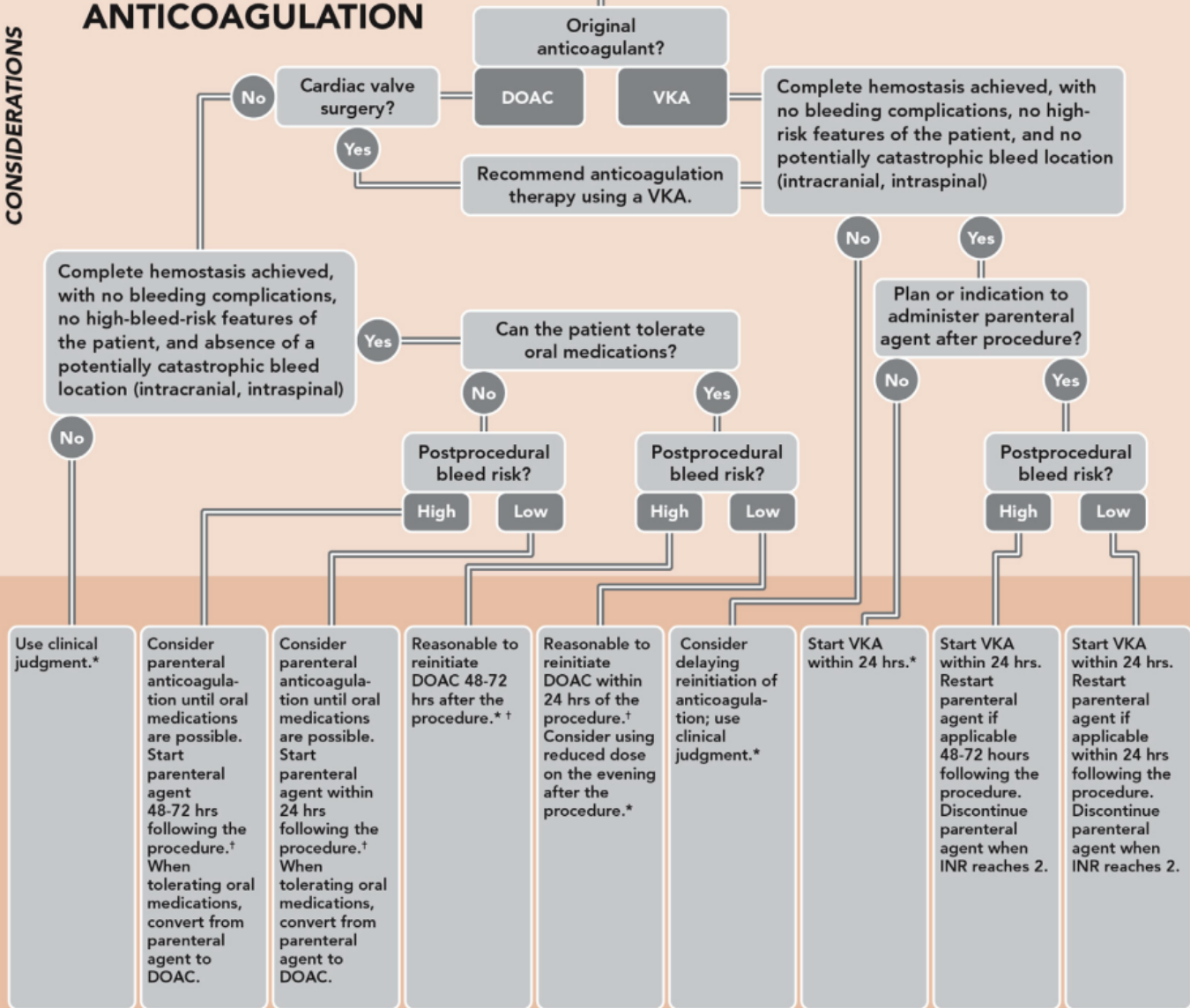
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**PERFORM THE PROCEDURE**

**HOW TO RESTART ANTICOAGULATION**

**CONSIDERATIONS**



**GUIDANCE**

\* In cooperation with the managing team and the proceduralist  
 † At a dose based on postprocedural renal function

# Fattori clinici per riduzione dose NAO

- Apixaban 2.5 mg x 2 (se concomitante peso corporeo  $\leq 60$  Kg o creatinina sierica  $> 1,5$  mg/dl)
- Dabigatran 110 mg x 2
- Rivaroxaban 20 mg

- Apixaban 5 mg x 2
- Dabigatran 110 mg x 2 (considera anche altri fattori: età 75-80 anni, gastrite, esofagite, reflusso gastroesofageo)
- Rivaroxaban 15 mg

Età  
> 80 anni

Rischio  
emorragico  
elevato

Funzione  
renale  
ridotta

Assunzione  
di verapamil

- Per clearance creatinina  $< 30$  ml/m' sono controindicati da linee guida ESC
- Per clearance creatinina  $\geq 30 < 50$  ml/m'
  - Apixaban 5 mg x 2 (verifica altri fattori clinici)
  - Dabigatran 110 mg x 2 (considera anche altri fattori: età 75-80 anni, alto rischio emorragico, gastrite, esofagite, reflusso gastroesofageo)
  - Rivaroxaban 15 mg

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- Rivaroxaban 15 mg

## Reviews

# Practical Considerations for Using Novel Oral Anticoagulants in Patients With Atrial Fibrillation

Irene Savelieva, MD and A. John Camm, MD

Division of Cardiac and Vascular Sciences, St. George's University of London, London, United Kingdom

## Review

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# Choosing the right drug to fit the patient when selecting oral anticoagulation for stroke prevention in atrial fibrillation

■ A. M. Shields<sup>1</sup> & G. Y. H. Lip<sup>2,3</sup>

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REVIEW

## Prevention

# Choosing a particular oral anticoagulant and dose for stroke prevention in individual patients with non-valvular atrial fibrillation: part 1

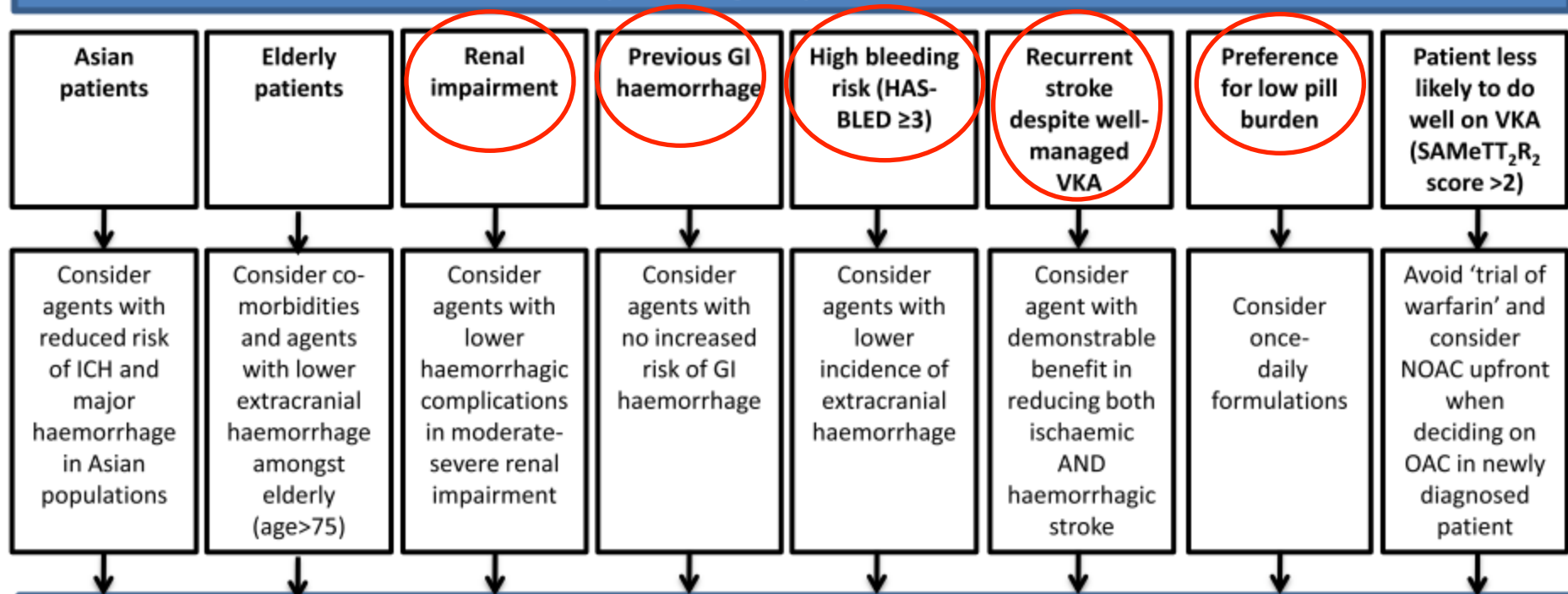
Hans-Christoph Diener<sup>1\*</sup>, James Aisenberg<sup>2</sup>, Jack Ansell<sup>3</sup>, Dan Atar<sup>4</sup>,  
Günter Breithardt<sup>5</sup>, John Eikelboom<sup>6</sup>, Michael D. Ezekowitz<sup>7,8,9</sup>,  
Christopher B. Granger<sup>10</sup>, Jonathan L. Halperin<sup>11</sup>, Stefan H. Hohnloser<sup>12</sup>,  
Elaine M. Hylek<sup>13</sup>, Paulus Kirchhof<sup>14,15</sup>, Deirdre A. Lane<sup>16</sup>, Freek W.A. Verheugt<sup>17</sup>,  
Roland Veltkamp<sup>18</sup>, and Gregory Y.H. Lip<sup>19,20</sup>

## Prevention

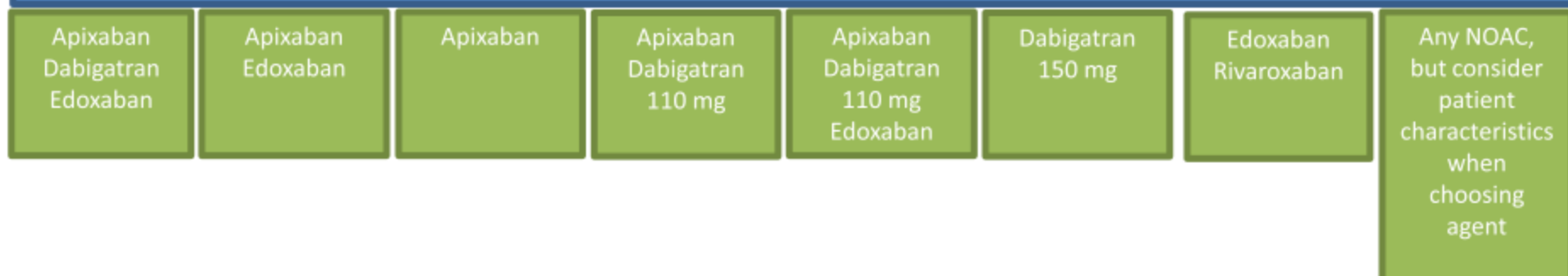
# Choosing a particular oral anticoagulant and dose for stroke prevention in individual patients with non-valvular atrial fibrillation: part 2

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Individual patient groups and characteristics



NOACs with characteristics beneficial to target group



# Quale anticoagulante scegliere?

- Caratteristiche del paziente
- Costo?







**GRAZIE PER L'ATTENZIONE**